IN THE COMPETITION APPEAL TRIBUNAL

Case Nos. 1275/1/12/17
1276/1/12/17

Victoria House,
Bloomsbury Place,
London WC1A 2EB

31st October 2017

Before:

PETER FREEMAN CBE QC (Hon)
(Chairman)
PAUL LOMAS
PROFESSOR MICHAEL WATERSON

(Sitting as a Tribunal in England and Wales)

BETWEEN:

FLYNN PHARMA LTD AND FLYNN PHARMA (HOLDINGS) LTD Appellant

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

- and -

PFIZER INC. AND PFIZER LIMITED Appellant

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

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HEARING – Day 2

A P P E A R AN C E S

Kelyn Bacon QC, Ronit Kreisberger and Tom Pascoe (instructed by Macfarlanes LLP)

Mark Brealey QC, Robert O'Donoghue QC and Tim Johnston (instructed by Clifford Chance LLP)

Mark Hoskins QC, David Bailey, Hugo Leith and Jennifer Macleod (instructed by CMA)

Tuesday 31st October 2017

(10.00 am)

Opening submissions by MS BACON

MS BACON: I appear with Ms Kreisberger and Mr Pascoe. The tribunal will have seen that there is a substantial degree of common ground between our case and that of Pfizer, but as foreshadowed yesterday, there are some important issues on which we have distinct grounds of appeal, so I propose to focus on those today.

So if I can set out the structure of my submissions, it will more or less follow the structure of our skeleton argument, which in turn follows the structure of our pleadings, so I'll start with a few comments on the factual background, picking up Flynn specific points.

I will then turn to market definition and dominance, which I hope I can take very briefly, and I will confine my submissions to points additional to those made by Mr Brealey yesterday. I then need to make submissions on the legal test. In that I do want to overlap with the discussion yesterday, but what I want to do is pick up a few points from that discussion and try and answer, for our part, some of the tribunal's questions, the main questions, I hope I've extracted, and particularly make points that on the law, relate to the distinct aspects

for Flynn's grounds of appeal.

THE CHAIRMAN: You must make your case, but we're thinking of new questions all the time.

MS BACON: I'm sure, and there will be lots more of them.

I hope to get through all of that relatively quickly because before lunchtime I hope that we can make a start on the ROS or costs plus analysis. I tend to quote the "ROS analysis" just because it is quicker to say.

That's the main part of the grounds of appeal, as you'll have seen, and that raises points that are not taken by Pfizer, so I do need to spend some time on that. The headline point, as you'll know, is the CMA only got to its figure for our supposed excess by applying input parameters into its cost plus or ROS analysis that we say have no resemblance to commercial reality. The two key parameters that I want to focus on in my submissions today are the 6 per cent benchmark ROS, and the cost allocation issue. Our submission is that if the CMA had used an appropriate benchmark and appropriate cost method allocation methodology, it would have been very clear that the profitability of phenytoin was not excessive.

We say that that is amply confirmed by other profitability comparisons that the CMA could and should have done, so I want to spend some time on that, looking

at Flynn's portfolio profits and the profitability of other generic companies. I think that will take up most of the day.

If there is time, I will make some short additional points on the tablet comparison before handing over to Ms Kreisberger for submissions on the fines, like Mr O'Donoghue did yesterday.

Can I start with comments on the factual background. Now the CMA says in their defence and skeleton argument that the factual aspects of the case are largely peripheral and they boil down to a set of short points turning on the scale of the price increases and the nature of the product. In our submission that's quite wrong for several reasons.

The first is that, as you'll have seen, the decision is at pains to set out at great length all of the facts that the CMA can find to besmirch my clients by suggesting in numerous places that my clients were uncooperative or even positively misleading - and that word is used in the decision several times - misleading in their interactions with the Department of Health.

Having done that, in my submission, it is not good enough for the CMA to try and avoid dealing with those points. Whatever the outcome of the substantive grounds of appeal, you'll understand that Flynn has an interest

in ensuring that parts of the decision that are factually incorrect are withdrawn by the CMA or all formally set aside by the tribunal, insofar as those in particular go to Flynn's reputation.

The other point is that there are a number of quite important factual points that the CMA has not really dealt with in its written submissions that do go directly to the findings that it's made, and include those not only the evidence of what Flynn did to set up a dialogue with the Department of Health, but other points such as the evidence of Mr Beighton, which I'll come to later.

What I want to focus on just for now is Flynn's conduct. The chronology of the early negotiations with Pfizer is set out in our notice of appeal. I'm not going to take you to that, Mr Brealey has shown you various documents yesterday that explain the basis on which the capsule price was set i.e., by reference to the tablet. That's also covered in Mr Walters' evidence.

What Mr Brealey did not have time to show you was the documentary record concerning Flynn's meetings with the Department in 2012, and those documents go to three things: the first is the Department's knowledge, from the outset, of how Flynn intended to price its product and why it had chosen that price point. The second is

that Flynn, far from refusing to negotiate, proactively sought meetings with the Department. So it wasn't even a case like Teva where Teva was summoned to a meeting with the Department and told to reduce its prices. In this case, Flynn were the ones trying to ensure that the Department was happy with the price that it was setting.

The third point that the documentary record shows is that the Department did not once ask Flynn to reduce its price, but simply went silent after November 2012, even when my clients explicitly invited further discussions.

Can I start with the 18th July 2012 meeting, and that was a meeting, as I said, initiated by Flynn, and Flynn's meeting note is at bundle G1, tab 68, with the Department's meeting note in the following tab.

I don't think it really matters which of those you take for these points because what they --

THE CHAIRMAN: Tab?

MS BACON: Sixty-eight and 69, and they're short documents. Flynn's is a single page, the Department's is a page and a bit.

Those meeting notes show several things. The first is that Flynn explained that it had two options. One was to retain the product as a brand, and apply for a one-off price increase under the PPRS, and you get that from the Department's note at paragraph 5. The

other option was genericisation. Then you see in both notes, that's in the Department's note at paragraph 8, about two-thirds down in the bullet points on Flynn's note, Flynn's explanation of its pricing, by reference to the tablets. At that point, it proposed either a ten to 20 per cent discount if the product was launched as a generic, or 25 to 30 per cent if it was launched as a branded product.

In neither note is it recorded that the Department expressed any concern with the use of tablets as a benchmark. That was before Flynn launched, in July 2012.

So then, Flynn launched in September 2012 and it's common ground that Flynn launched at a price which, for the 100mg tablet, was 25 per cent below the tablet price.

The next document I want to show you is in the same bundle, and that's an internal Department of Health e-mail. So tab 86, and this is dated 24th October 2012. The page I want to show you is the second and third pages of that tab. I won't read out the names of the individuals, but on the second page are the words:

"Thanks for this. Can I take it from this email that you did not in anyway 'challenge' the price and ask them to consider bringing it down? It was more an exploratory conversation as to the cost of the

manufacturer by the third party?"

Then over the page the answer comes:

"You are correct in your understanding that my phone call was just an exploratory conversation about costs."

So there's somebody within the Department noting that the price had not been challenged and Flynn had not been asked to bring down the prices.

The next meeting - and actually, the final meeting - is on 6th November 2012. The documents concerning that are in G2, Flynn's meeting note is at tab 94. Just to say that that was sent to the Department and you can see that from the cover e-mail at tab 97, but I don't need to go to that. You can see from the first line of Flynn's note of the meeting that this meeting was again initiated by Flynn.

You can keep a finger in there and look at the Department's note of the meeting which is at tab 96. That wasn't sent to Flynn before these proceedings and that's Mr Walters' evidence.

Now the Department's meeting note shows Flynn confirming, at paragraph 5, that it had set the price for the capsules at a 25 per cent discount to the tablets; the point I've just made. The Department there said for the first time that it had never confirmed that it was content with the tablet price, and at paragraph 7

that it didn't consider comparisons with the tablet relevant. What the Department did not, of course, say was what it did consider to be a relevant comparator.

Then in paragraph 7, a key passage that I think you saw yesterday, the Department said that it was likely to consider what other options it had available. It noted, for example, that:

"Previously there had been a maximum price scheme for generic medicines and actions such as this could not be ruled out in this case."

Just before I pick up that point and what Flynn understood, there is a point that I need to make which is that the CMA says that Flynn referred in this meeting to certain costs to justify the price increase, which the decision describes in various places as being inaccurate and misleading. We've dealt with that allegation in our pleadings and skeleton arguments, and the short point is that that seems to be based on a section of this meeting note which was very condensed and seems to have mistranscribed what was said. The section is over the page at paragraph 8.

That's a section which gives rise to various points made in the decision about Flynn using misleading information or making misleading submissions to the Department to justify the price. Now we've explained in

detail why that section of the Department's meeting note, which we never saw before these proceedings, is incorrect.

The points Flynn made are set out in more detail in Flynn's meeting note, which the Department did have, and what seems to have happened is that the CMA based those allegations and its decision on one meeting note without looking at the other. I don't think I need to go through the points in our skeleton argument, I just wanted to show you, that's where this point seems to have come from.

If the CMA doesn't dispute our account which it hasn't done so far --

THE CHAIRMAN: Before you go on, the document at 95 is a draft, it is a Flynn draft, is it?

MS BACON: Yes.

THE CHAIRMAN: Yes, and that led to the document at 94?

MS BACON: Yes, that must be right.

THE CHAIRMAN: Right. So we don't have to worry about that?

MS BACON: You don't have to worry about that, you only need to look at the document at 94, which is the final version.

THE CHAIRMAN: The document at 94 was sent to the Department?

MS BACON: It was and you get that from tab 97 which is the

cover e-mail from Mr Walters.

THE CHAIRMAN: Right, and did Flynn receive any comments from the Department of Health on its notes of that meeting?

MS BACON: I think the answer is no, but we're just getting instructions. I certainly haven't seen anything.

THE CHAIRMAN: What you're putting to us is that a meeting took place?

MS BACON: Yes.

THE CHAIRMAN: Flynn made one note of it.

MS BACON: Yes.

THE CHAIRMAN: Sent it to the Department, the Department made another note of it, but --

MS BACON: But didn't send it to Flynn.

THE CHAIRMAN: So we have to decide which account of the meeting we prefer?

MS BACON: Well the point is not -- it's not put exactly like that. The point is that Flynn's note explained the basis on which it justified the price increase, and it also made comments about what it was planning to do in the future, and it explained, for example, that it was planning to invest in the supply chain and that would involve validating the manufacturing capabilities and so on by bioequivalence studies.

Now all of that was set out in much more detail in

Flynn's note. It was also set out in Flynn's follow-up letter, which I'm going to come to in a minute. The CMA in the decision seems to have ignored those and focused on a much more condensed summary in the Department --

THE CHAIRMAN: We haven't got to the CMA yet, just the Department of Health. Are you saying that they misrepresented what was said, or didn't record it completely, or misunderstood it?

MS BACON: One or the other. We say it was either misunderstood or mistranscribed.

THE CHAIRMAN: Right. So you're inviting us to prefer your client's version of what was said at the meeting to the Department's; is that right?

MS BACON: Yes, exactly, on this point. At the very least, the way that the point is presented in the decision shows that the CMA has only looked at one of the notes without looking at the other and has drawn conclusions as to Flynn's honesty, essentially, because it said we misled the Department, without coming back to the Flynn meeting note or taking any account of that whatsoever. It is an example of what my learned friend was referring to yesterday of the lack of objectivity in the decision; it takes, one document, but ignores another one which paints a completely different picture of the event. Flynn's account of what is said at the meeting is

corroborated by Mr Walters and is also corroborated by Flynn's subsequent letter to the Department which was a follow-up letter that it agreed to send after the meeting. That's the point that's dealt with in our submissions.

Now, Mr Walters is here to give evidence and can be cross-examined on the point. So the tribunal is invited to draw factual conclusions from that and if the --

MR HOSKINS: Can I clarify one point? I think Ms Bacon suggested that the CMA had overlooked the Flynn note. It's actually referred to expressly. It's page 274 of the decision at footnote 836, you'll see the reference to document 145.585.

MS BACON: Sorry, just to clarify, I'm not saying that the CMA's decision didn't make any mention of it at all. What I'm saying is that on quite a key point, which is reiterated at several points in the decision, the CMA says that Flynn misled the Department, and that allegation is based only on the Department's note which Flynn had never seen, prior to these proceedings, and that allegation is contradicted by Flynn's own note and Flynn's letter to the Department, two contemporaneous documents, and by Mr Walters' evidence.

THE CHAIRMAN: I understand the point. I missed your reference.

MR HOSKINS: I'm so sorry, I'm trying to be as brief as possible, page 274, footnote 836.

THE CHAIRMAN: That's the second time you've had to refer to a footnote.

MR HOSKINS: I am hoping it is helpful because it gives you the picture.

THE CHAIRMAN: Okay. Thank you.

MR HOSKINS: It is actually mentioned about half a dozen times in the decision and this is one example. But if you want the references, we can produce them.

THE CHAIRMAN: In due course we may.

MR HOSKINS: They're not in my head.

THE CHAIRMAN: I'm very glad to hear it.

MR HOSKINS: So am I.

THE CHAIRMAN: Please continue.

MS BACON: So we have given in our skeleton other examples where we say we have been accused of misleading one or other authority. I'm not going to deal with them now, but I've highlighted that because it comes up in the chronology I'm showing you.

Now after that meeting, Flynn sent a follow-up letter to the Department on the 16th November, and that is at tab 99 in the bundle. That set out in detail again various points made by Flynn about its investments, what it was intending to do with the

product. It goes through, for example on the third page, points about building supply chain resilience. This was, from the outset, one of the points that Flynn had made to Pfizer in terms of its expertise, and Flynn makes in its evidence.

Then over the page, there's a crucial passage at the end of the letter.

"Flynn (and Pfizer) are fully aware of Department and stakeholder concerns in regard to the supply and pricing of this product within the UK and continue with best efforts, to pursue the strategies outlined in this letter. Flynn for its part has to ensure commercial viability and return is important, but we recognise also the legitimate concerns as to (NHS) cost and continue to discuss supply pricing with Pfizer. We welcome further discussions with the Department on these matters."

So there was an explicit invitation to the Department to discuss the matter further with Flynn saying, "Look, we do have to ensure that the product is priced in order to ensure commercial viability, but we recognise there are concerns about costs, so we'd welcome further discussions with the Department."

Now what Flynn received in response was a short holding e-mail, and that's in bundle C, tab 2. I think you probably don't need to turn that up because all that

says, if I can actually sort out my bundle, it's on page 8. All that says is:

"Thank you for your time last week and following up with this letter. We have obviously not had time to digest this in detail today. We will get back to you in due course."

That's page 8 of tab 2 of bundle C.

Mr Walters' evidence is that there was no further response and the Department did not at any time after that seek to discuss the price of the product with Flynn, it just went silent. The CMA invites the tribunal to conclude, as it set out in the decision, that the Department did nothing because it was powerless to act. But there is, as you've seen, no evidence from the Department that supports that conclusion. In the absence of evidence, the only conclusion must be that the Department decided, for unexplained reasons of its own, that it was going to take no further action, but was going to essentially hand over to the CMA. That doesn't mean that the Department couldn't act, it means that the Department chose not to act.

Flynn's understanding of the situation is set out in evidence, and that's in the evidence of Mr Walters. Mr Walters recalls the threat in the November meeting, which I've shown you, to use the Department's powers to

intervene in the price of the capsules, if necessary. Perhaps not surprisingly, Mr Walters says, "Well Flynn believed that the Department would indeed use those powers if the price of phenytoin was not acceptable."

He makes clear that Flynn considered the Department to have substantial purchasing power, and that's not a surprise. The Department is Flynn's only customer for phenytoin, and my clients put it to me, if your only customer for a product says that they're not happy about the price, you're quite obviously going to negotiate with them. But in this case, as we've seen and I've shown you, Flynn did speak to the Department. It explicitly requested two meetings with the Department. It explained the basis on which it had priced the product and was then met with silence, and so my client's evidence is that they took that to mean that the Department considered that the price of phenytoin was justified.

THE CHAIRMAN: Are you putting to us that the Flynn price was in the nature of an opening bid which finally became the price?

MS BACON: Well at the second meeting in November, they had launched the product, so that was the launch price for the product. What my clients have said quite explicitly is, for example, if the Department had invited them to

join scheme M they would have given that, they would have given that consideration and would have done that. And if the Department had wanted to discuss further, they would most certainly have done so.

There was an explicit invitation at the end of their November letter to do so. They recognised the Department's concern about cost. That's said explicitly in their letter. So I think one way of answering that is to say yes, they launched at 25 per cent below the tablet, but if the Department had come to them and said, "We're still not happy with that, let's have a negotiation and bring the price down", that they would have had to negotiate, they wouldn't have had any alternative because the Department was their only buyer.

That can be tested in cross-examination because unlike the Department of Health, he is here, we have tendered him for cross-examination and he'll be giving evidence on Thursday.

So can I now take you to what the Department told the CMA about that discussion with Flynn, and we went to this document yesterday but there's one passage which Mr Brealey didn't take you to, and the document I want to go to is a note of the Department's meeting with the CMA, bundle J2, tab 64. The passage I want to show you is paragraph 37, the bottom of page 7.

My learned friend has already commented on the poor evidential value of this note in circumstances where it's not backed up by any evidence from the Department of Health. But the point that I want to show you is that this passage of the note, which records what the Department told the CMA, is simply not consistent with the documents that I've shown you regarding Flynn's meeting with the Department, and in particular the follow-up letter. So paragraph 37:

"DH said that it had attempted to have similar discussions with Flynn regarding the prices of Flynn's phenytoin sodium capsules."

Pausing there, it is actually Flynn that attempted to have discussions with the Department.

Then it goes on:

"But, as described above, Flynn had refused to reduce its prices, and had said that it would consider discontinuing the product if it could not maintain its prices."

As you've seen, Flynn did not refuse to reduce its prices. The notes do not record any statement by the Department that it wanted Flynn to reduce its prices, the Department had queried the price of the product and Flynn had explained that and explained what it was doing and the investments that it had made and wanted to make,

and Flynn had explicitly said in its follow-up letter that I've just shown you, "We recognise the Department's cost and we welcome further discussions."

MR LOMAS: Is that quite fair, Ms Bacon? It's clear from what you showed us that the Department of Health was fundamentally unhappy with the price, and Flynn was seeking to justify its price, and putting forward reasons why it should be so, and the issue was left on that correspondence unresolved. Does it go much further than that?

MS BACON: Yeah, I think that's a fair summary to say the Department was unhappy, it came to Flynn and said, "We have concerns about the price. We now", for the first time in the November meeting, [they said] "we don't think the tablets are a comparator."

Flynn then responded and Flynn explained its position that it had to maintain commercial viability and that was where matters stood.

MR LOMAS: That's the last stroke.

MS BACON: That's the last stroke.

MR LOMAS: Yes.

MS BACON: My point is that it is not that Flynn refused. There was a dialogue, the Department said -- expressed concern about the tablet comparator, Flynn came back with various justifications, followed that up, the ball

was then in the Department's court. It wasn't that Flynn had refused. It had placed the ball in the Department's court, there was the holding e-mail saying "we'll get back to you in due course" and nothing ever came.

MR LOMAS: Flynn wasn't at that stage offering to reduce its prices, it was justifying its prices.

MS BACON: It was justifying and offering to negotiate further. It said, "We welcome further negotiations with the Department".

MR LOMAS: Okay.

MS BACON: But it was certainly not the case that the Department said, "We want you to reduce your prices" as it had done with Teva, and Flynn had said, "Sorry we're not going to do that." Because that statement, that request, is not in any of the meeting notes and you won't see it in any of the documents.

THE CHAIRMAN: But it's clear, isn't it, that the Department had judged for one reason or another that Flynn was unlikely to reduce its price and the negotiations probably weren't worthwhile doing. That appears to be what --

MS BACON: Well we don't know that because there isn't anything in the documents before the tribunal that shows that that's what the Department thought.

THE CHAIRMAN: Had this note at 37 recorded something to that effect, would you be equally concerned?

MS BACON: I would be concerned because there would be no evidence from the Department backing that up, but if there was evidence from the Department saying, "That is what we thought", then I wouldn't be making a comment about the inaccuracy of the statement that was being made to the CMA.

THE CHAIRMAN: If the decision had said the CMA was told by the Department that it had judged that further negotiations were unlikely to be fruitful --

MS BACON: And if the Department had produced evidence to back that up.

THE CHAIRMAN: -- (overspeaking) --

MS BACON: There wouldn't be an issue about the misreporting of what had happened at the meeting.

THE CHAIRMAN: Your issue is about what has been said rather than --

MS BACON: Yes, and I want to show you that the decision then actually took that at face value and recorded that there was an impasse, which is not true. The ball was in the Department's court.

MR LOMAS: Just before we go there, Ms Bacon the document at 94 at G2, which you took us to which, as I understand it, is Flynn's own note, does at least say, in Flynn's

own wording, "Flynn explained that whilst it was keen to maintain supply and availability, it could not do so at the Epanutin price or within the limits of a price increase permitted within the PPRS."

MS BACON: Yes.

MR LOMAS: At least the issue of whether it would continue to supply was on the table, albeit conditional on the price at which an agreement was struck.

MS BACON: Yes, what it was saying was "We can't supply at a loss-making price". That's not a surprising proposition and it's reflected in the follow-up letter which says, "We have to make the product commercially viable, nevertheless we recognise the concern about cost."

I just want to take you to the passage in the decision which records what the CMA got out of this meeting. Now this meeting note is referenced at various times. This is the only -- paragraph 5.290 of the decision is the only -- place that we found where paragraph 37 of the meeting notes that I've just shown you is explicitly referenced. This is one of the places where the decision relies on its allegation that the discussions floundered because Flynn had been providing misleading or inaccurate information in relation to their costs. That was the point I was making earlier.

At the end:

"Discussions reached an impasse and the DH brought the size of the price increase to the CMA's attention for its consideration."

Well that's not what happened. The Department had complained to the CMA before it had the November meeting, and the November meeting wasn't left an impasse, the November meeting was left with Flynn saying, "We'll discuss this with you further."

MR LOMAS: Sorry to interrupt again, looking at 5.290, is what you're saying in I think the second sentence:

"In particular, Flynn stated that it was not making significant margins on the product and would not be able to continue to supply the product if it could not maintain its prices."

MS BACON: Yes.

MR LOMAS: You would actually say no, if it had to supply at the old prices.

MS BACON: Yes, and actually at the end of the letter from Flynn, Flynn was saying explicitly, "We have to make -- it has to be commercially viable, but we recognise the concerns." If that's not an invitation to the Department to go back and negotiate on price which might lead, very well lead Flynn to reducing those prices, I don't know what is. So it was not saying, "We have to

maintain these prices that we have currently set."

So that is another instance of the CMA in the decision relying without criticism or reflection on a paragraph of a meeting note which is contradicted by the contemporaneous documentary record that the CMA had of that meeting. And it's very strange that the meeting note is cited for an explanation of what happened without the CMA going back to the contemporaneous records of the meeting.

Of course we have the point that was made yesterday that this was -- this meeting note was some time after the event.

PROFESSOR WATERSON: Your point is that the impasse, that there is no evidence of an impasse?

MS BACON: No evidence of an impasse, nor is there evidence of Flynn saying, "We have to maintain the current price" as in the starting price of phenytoin. That's not what they said.

Of course, as I've said, Flynn didn't know that the Department had gone to complain to the CMA. It was left thinking well, we've put the ball back in the Department's court, we've made detailed submissions to the Department as to what we've done with the price and what we intend to do with the product, the investments that we're hoping to make.

As far as Mr Walters was concerned - and he said that in his evidence - he thought that the Department had then taken that on board and was happy with the price. There was no suggestion in any of those documents, just to reinforce the point, that Flynn's price should be capped at cost plus 6 per cent and that's perhaps an obvious point to make.

MR LOMAS: Picking up a point we had yesterday, I can see that that question of what Flynn thought at that period may be relevant to fining, but is it actually relevant to article 102 breach?

MS BACON: Yes, because it goes to buyer power because Flynn would not have -- if Flynn thought that it was completely unconstrained as to the price, and the Department would have had no buyer power at all, in the first place Flynn would have not sought those meetings. If it really thought it could do what it wanted because it had a captive customer, it wouldn't have needed repeatedly to go to the Department. As I've shown you, the Department said, "We tried to negotiate" and it's not true, the Department didn't seek those meetings with Flynn, Flynn was the one that went to the Department because it knew the Department had concerns about the price and it wanted to make sure the Department was happy.

That's not the behaviour of a company that believes the Department doesn't have buyer power, nor is the explicit invitation at the end to negotiate further the behaviour of somebody who believes the Department has no buyer power. So Flynn's understanding of the constraint upon it is relevant to the buyer power.

THE CHAIRMAN: A rather odd sort of buyer power, isn't it? Buyer power by virtue of its capacity to regulate prices. I think Mr Brealey made the point yesterday, it's unusual to have a buyer who is also a regulator. Is that what you're saying?

MS BACON: Well, several points. It had a whole suite of powers - and I will come to buyer power in a minute - but the Department had a whole suite of powers available to it.

THE CHAIRMAN: But that's not the point my colleague was referring to. We're talking about Flynn's belief in the power of the Department to intervene to regulate the price.

MS BACON: Yes. The Department had powers and Flynn believed that they had powers. Because one of the points made by the CMA is that the Department had powers but, you know, they were completely useless and nobody ever thought they could be exercised. This is evidence that Flynn did believe it, and acted on that belief,

acted on that belief by some, you know, asking for the meetings with the Department and offering to negotiate further.

MR LOMAS: Are you slightly overstating that? There are many commercial organisations that will have discussions with their customers, whether the customers' buyer power is very high or very low, because that's how you maintain a good trading relationship.

MS BACON: Yes, but Mr Walters' evidence is that one of the reasons for having those discussions was that Flynn believed the Department could intervene to reduce the price if it wasn't happy. And it knew that it had already done that with Teva. So we have a market where it is known by Flynn, by Pfizer, that the Department had intervened in respect of Teva, that's why the price was set initially below the Teva price.

MR LOMAS: Okay.

MS BACON: The CMA then opened the investigation, and as you'll have seen, the initial focus was into whether there was some sort of anti-competitive agreement between Pfizer and Flynn. It was only in February 2014 that the CMA extended that investigation to include an investigation of Flynn's pricing under article 102.

But even then there was no suggestion that phenytoin should have been pegged to a benchmark of cost plus

6 per cent.

I was going to take you to a note of a meeting with the CMA where Flynn explicitly asked what a reasonable price would be, and the CMA said, "Well we haven't worked that out yet." I'm going to leave that to Ms Kreisberger because that does go more to the fine question.

Just to note for your note, the meeting with the CMA that I'm referring to is at J1/19. I'm not going to ask you to turn that up. But in that meeting, the CMA said explicitly, "We haven't concluded internally on what the relevant price should be." But it's certainly not just based on a benchmark that the CMA can just pull off the shelf. You'll see that when Ms Kreisberger takes you to it. What we now know is that pulling a figure off the shelf is what the CMA has done, but it didn't tell Flynn in that meeting that that was the way it considered that the excessiveness should be measured.

That brings us up to date in terms of the chronology, a few key factual points from Flynn's perspective.

Can I then turn to the market definition part of the case.

The essence of our case on market definition is that whatever the CMA has to say about continuity of supply,

is in fact largely irrelevant because in this case we do have observable market share data. We know how much product NRIM sold from month to month and we also know how much Flynn sold and we also have data on the total market size.

So one can look at that and draw conclusions about the market shares of the relevant parties over time. In those circumstances, in our submission, looking at what pharmacists claimed to do is at best uninformative and at worst positively unhelpful if that is actually contradicted by the observable market share data.

Certainly, in our submission, the CMA can't base its decision on what pharmacists say they do when that's contradicted by the evidence of what they actually have done.

That market share data in this case shows clear evidence of switching between Flynn's products and NRIM's and also that NRIM's entry into the market provoked a substantial price reduction by Flynn.

Those are hard facts. We know exactly, not exactly, but we know approximately what the market shares were and we know when the price reduction took place and what it was. In our submission, that should be determinative of the market definition.

MR LOMAS: You're making that point both in relation to pre-

November 2013 and --

MS BACON: Yes, because we know what the market share data were before November, and I'll come on to the alternative case on dominance in a minute, but we are saying that the entire period should be looked at as a whole, and one should look at the trends over the period as a whole.

Now, can I ask you first to turn up the table in our notice of appeal at paragraph 125. That is in bundle A.

I'm not going to read out the figures in this because most of them, or all of them, I think, are confidential to one or other party.

THE CHAIRMAN: Where is the table?

MS BACON: Paragraph 125. It's at page 38.

Actually you've got two tables on that page, one is the all doses and the other one is 100mg, but I'm focusing on the 100mg because 100mg is the only strength that NRIM supplied. So in order to ask yourself, "Is NRIM substitutable for Flynn", you need to look mainly at the 100mg. You'll see that NRIM's market share increased from nothing in quarter one of 2013, that was before it had launched, to the figure that you see at the end of the table on the right-hand side in the quarter 2 of 2016.

So by that point, NRIM's sales, at least during that

quarter, actually overtook Flynn's. The bottom line is parallel imports. We don't know exactly the parallel import figure. The parallel import figure is a derived figure, so we know approximately the total market size and we know the approximate sales of Flynn and NRIM, and so the parallel import is derived by subtracting the total sales of Flynn and NRIM from the total market size to get an implied figure.

You'll see in both tables we've got two highlighted cells, and those cells are highlighted because you can see that in that quarter the parallel import share is supposed to be negative, which implies that there is some kind of problem with the figures. That's the reason why we've said we can't place too much reliance on the figures for that quarter for whatever reason, which hasn't been explained by anybody, there is an anomaly.

MR LOMAS: But the figures for the other quarters are fine?

MS BACON: Well, in the sense that they show a trend but there's no obvious anomaly in those figures. And I think, and as I'll show you from the graph in a minute, I think it's unwise to place decisive reliance on any particular data point, what you have to do is look at the trend, and what you see in that quarter is that there is a distinct anomaly. So if any statement is made about NRIM not going up very much by comparison

with the figure in that quarter, that's a somewhat unreliable statement given that we know that there's a problem of reliability with the figures in that quarter.

But if you --

PROFESSOR WATERSON: Presumably there is also a potential problem then with Flynn's share in those quarters.

MS BACON: Yes, the reason why I've highlighted NRIM and the parallel imports is that NRIM, if you look at the trend, looks an anomaly, whereas the Flynn share looks about right if you're thinking about a trend line, and it's the NRIM figure that looks unusually high and there is a spike and you'll see that spike on the graph.

What you'll see is NRIM's market share increased significantly, Flynn's market share plummeted, overtaken by NRIM at the end of the period, and although the point isn't so marked across all strengths because of course NRIM doesn't supply the other strengths, you still see a marked drop in Flynn's market share and an increase in NRIM's, even on the table above.

That makes clear that there was switching between the two products and that NRIM's market share follows a clear upwards trajectory. If you turn up the page, there's a graph that shows the trend line. I think that's not very easy to read so I've done a larger

version of it, which we can hand up now. I've interposed on that also the implied parallel import market share, and I've put it, I say I, I have asked to be put in lines indicating various of the relevant points in time, the MHRA guidance and the reduction of Flynn's price.

PROFESSOR WATERSON: Can I just raise a technical question? These trend lines, how have they been constructed?

MS BACON: Yes, I asked for that, I thought you might ask that, Professor, and I have a technical and non-technical explanation. The non-technical explanation, which any of us who have done A level maths will probably remember, is that they are the line of best fit through the data points. The technical explanation is that the trend line is constructed so as to minimise the squared differences between the actual data points and the trend line.

What I don't know is --

PROFESSOR WATERSON: It's a linear regression (Laughter).

MS BACON: You may well be right, I'm reading out the explanation I was given. I understand the explanation I was given, what I don't know is why they used square differences.

PROFESSOR WATERSON: You always do.

MS BACON: Right. I'm very grateful, you're much ahead of me.

That's how the trend line was constructed, and you'll see the trend line then starts with the NRIM figures from the bottom and you can see that increasing and then overtaking Flynn's figures. And over the page, well, there are two pages here, one is the volumes and the other is the market share. You can see that although inevitably there are fluctuations, there is an overall trend of convergence in the market shares and the volumes that are sold, and that's why Mr Brealey said yesterday you get to a point in 2015 when it's basically thirds, as between Flynn, NRIM and parallel imports.

MR LOMAS: There's a danger in doing this by eye, but the general slant of those trend lines is presumably heavily weighted by what happened in 2013 and very early 2014. If you took the period from May 2014 onwards and drew trend lines there, I suspect they'd be more or less parallel.

MS BACON: It may be the case. You're right, it is difficult to do it by eye. Do you want us to try and do that, or do you just want to make that?

MR LOMAS: If it can easily be done.

MS BACON: Yes. The problem with taking any particular starting point is that the result may be weighted according to the particular fluctuation at that time.

So it may be that what one needs to do is take the trend line up to that starting point and use that as the start. I can ask our economists to rework that.

The general point being made is that things didn't seem to, even looking at this by eye, things didn't seem to come to a halt in November 2013, and you can see that from the detailed market share tables as well.

PROFESSOR WATERSON: The more interesting question is what happens after April 2014.

MS BACON: Yes. You can see that Flynn's market share plummeted. Sorry, there was a spike in Flynn's price at the point -- sorry, there's a spike in Flynn's volumes at the point at which it reduced its price and that's something that we have drawn attention to. Then what then happened is that NRIM reflected that in its own pricing, it followed suit and then Flynn's market share plummeted. You can see at least from that spike that it was correlated, or appears to be correlated, to an event that we know. That is another point that we rely on, because we say there was a price reduction, there was a spike in Flynn's market share volume of sales at the point at which there was a price reduction which one would expect, and then Flynn's market share volumes dropped again when NRIM followed suit.

MR LOMAS: Just to pick this up, and I am sure you want to

talk about the pharmacist data in a moment, but the two pharmacists who must not be named --

MS BACON: I think we can name them now.

MR LOMAS: We can?

MS BACON: Yes.

THE CHAIRMAN: Were, of course, very actively penetrating the market in that early stage, which will have driven quite a lot of this variance in the figures, and we know, or at least it is suggested, that their behaviour then stabilised. Does that explain what's driving these numbers?

MS BACON: Obviously there was an early spike in NRIM's product market share which may well, and probably was, explained by the two large pharmacists. What one can then see -- and I am going to come to the Alliance data -- is that it was not the case at that point in 2013 the market then ossified and nobody else then ever switched because we do have data of other pharmacies switching. Of course, naturally they weren't the two largest, so those market share switches will have been somewhat less than the initial spike in NRIM's product from the two, whether they can be named or not. I think they can be named. Yes, they can, Boots and Lloyds.

So the CMA makes several points about our submission that one looks at the overall trend line.

They say, "well actually you should start with the figures for quarter 4 of 2013", and they object that we haven't done so. That's the point I made to you about those figures being unreliable. That's the reason why we don't say that one has to start with November 2013 and look at what happened after then because what happened in that period is somewhat unresolved and seems to be an anomaly.

In our event, our submission - and I think the CMA also says this at various points in its skeleton - is that a more accurate view is gained from looking at the evolution of the market over the entire period, and so trend lines is more instructive than looking at individual peaks or troughs.

They also say that the figures for June 2016 were a blip and that NRIM sales went down the following month, and I've actually asked for this graph to include the July 2016 figures, so that does show you the figures right up to July. That does show a small spike in Flynn -- I think it is NRIM's product -- at the end of that period, which then corrects downwards, but that doesn't have a huge impact on the overall trend line.

Just to cover off the point, the reason why we didn't mention the July 2016 figures in our notice of appeal was that we didn't actually get those until we

received the CMA defence, so it was not that we're trying to hide anything.

Just to make clear, I think I said, we're not suggesting that the Tribunal should look at the 100mg figures in isolation, but the reason for drawing attention to those is that they make up the vast majority of the market and NRIM only supplies that product. So if one is looking at substitutability and competition between NRIM and Flynn, one would actually focus on the product for which there is direct competition, the 100mg product, and this should carry particular weight, therefore, in the market definition especially, as I've said, given that 100mg product accounts for 73-74 per cent of the market.

MR LOMAS: Is there a risk of drawing too much weight from quarter to quarter variations in these figures without understanding the purchasing or stocking policy of the supply chain, because if you're only measuring it at one point and people buy two days before the quarter end or two days after, or change their policy, that's going to affect the quarterly figures. So we should be looking at trends not quarterly changes.

MS BACON: That's why I say that it is more instructive to look at the overall trend, rather than doing as the CMA has done. I think they focused, they seemed to focus on

NRIM's share in quarter 4 of 2013, and draw a comparison with that where there was a blip, which is in any event anomalous, and then say, "Oh well, if you look at the rest of the period, NRIM's share appears to be stable by comparison with that."

That is the approach we reject. We absolutely agree that one should look at the overall trend throughout the period.

Now as we've said in our pleadings and skeleton, we're not only relying on the market share changes, but also the impact on price, and the fact that after the point at which the CMA claims that the market became ossified, Flynn then chose to reduce its price, which we say is inconsistent with Flynn thinking that suddenly it had become dominant because of the MHRA guidance, and you'll have seen what we say about the price reduction in our skeleton argument. I don't think I need to take you to that.

That's also dealt with in Mr Walters' evidence which can be tested, and his evidence was that the price reduction was in direct response to NRIM's entry. This is an event that occurred after November 2013.

The CMA's attempt to say that a price reduction at that point is not evidence of sufficient competitive pressure is, with respect, quite hard to understand

given that we have hard facts concerning the substantial price reduction by Flynn in April 2014. With witness evidence and contemporaneous documentary evidence that this was due to competition from NRIM, that would seem to us to be textbook evidence of products being in the same market.

Can I make some short points about the pharmacy data and continuity of supply? If I'm right about what I have just said, then, as I said at the beginning of this part of my submissions, it is not really that relevant to look at what pharmacies claimed to do in terms of their purchases. Their primary source of evidence for the market definition should have been the observable data, and the CMA could, as you rightly said, sir, have gone and gained further evidence to complete that picture, for example, by looking at stocking policies or whatever. But the observable market share data was available to the CMA and should have been their first port of call, and showing convergence of a volume sold and of market share, and it's very difficult to avoid the conclusion that by the end of that period, not only had there been switching, but Flynn was not dominant.

But just to cover off the point on the section 26 notices, we agree with what Mr Brealey said yesterday

about the difficulties in drawing reliable conclusions from them, and the basic problem is that whatever warnings may be given, pharmacies do have a clear self-interest in maintaining that they comply with the guidance. That doesn't actually mean they do comply with it.

Again, the CMA could have tested what the pharmacies were saying by looking at the actual wholesaler data. We know that we do have, and the CMA did have, actual wholesaler data from Alliance.

I do not need to ask you to look at the spreadsheets, just for your note, the detailed spreadsheets are at bundle I number 1, tab 17. That document was disclosed to us in unredacted form in mid-April this year. That's why we've dealt with it and Pfizer have dealt with it in their reply. We've all dealt with that in our replies.

As Mr Brealey pointed out yesterday, what the Alliance data showed is that, contrary to the claims in the decision that the only major pharmacies to switch were Boots and Lloyds, Walter Davidson switched to NRIM in June 2013, at least in its purchases from Alliance, and Morrison's and Superdrug, I have checked, I can give those names to you, started buying substantial quantities of NRIM's product in May 2014. That's

recorded in the graphs in the annex to Pfizer's reply, which I think are quite helpful.

Now, the CMA's response to that is to say, "Well this is all de minimis," and we don't agree, because if you look at the figures in the Alliance data, you can see that those three customers are actually within the top six purchases of phenytoin from Alliance. We've done a small spreadsheet just to show that, which we can hand up.

That summarises the information on the larger documents. We see Boots at the top of that because they were and are the major purchaser from Alliance, but then you see Morrison's, Walter Davidson and Superdrug coming in in the second, fourth, and sixth place respectively. You'll see there that Walter Davidson, which switched earlier in the period, it switched in June or started buying substantial quantities of NRIM in June 2013, bought more from NRIM in that period than from Flynn.

The reason why, in the case of Morrison's and Superdrug, or at least in the case of Morrison's, there's a much larger figure for Flynn than for NRIM, is that Morrison's switched much later in the period and this is only looking at sales between May 2013 and August 2014, which is what we have the data for.

If you add in Boots, you then see that four out of

the top six Alliance customers had switched to NRIM, or at least were buying substantial quantities from NRIM through Alliance, by the end of the period covered by the document.

Now we are not saying that this individual document should be determinative of the question of market definition, what we are saying is it should have put the CMA on notice that what it was being told by the pharmacists did not necessarily correlate to what they were actually doing. If it was interested in who was buying what and when, rather than relying on what the pharmacies said they were doing, it would have been better to go back to the original source material from the wholesalers of what their actual purchases were. Alliance has provided it, we don't have that for the other wholesalers, but the CMA could have got that.

Again, this document, and the information in this document does not seem to have percolated through to the decision which relies instead on the section 26 responses from the pharmacists in question.

We're not suggesting that this provides a complete picture, what it shows is that the evidence before the CMA was actually very incomplete and it should have tested its conclusions on switching and continuity of supply and the strength of the guidance in pharmacists'

minds, by looking at what they actually did.

PROFESSOR WATERSON: Just on the point about other pharmacists, I think you do have AAH data.

MS BACON: We only have aggregated data, and it doesn't break it down. So this kind of information can't be seen from the data that we have from AAH, but you're right to say they did get it, they did get some data.

What they could have done, if they wanted to build a complete picture of who was buying what, would be for the entire period in question to ask for precisely this data from all of the wholesalers, and they didn't do that. But at the very least, this shows that this would have provided useful insight that went beyond the section 26 claims and responses, claiming "oh we didn't buy very much NRIM", for example.

PROFESSOR WATERSON: Lloyds is, of course, broken out of the AAH data?

MS BACON: Yes. That was really all I wanted to say on the pharmacy side of the market definition piece. Can I just move onto the question that you asked me about the alternative market definition?

Now if NRIM is included in the market definition, our position is that the appeal must be allowed because for the period after November 2013, on the assumption that NRIM is included in the market definition, the CMA

doesn't say that Flynn was dominant.

For the period before November 2013, the CMA says that even if NRIM is included in the market definition, Flynn was still dominant during that small period. Our short answer to that is the CMA's own point that it's not appropriate to look at market share changes over limited periods of time, rather one needs to look at the evolution over the entire period. That's what the CMA says itself repeatedly in its skeleton argument.

Taking a step back and looking at what did happen in that period as a whole, Flynn launched in September 2012 fully anticipating generic entry. We know, and Flynn knew then, that NRIM had obtained its marketing authorisation the year before. Seven months later, after Flynn's launch, NRIM did enter as Flynn had anticipated, and Flynn started losing substantial market share, and we also know that that was the major reason why Flynn reduced its price in 2014.

If the Tribunal accepts that that sequence of events was enough to include NRIM in the market definition, and on the CMA's own case, to make Flynn non-dominant from November 2013, then the same should apply to the whole period because it was a trajectory of events.

The only other point to make on dominance that I want to --

THE CHAIRMAN: Sorry, can I just be absolutely clear? You're saying that were you to be able to establish that NRIM capsules are included in the relevant market, then it is not suggested that Flynn can be dominant?

MS BACON: Well, the CMA doesn't say Flynn can be dominant after November 2013. The CMA's case --

THE CHAIRMAN: It is possible to be dominant, even if there is a significant competitor, so my friends tell me.

MS BACON: Yes. Our position is that the market shares were basically in thirds by the end of the period and were going towards thirds through the period, and there was evidence of a price reduction in consequence of the entry of NRIM, and our position is that all that shows that Flynn was not dominant, it responded to the price increase. But more importantly, the CMA's decision doesn't make a claim that Flynn was dominant from November 2013, if NRIM was in the market definition.

THE CHAIRMAN: You include parallel import capsules?

MS BACON: As a constraint, yes. But there's no question that they are within the market definition because they are Pfizer's product. But for the purpose of dominance, they are certainly a constraint.

MR LOMAS: The only issue with them is calculating accurately the volume.

MS BACON: Yes, that's why I said we've had to do that on

a derived basis.

MR LOMAS: I'm sure you know this, the reimbursement price for parallel import products? Is that a price constraint or is that --

MS BACON: I'm told it's the same.

MR LOMAS: Yes.

THE CHAIRMAN: Shall we take a pause now?

MS BACON: That's a suitable moment, I'm going to go on to buyer power, which I can cover shortly.

THE CHAIRMAN: Ten minutes.

(11.10 am)

(A short break)

(11.22 am)

MS BACON: Can I start with a small correction? There was a bit of a debate about this question of whether the Department of Health had responded to our meeting note, and actually it seems that the email in the bundle where we send the Department of Health meeting note to somebody, whose name I won't read out, I'm being told she's actually not at the Department, or we think she's not at the Department. So I think that I don't make the point that we sent our meeting note to the Department. I've asked whether we know, whether we did or not and we actually don't know. We know that it was sent to this person, but apparently she wasn't at the Department. So

that just covers that question.

I was going to wrap up on buyer power, and that was covered in some detail yesterday, so I only need to pick up a few points.

The first is that, as I explained in answer to your question, sir, at the start, about the relevance of the factual points. One of the reasons for going to those, to the factual chronology and Flynn's interactions with the Department of Health, was that those are, we say, directly relevant to the issue of buyer power and I've made my points on that already.

Our position in short is if the Department chose to do nothing, that is a matter for the Department, but that then cannot be used against my clients to say that the Department was powerless. They chose not to act, but that didn't mean that they couldn't act.

The second point on buyer power concerns what the decision says about the Teva tablet price reduction, and I'm not trying to draw any coherent thread through these, I'm just trying to pick up a few points that we make in addition to those made yesterday.

Mr Brealey took you yesterday to paragraph 3.479 of the decision where the decision records that the Department told the CMA that it didn't actually set Teva's price or negotiate with Teva, and when Mr Brealey

made that point, the chairman, as I recall, responded that actually, in that paragraph of the decision, the CMA was not presenting this necessarily as being fact, but rather setting out what the Department had told the CMA.

I just wanted to, just for your note, refer to the other places in the decision and where, later on, the decision then does refer to that as fact. What it records here is simply what the Department told it and it then accepts that uncritically. Just to give you a couple of those examples, 4.322, the last-but-one sentence, or perhaps, even, starting in the middle:

"in any case, the CMA does not accept the party's submission that the price reduction that occurred in relation to Teva's tablets resulted in the exercise of sufficient buyer power by the DH. The DH has no power to limit the price of tablets and Teva's 2008 tablet price reduction was a voluntary act."

The CMA then presents it as a fact and the same point is made in a few other places in the decision. I'll just give you the references: 5.297, 5.303, and 5.310.

THE CHAIRMAN: You're saying that the CMA correctly recorded that the Department had told them something and then turned it into --

MS BACON: Yes, and then turned it into a fact, yes.
THE CHAIRMAN: You're not suggesting I read the wrong passage, or read it out wrongly?
MS BACON: No, I'm suggesting you put to Mr Brealey the fair point that in the paragraph that he took you to, the CMA was simply recording what the Department had said, but in subsequent paragraphs, that's then turned into a fact which we now know is not correct.
THE CHAIRMAN: Okay.
MS BACON: It wasn't a voluntary act.

Now the third and final point of my sweep-up points on buyer power is just in answer to a point of detail that was raised yesterday about scheme M and category M. The answer to the Tribunal's question is that they are indeed independent, so a company can be in scheme M if it has products that are in one of the other categories such as category C. And equally, a company might have a product in category M, even if it's not in scheme M. That's what I've been told.

That was just a clarification from yesterday.

Apart from that, I don't intend to go over the issue of buyer power again because it was covered in some detail by Mr Brealey, and it is also covered in detail in our written submissions.

MR LOMAS: Can I just ask one slightly legal question on

that, just to make sure I understand what it is that you're submitting?

If we assume against you, for all sorts of reasons, hypothetically, that a party is dominant in a market and is supplying a product at an outrageously excessive price which meets whatever test is set under article 102, is it your case that the fact that a regulator could have controlled that price down is sufficient to stop it being an abuse?

MS BACON: I would put it differently. I would say that - and the case law makes the same point - that you look at buyer power together with all of the other factors in the market. I would say in this case, there is, to use your words from yesterday, there is a basket of factors that one looks at in assessing dominance. One looks at market shares and price fluctuations and you look at buyer power, and we would put those together and say if you look at all of those in the round, it's clear that Flynn was not dominant, but --

MR LOMAS: Wasn't dominant, or that its price wasn't unfair?

MS BACON: Then on that basis you don't get to look at the abuse.

MR LOMAS: Of course, so you put it at the first stage?

MS BACON: Yes, I would put it in the first stage.

THE CHAIRMAN: You don't put it in the objective

justification basket?

MS BACON: No. Because, in a sense -- in our case you don't -- we don't have to justify the price, because the price is not abusive. An objective justification comes at the tail end of the 102 analysis. Our submission is that, for all the reasons we've given, the price wasn't abusive and excessive, so we're not into the -- we don't even need to get into looking objective justification.

I think part of what your question goes to is the factual question of the balance of power and what Flynn perceived, and it ties in with the debate that we had a bit earlier on as to what we've said about Flynn's perception and its acts go to buyer power, and for the reasons that I've explained earlier, we say that they do, because Flynn acted at all times in a way that showed that it thought the Department had the power to constrain its price.

MR LOMAS: There's something very unusual about this case, isn't there, because in this case the buyer also has regulatory powers? That is a very, very unusual set of circumstances.

MS BACON: Yes, and we rely on that point and we say that it is a very unusual situation where you have, in this case, a monopoly buyer who has regulatory power and can intervene under a whole suite of powers, and yet it is

said that Flynn is unconstrained in its pricing. It is not unconstrained.

It is faced with a buyer who very unusually has explicit statutory powers to intervene in its price.

MR LOMAS: So could any pharmaceutical company or wholesaler ever be dominant when supplying drugs to the NHS?

MS BACON: One question there might be the extent of the drugs that are supplied to the NHS, but I'm not addressing the hypothetical question, I'm addressing this particular question.

MR LOMAS: But in this market, on your definition, if the buyer and the regulator are the same party and the fact that you've got regulatory powers to control prices stops the supplier being dominant, presumably that would apply across the whole of the country's drug purchasing?

MS BACON: Yes, in principle, but fortunately the tribunal doesn't have to set out a general principle applicable across the board.

MR LOMAS: I understand that.

MS BACON: In this case we say that is the case, the Department was the monopoly purchaser. It did have powers and it had used them in the price of the directly comparable product, so it is a whole suite of factors. Then you wrap that up with the other points about the market share and the price interaction between Flynn and

its product.

THE CHAIRMAN: Aren't you rather assuming that the Department, NHS England, equivalents in other countries, commissioning groups, are a single monolithic purchaser when you put this buyer power point?

MS BACON: I'm not sure I understand that question.

THE CHAIRMAN: I mean, one of the points against you is that the Department may or may not have regulatory powers, it administers the National Health Service as we call it, the actual purchasing decisions within the National Health Service are actually made by specific bodies with purchasing functions all under a system of price --

MS BACON: Yes, I think that's belied by the evidence that we had discussions, Flynn had discussions, with the Department directly and it was the Department of Health that intervened in Teva's price. It may be that, for other individual products, one can make points about the decentralised nature of the purchasing process and the effect that that did or did not have on the powers. In this case, we know that the Department had the power to regulate the price and had informal powers as well and used whatever powers it did to bring Teva's price down. So we have a direct comparator here and that's a very -- I think a very compelling point in the buyer power story here.

Can I go onto the question of abuse because I did want to get through this with sufficient time before the lunch adjournment that I could start on the ROS analysis?

Now what I want to do in relation to the legal principles is to start by picking up a few questions that were asked yesterday and give our answers to those questions so you know what our position is on those, and then make a few, very few, points that are specifically of relevance to our case.

Now, the chairman's question yesterday, whether it is our position, the Latvian case, as we're going to call it, had at least equal value to United Brands, and our answer to that is yes. United Brands remains the starting point, but the Latvian case is the most recent consideration of that by the CJEU, and it is particularly important because the Advocate General has recognised precisely the point that the chairman made yesterday about context being everything and that is why his discussion, which I know you've all read, goes into the underlying general principles because he's trying to cater for different factual contexts and he thereby gives guidance on the nature of the benchmarks, among other things, which you'll have seen reflected in the court's judgment.

So that is why we say that it is not only that it's the most recent consideration of this, but that the Advocate General does try to set out some general underlying principles that run through the case law.

THE CHAIRMAN: You want us to take the court's judgment and the Advocate General's opinion as a seamless whole; is that right?

MS BACON: I wouldn't express it like that, I would say that, as in all these cases, the Advocate General is often much more discursive and academic in exploring the legal theory than the court, and the court then applied that to the facts. What I would say is that one needs to look at both of them together, and we would say that as -- and actually I've tried to do that in our skeleton argument by looking at the specific general principles that one can say are reflected in both the Advocate General and the court. But I don't need to go to my skeleton because I'll take that as read.

The second point, and another question from the chairman, is was the Advocate General in the Latvian case correct at paragraph 17 to define the benchmark price as the price that would hypothetically have been charged had there been effective competition? I think that's a very important question. Can I --

THE CHAIRMAN: Thank you.

MS BACON: Well, I say that to justify the fact I'm going to make quite a few submissions on that point.

THE CHAIRMAN: I'll take that as a compliment.

MS BACON: Yes, it was intended as such.

Can I start by answering that by looking at United Brands, because that's where this paragraph 17 comes from? United Brands is in authority C.

I'm sorry, it is authority C1, tab 3. I know my learned friend took you to these yesterday, but I wanted to ask you to look at them again because our submission is that the underlying test, the general principle, in United Brands is encapsulated in two paragraphs, and that is paragraphs 249 and 250. That's the underlying principle. Then what happened at the following two paragraphs, 251 and 252, is one means of testing that general principle, which the court then says is not necessarily the only method. The general principle I would say is in 249 and 250, and we've encapsulated that in our skeleton at paragraph 81 in this way: the question is whether a price exceeds what the undertaking would have obtained under normal and sufficiently effective competition to such a degree that it bears no reasonable relation to the economic value of the product. That was the single sentence encapsulation of the test that we would propose derived from 259 and 250.

The first question, as the Advocate General rightly identifies at paragraph 17, is whether there is an excess between the price charged and the hypothetical benchmark. I want to show you in a minute what is meant by normal and sufficiently effective competition, i.e. what is that benchmark?

Before we put away United Brands, can we just look very quickly over the page at a couple of paragraphs so I don't have to come back to them, paragraphs 260 to 267, because those are the paragraphs that deal with the point about the comparator being loss-making. The point that's being made is that the Commission had found that the prices charged to customers were making a substantial profit because they were considerably higher than the prices charged to customers in Ireland. Then at 261, what the court says is:

"What that doesn't take into account was that United Brands had pointed out the prices in Ireland had produced a loss."

The court then explores that information that was given by United Brands, commenting at paragraphs 264 that those particulars were really unreliable. But it says:

"However unreliable those particulars supplied by United Brands were, the fact remains that it is for the

Commission to prove that the applicant charged unfair prices."

Then at 265: "UBC's retractation" - that's where it had said that the prices in Ireland were produced at a loss.

"... which the Commission has not effectively refuted, establishes that the basis for the Commission's calculation is open to criticism, and on this particular point there is doubt which must benefit the applicant."

Then the conclusion at 266:

"It cannot be concluded that the price charged was automatically excessive and consequently unfair."

That's the source of what is then later said in a couple of Commission decisions, which I will come to later, but since we have United Brands out, I wanted to show it to you.

Now going back to the point about what is the hypothetical competitive price, that is addressed in one authority, which is Albion, and that's at bundle A2, tab 15. It's a very short point, and I only need to take you to one paragraph of that. Bundle A2, tab 15. It is Albion II and paragraph 212.

It is just the sentence in the middle of that paragraph:

"There is no mandate to equate normal and effective

competition in paragraph 249 of United Brands with the concept of perfect competition."

So what's being said is you're not asked to look for a precise benchmark based on conditions of perfect competition. It is just normal and sufficiently effective. That's all.

So that brings me into the question, well how one sets the benchmark, and all three of you asked questions about that yesterday. So I'm going to try to give our answer. Our answer, I put in the form of five propositions concerning the way in which the benchmark is set.

Now, proposition number 1 is that there is a requirement for there to be some form of a benchmark or more than one benchmark, and that's clear from United Brands. But without one or more benchmarks there's nothing against which to measure whether the disputed price is excessive or not. So there's got to be something. That's proposition number 1.

Proposition number 2, that doesn't require the Competition Authority to identify a single precise benchmark, and in most cases it will be difficult or impossible to do that.

Now, that by the way, answers the CMA's point about the National Grid case, which my learned friend made

some submissions on yesterday. All that was being said, in the bit of National Grid cited in the CMA's skeleton, is that it is not necessary in all cases of abuse to identify a clear benchmark setting out the dividing line between lawful and unlawful. That was an exploitative abuse case, and the CMA's skeleton says in the footnote "well, the same should apply" -- sorry, that was an exclusionary abuse case and the CMA's skeleton says in the footnote the same should apply here.

Even leaving aside the point that that wasn't an excessive pricing case, we don't disagree with the general proposition that there is no requirement to identify a precise dividing line. So we're not saying that the CMA should have done that. Having said that, it doesn't mean the CMA can decide an excessive pricing case without any benchmark at all, and that comes back to my first proposition, you need some kind of a benchmark to judge whether a price is excessive, but it is not necessary to set out a precise dividing line.

Proposition number 3, instead of trying to identify a single benchmark, what Advocate General Wahl is saying is that one should identify what, Mr Lomas, you described yesterday, as a basket of comparators or we could also say a basket of benchmarks. Those might be price benchmarks, such as the prices of similar or

competing products, or prices on different markets, and the basket might also include profitability benchmarks. In this case, in Flynn's submission for our case, we've relied on both, price and profitability.

So a basket of benchmarks where there are multiple benchmarks available is preferable, as Advocate General Wahl said, to just looking to try and identify a single benchmark.

Proposition number 4, what do you do with that basket? What the authority has to do is test the question of whether the price is excessive against that basket and Advocate General Wahl says the authority can only properly conclude that there is an excessive price if testing against that provides a sufficiently complete and reliable set of elements that points "In one and the same direction," namely the existence of a significant and persistent difference between the benchmark and the actual price. The one and the same direction point comes from paragraph 54 of his opinion.

That was not new, actually, because that was exactly the approach that was taken in Napp, and we've cited the relevant paragraph in our skeleton argument. As you've seen, Napp was, in turn, cited by Advocate General Wahl, so he was taking the approach used in Napp of looking at

a whole load of different benchmarks and seeing against all of them whether one would reach the same conclusion and that was the approach that he advocated and endorsed.

My last proposition, if there are difficulties in the course of that analysis, those should be resolved in favour of the undertaking under investigation because of the presumption of innocence. I've just shown you the similar point made in the United Brands, and that was picked up - and I'll just give you the paragraphs of Advocate General Wahl - paragraphs 52 and 53. He makes the same point about giving the undertaking under investigation the benefit of the doubt.

Those answers enable me to answer yesterday's question from the chairman to my learned friend which was apart from the tablet price and cost of production, what other benchmarks do we say the CMA should have looked at, as in this case, what else could we say it should have put in its basket? We say there are several things: Flynn's internal ROS on its other products in its portfolio, its gross profits across its portfolio, and the product contribution analysis, all measures of profitability looking at the profitability of its other products. Then we say the CMA could and should also have looked at profitability measures regarding other

generic companies, and it could have looked at both ROS measures and gross profit measures.

Those are the points I wanted to make which directly related to yesterday's discussion.

Now unless the Tribunal has got further questions on that bit of the discussion, I wanted to move onto making a few further points on the case law that weren't fully explored yesterday, but are of particular relevance to our case.

The first is that you will have seen that both the opinion and the judgment in the Latvian case place emphasis on the requirement for comparisons to be made on a consistent basis. That explained, what's meant by consistency is explained, and developed by the Advocate General at paragraph 84, where he says:

"The consistency of comparison requires not only that the products and services must be the same or very similar, but also that the economic context in which those products and services are supplied must be broadly similar."

His point is that it's not sufficient just to say that the products are the same or similar, if the economic context in which they're being supplied is completely different. You get an illustration of that in the Scandlines case which I would ask you then to

turn up, and that's in authorities bundle E1, tab 11.

There's a lot that can be said about this case, but in the time available I just want to point you in the direction of the key paragraphs from our perspective.

The discussion starts at paragraph 147. I'm not going to read all of those out. Can I take you to paragraph 157, where the point is made that:

"Comparison between the profits of the ferry operations in different ports would be too dependent on the markets in which they operate, the individual cost structure of the companies, possible economies of scope and scale, existence of cost efficiencies, the level of their investments and how these are financed, as well as internal decisions as regards the remuneration to shareholders."

Then Scandlines makes various comments and then over the page, at paragraph 169:

"The problem is to ensure that the comparison is valid and that the result of the comparison is meaningful."

The same kind of language you've seen in the Latvian case.

"It must be ensured that the figures which are compared are really comparable. The conditions under which such a comparison is made are therefore of the

utmost importance."

Then they say:

"It is not possible to find a substitutable product, but according to case law and decisional practice of the Commission, the contested price may however be compared to other prices charged by the dominant company and prices charged by other firms providing similar products or services."

It is endorsing, as a matter of principle, a comparison with other prices charged by other companies.

Then the next paragraph I wanted to look at, not exactly on this point, but again, since we have it open, I might as well show it to you, paragraph 179. That's the loss-making point. The last sentence of paragraph 179 reads:

"The fact that the cargo operations are run at a loss would imply that the price charged to the cargo operators could not be taken as a reference for the port charges."

The footnote reference is to the passage in United Brands that I showed you when we were looking at that case. That's the other authority that we rely on. Just as an aside, the exact same point is made in the Sundbusserne decision, which is the parallel decision to

Scandlines, which is in the next tab, but I don't think we need to go to it, but the two decisions are very similar and the same point is made there.

Just continuing on the cost comparison, the Commission then goes on to explain that the supposed comparators are not reliable and they make that conclusion at paragraph 202:

"There are difficulties in making meaningful comparisons with other ports."

And they explain why.

I think it is worth pointing out that, even though the Commission then says they're not reliable, what it then does is to say "well we'll have a look at them anyway", and then it says at paragraph 203:

"Against this background the Commission has nevertheless drawn up a comparison of the official tariffs published by several European ports."

Over the page at 206, they say:

"There is no evidence that prices charged would stand out as compared to tariffs applied in other Swedish ports."

So two points being made. One, and the main point I took you to this case for, that it's important to look at the economic context in which the product or service is supplied, two, the loss-making point. But

actually three, in any event, the Commission did do a comparison and said "well the prices don't stand out".

I mentioned the point about the consistency of the comparison and the case which explores that, because this of course has particular resonance when we look at the ROS analysis and the input to that, the ROS benchmark drawn from the PPRS, and the cost allocation. As you'll see when I come to those points, our basic position is that the benchmark was not an appropriate one because it wasn't meaningful in terms of the comparison between the companies. Also, if one, contrary to all that, were to try to attempt a ROS analysis based on the PPRS benchmark, it wouldn't be meaningful unless you do it on a similar basis as possible, so that you are comparing like with like, so you do have a meaningful comparison.

Now the next point to touch on in terms of the legal points is the multiple methodologies or basket of methodologies point. As you have heard, our position is that on the basis, not only of the Latvian case but also before it, Napp, if there are multiple appropriate benchmarks or comparators then they should all be put in the basket and looked at together. The reason for doing that is explained in the Advocate General's opinion as being to address the problem that there is inherent

uncertainty in identifying whether a price is excessive, and there is no single definitive test.

Now the way that the CMA has tried to deal with that point is to refer to Albion Water, and say that the Tribunal has said there, that is Lord Carlile, that it will give due weight to a finding based on an appropriate and reliable methodology, even if a dissatisfied party could suggest other ways of approaching the issue.

What I anticipate Mr Hoskins will say, and what I get the flavour of from his skeleton argument, is that he is saying "well, as long as you're satisfied with the method that we have chosen on some kind of, I think, almost says a judicial review standard, that it's reasonable, then we didn't have to look at anything else".

The answer to that point is that that's not what Lord Carlile was saying in Albion Water. What he was saying was not that the CMA or indeed the Tribunal could ignore a relevant comparator. All that was being said was that, given that there was no single right price -- and I absolutely accept and endorse that point, as I said, there will probably not be a single right price -- all he was saying was that the Tribunal would in those circumstances would give due

weight to a finding based on an appropriate and reliable methodology; and we don't disagree with that proposition.

What we are saying in this case is that the CMA's methodology was neither appropriate nor reliable, and it also erred by giving no weight at all to the multiplicity of other benchmarks that all pointed inconveniently for it in the opposite direction. Saying that the Tribunal should give due weight to an appropriate methodology doesn't mean that the CMA has carte blanche to ignore other comparators that are relevant and appropriate.

That brings me to the CMA's argument that, because of the two-part United Brands test, it can ignore comparators such as, in this case, the Teva tablet price, and we fundamentally disagree with that proposition in that we are absolutely aligned with Mr Brealey's comments yesterday.

Now, Mr Lomas suggested yesterday that comparators can be used for one of three purposes: one, to determine the benchmark; two, to determine whether the difference between whether the disputed price and the benchmark price is excessive; and three, to determine whether the price is unfair. And we agree with that characterisation of the use of comparators.

It's absolutely clear from both the Advocate General and the court in the Latvian case that they both regard a price comparison, where that is available, as being part and parcel of the question of whether there is an excessive and unfair price, and the CMA has not come up with any authority at all which says that if there is an appropriate and meaningful price comparator, it can be ignored in determining whether there is an abuse through an excessive price.

The lack of precedent is not surprising because the basic proposition which the CMA seems to be trying to advance is that a competition regulator can impose a fine on an undertaking, a quasi-criminal penalty, for a supposedly excessive price, even if there is a meaningful comparator which shows that the disputed price is not excessive, or which at least indicates that the disputed price is not excessive. That, in our submission, is an extraordinary proposition.

The CMA also relies on the Athens Airport case. We've dealt with that in our skeleton argument and I don't propose to say anything more about that now. If necessary, I can address that in closing.

The last point of my various supplemental points on the legal test is the loss-making price. I've taken you to the United Brands case on that, I've taken you to

Scandlines. It's clear from those that a loss-making price can't be a benchmark. So when the CMA says in its skeleton argument that a comparison of the before and after prices indicate that Flynn's prices were excessive, in our submission, that's simply wrong in law. It's contradicted by United Brands and it's contradicted by Scandlines because it is common ground, it is not disputed, that Pfizer's price before September 2012 was loss-making.

MR LOMAS: I think it is common ground that the prices in four other European countries are profit making, at least for Pfizer. Are those profit making prices also to be included in the basket in trying to determine the reference point?

MS BACON: You asked Mr Brealey that, and I give the same answer, which is that's the economic context point. And that was precisely the way in which it was used in the Latvian case because what was being said was you can't compare prices in different markets, especially different geographic markets, unless you first of all ensure that the economic context in which those are being supplied is the same. And the CMA -- I'm not saying the CMA can't do that kind of price comparison in principle, but in this case it hasn't made any attempt to look at the way in which those are supplied.

For example, just the question of costs.

MR LOMAS: You would say not --

PROFESSOR WATERSON: Surely what -- you've taken us to Scandlines and in Scandlines they did do that.

MS BACON: What they said in Scandlines was the primary position is that those are not meaningful comparators, but by way of an exculpation, not an inculpation, by way of exculpation, we've done that anyway and it shows they're not excessive. Actually that is what we have also said about the Athens Airport case. What they did there was to look at prices at other airports, but it was exculpatory and it certainly wasn't saying that one can ignore such comparisons and on that basis find an infringement.

Actually the point about loss-making prices - and this is the last submission I wanted to make on the law - the point about the loss-making price reflects the underlying legal test for excess in United Brands, because, as I've shown you, that refers back to the price that would have been obtained under normal market conditions and, in our submission, a loss-making price cannot be, as a matter of principle, regarded as the normal competitive market price.

THE CHAIRMAN: It's not that it was the before price, it is the fact that the before price was loss-making?

MS BACON: Yes, and that was why I think the correct approach is to simply just erase that, it's not a relevant benchmark at all. One can't regard it as the default or a benchmark or any kind of relevant comparator for what would be a normal competitive price.

THE CHAIRMAN: In this case.

MS BACON: In this case. Yes. In this case.

THE CHAIRMAN: You could have a situation where a before price was profitable.

MS BACON: Yes.

THE CHAIRMAN: And could be in the basket.

MS BACON: Yes, I agree.

I mean, there is one other point to be made about the -- there is some case law about before and after, and Advocate General Wahl in his opinion refers to a comparison over time and this may be where my learned friend is picking up the point.

Now in the first place, if he is picking up that part of the Advocate General's opinion, it's a little bit odd that he says one can do a price comparison over time but not a price comparison with the Teva tablet because this was all, that part of the Advocate General's opinion, was all talking about different types of price comparisons. But leaving aside that point, the cases that the Advocate General refers to, when he's

talking about price comparisons over time, are the same undertaking, so it's the same undertaking before and after, and also there's no suggestion in those cases that there was a loss-making price. In this case, we've got a loss-making price and it is not the same undertaking.

That brings me to our submissions --

MR LOMAS: I'm sorry to come back on this, very briefly, because I don't want to take up time. In relation to the other European prices, of course the economic context is different and the processes for setting those prices may be different. But as I understand it, those are at least profitable prices.

MS BACON: That I don't know. We can't comment on those because those are Pfizer's prices.

MR LOMAS: I understand, okay.

MS BACON: If I may then move onto our submissions on abuse applying the law to the facts. Can I set out a few preliminary points to explain our position.

The basic problem with a ROS or a cost plus analysis, which is what has been done in this case, is that because it is not an analysis that is ever in practice used for generic pharmaceuticals, if the CMA does use this to inform the analysis of excessive pricing, it needs to do so with caution, and that's the

point I made in my skeleton argument.

Now two particular consequences flow from that. The first is that the CMA must, in those circumstances, take particular care to calibrate the ROS calculation properly, and if there is doubt, as the case law shows, it must be resolved in favour of Flynn. It's also important to ensure that any comparisons that are made are done on a properly consistent basis. Again, those points are both made in the case law.

That's the first point about calibration of the calculation and resolving doubt in favour of Flynn.

The second point is that the ROS calculation shouldn't be the only method to test whether Flynn's price is excessive. What the CMA should have done was to consider alongside that other indicators of profitability, such as gross profit comparisons and also, if available, price comparisons such as the tablet benchmark. That's the multiple methodologies point and that's why I just wanted to set those points up by taking you to the relevant principles in the case law.

Those are the preliminary points by way of preamble to the meat of the ROS analysis.

Now, we have explained in our skeleton argument that there are three key inputs to the CMA's ROS analysis, what we've called the parameters of the calculation.

The first is the selection of the benchmark ROS. Now, can I just make a boring technical point concerning the terminology. We have used the term "ROS analysis" interchangeably with cost plus analysis, but of course mathematically they're different things. I just didn't want to be picked up on that because I do know that and I think in some parts of our skeleton argument that's not brought out, clearly it is a technical point.

Now, as you'll know, the ROS is derived from subtracting total costs, including an allocation of common costs, from total revenues and expressing that as a percentage of the revenue. So if you have a sale of 100 with total costs of 94, that generates a profit of six, and so the ROS is 6 per cent, i.e. 6 over 100.

Now cost plus puts it around a different way and that's why you have seen in Mr Williams's reports he talks about grossing up. Cost plus asks by what percentage you have to increase the cost base to get to the sales figure. If the profit is in that example 6, then to express that as cost plus, you calculate 6 as a percentage of the cost. So 6 divided by 94 which gives 6.38 per cent.

So ROS of 6 per cent equates to cost plus of 6.38 per cent. I'm sure you knew that but I just wanted to draw your attention to the point because it crops up.

THE CHAIRMAN: I'm sure we knew it, too.

MR BACON: Yes, well I had to get my head round it so I thought I'd put it on the transcript.

The key point here, leaving aside the mathematical point, the ROS figure that the CMA alighted on as representing its benchmark rate of return was 6 per cent. We say that's wildly inappropriate and there's absolutely no evidence that this is or should be the normal rate of return for the product. In a minute I'll take you through our reasons why.

Just pausing there to explain the significance of that, this 6 per cent figure is the single factor that makes the most significant difference to the calculation. If you change that one figure to something that is based, as we say it should be, on more empirically, for example, analysis of average profitability for generic companies - and we just put that up as a more appropriate way of working out a benchmark ROS - that alone reduces the supposed excess above cost plus to a level that we say the CMA couldn't tenably say was abusive, and I'll take you to the figures on that.

So that's the first key parameter.

The second key parameter is the cost allocation methodology and again, we say the CMA's methodology was

wildly inappropriate. Our evidence, which is from industry experts, is absolutely unanimous on this. The only appropriate methodology, in our submission, is to apportion costs by revenues, which is what is done in the industry if a cost allocation is done. Again, that has significant results on the calculation, although not as significant as the benchmark point.

The final relevant parameter is the common cost pool as in, what costs do you allocate? That's a smaller point, but still a material one. That's addressed in our skeleton argument, and I don't intend to say anything more about that today because it is a fairly self-contained point which we've set out fully in our written submissions.

What I want to do now is to start with the question of the ROS benchmark, the 6 per cent. The first point to make is a legal one and that's the question of what the benchmark is supposed to represent, and it comes back to the point about paragraph 249 of United Brands, and 17 of Advocate General Wahl's opinion.

"The CMA say that what is relevant is to ask what is a reasonable rate of return for the product."

But as a purely legal statement, that's not correct. The benchmark for the excessiveness part of the test isn't what the Competition Authority thinks is

reasonable in terms of the reasonable price, or the reasonable profit, but as I've shown you, what would be the price or profit under normal and sufficiently effective competition.

If the CMA is simply using the phrase "reasonable rate of return" in a loose sense to mean the rate of return that would have been made under normal and sufficiently effective competition, as in the United Brands test - and I don't disagree with the principle, they've simply expressed it wrong - if the CMA is using reasonable return to mean something else, and I detect hints of that in their submission, they are saying it means something else, to mean that the CMA can effectively determine what is a reasonable price or reasonable profit for a product, then that is an error of law, because that's not what the test is. The test is not what the competition regulator thinks the profit or price ought to be, but what it actually is under normal and sufficiently effective competition, again, bearing in mind the point that I've made that that doesn't mean perfect competition.

That's the preliminary legal point. What are we using this benchmark for?

Now can I come to the source of the 6 per cent. The statement of objection says explicitly and unambiguously

the 6 per cent comes from the PPRS. Can I ask you to turn that up. It is at bundle J1, tab 30, and it is at page 256. It's paragraphs 5.101 to -- J1 tab 30, the big document in J1.

PROFESSOR WATERSON: Thirty-one.

MS BACON: I'm sorry, 31, you're absolutely right. 5.101 to 5.103, and I'm going to come back to 101 in a minute because there are some submissions I want to make about it. That's the basic discussion, it explains what the function of the ROS in the PPRS is, and then at 103:

"Accordingly, the CMA considers that the PPRS ROS measure is both well known and understood and suitable for use in the CMA's estimation of a reasonable rate of return for each of Pfizer and Flynn."

I am going to come back to this, so please keep that open, but I want to show you what the decision then says about this, too.

Paragraph 5.163 of the decision, says that:

"The CMA has considered the following possible benchmarks for a reasonable rate of return. Flynn's internal ROS, other companies' ROS rates and the allowable ROS under the PPRS."

Well we know that the first two of those have been rejected, so that only does leave the allowable ROS under the PPRS. That's the benchmark, it's clear, which

the CMA adopted.

Then at paragraph 5.200:

"The CMA accepts that there are limits to the appropriateness of the PPRS/ROS rate of 6 per cent as an indicator of a reasonable rate of return."

Pausing there, that's one of the places where the CMA refers to reasonable rate of return and I say that's either loose language or just wrong.

But then at paragraph 5.201:

"Nevertheless, for the reasons set out below, the CMA considers that the allowable ROS of 6 per cent under the PPRS has some probative value for assessing what would be a reasonable rate of return for the purpose of calculating cost plus for Flynn's products."

So it's also clear from the decision, that the PPRS/ROS was the source of the 6 per cent.

The other point being, of course, that saying it has some probative value doesn't detract from the point that there is nothing else that produces the 6 per cent figure. As we've seen, the CMA had considered three possible sources for its benchmark: Flynn's ROS rates, other companies' ROS rates, and the PPRS. The only one of them left, because it rejected the first two, was the PPRS.

I know that my learned friend refers in his skeleton

and also this point emerges from his defence, that the CMA's case seems to be that one can rely on other factors, such as the nature of the product, or Flynn's activities, but none of those actually produce the 6 per cent figure. None of those produce any kind of figure at all. They might be reasons why you might move up or down from your particular benchmark, and while we disagree on the facts on that, I don't dispute the general principle that once you identify a benchmark, there might be reasons for saying that it's generous or conservative or whatever and that you might want to adjust it up or down. But you still have to start with your benchmark figure.

Of course, returning to the point about what is the benchmark, I'm not saying that one has to identify a precise competitive figure, but you still have to have a benchmark to test the excessiveness of the price, so you need the starting point, whether that is adjusted up or down. The only thing here that gives you that starting point, Mr Harman refers to it as the starting point, is the PPRS.

MR LOMAS: But you do accept they did then sense check that with other tests, like return on capital employed, and different assumptions?

MS BACON: Well actually, the ROCE sense check is Mr Harman

and, if you want, I can show you what he says about that because the CMA didn't do it. The decision says, "We don't do a ROCE analysis because it is not appropriate." Mr Harman started off by saying ROCE is a sense check and then he comes back in his second report and says actually ROCE doesn't tell you anything about whether the price is excessive or not. All it does is to set a floor.

THE CHAIRMAN: You'll have your chance to talk to Mr Harman.

MS BACON: Yes. I wasn't actually going to say anything else about that today. I hadn't intended to go to it. I'm just answering Mr Lomas's question.

I don't accept that the CMA did a ROCE sense check. What it did was it started with its benchmark of 6 which is quite clearly and explicitly drawn from the PPRS. It then tries to disguise it when it comes to the decision by saying, "Oh that's only one of the factors", but the problem is that the PPRS is the only source of the figure of 6 per cent. It is all very well to say "well, if you compare Flynn's activities with those of branded products, it may be showing that one can go up or down from that", but you still have to know what you're going up or down from, and the only source of that is PPRS.

The first question has to be the appropriateness of

that as a meaningful starting benchmark. If it is completely meaningless, no amount of adjusting up or down is going to cure the problem, because you are adjusting up or down from something that is not an appropriate starting point.

Now the CMA don't like the question of whether extracting the 6 per cent figure from the PPRS is meaningful. So they try to skate round that in the way I've just explained by saying the PPRS played a limited role in the selection of the 6 per cent, and it is worth seeing what they say about that in their skeleton argument.

If you keep the statement of objections open, because I am going to come back to that, if I can actually find the CMA's -- I wanted to refer you to paragraph 199. Paragraph 199 of their skeleton points to various comments in Napp that the PPRS concerns are companies' overall return and not individual products, and is not intended to guarantee the company the right to earn profits up to the limits of the scheme and so on.

Then, over the page at paragraph 200, he says at (a):

"The major component of the PPRS, the 6 per cent ROS, is an appropriate factor to refer to."

Then he says:

"The rate of return on a long out of patent ... product should be less than the average ROS under the PPRS."

There he's saying the 6 per cent in the PPRS should be an upper bound for the rate of return for phenytoin.

MR LOMAS: Well for the benchmark of cost plus analysis.

MS BACON: Yes. Yes. But the point is that he's just said "well, the PPRS isn't really definitive" and then he says "well, actually that should be our benchmark".

In my submission, you cannot have it both ways. Either the CMA is saying that because the PPRS concerns portfolios and isn't intended to guarantee a rate of return and so on, it can't be used as a relevant source for that starting benchmark. If the CMA is saying that, then we can go home now because if the PPRS isn't a meaningful source for the starting benchmark, then there isn't anything else that does provide that. There's nothing else that provides the 6 per cent figure. So I presume that's not what he's saying.

What I think he's saying is that the 6 per cent figure in the PPRS, notwithstanding all of his points about PPRS not being meaningful, he is saying it is a meaningful benchmark for the rate of return to plug into the ROS model.

If that is the CMA's case, then they have to justify it. They can't avoid, then, having to prove that that is a meaningful starting point, and they can't avoid having to prove that by looking at where the 6 per cent figure comes from and how it is intended to work in that scheme.

My learned friend protests, "well, that gives rise to a detailed debate on the intricacies and technicalities of the PPRS". Well that's intended, I think, to scare you off. I know it's Halloween but it's not really that frightening. It's true that we do have to look at how the PPRS works, but it's not a matter of looking at intricacies. What is needed is simply to understand a few quite fundamental points about how the PPRS works and how the ROS figure was intended to operate in the framework as a whole.

A good starting point for that is paragraph 5.101 of the SO which is why I asked you to keep it open. That contains a partial explanation of how the ROS benchmark came about.

Now can I ask you to keep that open and put it side by side with the Department's note, with the CMA's note of a telephone call with the Department, because, as I'll show you, that's where this paragraph comes from.

The CMA's note is at J1, tab 20. It's in the same

bundle as the SO, so what you might want to do is just take that out and put it next to the paragraph of the SO.

Can I just address the confidentiality on this note first? This is the first of the documents referred to in the Department's letter. The Department doesn't want various bits of this read in open court, because they say -- well, one of the points was wrong and another of the points -- well I'm not sure what problem they have with it, but they have a problem with it.

This document is not --

THE CHAIRMAN: I think they said both are wrong.

MS BACON: Both are wrong, yes.

THE CHAIRMAN: That was my understanding.

MS BACON: Yes. This document hasn't been redacted by the CMA. I understand that the CMA's position is that there isn't anything confidential in it. There might be points in it that are wrong but the CMA can make submissions on that.

THE CHAIRMAN: Do you want to refer to the passages that the Department of Health wishes us not to refer to?

MS BACON: Yes, I do want to refer to those.

THE CHAIRMAN: Could I hear what the CMA have to say on that?

MR BAILEY: The CMA's position is that the passages

identified by the Department of Health are not confidential within the meaning of paragraph 12 of schedule four, and have no further observations to make, so are content for the Tribunal to decide whether it agrees with the Department of Health or not.

THE CHAIRMAN: You're not taking any position as to whether they are right or not?

MR BAILEY: Correct. Well we set out our view, which is that we don't consider information that the Department of Health gave at this meeting, that they now disagree with, is a legitimate ground for claiming confidentiality. Of course, it is for the Tribunal to decide.

THE CHAIRMAN: I think I'm probably inclining towards you on that.

Mr Brealey, do you have any observations?

MR BREALEY: No, I agree with both my learned friends. It should be read out in open court.

THE CHAIRMAN: I think we proceed on the basis that you can refer to it. We are replying to the Department of Health, represented by the Government Legal Department, and I suspect the reply will include the point that disagreement with content of documents which has previously been expressed is not a ground for claiming confidentiality.

MS BACON: I'm very grateful.

So the reason why I wanted to take you to it is that, as far as I am aware, this is the only evidence before the Tribunal regarding the Department's position on the suitability of the PPRS benchmark and the interaction of the 6 per cent with the other elements of the PPRS framework.

Now, initial question, what weight should be placed on it? If it were uncorroborated or indeed contradicted by other documents, I would say possibly not very much, but the point I'm going to make is that this document makes for the most part precisely the same points that Mr Williams makes in his evidence.

Now, Mr Williams, who is sitting behind me today, is going to be tendered for cross-examination, so his evidence will be able to be tested. As you may have seen from his CV, Mr Williams has spent his entire professional career advising on the PPRS. So his evidence should, on any basis, be given some considerable weight, but even if that were for some reason in doubt, it's quite significant that the Department's explanations given to the CMA said exactly the same thing about the way the PPRS worked.

Now, what is a matter of concern, however, is that while paragraph 5.101 of the SO lifts almost verbatim

the Department's explanation as recorded in this note of the origins of the 6 per cent figure, what is airbrushed out are the bits where the Department explained its reasons why it had concerns about the use of the 6 per cent as a benchmark. What is airbrushed in is a statement about the applicability of the ROS figure to Flynn which the Department didn't make and was actually the opposite of what the Department was saying. That's why I said it's helpful to put the two side by side.

Now the start of paragraph 5.101 is consistent with the Department note, so the Department had explained that originally the target return was just a ROC measure, return on capital measure, but this became less relevant as the manufacturing base moved overseas. So that's the first three sentences of paragraph 5.101 which correlates to the paragraph in the middle of this page which contains some of the material the Department didn't want read out.

So in it there's an initial at the start of that that I won't read:

"Further noted that the target return was originally just ROC, reflecting a high manufacturing base for drugs in the UK. As the manufacturing base moved overseas and transfer pricing increased, the ability of DH to control medicine spend decreased."

Then this sentence:

"Transfer pricing in particular made the AFR numbers less scientific and therefore not reliable as a measure of prices."

Well the point about transfer pricing vanishes from paragraph 5.101. Instead, what the CMA says in that paragraph is that this was all about the UK entities becoming sales and distribution entities, meaning that ROC was -- we pick that up:

"As the UK manufacturing base moved overseas a large number of pharmaceutical companies' UK entities became sales and distribution operations meaning ROC was less relevant in assessing their profits."

This point about transfer pricing making the AFR numbers less scientific, is not in 5.101.

The CMA then says, at the end of 5.101:

"Flynn's activities are compatible with the type of operation ROS was included in the PPRS to assess."

But that was not what the Department was saying. The Department wasn't saying that the ROS measure was designed to address a standalone company like Flynn. What it was actually saying was the opposite: it was introduced to address transfer pricing and that is why, alongside the 6 per cent figure, the Department had to introduce a set of rules on the transfer price part of

the cost base, and the intention was that the revised framework would then adequately deal with the situation that goods were no longer manufactured in the UK but were bought under transfer pricing arrangements.

The point made by the DH was that the ROC measure didn't cater for that.

So the Department wasn't, as I said, saying that one could extract the 6 per cent and use it to a company that was not transfer pricing. This point about Flynn's activities being compatible was a gloss that the CMA appears to have had put on it.

Then I want to go back to the Department's note because the Department then went on to consider, as it had been asked to do, whether the 6 per cent was a suitable benchmark. It is very clear from this note that it didn't think it was.

Picking up two lines from the bottom, an initial, which I won't read:

"... stated that the 6 per cent ROS did not bind behaviour that much."

Then the two Department individuals set out potential issues with using ROS for benchmarking, including the measure covers the entire portfolio, and therefore there can be a wider range of drug returns with it, within it.

Next bullet point:

"There was negotiation between government and industry in relation to the level of returns."

Third bullet:

"The effect of allowances and transfer pricing on the calculation."

Now, those points about the portfolio calculation and the effect of transfer pricing are precisely Mr Williams's objections also to the use of the PPRS as a benchmark. And you can see here that this was the same point that the Department was making to the CMA when the CMA had asked it, "Is this a suitable benchmark?"

Now the fourth bullet point concerns the difference between branded and generic products, and that is one of the points that the CMA seeks to rely on to justify the benchmark.

Now, you will have seen, and you will see from the cross-examination of the experts, that our evidence provides a rather more nuanced analysis of the relative profitability of different categories of drugs. But what we can agree is that whether or not it is possible to make sweeping generalisations about branded versus generics, it is the case that the market dynamics differ for different products, and that will have an impact on

their profitability. That's a point that we rely on as another reason to show why the PPRS is inappropriate as a benchmark.

Now, returning to the memo, the next point to note under the bullets is that the CMA then asked what information was available on actual rates of return, and the Department's answer was to point to summary reports to Parliament setting out the returns. Now, those are what Mr Williams has referred to in his reports as giving some information on returns made through the PPRS, actual returns.

The Department then agreed to send the CMA a worked example showing the effect of the transfer pricing and other allowances on the calculation of the rate of return, and that is at the next tab, J1/21.

Now, I do want to look at the document in the next tab to make a couple of points, but -- yes, when I say it is at the next tab, it is J1/21, so I think we can now put back --

THE CHAIRMAN: Return 101 to its rightful place.

MS BACON: We can return this memo to its rightful place and then turn over to tab 21. Before I look at this in detail, I want to explain why it is relevant for me to take you through a detailed spreadsheet looking at transfer pricing.

THE CHAIRMAN: This is in case we're scared, is it?

MS BACON: Just in case you're scared. I'm not scared, Mr Hoskins is scared, but I'm not.

Now, why is it relevant? Well, Mr Williams devotes some time to the point about transfer pricing in his reports, and the reason he does that, as you'll have seen, is to make good his conclusion that the 6 per cent is meaningless because, as he explains, it is part of a complex framework which was designed to accumulate a local ROS with transfer pricing and other allowances, which leads overall to a much higher profitability figure and, he says, masks the profitability in the system in the framework.

I also need to show you this to explain what Flynn would have had done if phenytoin had been assessed under the PPRS, which is the point that my learned friend takes in his skeleton argument.

So, the Department spreadsheet, a multi-coloured spreadsheet. Now, there are two points on this page and I'm going to then hand you up a simplified example which sets out more or less the same thing.

Now, on this page, it's clear from this example that transfer pricing is an integral part of the model, and it has to be, because, as I've just shown you, the whole point of the insertion of the ROS target as a new and

alternative way of measuring under the PPRS was to deal with the fact that companies were using transfer prices to buy their products, and that was why the target was not just the 6 per cent, but rather the --

MR LOMAS: Presumably it dealt with the fact that as they restructured, their capital base had moved offshore.

MS BACON: Yes, exactly.

THE CHAIRMAN: So you couldn't use the return on capital because the capital wasn't there.

MS BACON: Yes, exactly, and that's precisely why the ROS was introduced, so it was introduced to reflect a transfer pricing scenario. That's why the target profit wasn't just the 6 per cent, but it was 6 per cent plus a percentage of the transfer price.

It is clear from this example, and it is the other simple point that I wanted to make looking at it, that there is a difference between the target profit and the acceptable or permitted profit. The target profit you see is the figure of 198.2 and it is close to the bottom in the right-hand column. That has to be increased by the margin of tolerance which in this example was set at 40 per cent, and you use that to get to the maximum acceptable profit. That's why you then have a figure of the assessed profit as a percentage of the target, so we see the maximum acceptable profit is 277.5, that's the

target profit grossed up by the margin of tolerance, and then you have in the box at the bottom various calculations, the assessed profit as a percentage of the target and we see that the assessed profit is coming in both within the target and within the maximum permitted. Then there's a line for the potential additional profit that could be made within the PPRS guidelines.

The other integral part of this spreadsheet is the margin of tolerance, and that was always a given.

Now can I hand up a somewhat simplified example of how this works in practice. You'll recall that Mr Williams's evidence is that every company that falls over the 25 million or the 50 million threshold, it's now 50 million, it was 25 under the old PPRS, every company that falls over the threshold for submitting AFRs, that's the returns, to the Department, is a multinational. That's how the companies that are typically assessed under the PPRS framework will operate.

MR LOMAS: Before you go on, I'm confused on one point. You've referred to the margin of tolerance of 40 per cent.

MS BACON: Yes.

MR LOMAS: Is that margin of tolerance entirely to take account of the transfer pricing issue, or is it

a separate question?

MS BACON: It is a separate question and it applies to both, and that's an important point that I'm going to come to which I've illustrated in my worked example, I'm going to come to. That's an important point because what happens in the transfer pricing part of the calculation, as I'll show you, is that essentially, the transfer price profit is taken out of one side, it is taken out of the costs side and put in the profit side, but the result of that is that it has the margin of tolerance applied to it. When you look at the total permitted profit within the model you have the 6 per cent figure, then you have the acceptable profit within the transfer price and you gross all of that up by the margin of tolerance, 40 per cent under the old PPRS, 50 per cent under the new one.

You will see that Mr Williams has used a weighted average because the period in this question, the period covered by this case, spans both the old and the new PPRS. So when he has looked at the permitted profit under the PPRS, he has used a weighted average to compensate for the fact that there were two different margin of tolerances applicable at the relevant time.

Now, what I hope that this diagram shows is that the point of a PPRS calculation is not to work out whether

a company makes a ROS of 6 per cent or less, but rather, to work out whether the total amount of assessed profit, with all of the various assumptions and adjustments in the framework, is lower than the total amount of the allowed profit.

The allowed profit, as you can see on the right-hand side in the red, accumulation of the three elements: the target ROS, the profit in the transfer price, and the MOT which is currently 50 per cent, so I've used that as the margin of tolerance in this.

The diagram illustrates several things in particular about the allowed profits. One of the points I've just made is the allowed profit includes the margin of tolerance. When the CMA says, as it does, in various points in the decision that the allowable ROS under the PPRS is 6 per cent, that's just wrong. The allowable ROS is not 6 but 9 per cent currently under the old PPRS, if you include the MOT the allowable ROS was 8.4.

Secondly, the allowed profit is much more than 6 per cent. Even on the Department's assumption, which is given in the bottom left-hand, and that's a default assumption that the profit in the transfer price is only 20 per cent of the transfer price, accumulating that profit element with the margin of tolerance, the point I've just made, and the 6 per cent, gives you an

allowable profit in this example of 28 per cent.

Of course, as Mr Williams has said, the actual profit in the supply chain is far more than that because the cost of goods sold in the transfer price will actually be far lower than the 59 per cent that is assumed. So he says because there's a very generous assumption that 59 per cent of the cost of the goods -- 59 of the transfer price is actually the cost of the goods, that's a very generous assumption, that masks a far greater profitability within this framework.

The other important point that is illustrated by this worked example is that the way that the framework is constructed means that it would make no economic sense not to purchase through a TP arrangement and I can show you that quite simply by looking at the figures in this diagram.

Now, suppose that the UK company purchased directly from an unaffiliated third-party manufacturer at a price of 65, so the same as the transfer price here. But it wouldn't be a transfer price, because on this assumption, the goods would be bought from a third party, and so there would be no notional split of the cost of the goods, the assessed costs would be therefore the 65 in the transfer price, plus the distribution and other costs which I've put at 20. So 85 total assessed

costs giving a total assessed profit of 15.

Now the other side of the ledger, the allowable profit, because this wouldn't be a transfer price case, would only be 9, so on that model there would be an excess profit of £6 or 6 per cent. That's what would happen if --

MR LOMAS: You'd say that is this case because Pfizer is not an affiliated company.

MS BACON: Yes, if you applied that to this case. But why would anyone do that? Because now suppose -- I change it, now I go back to this model. Instead of buying directly from a third party, the UK company sets up a procurement company and it sets up that company to buy all of its products. Let us suppose, absurdly, just for the sake of argument, that the procurement company didn't put any mark-up at all on the cost of the goods. So it doesn't take anything for itself. It buys at 65 and sells at 65. On that case, the figures are as set out in my diagram because the calculation, it doesn't matter how much they bought the goods for, it doesn't matter whether it is 10 or 65. The result in that case, as this diagram shows, is that the assessed profit is actually below the allowable profit, assessed profit on the left, 28, allowable profit, 28.5.

Simply by setting up a procurement company to buy,

enabling you to take advantage of the transfer price that was designed to be in the system and was there as a reason why there was a ROS, simply by setting up a procurement company so that you could use the transfer price allowance, brings you within the PPRS guidelines.

Of course no affiliated procurement company does sell on at the same price it buys and that's why in this diagram I've used the figures of buying at 10 and selling at 65. Now on those figures the need to interpose a procurement company is even more stark because if the UK company bought directly at 10, the excess profit would be massive, but by using a procurement company it remains within the PPRS profitability allowance.

If you were that hypothetical stand-alone company approaching the PPRS threshold, now 50 million of branded sales per annum, and if you didn't buy in your third-party products through either a procurement company or an affiliate, you should be sacking your finance director because the PPRS is set up and is designed in a way that it makes no economic sense to do that. Put it another way, if you have a system set up to deal with transfer price arrangements with an interlocking network of allowances and adjustments that are designed to address a group structure system - and

that is what the Department told the CMA - then it would be completely foolish if you didn't structure yourself on that basis.

Now, of course, the finance directors of all these companies don't get sacked, at least not for that reason, because the companies that are approaching that level of sales to the NHS know that's how the PPRS works and if they don't know it, they go to Mr Williams for advice. So any company that comes close to that threshold where it knows it is going to have to start filing AFRs and it's going to have its profitability measured by reference to this framework, will, if it doesn't already have it, put in a structure that enables it to take advantage of that framework, and take advantage of it in the way that the framework was designed to operate.

Now, there are obviously other points of detail about how the PPRS works which are explained in Mr Williams's evidence. He explains not only the transfer price allowance that works in favour of the group structure, but other allowances and adjustments, such as the injected costs and grossing up the R&D, and that's probably what my learned friend would describe as the intricacies and technicalities of the PPRS.

Now those all go in the same direction as the

transfer price point, because they reinforce that what we're dealing with is a framework with a set of interlocking rules that were intended to be applied cumulatively and are in practice applied cumulatively. But I don't need to have a detailed debate about things like grossing up R&D because firstly, Mr Williams's evidence on this point is not disputed by the CMA, obviously we'll have to see what Mr Hoskins puts to Mr Williams in cross-examination.

But anyway, for my purposes, it's sufficient just to make the point about the transfer price framework which, as I've shown you, is the point that the Department made itself several times when it was asked to comment on how the PPRS worked and the suitability of the 6 figure as a benchmark.

PROFESSOR WATERSON: Just to check, this is the sole model that is used under PPRS? There isn't a different model?

MS BACON: Well there is the return on capital model, but this is the way that the return on sales model works. What I've tried to do in this diagram a bit more graphically is to simplify the information that's given on the spreadsheet, the more detailed spreadsheet. What I haven't done on this diagram is to include all the points about grossing up, for example, R&D and knocking off the bits which aren't allowed, which isn't on the

spreadsheet, and I haven't put that on because, as I've just said, I don't need to go there. I just made the point that because this was -- yes, because this was designed as a transfer pricing framework, that was why the ROS was introduced, it makes no sense at all to try to extract a figure from that which is not in practice applied on a stand-alone basis.

I'm just being reminded that almost everyone uses the ROS model rather than the ROC model, and that's because almost everyone has offshore for the manufacturing base.

I had to take you to that to explain, I hope, reasonably succinctly, why Mr Williams says that the 6 per cent figure is meaningless. Not only was the allowable ROS not 6 but 9, or in the earlier period 8.4 because of the MOT, but more fundamentally, the ROS figure was never intended to apply in isolation to a company like Flynn, which doesn't use that group structure. As one expects, as I've just explained to you, the result of designing the PPRS in that way to include those interrelated allowances is that in practice, the companies that do routinely file AFRs, not Flynn because it doesn't have the sufficient sales, but the companies that do file AFRs because they come over the threshold and those are the companies that have

their profitability assessed under the PPRS rules, those companies in practice, Mr Williams has said in his evidence, have structures that enable them to take advantage of those interrelated allowances.

Mr Williams makes the additional point that in any event, those companies, because they are using LRD, limited risk distributorship models, in those cases their local ROS figures are completely notional because they're fixed at below 6 per cent because of the way the LRD model works.

THE CHAIRMAN: Your submission is that the CMA have taken one percentage out of a complicated and intricate network of different percentages and allowances, and given it an authority that you don't think it has?

MS BACON: Yes, although I would say it's actually not that complicated when you look at it, but yes. The point is, it's a network of interrelated allowances.

THE CHAIRMAN: So not a complicated network, just a network.

MS BACON: Well given the Tribunal's rebuke at me for explaining the grossing up, I would hesitate to suggest that anything was too complicated for the Tribunal.

THE CHAIRMAN: If that was a rebuke, you should see when we really try. (Laughter)

MS BACON: That is the reason, and I had to take you to that in some detail, but that's the reason why in the

telephone call with the DH where the DH was asked to comment on the suitability of the 6 per cent figure, the official from the Department said that the 6 per cent didn't bind behaviour that much, because companies aren't being held to the 6 per cent.

MR LOMAS: Sorry to interrupt, picking up the president's point.

THE CHAIRMAN: Chairman.

MR LOMAS: The chairman's point. I understand that you're saying or submitting that the 6 per cent figure is the wrong figure because it's not measuring the totality of the economic activity, because of the off-shoring, but what it's trying to do is to deal with an integrated company where some of those profits are being generated offshore in the level of the transfer price that's set to the sales and marketing distribution company in the UK.

MS BACON: Yes.

MR LOMAS: Flynn, of course, doesn't have that offshore element, that is replicated by the Pfizer part of the distribution chain for this particular product.

MS BACON: Yes.

MR LOMAS: So are you not still with your 6 per cent measuring a similar factor for a similar part of the distribution chain?

MS BACON: No, because if Flynn had been within the PPRS, it wouldn't have structured the operation in that way.

MR LOMAS: It would have had an offshore marketing --

MS BACON: It would have had an offshore procurement company. That's my point, because one may look at the PPRS and say, "Well look there's a 6 per cent ROS, can't we apply that on a local basis?" The answer is that the companies that do submit AFRs, and those are the companies that are measured to this standard, they all do have that offshore element, but it doesn't have to be offshore, they have the group structure, and they can therefore take advantage of the allowances, so it is quite meaningless to say that one can extract this figure because the figure was never really intended to be applied in isolation, and Mr Williams's evidence is that in practice it never is applied in isolation. So you can't measure Flynn against that standard. That's the problem.

So that answers the CMA's point, well, if phenytoin had stayed within the PPRS, which was, as I've shown you earlier this morning, one of the proposals, it would have been bound by the PPRS, and the CMA says, "Oh therefore we must be taken to be agreeing that 6 per cent is reasonable" and the answer is the one I've just given you: if Flynn had come within that, like

every other company who falls within that category, it would have been economic lunacy not to have in place a structure that would allow it to take advantage of the different elements of the test.

So having gone through that, I can summarise the fundamental problem with the ROS quite shortly. The first headline point is that the PPRS applies to portfolios of branded drugs, and the ROS thresholds and the PPRS are designed to be applied, as the president -- I've done it now -- the chairman just summarised in conjunction with a set of other interrelated allowances and adjustments. In those circumstances, our submission, basic submission, is that the PPRS is a completely inapposite comparator. It doesn't even begin to meet the requirements in the case law for a comparator to be a meaningful one based on products or services supplied in a similar economic context, and that's why I took you to Scandlines and made the point about the consistency of the comparison.

Now, oddly, the CMA doesn't dispute the consistency point, because it says repeatedly in its skeleton argument that comparators are only valuable insofar as one is comparing like with like. In our submission, as I've just shown you, one isn't comparing like with like if you use the PPRS as a benchmark, because the CMA is

trying to draw conclusions about the profitability of phenytoin from looking at a framework applicable to different types of drugs with different market dynamics, different group structures, to that of Flynn.

The second and related point is that, even if contrary to all of that, one can draw out from the PPRS some appropriate benchmark based on the profitability of branded products sold under the PPRS, the 6 per cent figure is not the average ROS under the PPRS, and it is not even the allowable ROS under the PPRS. The allowable ROS is 9, but even that's not the average ROS, because of the various interrelated allowances.

What the CMA doesn't have is actually any analysis of what companies supplying under the PPRS do make on average. They haven't done it. So they make comments about this being the 6 per cent being the average ROS under the PPRS, that's what they say in paragraph 200 of their skeleton. It is not the average at all. There's no evidence at all that any company is making 6 per cent.

So that means, as Mr Williams says, that it's meaningless to pluck the 6 or even the 9 per cent out of the framework to apply to Flynn because no pharmaceutical company actually is ever held to that figure and there is no evidence showing that any

pharmaceutical company does makes that figure on its local activities. There is no evidence at all.

That's a factual point, the meaningless point, and the Tribunal will be able to decide whether we've made that point good, not only after listening to my submissions, but also after hearing Mr Williams's evidence. But as I started off making the points, what Mr Williams says about the appropriateness of the benchmark is corroborated by what the Department of Health told the CMA.

Now if Mr Williams is correct and if we're correct to say that as a matter of fact, and an economic assessment, 6 per cent is meaningless or 9 per cent is meaningless, then no amount of adjusting upwards or downwards is going to help because the starting points are meaningless.

I think that's an appropriate point.

THE CHAIRMAN: I think that would be a good time to draw breath. Thank you, Ms Bacon. We'll resume at two o'clock.

(1.00 pm)

(The Short Adjournment)

(2.00 pm)

THE CHAIRMAN: Ms Bacon, how are you getting on, time wise?

MS BACON: Well with a fair wind I'm hoping I should finish

my part of the submissions between 4 and 4.30. Where do we stand on sitting late?

THE CHAIRMAN: We did start early. We are human.

MS BACON: It sounds like I should try to finish my part of the submissions by 4, so that Miss Kreisberger can then have half an hour; is that all right?

THE CHAIRMAN: Yes, thank you. Assuming you're happy with that?

MS KREISENBERGER: Yes, I'm grateful.

MS BACON: I finished on the point that if the starting benchmark is not a meaningful one, you can't cure that by adjusting up or down. Of course what the CMA says in this case is that one adjusts down or regards it as generous, that point falls away if there isn't something meaningful to regard as being generous.

I didn't want to lose sight of the point but we do have a factual point on the generous point, which is that in any event, the CMA's argument that the PPRS should be regarded as generous because Flynn is not a brand falls somewhat short because they aren't based on any evidence. We have got evidence from Mr Williams, in particular, who says one cannot simply assume that a generic product will earn or should earn a lower profit margin than a brand, it really depends, and he points to the position of specialist generics in

particular.

I am not going to take you to that, but I didn't want you to forget that we had a point on the facts anyway, and we say it comes down to a matter of evidence for which the CMA has none.

Now, can I move on, because I've spent some time making good or hopefully making good the submission that the PPRS was in any event an inappropriate starting point, but we say that that can also be tested, and should also have been tested, by looking at other indicators of what might have been an appropriate ROS to plug into the CMA's cost plus analysis. This goes back to the point that if there are doubts or uncertainties, then one should use multiple methodologies. We say that applies not only to the question of whether one does a ROS as opposed to completely different methods of assessing a price, such as gross profits or a price benchmark, but it also applies to the parameters that are chosen within the ROS if there are uncertainties about that.

At its very highest, the 6 per cent should have been regarded by the CMA as a doubtful starting point for the ROS. So what the CMA should have done was to test that 6 per cent figure by seeking evidence from other sources and there were two sources that it could have drawn on,

and they are set out in the passage of the decision I took you to, the possible sources for the ROS figure. One is Flynn's internal ROS figure, its portfolio, and the other would be the return on sales made by other companies in the generics industry that were comparable.

Starting with the internal ROS analysis, the oddity is that the statement of objections did rely on Flynn's internal ROS rates as being informative, but only in circumstances where the CMA looked at the average ROS across the portfolio.

Now, Flynn's response to the SO pointed out that that wasn't an appropriate comparison because we know that the average figures were distorted by several outlier products that were extremely unprofitable. Of course, if one is looking at other companies you wouldn't always have that information, but in Flynn's case, we know that the average ROS rates were distorted in that way. So what we said was yes, it is helpful to look at the return on sales of other products in the portfolio, but what you should do in that case is to look at the range of rates on individual products, given that we know what they are.

That is, if you like, an analogue of what the Department was telling the CMA in relation to the PPRS because it had made the point, as you saw in that note,

that the difficulty of looking at any portfolio is that it masks individual rates of return on specific products and that is a problem. So we said "well, look at the range", and if you look at the range, you can see that the return on sales for phenytoin was at the median level of the ROS rates for the products that were profitable. I can show you that by reference to CRA's evidence. That's in bundle D tab 2, and it's the figure below paragraph 66.

Now that's a good point to introduce CRA because what we had asked CRA to do initially was to look at comparisons with Flynn's -- have I given you, the wrong reference?

THE CHAIRMAN: I'm sorry, I misheard you. Which bundle?

MS BACON: Bundle D, tab 2.

THE CHAIRMAN: D?

MS BACON: D, tab 2. I'm picking up at the figure below paragraph 66. I was just saying that we asked CRA to focus in their first two reports on this question of comparing profitability across the portfolio and, as you may have seen, they have done so on a variety of different bases. I'll come to the bases a bit later, but I wanted to show you what they say about the ROS comparison for the purpose of this point.

This is all blue, so I won't read out the figures,

but you can see there the red line which is phenytoin compared to the other products. You will see there the point I make, that if you look at the products that were profitable, phenytoin is in the middle of those.

Just to note also that that comparison is done on a like-for-like basis, so that uses the CMA's own cost allocation methodology and that was the basis that the CRA did their diagram.

We have presented an earlier version of this to the CMA in response to the SO. What then happens in the decision is that the CMA does a volte-face and says looking at Flynn's internal ROS is not informative.

Various reasons are given in the decision which are obviously wrong for the reasons set out in our skeleton argument, and those reasons are then largely abandoned in the CMA's pleadings, and what we now see is that the objections to looking at Flynn's internal profitability are reduced to two points.

The first is to say that any comparison would need to be with products with similar levels of risk and investment. Now, as we pointed out, the CMA conspicuously didn't apply that test to its PPRS benchmark, but in any event, if you do limit the comparison to products with similar risk and investment, the comparisons are even more favourable to Flynn.

That's what the CRA does over the page at figure four.

That is limiting the comparison to Flynn's products with no promotion or amortisation costs. So products that can be said to have a similar risk and investment to phenytoin. That shows that even on that basis, phenytoin doesn't have an unusually high return on sales. It also shows that the average ROS rates on this methodology are far higher than the CMA's benchmark, the 6 per cent.

MR LOMAS: Can I just understand what we're using this for? I thought, when you started out this submission, you were using this to show that 6 per cent wasn't the -- (overspeaking) -- figure --

MS BACON: It's both, yes.

MR LOMAS: -- sometimes you're saying that it shows that the outcome is not excessive. Is it both?

MS BACON: It's both. Sorry, I should have made that clear. Yes, it shows both that the 6 per cent is wrong and that Flynn's ROS is not an outlier. If you looked at -- if you were benchmarking against the return on sales, using a ROS measure rather than a gross profits measure and the gross profits shows a similar thing, but if you're looking at a ROS measure, Flynn's ROS is below that of its other products.

MR LOMAS: While I've interrupted your flow, how do you deal

with the point that, as I understand it, the PPRS covers some 80 per cent plus of all drug purchasing in the UK, so it's a very, very big sample size to be averaging, whereas Flynn is a much smaller size.

MS BACON: There are several answers to that. The first is that the 80 per cent is actually 80 per cent by value, not volume. That's an obvious point. Lots of stuff in the PPRS is going to be very expensive, new, patented drugs.

That's why that's not a good measure of the number of different products.

Second point, actually Mr Williams has been doing some more research, I think the figure is now not 80 per cent, I've got to follow that up with him, but I think the 80 per cent figure comes from some older documentation which he had used. I believe now it's significantly below that anyway, even in terms of the value.

He's saying yes. He's saying it's about two-thirds now.

The other point is that of course it's not really a -- the quality of a benchmark should be measured by its quality, and not by its quantity, and it is perhaps a trite observation, but the fact that there are lots of products assessed under the PPRS, which I accept there

must be lots of products assessed under the PPRS, doesn't make that a good benchmark for a product that is not under the PPRS. Even if you look at the products under the PPRS, recall that the products that are held to the 6 per cent are the products supplied by the companies that submit an AFR, which is a --

MR LOMAS: Understood.

MS BACON: -- a small number. Just to explain that a little bit more, there are two bases on which you might have to submit an AFR: one is that you come above the threshold and the other is that you're applying for a price increase.

But we've focused on the products that routinely submit AFRs, there's a small set of those, they have to be above the relevant threshold, and even actually on Flynn's total sales to the NHS, it would come below the 50 million threshold. Sorry, the total sales to the NHS of branded and unbranded products it would come below that threshold, it wouldn't get close to it for the branded sales.

There's a number of answers to say if the PPRS is not a relevant comparator, because it concerns different products on a portfolio basis, supplied by companies for those who are held to the benchmarks have very different structures, then it doesn't cure that problem by saying

"well, there are, you know, a number of products assessed under the PPRS".

We say a starting point at least is to look at Flynn's internal ROS, but we don't say that that's the end point, we are saying that there are number of things that could have been done and this is one of the things that could have been to look at whether the 6 per cent was appropriate.

Now the other answer that's given now by the CMA to the internal ROS comparison is to say "well, you don't know that the other products themselves weren't excessively priced". The response to that is that there is no suggestion from the CMA that any of Flynn's other products are excessively priced, so one cannot reject the comparison on that basis, it is wholly speculative.

That's not a defence that everyone does it. The CMA says "well, we're saying everyone does it". We're not saying that. We're saying the CMA bears the burden of proof. If we put forward what is on its face a suitable comparator, may not be perfect but it is an appropriate comparator, that can't be rejected on a speculative basis that that might itself be excessively priced when there's no evidence for that at all.

For those reasons, our submission is that the internal ROS rates couldn't properly be rejected as

a suitable benchmark. As I said, the SO seemed to think that they were -- it was relevant to look at this until we pointed out that they pointed in the wrong direction, and actually they were in our favour, at which point we get this retraction.

THE CHAIRMAN: Your submissions were too successful.

MS BACON: They were, obviously. But, you know, that's a point that we've made. Whenever anything comes along that looks like it's going the wrong way, the CMA says, "Oh, can't look at that."

The other suitable comparator would be the ROS rates of similar generic companies, and the CMA could have sought evidence on that, but it didn't. Now, we are obviously not in a position to obtain commercially sensitive profitability information from generic competitors as to the individual products in their portfolio, so we can't look at individual products as we've done with our own portfolio. What we can do is look at average profitability. Again, we don't say that's a perfect benchmark, but we do say that it's a more appropriate benchmark as to what ROS figure should have been plugged into the calculation than looking at the PPRS.

Now Mr Williams and Mr Davies --

MR LOMAS: Let me make sure I understand. You're saying

that an average across generics is simply a more appropriate benchmark than an average across PPRS.

MS BACON: Yes, because we're looking at a closer comparator. Both are averages, so I'm accepting that both have the problems of individual products being more or less profitable.

MR LOMAS: But they're a better comparator?

MS BACON: They're a better comparator, yes. I make the point that the CMA could have sought more detailed information. We can't do that. So in a way we're trying to show what the CMA could have done.

Now Mr Williams and Mr Davies both looked at the ROS rates of various samples of generic companies, and I think the best place to show you the results of their analysis is in our skeleton argument at paragraph 157 because we've set out a summary there. That's page 49 of our skeleton argument, paragraph 157, what we've sought to do there is to summarise the various comparators that Mr Williams and Mr Davies have used.

So starting with the ROS rates of two companies which Mr Williams says are very closely comparable to Flynn, he's calculated those ROS rates as being on the basis of accounts to 30th June 2016, 27.2 per cent and 26 per cent.

PROFESSOR WATERSON: These are return on sales on the same

basis.

MS BACON: Yes.

PROFESSOR WATERSON: Including after taking off the various elements that have been taken off in the Flynn data; is that right?

MS BACON: Well it's a return on sales used to calculate what should have been, or what could have been, the benchmark in the cost plus calculation.

PROFESSOR WATERSON: I'm just looking at the definition, what the definition of return on sales was, whether it was the same definition as I think --

MS BACON: Ah, operating profit before tax.

PROFESSOR WATERSON: Okay.

MS BACON: That's two comparator companies, two individual comparator companies.

Then Mr Williams has looked at a sample of a number of other UK manufacturing -- non-manufacturing generics companies, and he comes up with a weighted average of 21 per cent from those. He's also looked at adding into that a number of other companies with some manufacturing activities and on that basis, it's a range of 22-25 per cent. The sources for all of these figures are given in our skeleton argument.

Mr Davies has looked at a group of eight generics, I think some of those overlap with some of

Mr Williams's, but not all of them, and those produced the same average ROS figure of 21 per cent, so there's a degree of convergence.

Then there's UDG, which the CMA has referred to as being an appropriate comparator. We've said -- Mr Williams also covers this in his evidence -- actually it's not very comparable because it's a pre-wholesaler and distributor rather than a speciality pharmaceutical company as such, but even then the ROS of the UDG was 24.4 per cent for that year ended 31st August 2015. That's the company that the CMA itself relies on.

In our submission, those figures speak for themselves as to the appropriateness of a 6 per cent ROS plugged into the CMA's cost plus analysis.

Now again, various points on those comparisons made in the decision are now abandoned and the CMA's answer now seems to come down to the same points that it makes in relation to our internal ROS rates. Number 1, that the comparisons would need to be like with like. I've made the point that that wasn't the basis that they used for the PPRS, but in any event, Mr Davies does actually address this in detail, and his evidence, which again will be tested next week by Mr Hoskins, is that if you look at the various activities carried out by Flynn and the commercial risks, those activities and risks are

typical of any other company supplying generic medicines.

Mr Davies is an industry expert, the CMA has not put forward any evidence of its own to rebut that.

In any event, as the reports of Mr Williams and Mr Davies make clear, they have tried to limit their comparisons to companies that are reasonably similar to Flynn in terms of their products and revenues and structures. They've chosen companies that sell either generics or have mixed portfolios, they've chosen revenue ranges that are reasonably comparable to that of Flynn, so they haven't gone for very large or very small companies. That's the basis on which they have done their comparison, to try, as far as possible, to have a like with like comparison.

In any event, remembering the purpose of this exercise, it is not to show the precise benchmark that should have been adopted, they've done that to show that 6 per cent was the wrong figure.

The other point is that other products might have excessive prices, too, and the answer to that is as I've just given, it is wholly speculative and it is that the CMA that has the burden of proof, it cannot satisfy that by relying on speculation as to the inappropriateness of other prices for that reason when

there isn't any evidence on that.

THE CHAIRMAN: Your point is it's not for the CMA to pick holes in your experts' work because all the experts' work does is to suggest valid lines of enquiry which the CMA didn't themselves pursue, is that --

MS BACON: Slightly more than that. One, valid lines of inquiry that should have been pursued and, had the CMA looked at that, it is very clear that, whatever might be said about the precise benchmark, and there are a range of figures set out in that paragraph of our skeleton, it is way more than 6 per cent. That's why I say 6 per cent was wildly inappropriate. There is no evidence that any company is held to that and, if you look at the average ROS rates, which is the best evidence that we as an individual pharmaceutical company can get, you can see that the average ROS rate is way more than 6 per cent.

THE CHAIRMAN: They wouldn't be held to it, would they, because there isn't anything to hold them, is there?

MS BACON: No, the generics -- my other point was that even under the PPRS, no company is held to that, but if you look at the evidence that we have on generics which are the far better comparator, you can see what ROS they are making because you can derive it from their published accounts and it is way more than 6 per cent.

The CMA simply ignored that on the basis of points that it didn't apply to its own comparison with the PPRS.

PROFESSOR WATERSON: It is, of course, a little less than the return on sales on phenytoin.

MS BACON: Well some of them are.

PROFESSOR WATERSON: They all look above 30 per cent to me, in the figure 4.

MS BACON: Yes, and Mr Williams calculates -- I mean the thing is that if you just look at the ROS on phenytoin, the question is, is there a ROS based on which costs allocation might be produced. That was why I made the point in the CRA's figures, they were doing the CMA's cost allocation methodology. Mr Williams has calculated the ROS for phenytoin.

Let me find where that is.

MR LOMAS: This part of your argument pushes the floor up and the second part brings the ceiling down, isn't it?

MS BACON: The?

MR LOMAS: This part of your argument pushing the floor up saying the 6 per cent is not right, to somewhere around 20-25 per cent, the second part of the argument brings the price down when you've reallocated the costs.

MS BACON: Yes, exactly.

THE CHAIRMAN: Are you still claiming that the Flynn return

on sales on actual phenytoin is confidential, isn't it?

MS BACON: Yes, I believe so. You can look at the actual figure using the CMA's cost pool, but a revenue based costs allocation. That is in Mr Williams's 2, that's bundle D, tab 12, paragraph 59. That is confidential, but you can see the figure there is blue, and that's the reason why I said it's not necessarily above the comparators I've shown you, it is actually within the range.

THE CHAIRMAN: Is this the same figure as is shown confidentially in paragraph 158 of your skeleton?

MS BACON: That may be. Yes, that's right. Can we just keep open the expert bundle because I wanted to show you what the effect was of just correcting for the ROS, because I said at the start of this part of my submissions that that was the single biggest factor, so I want to just show you how that changes the calculation if you just change that. For the purpose of this, we put in 21 per cent, because that was the figure that Mr Williams and Mr Davies had both alighted on looking at a sample of generics.

Just to emphasise, we are not saying that 21 per cent is the right figure; we're just saying, if you use this, it shows you that the calculation then reduces dramatically.

Williams 3 is in tab 13 of the expert bundle D, this uses the 21 per cent as the ROS, everything else is the same as the CMA's analysis. So the CMA's costs allocation, the CMA's cost pool, but changed the 6 per cent figure to 21, and you get the figures that are set out at the bottom which are the excess over cost plus.

PROFESSOR WATERSON: Which paragraph?

MS BACON: Paragraph 56. The right-hand column is the total across all strengths and then you have a broken-down distribution across the different strengths.

As you will see, what he's done for comparison is to put the CMA's figures underneath it and you'll see that the figures that he calculates, especially the totals, is dramatically different from the excess that the CMA relies on in its decision.

Remembering that's just calculating for one of the two major disputed inputs, just amending the ROS, doing nothing else.

MR LOMAS: Just for completeness, do we assume that, if you like, if you succeeded on that and nothing else, you'd still be submitting that the differential that we see there is not significant or persistent.

MS BACON: Yes. There are number of reasons for that. One, it is way below the CMA's excess figure. Two, the

21 per cent that we've used is an average figure and so one has to build into that acknowledgment of the fact that there will be within that a range of return on sales rates that are -- I mean, mathematically about half of them will be above the average and half below, so finding that there is a difference of the order of magnitude that Mr Williams calculates, the figures that I've just shown you, does not indicate a significant or persistent excess.

But in any event, that's not what the CMA has done. The CMA could have looked at that and it could have then come to a conclusion as to whether that was also excessive, but it didn't. It doesn't have a fallback case. Its case is solely predicated on the excess in the amounts that it's found in the decision. But you're right, our submission is, even if it had looked at that, it couldn't tenably have found that those were significantly and persistently excessive.

That does conclude what I wanted to say about the benchmark. Unless the Tribunal has further questions on that, I would then propose to move onto the second major element of the costs plus analysis, which would be costs allocation.

There's no dispute that there is no uniquely correct way to allocate costs. It is a fact-specific exercise,

I think everyone is agreed on that and it requires examination of the products in the markets in question.

Now, our witnesses are unanimous in concluding that a cost allocation by pack volume is wrong. That's addressed in Mr Walters' evidence, in Mr Davies's evidence and Mr Williams's evidence and they are all ad idem on that point. It's not what Flynn does -- that's what Mr Walters says -- but more importantly, it's not what any pharmaceutical company does.

Mr Williams states categorically that he has never seen anyone using a costs allocation by pack volumes, whether under the PPRS or more generally in the industry. Mr Davies says a volume-based costs allocation doesn't provide a meaningful basis for decision making by pharmaceutical companies. He makes the point that commercial decision making is driven by looking at profits. The volumes of different products sold provide no insight into that, especially for a company supplying predominantly generics.

By contrast, as Mr Williams explains, revenues are used to allocate costs and they're used routinely to allocate costs for the purpose of the PPRS AFRs. The AFRs require companies to split their costs across supplies of NHS branded products and their other sales. So in order to complete a PPRS AFR, you have to say how much

costs you are allocating from your total common cost base to the NHS branded products that are being assessed under the PPRS.

So any company that submits an AFR does have to do a costs allocation exercise if it has any other activities other than branded sales to the NHS. So companies are allocating costs for that purpose, and when they do it, Mr Williams says, on the basis of his experience, it will almost invariably be done by revenue, and he says he has advised on or audited over 100 AFRs throughout his career. I think he's been doing it since 1978 and is still doing it, and that's the basis on which he says that companies do it.

Even leaving aside those points, which are significant because they show what is done in the industry, there is also a serious practical difficulty with a volume-based allocation for pharma products and that's because, as is brought out in the evidence of both Mr Walters from Flynn and Mr Williams, the products are not sufficiently homogeneous that a volume allocation could be meaningful, and Mr Williams and Mr Walters' conclusion is that actually allocating costs by reference to the numbers of packs sold leads to quite absurd results.

One of the absurd results is that, if you have

within your portfolio a very inexpensive product selling in very high volumes - and Mr Williams's example is that of an oral contraceptive - that would be allocated far higher common costs than a very high value, but low volume oncology product. That's just counterintuitive.

There's also the problem of products being sold in multiple pack sizes and there's an example of that within Flynn's portfolio, as you may have seen in the evidence, because Vancomycin is sold both individually, in individual vials, and in packs of 10.

So that would mean if you allocate common costs on that basis, 10 individual vials of vancomycin would be regarded as ten packs and that would attract ten times the common costs of a single pack of 10 vials. So looking at the different numbers of different products doesn't really tell you anything meaningful about either the decision making or the costs that ought to be allocated to particular products.

All of these points are, in our submission, quite compelling reasons to conclude that a pack volume based allocation is inappropriate.

Now, set that evidence against what we have from the CMA, one would have expected the CMA to produce an industry expert to explain, rebutting the points of Mr Williams, Mr Davies and Mr Walters, why a pack volume

based allocation for this industry and for these particular kinds of products and for Flynn's portfolio, would be meaningful. But they don't have any industry experts. They only have Mr Harman, and no disrespect to Mr Harman, but he says himself that he's not an industry expert, so all he can make are technical arguments, because that's the explicit limit of his expertise.

His only argument really is the technical point on circularity, which is that if the CMA is testing for an excessive price, then there will be a circularity concern that a revenue based allocation might mask that excessive price, if there is one, because it would weight the common costs towards phenytoin.

MR LOMAS: He makes another point, doesn't he, that one of the problems with your revenue based allocation is that revenue is volume times price, so some of your volume criticisms equally carry over to a revenue basis.

MS BACON: Yes, but that's a neutral point because --

MR LOMAS: Yes, it applies to both.

MS BACON: It applies to both, yes. We say, well why should the price make a difference? We say, well it does make a difference because it makes a difference in commercial decision making by companies who look at profits and Mr Williams says, in his view, the product which has the broadest shoulders should bear the most common cost.

Looking simply at the product that sells the most packs, like a contraceptive, which packs fly out the door because it's taken routinely every day by lots of women, shouldn't necessarily have an allocation of common costs that is many times that of a very specialised, very expensive, very valuable oncology drug that has far lower volumes.

A number of the points, you're right, do apply to both, and which is why -- I mean, actually that's why costs allocation is so difficult and is one of the reasons why we say don't just do a ROS because on any basis, the starting point is an acceptance, and this is common ground, that the common costs in this case aren't driven by either volume or price. So you start from the point that you have to make an uncertain methodological choice. So you can cure that methodological uncertainty in two ways: one, not do it, so look at something else, gross profits, which don't have that problem; two, do it but alongside those, so do multiple methodologies (inaudible); three, do both. We say we'd prefer one and two because actually the volume-based methodology doesn't tell you anything and is never used.

THE CHAIRMAN: What do you say to the argument that assessment of profitability and associated allocations of costs are done for different purposes? One purpose

would be for directors of a company to work out what is a profitable product and what is a less profitable product and to make informed management decisions. That's not necessarily the same thing as a public authority trying to come to a view as to what price is acceptable under article 102. You could have a different approach. Would you agree with that?

MS BACON: That's quite right, but it is still, I'd say, relevant to look at the way that the directors of a company look at the decisions that they make because of course one of the decisions they make is whether or not to discontinue a product or not.

If they look at a product and they apply a costs allocation that is meaningless, then that might result in a decision that would also be commercially meaningless. So if you look at the reasons why --

THE CHAIRMAN: Meaningless is rather a strong word. I'm suggesting it has a meaning, not a meaning that the directors of the company would necessarily agree with.

MS BACON: Yes. The basic point, and it's one that we've made in the evidence, is that if you based decision making on something that turned on the numbers of products, the numbers of packs of a product that flew out of the door, that would be a poor basis for decision making and therefore that is a relevant factor, I'm not saying it

is decisive, but a relevant factor, to build into your assessment of which allocation methodology to prefer in a case.

I start from the point that of course we accept that in this case Flynn didn't do it either way. So you either have to look at both or you choose the one that is most preferable on a number of different bases.

We say look at what companies did, look at what companies did not only as a matter of their decision making - and that's what Mr Davies addresses - but also look at what companies do when they allocate costs.

That answers your point, sir, because of course in this case we have evidence not only as to what the relevant commercial factors taken into account are, but we know what companies actually do when they allocate costs in this industry, and that is to do so by revenue and not by pack volume.

THE CHAIRMAN: But I think you accepted a minute ago that it would be possible in theory, at least, for an authority to decide to allocate costs in a way that suits its purposes, even if the company in question doesn't do that for the -- (overspeaking) --

MS BACON: No, I don't think I would accept that the authority can simply allocate costs in a way that would suit its purposes. The authority needs to look at the

most appropriate way of costs allocation, if it has to do it at all, and adopting a method of costs allocation which is never done in the industry, is, in my submission, a very poor starting point.

THE CHAIRMAN: I thought you were saying that it's not what you're suggesting is right, because none of these methods is right, but the authority ought to have considered it and, if it didn't like it, it ought to have said why it didn't like it and rejected it and come up with something it could justify. I'm not sure you were ruling out that the authority could, in fact, decide to allocate costs in a way that is not done either in the industry or by the company in question.

MS BACON: Ah.

THE CHAIRMAN: If public enforcement purposes so require.

MS BACON: Well, I don't accept that public enforcement purposes allow the authority to disregard business reality. Now if there is a particular justification for adopting a particular cost allocation methodology which is compelling and outweighs what may or may not be done in the industry, then that is, you know -- that may be something that the authority can take into account. Claymore Dairies says that the cost allocation should reflect the underlying business reality. As I said, I'm not saying that that's decisive, but it's a compelling

reason why one or other cost allocation methodology should have been chosen in this case and in this case because of the way in which decisions are taken.

Moreover, the way in which it's always done when there is a costs allocation, both of those are reasons why a revenue approach ought to have been preferred.

In my submission, the CMA can't simply say, "Well we preferred this other approach because it gives a better result for us", which is effectively what the CMA has said. I was going to come onto the circularity concerns because actually, we've addressed that concern. The circularity reason is the only positive reason that the CMA has come up with for its methodology.

There are, as I've said, neutral factors that don't point in one way or the other. There are compelling factors that point in favour of a revenue allocation, and the only factor that the CMA has come up with that suggests that it ought to have done something else is the circularity point. I wanted to just look at the theoretical underpinnings of that because we have a paper written by Oxera for the OFT, which is cited by the CMA as supporting its costs allocation method, but as I'll show you, it doesn't actually do that. The paper is in several places in the bundle. I'm going to go to it at H1/10.

The paragraph I wanted to start with was paragraph 6.18 at page 95. The CMA is right to say that this paper raises a concern with value-based cost drivers such as revenue, but it's important to see what the CMA says about that and what their solution is. So the starting point is at 6.18 and they say "Value-based cost drivers should be used with caution because of the potential circularity problem". Then the next paragraph says "The primary solution is to use a costs allocation method that reflects cost causality".

But then the next paragraph says:

"However, cost causality cannot be applied to all common costs, nor, by definition, to any joint costs."

For costs where allocation on the basis of cost causality is not possible, they say other types of cost driver, including value based ones, must be used.

Then it says:

"Again, there is no single correct allocation method in these cases. A sensible cross-check would be to test the sensitivity of the FDC figure to different methods of allocation, and also how it relates to the incremental and stand alone costs…"

In this case, you are in a situation that's being

discussed in paragraph 6.20, where it's common ground that the common costs here don't vary by volume or revenue. As I think everyone can understand, that's why I say, if you look at what Flynn does, it doesn't point in one direction or another and you can't base your decision on what the cost drivers actually are. We're in precisely that territory where allocation on the basis of cost causality is not possible.

The correct approach, according to this, is not to simply reject a revenue based method out of hand, but rather to test it, if you use it, with appropriate crosschecks.

It doesn't support the suggestion that one must abandon looking at a revenue-based allocation. What it's saying is, it's therefore uncertain, so test it by appropriate sensitivity analyses and crosschecks and --

MR LOMAS: Isn't that what Mr Harman has done?

MS BACON: No, Mr Harman comes up with various crosschecks which Mr Williams says nobody has ever put forward. He doesn't test it against what Mr Williams does, except on one of the lines. He tested it against other methods which Mr Williams will think that's possibly best explored with Mr Harman. He tested it against other methods which are absurd, rather than testing it against something sensible. Mr Williams says, start with the

revenue analysis, and see if that is biased by testing that against sensitivity checks which eliminate any bias that there would be if there is one. That's what he does with his sensitivity checks. By looking, first of all, at reducing the notional costs -- the notional revenues down to what the CMA say --

MR LOMAS: That's his adjustment.

MS BACON: Yes. Both of those adjustments, he says, are very unfavourable towards phenytoin. The first one because it assumes that the CMA is right as to its 6 per cent benchmark, which we don't accept, and secondly by removing all profitability at all, removing the notional revenue down to direct costs only.

The point there is that because the results of those sensitivity analyses aren't very far away from his base case, what they show is that it's unlikely that the base case is actually biased, because the calculation changes ultimately by only some percentage points, two or three percentage points.

He's testing the revenue costs allocation and he's testing the hypothesis that it's inappropriate because it's possibly biased by looking at sensitivities which remove any possible bias and showing that, even on those adjusted figures which are very unfavourable to Flynn, the result of the calculation is only a few percentage

points away.

The CMA effectively acknowledges that those approaches do resolve the circularity problem. They say they sidestep them, but actually that's a lawyerly language for "We can't find a reason why those actually still -- why there is still a problem for those."

The two sensitivity analyses do resolve the circularity problem because they take any potential problem of bias through the revenues which are said to be excessive out of the picture.

Then the CMA finds some other reasons to object to what Mr Williams has done. They say "well, the revenue analysis, even if you do the sensitivity checks, is still distorted by the input price to Pfizer". The short answer to that is that the whole purpose of the calculation is to work out what the difference is between Flynn's price and Flynn's costs, so you have to take the costs that are given.

Putting the point another way, if there was a concern about Pfizer's prices, as in the point they're making here that there's a distorted input price, that is excessively high, if that concern caused the CMA to adopt a costs allocation method that's very unfavourable to Flynn, then what's happening in that scenario is that Flynn's profitability, supposed profitability, is being

artificially inflated because of the unfavourable methodology designed to address Pfizer's supposedly putatively excessive supply price.

So we're being hung because of the supposedly excessive input price that we are paying, we are held to, and that is a given in our supply and that cannot be right or lawful. It is certainly a clear breach of the principle that any doubt should be resolved in favour of the undertaking under investigation. That doubt point applies to really everything that I've just been saying.

PROFESSOR WATERSON: This point that you take the Pfizer price as given, is a submission, not a matter of pure fact, in the sense that in the original discussions, when Flynn put the proposal forward, the discussions incorporated material about Pfizer, and how Pfizer would benefit.

MS BACON: Yes, but once -- I mean once there is a supply price agreed, that's what we did pay, and if one is looking at what the difference is between our cost and the price at which we then sold the product, that supply price was what we did pay. So if you were looking at whether we were excessively profitable, that is a given. So I would say it's a fact.

MR LOMAS: Is it not the case that what we're talking about here is the allocation of the common costs, and on your

volume test that's a function of price. That would be the same thing whether the input cost was 1, 2, 5 or 10 because the allocation -- the amount of common costs which aren't in that input price go across as purely a function of the price you're charging plus the volume, it's not affected by the input price from Pfizer.

MS BACON: Yes.

Now the CMA's second point is the tautology point. They say, "Well on the sensitivity checks, we're allocating common costs to allocate common costs."

Now I understand what they're saying, but we don't understand why there's a problem with that. All that Mr Williams is doing, as I think I have just explained, is recalibrating the costs allocation using unfavourable assumptions and by reducing the notional revenues to levels that can't be said to be excessive, and he is just using that as a sensitivity check against his base case.

The third objection that the CMA comes up with is that we're not comparing like with like because we're using a proxy figure for the phenytoin revenue on the sense checks, and an actual figure for the revenues of the other products. The answer to that is yes, we are using a proxy figure for phenytoin, but again only for

the purpose of the sensitivity checks in order to ensure that on those sensitivity checks there is not a circularity concern, or cannot be said to be a circularity concern.

The overarching point in relation to all of these objections that the CMA makes is that they do really miss the point, which is that the sensitivity checks are used to test the proposition that the circularity concern means that one has to disregard the revenue-based costs allocation as producing an unreliable result. As I've said, if you show on your sense checks, as Mr Williams has done, that even using quite unfavourable assumptions, the results are only a few percentage points away from the base case, then that tends to show that the base case isn't unreliable in the way that the CMA claims. That is really the crux of the CMA's case on the costs allocation, because as I've said, the only positive reason for rejecting a revenue-based allocation is the circularity point.

Now there's one more important point on costs allocation to make and then some sweep-up points.

The important point is one about consistency, and I come back to this. As I've said, it is common ground, a point both we and the CMA make, that comparison for the purpose of an excessive pricing analysis should be

made on a consistent basis. As consistent as possible.

That means that if, contrary to my primary case, the PPRS can legitimately be used as the source of the benchmark, then it's even more important to use a revenue-based costs allocation because we know from Mr Williams's evidence that that's the way it's done for PPRS AFRs. So it doesn't matter that the PPRS doesn't prescribe that approach, if we are being held to a benchmark which is claimed to be the benchmark that represents allowable ROSs or average ROSs for a group of products, then you can't even make any headway with that if you allocate costs from a different basis.

MR LOMAS: Are those alternatives, though? You could run with that and say against your case, "Okay, give me 6 per cent, but I've got to have costs allocated by revenue," or you can say, "I drop 6 per cent and I go to comparators which brings me to 21 per cent." But are you trying to conflate the two arguments?

MS BACON: Well I am saying that on any basis, I want costs allocated by revenue for the reasons I've given, but I'm saying that it's even more important to do that if your benchmark is drawn from the PPRS, because then there is a real problem about the consistency of the comparison. Because if you are comparing like with like, then you need to try and calibrate the comparison to be as

similar as possible. The point was made in Scandlines, if you're looking at different economic contexts, then you may have a comparison which is ultimately meaningless. So if you know that the PPRS benchmark, whatever it is, is used in the context where everyone accepts that the relevant costs allocation method is a revenue based one, then it is completely meaningless to compare that with something done on a different basis.

MR LOMAS: You would say, "If I'm tied to 6 per cent, I have to have had revenue based allocations."

MS BACON: Yes.

MR LOMAS: But even better than that would be a market-based --

MS BACON: Yes.

THE CHAIRMAN: -- plus for my cost of, say, 21 per cent, and revenue allocation because that's what the market does.

MS BACON: Yes.

MR LOMAS: Okay.

MS BACON: I mean, the other point I've made about the non-homogeneity of the products, which is addressed in our evidence, that was the consistency point and that was the important point. Then I said I had three sweep-up points. Number 1 is Genzyme and that's referred to in

the CMA's skeleton.

Now, it is quite true that a purely revenue allocation was rejected in that case. Mr Williams was one of the experts for Genzyme in that case and he's told me all about it, and if you want to ask him about it next week, I'm sure he can tell you about it, too.

Now, the issue there was to work out what the appropriate price was for providing home care services to particular patients, and those home care services, in some cases, involved the administration of the drug that was disputed in this case, it was Cerezyme.

What was being allocated was the various costs associated with the business of providing home care services such as nursing services, and as I've said, some of those services were where people did give Cerezyme and others didn't. In other cases, they might have been administering a drug that cost much less, or they might not have been administering a drug at all, but doing some other nursing service.

The problem with using revenue as the basis of allocating common costs in that case was that the costs allocation would have been skewed by the price of Cerezyme.

In circumstances where what was actually being provided, the nursing service, the home care service,

was fairly homogeneous, so there wasn't a dispute that delivery costs were more or less equal for each patient and there was some variation in the amount of nursing times that each patient required, but that could be accounted for by adjusting for complexity, although there is some debate around that.

What you had in Genzyme was a combination of a generally homogeneous service and an obvious problem with a revenue based analysis if the costs were allocated on a basis that included the product that the company had to buy in order to provide that service, which varied greatly from, you know, services, as I have said. Some patients were getting Cerezyme, some patients weren't getting it at all.

So as a result, the parties were agreed that general overheads, including things like finance and IT, should be allocated on the basis of delivery numbers.

Now, that's very different from the present case where the product is not, as we've said, homogeneous, there's not an obvious problem with the revenue analysis, that's the sensitivity analyses that Mr Williams had done, and the costs allocation methodology is not agreed. As I've said, if you want to explore that further with Mr Williams, then the opportunity will be there.

The second sweep-up point is the Socrates case and that was about an accreditation scheme for law firms doing residential conveyancing. Now it's cited in the CMA's skeleton argument, that has absolutely no bearing, it's a completely different market, has no bearing on how costs should be allocated in respect of a portfolio of pharmaceutical products. I come back to the point that every case is fact specific and needs to be addressed on the facts of the market, and the appropriate evidence, factual and expert evidence, as to how that market operates.

The last sweep-up point, and I said I was going to come to this, was the crosschecks, and that's addressed in detail in Mr Williams's evidence, and most of the crosschecks he says are meaningless and inappropriate. EPMU, Mr Williams says he doesn't have a big problem with it, although he has not often seen it done in practice, but in any event, the results of doing that are similar to his own revenue based analysis.

Leaving aside those points, the fundamental problem with the crosschecks is that Mr Harman misses the point as to what they're there for. He uses them to show that whatever costs allocation you do - and he sets out his table of different possible approaches - he says Flynn's prices still materially exceed costs plus.

As we've said in our skeleton argument, that does miss the point because we're not saying that costs allocation alone is the silver bullet. We do say that the ROS benchmark is a silver bullet. We don't say the costs allocation alone is a silver bullet. What we are saying is that it's the second biggest input that needs to be corrected and, if you combine that, and that's your point, just put to me, Mr Lomas, that once you accumulate that with the ROS benchmark, then you get to a very different picture.

One cannot say well, "Well I've tested my cost allocation by doing a load of other analyses most of which are complete nonsense, but anyway, here you are, the results are all still above costs plus", if you still kept the original benchmark, because we've never suggested that that's the only basis on which the decision should be set aside.

The best place to look at the accumulation is in Williams 3, tab 13 in bundle D, starting at paragraph 56, which I've shown you, and then going over the page. So paragraph 56 of the figures I've shown you just changing the benchmark, but keeping the CMA's costs allocation. That's what we've seen already, so that was the effect of only changing the benchmark.

Now over the page is accumulating the benchmark with

an appropriate cost allocation, the revenue based costs allocation, and that provides the excess figures at the bottom in blue. So it's the blue line. So that's the base case with the revenue based allocation, and then on the opposite page, under paragraph 58, this shows you the most extreme sensitised basis, as in reducing phenytoin's notional revenues only to direct costs. And that makes good my point that the two are only a few percentage points apart.

You asked me, Mr Lomas, would I have said that the figures under paragraph 56 were --

THE CHAIRMAN: A fortiori for 57 and 58.

MS BACON: That's the point.

MR LOMAS: What about the 25 and 50mgs?

MS BACON: The point there is that the main product that's supplied into this market is 100.

MR LOMAS: 75 per cent.

MS BACON: 75 per cent. I don't know which comes next, but if you look at the 100 and the 300 together, I did that for some other purpose. I can tell you where the different strength table is in the decision. It's under paragraph 3.16 of the decision.

Now, in 2015, the --

THE CHAIRMAN: 3.16?

MS BACON: Yes, table 3.1. Right, so if you look at the

100mg and 300mg together, those account for 81 per cent of the market, 25mg accounts for 6 per cent of the market, 50mg, 13 per cent.

Now, the CMA hasn't done a separate market analysis here. In our submission, it couldn't take a 6 per cent market --

THE CHAIRMAN: I understand, yes.

MS BACON: I can make that point without referring to those figures.

Right, that is, you will be very relieved to hear, it on costs allocation, unless the Tribunal has questions. If you do have questions, I can deal with them now or after the break.

THE CHAIRMAN: I think we're fine. We'll take a break now.

(3.07 pm)

(A short break)

(3.21 pm)

THE CHAIRMAN: We're still every bit as alert as we were when you started.

MS BACON: I'm very pleased to hear it. I wish I could say the same.

We're on the home straight before I hand over to Ms Kreisberger. I want to deal with gross profits and other profit measures, tablets, shortly, and very quickly, the other contextual factors. So gross profits.

Now I spent some time on the costs plus analysis because that's what the CMA did, but you'll appreciate that our case is that whatever the calibration of that, that shouldn't have been the only thing that the CMA looked at. It should also have sought to test its analysis by reference to other appropriate measures of profitability. We say that for three reasons: the first I've already given you, which is that cost plus is not an analysis that's in practice used in the industry, so that was my caution point at the start. The second is that, as we've just seen, a cost plus analysis is highly sensitive to the parameters chosen. And in this case the parameters are not agreed, but are very much disputed between the two parties.

The CMA cannot, in our submission, say that its conclusions are so obviously correct as to leave no room at all for doubt, so it should have done two things. One, is to resolve any doubt in favour of Flynn, and that's required by the case law, especially at the Latvian case. The other is to use other benchmarks or methodologies which are not susceptible to the same calibration problems which, in this case, would involve looking at gross profits and/or product contribution.

The other reason for looking at other methodologies - and perhaps it's the most important point - is in any

event, that's recommended by the legal theory and economic theory and, as we've seen most recently, in the Latvian case. The Advocate General spends some time explaining why that's the right result, given the basket of methodologies point is the right approach, given the inherent difficulty in determining appropriate benchmark prices.

I mentioned earlier that the multiple methodology approach was adopted in Napp, and it is notable there that the OFT did compare Napp's gross margins on the disputed product with its -- with the gross margins on its other product, as well as the margins of its next most profitable competitor.

We submit that the CMA should have done that in this case anyway, whatever else it did do, and the CMA has not come up with any convincing explanation as to why it was appropriate to look at that in Napp, but not here. Really, the only reason we can see that it has not done that is that, from the CMA's perspective, the results didn't point in the direction of the conclusion that it wanted to reach.

Now can I show you, first of all, our internal gross margin analysis which was submitted to the CMA initially in our response to the SO. That brings us back to CRA. I said that they did a ROS analysis, but

they also did other measures, so now I want to show you the other profitability measures that the CRA looked up. I think we can pick this up at CRA 1, which is at bundle D, tab 1. We can go through this quite quickly, I think, because it's just a matter of looking visually at the various graphs they've done.

This is CRA 1 pages 3 and 4, this is gross profits, comparing phenytoin with Flynn's other products. Again, the red line is phenytoin and again, these figures were all confidential, that's why these diagrams are blued. Gross profits, pages 3 and 4, the figures 1 and 2. Then over the page, figure 3 is the product contribution.

The difference between that and the gross profit figure is that the product contribution figure takes account of distribution, sales force and amortisation costs that are directly attributable to the different products.

MR LOMAS: Sorry, just to pick up here, unlike our debate about the allocation of common costs, the results on this graph will be affected by the high input costs from Pfizer because these are gross margins.

MS BACON: In a way yes, but what we also know is --

MR LOMAS: Basically this is revenue minus costs of goods sold, isn't it?

MS BACON: Yes, it is an input into it, yes. But if that were to be used against Flynn, and I don't think the CMA has actually made that point, but if that were to be used against Flynn, what they would have to show is that looking at the input costs of the other products, that meant phenytoin was not comparable, which they haven't done.

MR LOMAS: Conversely, if the split of the increase across the time between Flynn and Pfizer had been different, and Pfizer had taken a smaller share of that increased profitability, then -- (overspeaking) -- it would move very, very quickly.

MS BACON: Yes, it would affect the margin, yes. If Pfizer's supply price had reduced but the sales price had remained the same, then that would have affected it, yes.

MR LOMAS: Yes, very sensitive to that.

MS BACON: Yes. The point is, of course, that when Pfizer reduced its supply price to Flynn, Flynn then reduced its sales price and that was what happened in April 2014. So that's, you know --

MR LOMAS: That's a wash, more or less.

MS BACON: Yes, and the same after the directions that were given as a result of the decision. So both changed. Those are the gross profits and product contribution figures which, as you rightly note, they deal with the

problem about the costs allocation.

Now, of course the other point to make about the sensitivity of the results to the input prices is that that will, of course, apply to any number of products. That's why it's useful to look at a lot of different methodologies because of course that will equally apply to the PPRS and perhaps one should say that for the PPRS it will apply in spades because of the transfer price. The whole PPRS mechanism was designed to deal with the fact that there were high transfer prices and we know that in -- from Mr Williams's evidence, he says that the average transfer prices are between, I think, 60 and 70 per cent of the sales price, and the --

MR LOMAS: Almost as a pre-set figure, yes.

MS BACON: Yes, and the transfer prices are usually calculated by reference to the sales price, we know that.

MR LOMAS: Yes, of course.

MS BACON: When one is making that point, we see that point applies equally to the PPRS, and unless, as I said, one looks at the input prices of other products to show that they're completely not comparable, then one can't dismiss the comparison on that basis. Mr Harman does do some outlier analyses and those are addressed in our evidence.

So that's the product contribution.

THE CHAIRMAN: This was the opinion that was put to the CMA --

MS BACON: That was put to the CMA, exactly.

THE CHAIRMAN: -- (overspeaking) -- administrative decisions.

MS BACON: Yes, exactly. That was CRA 1, and Williams 1 was also put to the CRA. So what we submitted to the CMA was CRA 1 and Williams 1, not Davies, and Davies was in response to the decision.

Then we get to the further analysis submitted with our notice of appeal and that's the next tab, CRA 2. I think we can pick this up at page 24, figure 7.

Now, that's the product contribution figure I've just shown you, but just larger, so if you want to look at any one figure for that product contribution, that's probably the best starting point.

Then over the page, figure 8 is a gross margin analysis looking at products with a similar cost structure. So that's products with no promotion and amortisation costs.

Then we've got product contribution analysis at figure 9, again the same smaller group of more similar products.

PROFESSOR WATERSON: It's interesting incidentally how some

of the figures jump around an awful lot depending on the method. Earlier I think we covered figure 4, well a product --

MS BACON: Yes, I think we can't actually read out any figures, but --

PROFESSOR WATERSON: No, but a product, okay.

MS BACON: Yes.

PROFESSOR WATERSON: Has a strongly negative contribution, and later it has a contribution which sometimes exceeds phenytoin.

MS BACON: So figure 4, that's the return on sales. So that's -- what we're looking at in figure 9 is product contribution, not return on sales.

PROFESSOR WATERSON: Yes, I was looking at the gross margin, figure 8.

MS BACON: Yes, then figure 8, yes, is the gross margin. It's two different things, because of course return on sales would include an appropriate cost allocation.

PROFESSOR WATERSON: Yes, I'm making a point really about cost allocation.

MS BACON: Actually that point is absolutely right and it shows the sensitivity of the results to the cost allocation. As I said, CRA's figures are prepared on the CMA's cost allocation basis. But you're absolutely right, it produces very different results.

That's another reason why we say it is important not only to look at a ROS figure, but also gross profits, which strip out the costs allocation.

Using this particular one as an example, looking only at ROS, you'd have a very different impression of its profitability compared to the gross profit.

That's the analysis of gross profits and product contribution, so that's all in CRA.

The short summary is, whether you look at Flynn's portfolio as a whole, or you confine your comparison to a smaller group of products with a similar cost structure to phenytoin, the profitability of phenytoin is at the lower end of the range for Flynn's portfolio.

We've also then looked at the profitability on a gross profits basis of other generic companies, and that's the compliment, if you like, to Mr Davies and Mr Williams's analyses of the ROS rates for other generic companies.

Mr Davies's analysis we can go to first because it is next in the bundle. That's D5, paragraphs 46-48. Again, these can all be explored in more detail next week, but I just want to introduce you to these, so that we know what we're working with when it comes to Mr Davies's cross-examination.

Paragraph 48 he sets out in tabular form the results

of his analysis on gross profit margin of the companies in his sample set. His conclusion is that the gross profitability of phenytoin is below both the mean and the median of the UK generic companies in his sample of eight, and his methodologies are explained in more detail in annex 3 to his report. So that's Davies.

Mr Williams looked at a set of, as I said, a slightly overlapping set, of other generics companies, and that's at Williams 2 which is at tab 12 in the same bundle. Paragraph 41 of that shows the results of his analysis. Now paragraphs (a) to (c) are his ROS results. Gross profits are at (d), (e) and (f).

MR LOMAS: These are other generic companies of a similar size to Flynn?

MS BACON: Yes, yes. If you want the comparison with the gross margins of phenytoin, that's as set out in the CRA report we just looked at, and you can see that on his comparison, probably the best of his comparisons is then, if you want a single figure, the weighted average gross margin percentage for non-manufacturers, and that's at 41(e).

MR LOMAS: Where does one find the equivalent figure for Flynn? We were just looking at it, weren't we?

MS BACON: Turn back, we were just looking at it. Yes, I think the best place you can get that is --

MR LOMAS: Paragraph 48.

MS BACON: Yes -- well --

MR LOMAS: Page 15 of --

MS BACON: I was looking at CRA because it gives it broken down by year. CRA 2 that we were just looking at has the figures for 2013, 2014, and 2015. Page 25, that's gross margins. It's the red bars. You'll see that those red bars are in all cases below the figure of 41 per cent.

MR LOMAS: Figure 8 --

MS BACON: Yes, figure 8, exactly, yes.

That's gross margins and product contribution. I've explained why, in my submission, as a matter of principle, the CMA couldn't simply ignore these comparisons and the point is even starker when one sees what they show, because there is no uncertainty or ambiguity about those results. All of those different comparisons done by two different experts show three different -- three different experts -- show that Flynn does not make excessive profits on phenytoin.

That being the case, it's really for the CMA to demonstrate to the required standard of proof, strong and compelling evidence -- and giving Flynn the benefit of any doubt -- that it's entitled to simply cast aside that evidence in favour of a single benchmark drawn from

a regulatory scheme that applies to profits and companies that are in no way comparable to Flynn. So where is that strong and compelling evidence? Well, what the CMA says in its skeleton argument is quite revealing. It addresses this point at paragraph 212.

The argument is described at paragraph 209. Flynn's seventh ground of appeal. You can read that. So that's where they address it. Of course, they omit to mention that we also raise not only our own gross margins, but also gross margins of comparators under our seventh ground of appeal.

So they misstate it anyway. Then the answer is this, 212.

"There is little to be gained in a painstaking analysis of the economic arguments presented on these issues."

Well, that's quite an astonishing statement. The CMA has adopted a decision running to over 500 pages, and it's now saying it can't be bothered to make any submissions at all about a few quite simple sets of figures and some bar charts that frankly a child at primary school could understand.

THE CHAIRMAN: Well. [Laughter]

MS BACON: I speak with experience of a parent of a child at primary school who routinely produces bar charts done on

all kinds of surveys like what kind of 12 television programmes you like, and so on.

THE CHAIRMAN: We've all been there, Ms Bacon.

MS BACON: Yes.

THE CHAIRMAN: Some of us many times over. (Laughter)

MS BACON: Yes, well.

The point is that these bar charts are not complicated and you don't need a degree in economics to understand what they're showing.

What the CMA is really saying is that it has no answer to the point.

THE CHAIRMAN: Their answer is that the price exceeds cost plus and that's the answer.

MS BACON: Yes.

THE CHAIRMAN: Exceeds costs plus substantially.

MS BACON: So they didn't have to do anything else, is what they say, and they don't even address it in their skeleton argument.

So, that brings --

MR HOSKINS: To be fair, sir, we do refer to the decision paragraphs 5.214 to 5.233 which do make other points simply beyond the one you put, which is one of the ones we rely on.

THE CHAIRMAN: Yes, that section is headed, "The amount by which Flynn's prices exceed costs plus". That section.

MR HOSKINS: Yes, but there are points in there which are not simply costs plus.

MS BACON: Can I then turn to the tablet comparator. There are two points here, the first is whether as a matter of law the CMA should have had regard to the tablet as a comparator, and I've dealt with that, that's the legal test, and the CMA's point about the two alternative parts of the second limb of United Brands.

The second point is whether, as a matter of fact, Teva's tablets were and are a reliable price comparator, and that's the point I'd like to deal with quickly.

The starting point on that is that it really is difficult to envisage a better price comparison than with a product that consists of precisely the same molecule which we know has been found to be bioequivalent to phenytoin capsules.

The CMA makes various arguments which are addressed in some detail in our skeleton argument. What I will limit myself to now is submissions which I think are the high watermark of the CMA's arguments on this, and there are three of those. One, the tablets are not in the same product market. Well, that's irrelevant.

The CMA's skeleton itself says at paragraph 143(b), and I quote:

"Products do not have to be identical or on the same

product market. However, the comparator has to be sufficiently similar to the product concerned in order for any comparison to be meaningful."

I respectfully agree and adopt that.

If the Commission and the European Court in, for example, Athens Airport, could consider the prices charged at different EU airports to be suitable comparators for the disputed prices at Athens, it's very difficult to see why the price of the same drug molecule used for the same indications in the same country should be so dissimilar that the price comparison is not even worth doing, not even alongside other methods.

That point also disposes of the argument that the tablets fall into category M, whereas phenytoin falls into category C and the arguments that the tablets are only supplied in the 100mg strength. I mean, it's actually quite astonishing that the CMA is still putting forward those points where its own case on excessiveness rests on extracting a ROS figure from a framework applicable to portfolios of completely different branded products, and yet it's saying "Well here you are, you've got the same drug molecule, well that's not relevant because it's supplied under a different category of the Drug Tariff and they don't have the same strength."

I just don't understand that point.

I think the very high watermark of the CMA's rejection of the tablet comparator is the speculation that that price might also be excessive. That is a point that we've answered. The answer is that the CMA cannot reverse the burden of proof in that way.

The starting point must be that if there is a product that is sufficiently similar that a comparison is meaningful, that's a reasonable benchmark to look at, particularly if, as in this case, we know that the price of the product was reduced by the Department of Health. So it's therefore on the CMA to prove that despite the similarity of the products -- it's an identical bioequivalent product -- and despite the fact that the benchmark was the result of an agreement between the company concerned and the Department of Health, that benchmark should nevertheless be regarded as inappropriate and, in fact, just cast out of the window because of a speculation that the product is also excessively priced. In our submission, speculation just can't satisfy that burden of proof.

The CMA tries to say "Well we shouldn't have to conduct a full investigation into the legality on the tablet price", but it's not a matter of conducting a full investigation, they didn't conduct any investigation whatsoever. Paragraph 3.448 of the

decision says that explicitly. The complaint was made about the tablets as well and the CMA decided not to investigate because it wasn't a priority.

Having decided that, they cannot then turn that against us and say: "Well we think the tablets might also have been excessively priced, so that's no good as a comparator."

That's a short answer to some very bad points made in relation to the tablet comparator.

I can deal in a few minutes with the other indicators of abuse. We've addressed that in our skeleton argument and pleadings. These are the various contextual factors. Now the CMA is not contending, for the most part, I think, that these various contextual factors that it relies on are sufficient in themselves to demonstrate that the price of phenytoin was abusive. What the CMA says in its skeleton are that those factors are points to be considered in the round, but are not determinative, and they are points such as the effect on the NHS.

We'd go further and say that they don't add anything at all. So, not to be considered in the round, even as a starting point.

Now, in relation to the factor about Flynn's supposedly limited activities in relation to phenytoin,

you have the point that in our submission that's simply wrong in the light of Mr Davies's evidence, and as you'll recall, I said a bit earlier, his evidence is that compared to other generics, phenytoin is quite normal in terms of its risks and Flynn's activity.

The other points are dealt with in our written submissions.

The only factor that in the CMA's skeleton seems to be elevated into a different category from these various contextual factors is the argument about before and after price increase, and the CMA does now seem to be saying that this in itself, as a standalone point, shows that Flynn's prices were excessive and abusive, and that rests on the validity of a loss-making price as a benchmark. I've dealt with that, that's wrong in law.

Now as far as I can see, the CMA's only response to our submission --

MR LOMAS: Your submission is that you can look at progression across time, but not from a loss-making starting point?

MS BACON: Yes. The only answer that I can discern in any of the CMA's written submissions to this loss-making point is to say, "Well, Pfizer recovered its losses within a short time of increasing the prices." But that's just not an answer. The question isn't how

quickly Pfizer recovered its losses but whether a loss-making price is the relevant starting point, as you've just said. The short answer is that, as a matter of law, it is not a relevant benchmark and that should be the end of the matter.

THE CHAIRMAN: Mr Brealey gave us quite a lot of context yesterday, that's probably not something you can take responsibility for.

MS BACON: No. I'd love to take responsibility for all the great points he made yesterday, but no.

THE CHAIRMAN: Those points are context points.

MS BACON: Yes, and as I said --

THE CHAIRMAN: So you're not objecting to context points, it is just that you are saying that the CMA's context points are not good points?

MS BACON: Well I think that's a little bit unfair. There are various factual issues which feed into the analysis. It is a factual issue that the Epanutin price was loss-making. That feeds into the question of whether one can take a before and after as a benchmark.

The CMA's context points are rather different, and they are addressed in detail in our submissions and the fact that, for example, the price of phenytoin has an impact on the NHS is neither here nor there. It doesn't prove an abuse if the price is not excessive. The price

of any product will have an effect on the NHS and, as Mr Brealey said, there are lots of prices far higher than phenytoin.

MR LOMAS: Can we just unpack this for a second. I appreciate that in the Latvian case the Advocate General is talking about price progression in the context of a benchmark. But are you also saying price progression is irrelevant to the questions of deciding whether a particular differential between benchmark and price is excessive, or whether it is unfair whether in isolation or reference to other products? If something moves from a price of two, which is marginally loss-making, three which is break-even, but then moves not to 8 or 10, but 25 or 200 or 400, is that progression irrelevant to each stage of the application of 102, or would you simply say it is ruled out from benchmark calculation?

MS BACON: I think the answer to that lies in the question of how you use a price comparator, any price comparator. I mean, what this is, is a price comparator. It happens to be a price comparator of the same product sold by a different company at an earlier point in time, but it is a price comparator.

We know that in United Brands, the question of a price comparator is dealt with in the unfair part of the test. We know that in the Latvian case, it's dealt

with in the excessive part of the test.

Now, the Tribunal, in our submission, doesn't have to resolve that because all you see or all you need to decide is that one can take price into account at either or both stages. But in my submission, you can't take a loss-making price into account at either stage.

MR LOMAS: At any stage.

MS BACON: At either stage because it is not a relevant -- if you look at the basic United Brands test, which I encapsulated right at the start of my submissions, or maybe not at the start, but about a third of the way into my submissions, in paragraphs 249 and 250, it's whether the price is above what would normally be charged on the competitive market, to such a degree that it bears no reasonable relation to the economic value and so on. It's the conflation of 249 and 250, which I've set out in paragraph 81 of my skeleton argument. Now, that being the test, given that benchmark is that of normal competitive conditions, I would say that a loss-making price doesn't come into it at all.

That concludes my part of the submissions. I've even finished five minutes early, so I've got five minutes for any further questions that you might have, or I can sit down and hand over to Ms Kreisberger immediately.

THE CHAIRMAN: I think hand over to Ms Kreisberger.
MS BACON: I'm grateful.

Submissions in opening by MS KREISBERGER

THE CHAIRMAN: Fines come last but not least.
MS KREISBERGER: I wasn't, but I hope to prove you right, sir. I don't want to keep anyone from trick or treating tonight, so I will try to keep to my allocated 35 minutes now, and hope not to have to ask for a margin of tolerance, even though that would be in keeping of course with the PPRS approach.

My submissions are on penalty, so I begin by taking the tribunal to table 7.2 in the decision which is at page 446. That's the table that sets out the penalty on Flynn. You will see there the final amount of the penalty was over 5 million, but the key point that emerges from this table quite clearly is that Flynn has been fined to the max, as they say, to the level of the statutory cap, which is 10 per cent of Flynn's overall turnover.

That's really a function of the 30 per cent seriousness starting percentage. So at step one, we already have a fine that is over the 10 per cent cap, so although the absolute number is smaller than Pfizer's fine, the level is at the highest fine that the CMA can

lawfully impose on the company.

I'd start by saying I unreservedly adopt the points made by Mr O'Donoghue - and I won't repeat those as they apply to Flynn's penalty - and given the timing constraints, the focus of my submissions are on the particular issue of intention and negligence, which provides the CMA with the jurisdiction to fine, that's what they must establish.

Now, I deal with this point in opening because Flynn's evidence is obviously relevant to that question. The question, the CMA's contention, is that Flynn did know or ought to have known that its prices were unlawful. That's the threshold question.

Now just to mention in opening that if the Tribunal is not with me on jurisdiction to fine, in what I hope is the unlikely event that we get to penalty at all, then the same points go to mitigation of the penalty, based on the provision in the guidance that genuine uncertainty is a mitigating factor, also our argument is that novelty is often reflected by no more than a nominal fine. So my arguments go both to jurisdiction to impose a penalty at all, but also the size of the penalty.

Flynn's appeal on penalty has two further elements that I won't address you on now, and that's arguments

that go to the seriousness of the starting percentage and also overall proportionality of the fine, and Flynn has set out some financial indicators which also compare the impact of the fine on Flynn as compared to Pfizer.

Now, given the time constraints, those are points I will address in closing only. The evidence simply doesn't go to that, so it avoids duplication.

Turning then to the substance of my submission on whether the CMA has made out its case on intentional or negligent infringement, as I said, the overall question is whether Flynn did or should have known that its prices infringed article 102. Obviously, this question raises issues that are inevitably intertwined with those on abuse, but I am going to address them specifically in relation to my submission, which is that the decision does not come close to the threshold of foreseeability, which must be met before a penalty can be imposed.

Now, the legal test sets out what that threshold of foreseeability is, what's the standard. The one authority I'd like to take you to now is the latest word from the Tribunal on this issue on the relevant test and that's the Sainsbury's case. We have set it out in Flynn's skeleton at paragraph 232, just for your note, but Sainsbury's is at authorities bundle A3, tab 27 and the relevant paragraph is on page 193. It's paragraphs 322

and 323 that I would draw to your attention.

The short point really -- sorry, it's A3, bundle A3, and then tab 27.

Then page 193 in that authority. Paragraph 322 sets out the threshold. The threshold is high. What the Tribunal said there, is it set out a scale and that scale is drawn from another judgment of the Tribunal, Cardiff Bus, that's at the top of the page cited there, paragraph 489 of that judgment, but the scale you see at the very bottom of page 193, one has "Clearly lawful", "Probably lawful", "Possibly lawful", "Wholly unclear". Those four categories fall on the wrong side of the line. Where the legal case is wholly unclear or upwards from that, there is no jurisdiction to fine.

In order to pass the threshold, the conduct -- the impugned conduct -- must either be probably unlawful, category five, or clearly unlawful, category six. On the facts of the Sainsbury's case - and I'm not the most qualified person in the room to talk about this case - they said it was no more than wholly unclear, so it didn't fall into intentional or deliberate breach.

Just coming back to page 193, I would just draw your attention to the preceding sentence more than halfway down paragraph 322 where it's stated that:

"Of course MasterCard would have appreciated that

there was a risk that it might be found to be in breach of competition law."

So an appreciation of risk was on the wrong side of the line. So that's the scale.

Then just the last point I would make on Sainsbury's, it's in the next paragraph, 323. The Tribunal there really sets out a pragmatic and practical litmus test. What it says is that it would not have been clear to MasterCard that it was infringing article 101 by the imposition of interchange fees. We consider that any legal advice given to MasterCard to this effect could not properly have been described as negligent, so to the effect that the position wasn't clear. So that's a sort of practical litmus test that I would invite the Tribunal to keep in mind.

THE CHAIRMAN: Nobody has mentioned legal advice so far in this case.

MS KREISBERGER: Sir, I accept that of course.

THE CHAIRMAN: There was legal advice in Cardiff Bus.

MS KREISBERGER: What I'd invite the Tribunal to do here is to put itself into the shoes of a reasonable legal adviser, so that the shape of my submission is that legal advice, on the basis that for Flynn, the position is wholly unclear, would have been reasonable, and that is

a sufficient basis for you to find no jurisdiction to impose a penalty. That's really set out in terms in Sainsbury's.

Now that test, that legal test, is not objected to by the CMA. Mr Hoskins is of course very familiar with Sainsbury's, and no objection to that test is made in the skeleton. I understand it to be common ground.

MR HOSKINS: I should say it's -- this is a passage of judgment that's ex turpi causa, so this is not a fining case.

THE CHAIRMAN: Sorry, it's not what?

MR HOSKINS: This passage of the judgment is dealing with ex turpi causa because MasterCard won that. It's not a fining case, by definition there was no fine in MasterCard.

MS KREISBERGER: That's accepted, but there's no reason why any different analysis should be brought to bear.

I should say that the same submissions were made in the Paroxetine case before the Tribunal and it was effectively taken as common ground because the terms are the same: intentional negligent infringement. Given Mr Hoskins's interjection, I think it is then worth just turning to paragraph 268 of the CMA's skeleton.

THE CHAIRMAN: Sorry, just before we get too bogged down on this, you're not suggesting that because Sainsbury's

found that MasterCard's practices were not intentional or negligent, that therefore you are in the clear. You're just setting out the test?

MS KREISBERGER: Absolutely. I'm not relying on the facts of that case, purely the test.

THE CHAIRMAN: You're giving the test some kind of authority by elevating the Tribunal to something we should take account of, which I think we probably will.

MS KREISBERGER: That's quite right, I'm simply saying that the Tribunal gave careful consideration to the question of what do these concepts mean, and there's nothing in there to suggest that it's confined to turpitude, and one would have hoped that if that was part of the CMA's objection, that would have been set out in its skeleton argument.

THE CHAIRMAN: I think Mr Hoskins was just trying to be helpful.

MS KREISBERGER: I'm very grateful.

MR HOSKINS: Sometimes I am.

MS KREISBERGER: I'm very grateful to Mr Hoskins.

THE CHAIRMAN: Giving Mr Hoskins the benefit of the doubt.

MS KREISBERGER: I'm grateful for that, but I think it's understood then that we're both agreed that the same analysis ought to apply, unless there's any reason for taking a different approach.

If we turn to skeleton paragraph 268, the CMA's skeleton, they note that Flynn refers to Sainsbury's, and it says:

"But this case does not involve conduct whose status under competition law was wholly unclear."

So they're attacking my submission on the facts, they are not attacking the legal test. And then they go on to explain why it was all completely clear, and paragraph 271 is the passage where the CMA says there was just no uncertainty here. So unless Mr Hoskins says otherwise, I think the test is common ground, the way in which that test should apply to the facts is not.

MR BAILEY: I hesitate to rise. I will be addressing the question of penalty tomorrow, the CMA will be making submissions in relation to the suitability of the Sainsbury's judgment, inasfar as it concerns jurisdiction to impose fines. It is not common ground that the passages set out in the Sainsbury's case are appropriate for determining jurisdiction under section 36, not a matter attended to by the Tribunal at all. The fact that in our skeleton argument we just sought to address the terms upon which Flynn was making its case, doesn't mean to say that we won't be addressing the Tribunal on the applicable law.

THE CHAIRMAN: Look forward to hearing it.

MS KREISBERGER: I just observe it would have been helpful to know earlier that was the position, but at least that's been clarified now.

Turning to the facts, my submission is, it is appropriate for the Tribunal to address the question whether it would be negligent for an adviser to have advised Flynn that the position was wholly unclear. We say it would not have been negligent. And whatever the CMA's position is on the legal test, they do assert in the skeleton that in fact, as a matter of fact, the position was wholly clear, and I'm going to address you on that, sir.

That submission, I say, is wrong. It's a fiction. Flynn had every reason to believe that its prices were lawful, and I say that's far above the relevant threshold. The Tribunal need only be satisfied that the position was unclear. The reason for that submission is essentially three elements, three aspects of the case before you. The first is one that you have heard much about already, and that's the conduct of the Department of Health as sectoral price regulator, and how Flynn understood that conduct, which you have also already heard something about.

Closely related to that is my second point, Flynn's

transparent and cooperative attitude with the Department of Health throughout.

Thirdly, and critically, the novelty of the CMA's decision, particularly in terms of the legal test which has been applied, and the single bright line adopted of the 6 per cent ROS which you have heard an awful lot about and Ms Bacon has done the hard work for me there.

I will take the Tribunal through those three points. The first point, I'd like to put the overarching point rather shortly, and then just briefly touch on the evidence.

It was reasonable for Flynn to assume that the Department of Health would pursue any concerns it had over price with Flynn. The fact that the Department of Health did not, meant that Flynn assumed -- and assumed quite properly -- that the Department of Health was satisfied with Flynn's prices. On that basis, the Department of Health's inaction is a sufficient basis on which to find that Flynn did, and was entitled to, make the fair assumption that its prices were not so unfairly high that they were in breach of article 102. So on that basis alone, we say no fine should be imposed.

Just a brief word on the evidence and Mr Lomas has

already commented that this evidence is obviously relevant to the fine. Ms Bacon has taken you to the documents recording Flynn's interactions with the Department of Health, the meeting notes, so I wasn't intending to go back to them unless it would be helpful to do so, but I will give the bundle references for your note.

Now, the headline points for the purposes of the fine, which emerge from those documents, so their significance in relation to fines, is that the entirety of the Department of Health's interactions, substantive interactions with Flynn, amounted to two meetings. One meeting pre-launch at Flynn's behest in July 2012, and one meeting post-launch, also at Flynn's behest in November 2012.

I wanted to emphasise a point that perhaps not much emphasis has been placed on it yet, which is that the Department of Health complained to the CMA, it brought its complaint to the CMA's door, before that post-launch meeting. That was September 2012, after the first meeting in July. So in fact, prior to the complaint, the Department of Health had one single meeting with Flynn.

So Flynn didn't know at the November meeting that in all likelihood the horse had bolted by that time, the

Department of Health had passed the baton on to the CMA, which we say is something of an abdication of regulatory responsibility after that one meeting.

So the full extent of written communications following the meeting -- so following the complaint, involved, as you've heard now in detail, a detailed letter from Flynn on its pricing, welcoming further discussions with the Department of Health. That's at G2/99, which was met by a single holding response thanking Flynn for its time, a promise to digest and revert, on which promise we know it never made good, and perhaps -- and we don't know because we can't ask the Department of Health in these proceedings -- but perhaps they never intended to revert because, as I said, they'd taken it to the CMA by this point.

But Flynn didn't know that. Flynn believed that it was discussing price with the Department of Health in good faith.

So it had no way of knowing, because of course the Department of Health had conducted itself in secret. So it took the problem to a non-specialist competition regulator, not the sectoral, in its position as sectoral regulator. So one might comment that that does not appear to be a model of responsible sectoral price regulation, keeping the company in the dark. But as

I said, the Department of Health is not here for us to put that to them.

Now as Ms Bacon --

MR LOMAS: And it is not strictly relevant to your point, which is was what was Flynn's state of mind, not was the Department of Health to be criticised?

MS KREISBERGER: You are of course right, but we make that criticism given the points that the CMA makes about Flynn's state of mind. So what I want to emphasise to you is that Flynn was kept in the dark, and therefore had a bona fide belief that it was having active discussions with the Department of Health which hadn't reached their fruition after a single meeting.

THE CHAIRMAN: There must have come a point where you realised that there was no active discussion.

MS KREISBERGER: I'll come on to that point immediately, sir. I'm grateful for that.

Just before I do, just to observe that Ms Bacon has already made the point that throughout that process, if we can call it that, the Department of Health didn't actually ask Flynn to reduce its price, let alone engage in a price negotiation. In fact, what the Department of Health did, and we get this from the note of the November meeting in 2012, which I won't take you to, but the Department of Health's note of that meeting, they

informed Flynn that without more information, the Department of Health said it could not take a view on whether the price was justified. It could not take a view. So it hadn't taken a view and it could not. And that's precisely why Flynn came back with more information.

As you know, sir, the other point the Department of Health did make was again, according to its own documentary record of the meeting, is that it was likely to consider the options available to it, that's the regulatory options, including some sort of maximum pricing scheme. And we say look, this was a clear expression of intent to pursue regulatory enforcement action if, after completing its review, it decided that the prices were not justified. That's precisely why Flynn came back with more information in writing, really in a very formal manner.

As you say, the Department of Health then went silent, so how did Flynn construe that silence? Well, initially Flynn understood that its prices had been, and the phrase Flynn used is "sanctioned by default". Now I'm quoting from Flynn's note of the meeting there, so for your note that's G2, tab 94. So in November 2012, Flynn explained to the Department of Health that it thought its prices had been sanctioned at default at

launch.

Flynn nevertheless went on to request that second meeting, and Flynn understood at that second meeting that it had been put on notice by the Department of Health of its intention to take regulatory steps if it remained unhappy about the price. Now, the Tribunal will hear Mr Walters' evidence on this. But what is critical for this point is that Flynn believed that the Department of Health was empowered to intervene on price if it decided to do so.

If I could just take you to Mr Walters' first statement. That's here in bundle B, tab 4, page 9. The relevant paragraph is paragraph 29. Mr Walters says:

"In fact, we believed throughout our discussions with the DH that it had the power to intervene in the pricing of Phenytoin. At the very least, we considered that the DH might eventually invite Flynn to join Scheme M if it wasn't satisfied that our pricing was reasonable. Alternatively, it could have intervened in the price of the Teva tablet."

The point is not what were the Department of Health's powers for these purposes, which Mr Brealey has made submissions on so eloquently, but the point for my purposes is whether Flynn took the Department of Health

at its word, which it did. It believed that it had the powers to regulate price.

MR LOMAS: Post the 6th November 2012 meeting, which is what this statement is talking about, whereas the product was launched on 24th September 2012, so the product was already in the market at that price by the time this occurred.

MS KREISBERGER: That's correct, but --

MR LOMAS: But you're saying it is relevant to the state of mind of Flynn --

MS KREISBERGER: Throughout.

THE CHAIRMAN: -- at the time they launched six weeks earlier.

MS KREISBERGER: Correct, correct. That is Flynn's clear evidence, that it believed throughout that the Department of Health could regulate its price, and that's why it understood that the launch price had been sanctioned by default. Of course there would be no reason to have a change in belief on a --

MR LOMAS: You would say the first sentence of paragraph 29, then, is not to be seen as a consequence from the context of the 6th November meeting but for all time?

MS KREISBERGER: Absolutely. This was Flynn's only customer. Flynn's business was to know how to keep its customer happy, and what the customer could do if it was

not happy.

Now, of course the Tribunal can put questions on this to Mr Walters, but his evidence is that Flynn believed throughout -- and this is precisely why it came back and it came back again to the Department of Health -- it believed that if the Department of Health wasn't happy, it would intervene. But the November meeting is critical because Flynn -- it shows Flynn was simply taking the Department of Health at its own word.

THE CHAIRMAN: Do you regard the fair price in the Department of Health's guidance as effectively the same as a non-excessive price under article 102? And if so, why?

MS KREISBERGER: I think I don't need to go so far as to say that it was the same.

THE CHAIRMAN: I think you did go so far as to say that what you've just described justified Flynn believing they were not in breach of article 102. I am suggesting you are assimilating the two tests in some way.

MS KREISBERGER: Let me be a little bit more precise about that. Let me put it this way: my submission is that it was reasonable for Flynn to understand that its prices did not infringe competition law on the basis that the specialist sectoral regulator was content that its prices were reasonable within its own pricing scheme.

So for these purposes, that's a strong --

THE CHAIRMAN: That's a process of reasoning that one would, in a sense, quite like to see articulated because it's not automatic, it's axiomatic.

MS KREISBERGER: I make a separate point --

THE CHAIRMAN: Different jurisdiction -- (overspeaking). They are different jurisdictions.

MS KREISBERGER: They are, sir.

THE CHAIRMAN: History of regulation is littered with cases where people thought they were clear under one regulatory regime and were then not to be clear under another. Isn't it a bit like that here?

MS KREISBERGER: I accept that. So let me emphasise that we have other points on the novelty of the case.

THE CHAIRMAN: Yes, I am just trying to be precise.

MS KREISBERGER: I think for the purposes of penalty, my submission is if you have a specialist sectoral regulator endorsing your price, it is reasonable to believe, and proper to do so, that those prices do not infringe competition law unless there are some exceptional circumstances to think otherwise.

MR LOMAS: Do you think the Department of Health did endorse? "Endorse" was the word you've just used.

MS KREISBERGER: Flynn understood that the Department of Health had endorsed its -- the Department of Health

certainly hadn't, because it asked someone else to step into its shoes. Now we would say that's extraordinary conduct for the sectoral regulator. This is a sectoral regulator that has pushed for and obtained revised legislation to, as Mr Brealey explained yesterday, to clarify that there was no loophole, that certainly there can be no doubt now. This is an active sectoral regulator.

Now, can I come back to this point, because I'm going to take you to what an economist would say about this particular point, which I think is highly relevant.

I can skip ahead. It is a couple of paragraphs away. But I think it is relevant to answer your question, sir, as to whether one can align the two. I say one certainly can, for the purposes of penalties. There's a different technical legal question that doesn't arise in this case about whether state compulsion, and so on, is the case law you may have in mind. But for these purposes on penalties one can align the two.

All I was going to do before I come to that point is highlight two further passages of Mr Walters' evidence in advance of you hearing from him later in the week. And the first is paragraph 32, where Mr Walters said -- that's just over the page -- where Mr Walters explains

that:

"The Department of Health had never followed up on Flynn's written response, didn't attempt to engage with Flynn. I'm surprised because Flynn's understanding" --and Mr Lomas, this answers your point– "throughout our discussions was that the DH had the power (both formally and informally) to intervene in the pricing of drugs."

Mr Walters comes on to the successful intervention in Teva tablets. So Flynn knew about that and relied on it, and it expected to have a proper commercial negotiation with the Department of Health about pricing, which didn't happen. So this is Flynn's clear evidence on the point. There is no doubt about it. And this is how it engaged with its only customer.

Then just lastly, Mr Walters' second statement at paragraph 11. I want to take the Tribunal to this one because it also responds to the chairman's question earlier, which is whether Flynn simply regarded its launch price as an opening gambit which it was expecting to be forced down. In fact, what Mr Walters says at paragraph 11 of his second statement is:

"Although we were confident that our prices had been set at an appropriate level, given the substantial discount to Teva tablets, we fully expected that if the DH nonetheless had any concerns about our prices, they

would negotiate with us to arrive at a mutually satisfactory outcome, exactly as they had done with Teva, and we would have engaged in negotiations in good faith."

Now I see I may be venturing into the margin of tolerance.

THE CHAIRMAN: Well you're in the margin of tolerance, but we would like you to finish and also to make your case.

MS KREISBERGER: Sir, I understand. I will be as quick as possible.

So I was anticipating your question, sir, in my next section, which is to answer Mr Hoskins' submission which would be that Flynn is not entitled to rely on Department of Health inaction as an indicator that prices probably weren't excessive. That's the point you make, sir.

I say not only is that submission unreasonable because intuitively it is unreasonable if one has the sectoral price regulator; it is common sense to -- but it is also of the correct position to someone familiar with the writings on excessive pricing, the economic commentary. For that, I'm going to take you to Mr de Coninck's second report, which is at bundle D, tab 2, page 6. I'll do this very briefly, but sir, since you've raised the point, it is an important one.

Now, at paragraph 21, Mr de Coninck refers to what's actually a seminal article on excessive pricing by Motta & de Streel. You can see there right at the bottom of page 6, subparagraph 3, he there sets out the three stage test proposed. These are the economic conditions which justify direct interference in price. The third condition is that there is no sector-specific regulator which has jurisdiction to solve the matter. And the explanation is that if an industry-specific regulator exists, which is likely in industries in which the previous two conditions hold, then the regulator is more suitable to intervene in questions of excessive pricing.

And Röller, his seminal writings are summarised in the passage above, and he makes a similar point at subpoint 4 in paragraph 20.

So this is well recognised. So an economist would say yes, it is entirely appropriate to assume that the point will be taken by the sector specific regulator; they're more suitable to intervene.

Again, for the penalty threshold, it is appropriate for Flynn to have understood there was no issue with price.

THE CHAIRMAN: It's fair to say this literature is about whether it is wise for competition authorities to intervene in excessive pricing cases.

MS KREISBERGER: But it is looking at the economic conditions which ought to prevail to justify interference in price, so conceptually --

THE CHAIRMAN: There's a policy.

MS KREISBERGER: It is policy, which informs -- which reflects the conceptual underpinnings of intervening in price at all. It is exactly the policy that Advocate General Wahl is addressing in his opinion. What is the analytical justification for interfering in price? Now the reason they say sector-specific regulator is because of the scope for error, which is another point that Advocate General Wahl makes. Now, given the scope for error, far better to have a regulator who understands how the industry works.

THE CHAIRMAN: I understand all that, but what we're talking about is whether it was reasonable for Flynn to assume that if their launch price had been sanctioned by a default and not further objected to, they were therefore safe from article 102. That's the question.

MS KREISBERGER: My submission is that's entirely reasonable, and I've given you the context there. I'm not saying that it's a foolproof legal answer, a foolproof watertight legal defence, because there are legal answers depending on the facts. I mean one is now speaking in the abstract, where one might say "well, the

regulator has sanctioned it", but there's still a breach. But for the purposes of penalties, the threshold is effectively reasonableness. Was it reasonable for Flynn to think: my single customer, who regulates my price, has satisfied itself that my prices are okay? To suggest that in those circumstances Flynn should have said, "Oh, but, you know, should I worry about the fact that I'm excessively pricing?" in any event has an air of unreality, particularly when understood in conjunction with the points I'm going to come on to about the novelty of the case. There is nothing exceptional.

THE CHAIRMAN: You'd better get on with those.

MS KREISBERGER: What I'm going to do is I'm going to skip over my second point. Sir, I think you have it in mind that Flynn was transparent, all the contemporaneous documents are consistent. Flynn said all the way through to Pfizer, to the Department of Health, to the CMA, that it benchmarked the tablets. It wasn't only cooperative but it repeatedly sought to engage an apparently disengaged regulator. It didn't know the reason why it was disengaged, the real reason.

So this isn't the conduct of a party covertly seeking to exploit market power, or frankly who even thought its prices were unlawful. It was convinced that its prices were lawful and justified, and sought endorsement

from the Department of Health on that basis.

Now I think I had better move on to the point about the novelty of the case. I'd like to make just one point very briefly. One of the answers that the CMA gives to this is that Flynn's contention that it would have had a discussion on price, it would have altered its price had the Department of Health come back to it, the CMA says "That's just not true, we don't buy the evidence, because look, Flynn didn't alter its prices when it saw our SO."

Now I'd invite the Tribunal to disregard that submission in terms, because it is unfair to Flynn, because once Flynn saw the SO, it took the view that the basis of the SO was unlawful. It took the same view, having received the decision, and it is exercising its rights of defence by bringing this appeal. To say it should have nonetheless reduced its prices on the basis of an SO that it considered to be unlawful, is unfair and inappropriate. So I just wanted to make that point now in opening.

Now, finally, moving on to my final submission, which is that the basis of the decision was not foreseeable. This obviously is a critical one. Even if the Tribunal finds, contrary to our primary case, that the decision has some lawful basis, it represents a radical departure

from existing case law in principle, and also the economic consensus. It draws a bright line for determining excessiveness, 6 per cent ROS, which could not have been foreseen, could not have been foreseen by any adviser who did not have telepathic powers.

We of course go further. We say it is arbitrary, it doesn't work. But certainly it does not have -- it could not have been foreseen with the degree of certainty necessary in order to impose a fine.

We make four principal points on that. The first one I take very briefly. At a level of generality, the whole question of when prices will be deemed abusively high is fraught with practical and conceptual difficulties. Just for your note, Mr de Coninck comments on this at D2, pages 4 to 7. At paragraph 12 he says:

"The consensus among economists is that these findings of excessive pricing should be very rare."

Advocate General Wahl makes a similar point. Sir, you'll be familiar with this commentary. It is borne out by the sparsity of the case law, as Mr O'Donoghue observed. Just so you have it, it is paragraph 42 of Advocate General Wahl's opinion that makes a similar point and refers to the risk of type 1 errors.

Turning to the specifics of the case, the second point is that Mr de Coninck also explains that this case

does not have any of the hallmarks which economists would look for in making a finding of abusive pricing. Given the time, I won't take you there, but it is paragraph 22 of his second report, which is at bundle D, tab 2, page 7. But this really gives some context to why this is a surprising decision, and it's relevant. There was no exclusionary practice by Flynn to gain a dominant position. It had no special rights. It is highly unusual to have a purely exploitative allegation of excessive pricing, when there were no regulatory barriers to entry or IP rights that barred entry. And as I've said, there exists a suitable regulatory framework on competition policy. So from an economic perspective, the case is surprising, and one would seek economic advice.

Generally, these aren't matters even addressed in the decision.

Thirdly, and this is a point Ms Bacon didn't have time to address you on today, the CMA itself clearly found it far from obvious, contrary to what they now say in their skeleton, as to whether this price was excessive. If we turn briefly to J1, tab 19, that is the note of Flynn's meeting with the CMA in July 2014. This is the CMA's note. If we turn to paragraph 30 of that note:

"AP, on behalf of the CMA, noted that the test is

simply excessive pricing, and in reality, the decision of whether or not the price is excessive is not just based on a benchmark or value that sits in case law that the CMA can just pull off the shelf."

It's not an obvious question. So that was acknowledged in July.

Now, the CMA's difficulties are reflected in the protracted investigative time frame. It received the complaint in September 2012 but by July, the date of this meeting, two years after the complaint, two years after the complaint, the CMA still had not formed a view on whether Flynn's margin was unfair, or indeed what a fair margin might be. So if we turn to paragraph 27 of the same note of the meeting:

"AP acknowledged that the reasonableness of the margin is at the heart of the issue, but there are lots of issues before one gets to that stage. AG acknowledged that it's a fair question to ask what is a fair margin, and these are issues which the CMA is considering internally and has not yet concluded. At the moment, the CMA has a reasonable suspicion that the price is unfair."

"AG explained that this issue would not be concluded in the meeting [two years after the complaint]. The question of whether the margin is unfair will be

considered in the stop/go and if the outcome of the stop/go is that the margin might be unfair, the CMA will then bottom out the issue of what the fair price might be and what the differential is between the price and a fair price."

These are not simple questions, and it's rather at odds with the CMA's categorical tone now in these proceedings that there is no uncertainty at all about the issues of price. That's paragraph 271 of the CMA's skeleton.

My fourth and final point relates to the novelty of the case, and I will take these briefly. I have five subpoints that I will just refer to. And these are points on novelty in terms of legal analysis and technical methodology applied.

So the basis of this decision could not have been foreseen by Flynn, it was not and could not have been foreseen, because it's a decision which defies prediction.

The first aspect of novelty is the legal analysis, and this relates to the construction of the United Brands test which lies at the heart of this appeal.

Now, this is the first time -- the first time the Competition Authority has argued that it's legally entitled to disregard comparators, even if those comparators are meaningful. Quite a surprising

proposition. That's why it's unprecedented. And what this regulator has done is adopt a literalist interpretation of the language of United Brands. It hangs on the use of the word "or" in limb two. And there's no direct authority for this approach that one can ignore part two of limb two, comparators, and it is not borne out by the conceptual underpinning of the exercise, the analytical approach, namely that you have to take account of all price and profitability benchmarks, as Advocate General Wahl comments.

So this is a surprising decision for an antitrust regulator with in-house economic expertise, this literalist approach, which we say in any event is an error of law.

The second point relates to the above: if one were advising Flynn, it would be reasonable to assume that Napp would be treated as the leading authority on how the excessive pricing would be approached. One might expect the CMA to broadly follow the guidance laid down in Napp.

Now Mr O'Donoghue emphasised the different point about Napp, which is the one about that it related to exclusionary harm, but Advocate General Wahl commented that the OFT's analysis in that case rested on multiple benchmarks, both in relation to profitability and price.

And Ms Bacon has addressed you on that.

So the key point is the OFT in Napp did not adopt a cost plus approach. It looked to see whether both Napp's prices and Napp's margins were outliers on a variety of different bases, in particular, taking account of internal gross profit margins.

So my third point is then that the CMA's approach here is in fact the antithesis of Napp, and that is unforeseeable and surprising, because they have adopted a costs plus approach, and they have adopted a non-evidenced based approach. And here I am building on what Ms Bacon has said to you, and really standing on her shoulders. To summarise, they've rejected every price comparator and industry benchmark proposed by the parties. They relied instead on a single data point wrongly extracted from the PPRS which applies as a portfolio cap. So it says nothing about individual product profitability and it bites on a different category of drugs.

The CMA does not rely on evidence of the ROS of comparable unbranded generic drugs, as well as being based on a cost allocation methodology that's not used. So my point is this is not an evidence-based decision, and that is surprising.

As I've mentioned, the 6 per cent ROS, we say, is

essentially an arbitrary line in the sand, and it's not one which could have been anticipated, because this is certainly going to come as a surprise to suppliers of generic drugs on the ground.

My fourth point is the fact that it relies on a loss-making price as a benchmark.

My fifth and final point on the surprising aspects of the analysis, technical analysis set out in this case, although it rejects the evidence-based comparators that I've just referred to, that one would expect to operate as yardsticks, it does something really surprising. If we could just turn up the decision at paragraph 5.227, which is on page 345, in fairness to the CMA, they say this is not determinative, but they nonetheless rely on this. They do something really surprising. They rely on cost price differentials in other cases which relate to completely unrelated sectors, Albion Water and Deutsche Post. These are incomparable, so they reject generic drug comparators, but they do think that Albion Water's cost price differential is relevant.

Now, just to give you the flavour of how out of line this is, how surprising this is, how it defies prediction, I won't take you to the case now, but for your note, sir, Deutsche Post is at authorities

bundle E1, tab 7, page 73 of that decision, paragraph 162. What the Commission says there is that it should be stressed, and this is in the context of its analysis of excessive pricing, that postal services, and in particular, the bulk mailings examined here, involved the processing and mailing of large volumes in respect of which the profit margin item came to 3 per cent. That just tells you, this is not a relevant comparator. So one would not have expected this.

In fact, what the CMA has done here is precisely what they said at the July meeting they wouldn't do: they've pulled a yardstick off the shelf from the case law.

THE CHAIRMAN: And we know Albion Water so you don't need to --

MS KREISBERGER: I wasn't going to go there, sir.

If I have the Tribunal's forbearance, I would just refer to what the CMA's answer to these points is.

THE CHAIRMAN: You're trespassing on the Tribunal's forbearance quite severely.

MS KREISBERGER: And possibly trick or treating, so I'll make the point briefly, which is the CMA comes back and says it is unnecessary to point to a carbon copy of the decision. Well, that is not my submission, and I do hope that's clear from what I've said. It's that this decision is not consistent with principles well

established in the case law and the decision practice and economic writings. In fact, in many ways it is directly contradicted by the case law.

Sir, I can end my submissions there, if I have exceeded my margin of tolerance.

THE CHAIRMAN: Thank you very much.

Tomorrow?

MR HOSKINS: I've got a lot to get through, for obvious reasons. If you can bear it, 10 o'clock. I'd be very grateful.

THE CHAIRMAN: I can bear it. My colleagues?

MR HOSKINS: Thank you, I'm grateful.

THE CHAIRMAN: We'll see how we get on.

MR HOSKINS: I'll be as quick as I can. I mean, you've read, you've heard. I'll be as quick as I can.

THE CHAIRMAN: We have been very tolerant and listened to a great deal of material we've already read, but that's the nature of the process.

MR HOSKINS: I understand. I'll do my best.

THE CHAIRMAN: Thank you. Right. 10 o'clock, then.

(4.49 pm)

(The hearing adjourned until 10.00 am the following day)

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