IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

21st November 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 10

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, 21 November 2017

(10.30 am)

Closing submissions by MR BREALEY

THE CHAIRMAN: Welcome back everyone after your break.

MR BREALEY: Pleased to be back.

THE CHAIRMAN: Mr Brealey, are you on?

MR BREALEY: Yes, I am on. The batting order for today: I would like, with the tribunal's permission, to deal with economic value this morning. I would like to do that by looking at the evidence on economic value and the law.

THE CHAIRMAN: Economic value is one of your grounds, is it not, as I recall. We are going to have to get back to the grounds at some stage.

MR BREALEY: At some point we will. So I would like to deal with economic value. And then that may go into the afternoon session but, if not, I would like just to deal with continuity of supply.

Then at tea, as it were, taking a cricket analogy, Mr O'Donoghue will then take over and will spend some time on ground four and penalties. So that is essentially what we are going to do.

THE CHAIRMAN: Fine. And you are having the whole day?

MR BREALEY: We are the whole day and Ms Bacon is tomorrow --

THE CHAIRMAN: The day, the whole day and nothing but the day.

MR BREALEY: Something like that. And then obviously Mr Hoskins is on Thursday and then we have Friday morning for replies.

THE CHAIRMAN: And there is no change from that timetable that anybody wants to raise? No. Fine. We are all ears, Mr Brealey.

MR BREALEY: Thank you very much indeed, sir. Clearly the economic value is very important to our appeal and, as I say, I would like to do it in two stages, look at the evidence and then the law.

On the evidence, I would like to draw the tribunal's attention to six issues, and I have tried to pull these six issues from the skeleton arguments. I just do not want to repeat what is in the skeleton, I want to actually try and -- skeleton arguments in closing. I would like to draw together six issues where we say that the CMA has not addressed various issues and not challenged the evidence.

So the six issues, if I can just float them first, the first issue is the evidence on epilepsy, so the evidence on epilepsy, the neurological disorder we know as epilepsy, that is the first issue.

The second issue is the importance of Phenytoin in

treating this condition, and the reason for that is the CMA still downplays the importance of Phenytoin, so that is the second issue, the importance of the AED, Phenytoin, in treating epilepsy.

The third issue is the comparison between Phenytoin and the other AEDs we refer to in the treatment of epilepsy. So that is the comparison between Phenytoin and other AEDs in its treatment of epilepsy.

The fourth issue is what I call the intrinsic value of AEDs, the intrinsic value of AEDs, and there we will be going to in particular the expert evidence of Mr Ridyard.

The fifth issue is the price of these AEDs.

And then sixth, I want to draw the tribunal's attention to the tablet, the Phenytoin tablet, and I shall do that basically by reference to the closing. We dealt at length with the tablet but I do need in closing to deal with it.

So if I could start with the first issue, that is the evidence of the medical disorder which we call epilepsy. Just as a general point, this is a case about the price of Phenytoin, the price of Phenytoin, which is a pharmaceutical drug. There are many strange things about this case but one of the strangest things when one looks at the CMA's closing is it hardly mentions the

medical condition, it hardly mentions -- well, I do not think it does mention -- other AEDs of any substance, and Phenytoin gets a brief mention halfway through the closing.

I think this is important because if one is going to decide a case on excessive price of a pharmaceutical product, it is in my respectful submission fundamental to know, first of all, what the medical condition is and what the drug does to treat it if one is looking at an excessive price allegation about this particular drug.

Before I get into the evidence on epilepsy, I just want to emphasise the expert evidence of Professor Walker. The reason for this is that the CMA, as we know, adduces no independent expert evidence from any specialist that would assist the tribunal in the disordered epilepsy or how it is treated. No independent expert evidence at all.

I want to just show the tribunal how the CMA regards the evidence of Professor Walker. If we can go to the transcript bundles -- I am going to be going to the transcript bundles a little just to look at the evidence, and this is Day 5. I would ask the tribunal to keep the transcript bundles open. I am going to refer to Day 3 and Day 5. So the transcript bundle, Day 5. It is page 56, line 6. This is important

because it shows how the CMA regards the evidence of Professor Walker. This is page 56. So just to clarify, this is Mr Hoskins' cross-examination of Professor Walker, this is his blush moment:

"Just to clarify your area of expertise, I do not want to make you blush, but it is pretty clear from your CV that you are an eminent and specialised consultant with particular expertise in epilepsy, that is what you do?

"Answer: That is correct, yes."

Not the most difficult question for him to answer but nevertheless that gives an indication of how the CMA is regarding the evidence of Professor Walker.

As I say, we will come back to Day 5. If we can go to Day 3, this is a passage in opening from the CMA, from Mr Hoskins. So transcript Day 3, page 17. I am going to have a look at the whole of this page in a moment, but just for present purposes if we can go to line 23, this is how Mr Hoskins is going to treat Professor Walker's evidence:

"Question: In relation to this question of is Phenytoin still an effective product, Professor Walker says it is, and we are not going to dispute that because he is the expert in these things."

It is important, as I say, because the CMA have

adduced no independent expert evidence of its own to challenge what Professor Walker says. If one reads the cross-examination of Professor Walker there is very little challenge to his evidence, and I will come on to a little bit of it in a moment, but in fact the CMA defers to his expertise. I say this because in my submission, the tribunal can safely rely on his testimony.

For example, and we are going to come on to it, but Professor Walker says the capsule and tablet are identical products. That is his opinion as an expert. The CMA say he is an expert, they have not challenged that evidence as we shall see. So when we come to our case on comparators and the tablet and the capsule we have expert evidence to which the CMA defers, does not challenge his view that the tablet and the capsule are identical, and so the result of that is you can safely rely on his evidence to see whether the tablet is a comparator or not. That is just one area we are going to have a look at. But that is why I say it is important to see what his evidence goes to and how it was not challenged. Indeed it seems to be accepted.

So that is the expertise of Professor Walker. Could I go to the seriousness of the condition now, the seriousness of epilepsy. We will come back to Day 5 and

Day 3. I took Mr Harman to this, not very successfully because he hadn't been shown Walker 1. I want to go to Walker 1 at bundle D at tab 9.

Again, why am I going to this? I am going to this because it is relevant to, as we shall see, the value, the economic value of a drug that treats a serious medical condition. So this is the issue relating to seriousness of the condition. It is bundle D, tab 9, and he starts as we know at paragraph 3.1. Really it is 3.1 to 3.10 where there is the unchallenged evidence of the nature of epilepsy and how serious it is.

So at 3.1 we see -- this is a neurological disorder of the brain, epilepsy:

"The brain comprises over 100 billion interconnected nerve cells ..."

He goes on about how the proper working of the brain requires a balance, and if there is an imbalance there is an electrical storm and that leads to a seizure, and we shall come on to seizures and how AEDs control seizures. This is an important point.

So he is giving evidence about how there is a seizure. And then 3.2, how it spreads. At 3.3, we get the generalised seizure where the seizure involves the whole brain and the focal seizure where it begins in a specific part. That is mid-way down 3.3.

At 3.4, epilepsy is a not uncommon, one in thirty people develop epilepsy in their lives.

And then:

"The main drug treatments either decrease the excitability of nerve cells ..."

This is 3.4.

"... or enhance inhibition."

So correcting the imbalance that causes the seizure. So it is important that -- he is starting to talk about how AEDs control seizure.

Then at 3.5 to 3.7 he gives evidence again -- I do not think this is much in issue but I simply do not want this to be swept under a carpet. I do not want the evidence to -- and obviously the tribunal can ignore it, but personally from our side I do not want the tribunal to underestimate this evidence.

At 3.5 to 3.7 he is giving evidence about the medical impact, so increased mortality rates, risk of drowning, heart attacks, suicide, sudden death, depression. This is what epilepsy can lead to. So it is a life-threatening condition. It is not just a life-threatening condition, the medical aspect, then at 3.8 he refers to epilepsy having significant social implications.

Again, one simply cannot ignore this type of

evidence: it has significant social implications, incidents of unemployment, social stigma, relationships. People who have epilepsy find it difficult to have relationships. So again the importance of a serious medical condition.

Then at 3.9 and 3.10, again not an unimportant point, he is referring to the cost to society of epilepsy and he refers -- so these indirect consequences are reflected in the costs, and he refers to direct health costs. When one looks at the appendix, the direct health costs are basically the in-patient care costs, visiting hospitals. The non-medical costs are, you will see if one goes to that annex, the Social Services type costs, people visiting people with epilepsy. And then you have the indirect costs, and these are the costs associated with death and unemployment and they constitute over half of the cost to society of epilepsy.

So we get at 3.10:

"In conclusion, epilepsy is a common neurological condition ..."

Different causes, significant associated morbidity and mortality, it has a significant impact on quality of life. The main cost burden of epilepsy to society is indirect costs, mainly reduced productivity, ie death or

unemployment, rather than the cost of AEDs.

So I know the tribunal have this, but simply if one reads the CMA's closing submissions one does not get a sense of this at all.

So that is what I wanted to say about the first issue on economic value. That is the serious medical condition that we know as epilepsy.

The second issue that I want to refer to is the importance of Phenytoin in treating this. The CMA has throughout the whole process sought to denigrate Phenytoin and the disparaging remarks have centred on essentially three things: the efficacy of Phenytoin, the age of Phenytoin and the allegation that it is simply an irrelevant third line treatment. I want to highlight the evidence on these three issues because the denigration is simply wrong.

So on efficacy, I believe this is no longer in dispute but it is not a point again I want the tribunal, with respect, to skirt over because it is relevant to value.

So if we can go back to the transcript bundle, Day 3, that is at page 17 that I referred to. This is the opening so this is what we are faced with in this appeal.

So page 17, this is how it was opened. And if one

remembers, in their opening they said we will deal with Professor Walker in closing. I made a little moan about it. And then the chairman asked Mr Hoskins, could you give us a clue as to what you are going to say about the evidence of Professor Walker.

So this is page 17, Day 3. Mr Hoskins said:

"I think, if I am pushed, the big point in relation to Professor Walker is he says Phenytoin is still an effective product. That is the big point. That point was originally not made by the CMA, it was made by Pfizer to the CMA in a Section 26 response ..."

And I will ask the tribunal to note this because it is incorrect:

"... where they said Phenytoin is no longer an effective product, it has been superseded by other products. So that is a point that came originally from Pfizer but Professor Walker disagrees with it. The point in relation to that is he also accepts that even though it is still an effective product, there are other reasons, in particular the NTI, the pharmacokinetics, which mean it is no longer used or recommended for a first line treatment ..."

And I underline the words "used or recommended":

"... it is only used when other treatments have failed generally."

So this is where he now accepts that Phenytoin is an effective product.

"In relation to this question of is Phenytoin still an effective product, Professor Walker says it is, and we are not going to dispute that because he is the expert in these things. One point is going to be, yes, but it does not matter because it is common ground between the parties that whilst it is still an effective product, in terms of pure efficacy it is not a product that is recommended for use or used routinely or at all as a first line treatment or a second line treatment."

So we have moved to a certain extent away from it not being a product which is efficacious and the point remaining is that it is a third line treatment.

I want to just show the tribunal, although this seems to be agreed, where all this comes from. So the Section 26 notice is at J1, tab 2. Because it is not correct that Pfizer said it was no longer an efficacious product. If one goes to J1, tab 2, this is the first paragraph, so tab 2, this is a Section 26 response from Pfizer. If the tribunal remembers, Mr Hoskins took Professor Walker to this paragraph, asked him whether it was correct, and he said it was, which it is. It's the last few lines which are relevant which the CMA latched on to:

"Phenytoin has been on the market for decades, has been superseded in many clinical situations by newer medicines which have a better safety and tolerability profile, a wider therapeutic index, no requirement for blood monitoring and fewer drug interactions."

The important point there is Pfizer was not saying that Phenytoin was not efficacious, and the submission, with the greatest respect to Mr Hoskins, that Pfizer was saying it was not efficacious was wrong.

Before we put that away, before I forget, in tab 2 one also sees at the bottom of that page there are many other AEDs beside Phenytoin and at the annex on page 15 Pfizer draws the CMA's attention to other AEDs. We are going to come back to several of these. But Pfizer is at least putting the CMA on notice of other AEDs that control seizure.

So we get the same old Lamictal, which is Lamotrigine. We've got Topamax, Topiramate, we've got Keppra. All these ones we see have been here all along.

THE CHAIRMAN: Where is this point going, Mr Brealey? We are being told that the product is no longer recommended as a first line therapy but it is effective when it is used.

MR BREALEY: Yes. Where is it going? It is going to submission on value, economic value. It is very

important --

THE CHAIRMAN: So you are saying it has value.

MR BREALEY: Yes.

THE CHAIRMAN: In that when it is administered it is effective.

MR BREALEY: Yes. And if we can then just have a look at what Professor Walker did say, which is unchallenged. If we go back to his first report, Walker 1, bundle D, tab 9, I am trying to deal with the description of Phenytoin in the decision, it is denigrated as old. In the defence, it does not really do anything, and that is repeated in opening but then is accepted in the light of Professor Walker's statement.

So at tab 9, if we go to paragraph 5.6, just a few paragraphs. A lot of his evidence goes to this, I will just emphasise a couple of paragraphs. So 5.6, this puts that section in context:

"Whilst there has been a growth of better tolerated AEDs with similar modes of action, it remains the case that Phenytoin is extremely effective at controlling seizures. The comments in the CMA's decision in paragraph 3.43 that Phenytoin sodium has been superseded by a number of newer medicines with improved efficacy is in my opinion inaccurate as other AEDs have not been shown to have improved efficacy."

So that is in the CMA's decision, Professor Walker has said it is inaccurate and the CMA has not challenged that. So that is a relevant point to economic value, the way that the CMA in the decision and in the defence have denigrated Phenytoin.

THE CHAIRMAN: It's the words "with improved efficacy" that you take exception to?

MR BREALEY: Absolutely, yes. The reason I showed you again the serious medical condition, what is it? What characterises epilepsy, one is prone to seizures. And that then gives rise to the risk of mortality, risk of drowning, whatever it is, you cannot have your driving licence, it is a seizure. And if a drug is very effective at controlling a seizure, it is very effective at treating epilepsy, and that is the thrust of his evidence.

It is not just the efficacy. At 5.8:

"There has been, to my knowledge, no good study demonstrating that Phenytoin has inferior efficacy as a first line therapy for epilepsy. To the contrary, my experience is it remains one of the most effective drugs at controlling seizures."

I am going to come on to the first line, second line, third line in a moment. But again unchallenged evidence as a first line therapy in epilepsy. And there

are nuances here, but it is incorrect to say that Phenytoin is not used in first line therapy. But all I wanted at the moment to emphasise, as you rightly pointed out, sir, is improved efficacy.

THE CHAIRMAN: Professor Walker's evidence is summarised in 5.11, which of course we have read, and it draws all that section together.

MR BREALEY: Yes, he does, and Mr Hoskins took him to that. And also I think in order to look at 5.11 one has to look at 5.10 as well.

THE CHAIRMAN: Okay. You are saying this is all in fact not contested?

MR BREALEY: Not challenged at all. In fact the one area where Mr Hoskins asked Professor Walker about first line therapy, Professor Walker emphasised that Phenytoin is used in first line therapy in emergencies, and I am going to come on to that in a moment.

Mr O'Donoghue says none of it is in the decision which is true.

So the first point is efficacy, the second point before I get on to third line treatment is age. The tribunal will have seen repeated references to the description of Phenytoin being "old". Just for the tribunal's note, we do not need to go to it, but in the decision for example it is paragraph 5.97 at

page 310, it is at paragraph 5.268 at page 355. So 5.97 at 310, 5.268 at page 355. We saw repeated reference to it being old in Mr Harman's expert report. So again, one reads the decision and one gets the impression that it has very little value because of its age.

So if we go to Professor Walker, his second at bundle D, tab. So at paragraph 3.1(b), page 6, all I am concentrating on is this disparaging remark about it being old. At 3.1(b), again this is his evidence, it was not challenged and I would ask the tribunal to accept it. So Walker 2, at page 6, tab 10 of bundle D. He says:

"In paragraph 2.7(b) the CMA suggests that the age of Phenytoin sodium is a disadvantage. This puzzles me since I do not consider the age of a drug to be a relevant factor when considering which drug to recommend or prescribe. Penicillin is an example of an old drug that remains as effective as newer antibiotics. Ethosuximide is an example of another AED which is old and which is now a first line therapy for children with absent epilepsy."

THE CHAIRMAN: We are talking about the characteristics of the product and the efficacy and how it is administered.

MR BREALEY: Yes.

THE CHAIRMAN: We are not talking about arguments about

return on research and development and innovation and that sort of thing.

MR BREALEY: No. All I am --

THE CHAIRMAN: I suspect Mr Harman was.

MR BREALEY: Mr Harman definitely was. I am looking at it from the value to the patient, the value to society, of treating someone with epilepsy, and for some unexplained reason, it is never explained in the decision, all we get is that it is old. Whether that, as you rightly say, sir, is because all they are doing is looking at it from a reasonable return sufficient for you to stay in the market. I am emphasising that the age does not detract from the way that it treats these patients. And paragraph 3.1(b) is relevant to the CMA's denigration of Phenytoin as being old. Age should not affect the value of a drug if it is extremely effective at controlling seizures.

So that is the age. The last thing I want to refer to now is the third line treatment point. So we saw from Day 3 Mr Hoskins accepted it was efficacious. He then went on to say, well, it is used and recommended as a third line treatment.

Two points here. First, it is not true that it is only used as a third line treatment, and secondly, even if it is, it is very important to many thousands of

people.

So the first point is it is not true, because if we go to Walker 2 -- I will go to Walker 2 and then back to Walker 1. If one looks at paragraph 3.1(c):

"Finally, the CMA states that Phenytoin has been superseded. As explained in my first report, evidence indicates that Phenytoin sodium is at least as effective as other AEDs including newer AEDs at controlling seizures. It is my experience that Phenytoin sodium remains one of the most effective drugs at controlling seizures, and it is for this reason that it remains a first, second line treatment for the emergency management of acute seizures in status epilepticus."

So again it is a first line treatment dealing with emergencies. If one turns back to tab 9, Walker 1, paragraph 5.10 --

THE CHAIRMAN: Can we be clear, is Professor Walker talking about Phenytoin capsules here?

MR BREALEY: It is both. Emergency, we will see in a moment, can be both. So in emergency you get an injection, and then after that you will be prescribed Phenytoin orally and it can either be capsule or tablet.

So 5.10, again he makes the same point, and I will go to this and then we will see what Professor Walker said in cross-examination:

"In addition to being very effective, Phenytoin has the advantage that the dose can be rapidly increased to an effective dose. Other AEDs, such as Lamotrigine, need to be introduced slowly increasing the dosage often over a period of weeks or months. By contrast, a therapeutic dose of Phenytoin can be achieved in a day or so. For this reason, and also because to us highly effective at controlling seizures, it remains a first line treatment and one of the most frequently used drugs in the treatment of prolonged seizures status epilepticus which is a medical emergency. It is the injectable formulation of Phenytoin that is used in this situation. However, patients treated with this indication who were not previously taking Phenytoin will often continue with oral Phenytoin for a variable period, usually months, after the status."

So that the tribunal has the whole picture, Professor Walker was cross-examined on this. So if one goes back to the transcript bundle at Day 5, this is at page 52. Day 5, page 52. At the bottom, so it starts at line 21, Mr Hoskins says:

"In relation to emergency treatment, is that what you deal with in paragraph 5.10?"

And then he reads it out.

"Answer: Yes, it is.

"Question: That is the emergency you refer to."

Then you go on to refer to injectable formulation.

"Question: So clearly that does not involve the use of Phenytoin capsules.

"Answer: No, not for the emergency situation but it does thereafter. So people are given the injectable formulation and then will be given tablets or capsules afterwards."

MR LOMAS: I do not think it is said against you that Phenytoin is of no medical benefit. I think the difficulty is relating the medical benefit to the economic value for the purpose of applying the test.

MR BREALEY: I am going to come on to that.

MR LOMAS: Please.

MR BREALEY: Well, you say that, sir, and I take that on board, but I am having to deal with first of all in opening saying, well, we thought -- I am having to deal with a decision which basically said it was not efficacious and I need to show the tribunal how the CMA accepts that is no longer the case.

In the Day 3 opening there was a reference, well, it is a third line treatment, as if it is not such a good product. And again I need to deal with that before I get to the value. I will certainly come to the value. But I need to set the scene about how Phenytoin treats

epilepsy, how it compares to other AEDs, and then when I get to the value I will show the tribunal the comparison in the price between Phenytoin and the other AEDs. And that, in my submission, is a valid comparator as to economic value. How does one value a life-saving drug? It is difficult, I agree. But one of the ways you will value a life-saving drug is to see what the Department of Health pays for similar drugs that perform similar functions, treating the same patients, or similar patients.

THE CHAIRMAN: I am sure that is what my colleague is getting at, Mr Brealey.

MR BREALEY: I will come on to that. And I need to do it because I do not want Mr Hoskins in his closing to repeat the point that, oh, somehow Phenytoin is not a good product, it has less value or no value because it is a third line treatment.

THE CHAIRMAN: You will be able to reply.

MR BREALEY: I am trying to prevent him from saying it.

So on the third line treatment, first of all it is not true, and the second point is third line treatment is important. I will deal with this more quickly and then I will get to how it compares with other AEDs.

The third line treatment is important. If we can go to bundle M. I am going to come back to this. This is

Walker 3, it's tab 2. And I will come back to this because this relates to the third issue, the comparison with other AEDs. But for the present purposes, for this third line treatment is important, paragraph 2.4 is key:

"As mentioned in my first report ..."

And one can put in brackets "bundle D, tab 9, paragraph 4.6", that is where he says in his first report about the 40 per cent, that is at paragraph 4.6 of his first report.

"As mentioned in my first report, approximately 40 per cent of patients will not respond to or will only achieve partial seizure control on monotherapy. For those patients an adjunctive treatment is introduced and the results of the meta-analysis show that Phenytoin is likely to perform a better than several first line treatments in terms of seizure control."

So the point is that, okay, it is not recommended bar in emergencies for first line treatment, but a lot of people do not become seizure free and Phenytoin is used to treat these patients. We are not dealing with spot cream here, we are dealing with a neurological disorder, they are prone to seizures, and Phenytoin is very effective at controlling them.

I remind the tribunal of what the decision says, not when it is about old, but there are two passages in

the decision the tribunal should be aware of. Paragraph 1.4 of the decision, we do not have to go to it, where it is said that 48,000 people are on Phenytoin. So paragraph 1.4, 48,000 people are on Phenytoin. And the paragraph that I took Mr Harman to, but he could not really deal with it, paragraph 7.70 at page 449 where in the fines section the CMA say it is an essential AED medication and it is used in about 10 per cent of the epilepsy population. So about 10 per cent of people in the UK with epilepsy. That is paragraph 7.70.

So what I have tried to do is show that epilepsy is a serious medical condition and that Phenytoin, notwithstanding what the CMA say in the decision and in the defence, is highly effective at controlling seizures.

I now want to go to the third issue, and this is kind of building up to the ultimate submission that Mr Lomas wants me to make, which is how one is going to value this product. So how does Phenytoin compare with other AEDs? The first point, it is a minor point but not unimportant, if one goes to Walker 1 at bundle D, again tab 9, paragraph 4.3. So bundle D, tab 9, 4.3. At page 5:

"There have been a increasing number of AEDs

available but most of these work through similar mechanisms. Many work through targeting voltage sodium channels. It is also the main mechanism of action for Phenytoin."

So, again I do not want to get too techie here, but this is relevant to AEDs having a similar mode of action, again relevant to whether these can be comparators. And he refers to page 27 of the exhibit, that is at bundle E. Just quickly have a look at this and then we can put it away. This is bundle E, tab 3, page 27, how Phenytoin compares with other AEDs and what I am dealing here with is the mode of action.

This is what he says at 4.3 of his report, that they work in similar ways. And I just want to show the tribunal this because again I do not want to get too technical about it. But he says basically, if one looks at the bottom left-hand side, that sodium channels are the major target for a number of anti-epileptic drugs. And then you see the table. And then one sees Phenytoin with several of our friends that we have in front of me.

At 30, table 6.2, again epileptic drugs on calcium channels. So the first one is on how drugs act on sodium channels and then how they act on calcium channels. Again this is a comparison of AEDs and we see many of the drugs that I have referred to and will refer

to in a moment: Levetiracetam, Lamotrigine, Topiramate. These are the often prescribed AEDs at controlling seizures. They work in a similar way.

So we can put that away. But I think it is important again when one is coming to: are these products similar, are they a sufficient comparator, do they have similar modes of actions? I do not want to go over old ground. So Phenytoin we have seen is just as effective as other AEDs. I will just give the tribunal the note on Walker 2. Walker 2, it is paragraph 3.1, paragraph 3.2. But I think one should just have a look at Walker 3 which is bundle M, which hopefully you still have open, which is tab 2. Bundle M, tab 2, Walker 3.

Again none of this was challenged. So again, why am I doing this? I am doing this in order to show that these other AEDs are a comparator. Why is this relevant to that submission? It is because many of these products are being compared with Phenytoin. So they are being compared with Phenytoin with modes of action. Here they are being compared with Phenytoin for how it treats epilepsy.

So the key findings at paragraph 2.1. So Professor Walker summarises what we see in the whole report. Figure 8:

"Compare all the drugs considered in the study

against each other."

So there is a comparison between Phenytoin and other AEDs. And it is the footnote, you see the AEDs, and again we have Phenytoin, Oxcarbazepine, we have Lamotrigine, we have Topiramate, we have Levetiracetam. This is at footnote 1 of tab 2. So Phenytoin is being compared to these other AEDs.

"Figure 8 of the meta-analysis shows that Lamotrigine and Levetiracetam were significantly superior to all other drugs with respect to time to withdrawal in partial seizures. Phenytoin was, however, comparable to the other drugs, except ..."

And then:

"... including newer drugs such as Topiramateand Oxcarbazepine.

"Figure 9 shows Phenytoin performed in a way that was similar to the other nine drugs in respect to time to withdrawal in generalised seizures. In terms of time to first seizure, a measure of efficacy, Phenytoin was significantly superior to Lamotrigine and to Topiramate in generalised seizures. There was, however, a general trend for Phenytoin to be superior to all other drugs except Phenobarbital."

Then the conclusion at 2.3:

"However, this study clearly indicates that

Phenytoin is not only an efficacious drug but also more efficacious than several newer drugs such as Topiramate, Lamotrigine."

Again, this is teeing up for the submission as to the value of Phenytoin. Phenytoin is being compared with these other AEDs. So that is the third issue, how Phenytoin compares with other AEDs. Can I go to the fourth issue which is the beginnings of the intrinsic value attached to AEDs. So the fourth issue is the intrinsic value attached to AEDs.

For this I would like to go, please, to Mr Ridyard's first report, that is at bundle D, tab 7, and we will also have a look -- I think we can put all the bundles away except for bundle D and then the transcript bundle, Day 5. So having referred to epilepsy as a serious medical condition, Phenytoin being important at treating that, it is just as important if not more important often as other AEDs. We now start on the fourth issue to look at the intrinsic value attached to AEDs.

At bundle D, tab 7, paragraph 106, and you probably need at the same time the transcript bundle, page 192. So it is easier if one looks at the paragraph in Mr Ridyard's expert report, and the transcript where Mr Hoskins is asking Mr Ridyard certain questions, all going to this question of valuation. So Mr Ridyard at

106, page 36:

"I do not agree with the reasons provided by CMA for ascribing no incremental value to Phenytoin sodium over and above the cost plus 6 per cent ROS. Set against this, I consider there are good reasons why Phenytoin sodium's value is likely to exceed this level. First, I note that as indicated in the expert report of Professor Walker AEDs, of which Phenytoin sodium is one, are a class of drugs that treat a very serious medical condition and which have a significant social as well as medical impact on the individual. By treating that medical condition, AEDs have a potentially significant benefit both from the perspective of patients and from the perspective of society by reducing the costs. As a class of drugs, AEDs therefore have a significant intrinsic value to the people that use them that exceeds their costs of production."

So here is evidence from an economist saying in his view, a drug that treats a serious medical condition has an intrinsic value. And we will go on:

"Second, I understand from Professor Walker Phenytoin is extremely effective at controlling seizures. Studies indicate there is no advantage of regularly prescribed AEDs ..."

And then he goes on. So that is paragraph 107 to

108.

The cross-examination on this, as I say, starts at 192 and none of this is really challenged as we shall see. So 192, if one goes two-thirds of the way down, line 17, Mr Ridyard is taken to his paragraph 107, the intrinsic value:

"So this observation here applies to all AEDs, not just Phenytoin, does it?

"Answer: All AEDs that do the job, yes."

So there is a question: do all AEDs that treat this serious medical condition have an intrinsic value? And the answer is yes.

"Question: And you could apply this argument indeed to all medicines that treat serious medical conditions, could you not?

"Answer: Yes, and the value of them depends on what they do. There is a further question which is addressed in the NICE approach to looking at pharmaceutical pricing."

I will not go through that but the CMA basically skirts over that.

But so far the question is being put, well, is there a value to a drug that treats a serious medical condition? And the obvious answer is yes.

Then at 194, one sees again a similar line of

questioning: is it that a value is attached to a drug that treats a very serious medical condition?

We then can go to page 195 at line 19:

"Question: So you are focusing here purely on efficacy as a justification for charging a premium for Phenytoin, are you not?

"Answer: I am simply looking at -- well, I am relying on the Professor's expert knowledge ..."

And then over the page:

"Question: And the one point from his report that you are relying on for this argument is efficacy, is it not?

"Answer: That is one point ..."

Then there is an intervention. I know it is a bit bitty but it is important to see what actually is being put to Mr Ridyard on these paragraphs of his report.

So there was an intervention and then at the bottom of 196 --

MR HOSKINS: I think it is important to read the intervention if there is going to be a point about what questions were put, if you wouldn't mind.

MR BREALEY: Mr Hoskins can make that in closing. I do not know what the point is.

At the bottom, 196:

"Question: The position is, Mr Ridyard -- I do not

know whether you are aware of it -- it is in fact common ground between the parties that in spite of its efficacy Phenytoin sodium has been superseded by a number of new medicines ...

"Answer: It has not been superseded because of efficacy, which is the statement I picked up as being disagreed with by Professor Walker ..."

"The position is, Mr Ridyard, I do not know whether you are aware of it, it is in fact common ground between the parties in spite of its efficacy new medicines, it has not been superseded because of efficacy which is a statement I have picked up being disagreed with by Professor Walker."

So we go on.

Then we are coming more to the crux of it. At 198:

"Question: So is it fair to say that your view is the fact that patients stabilised on Pfizer's capsules should be maintained on Pfizer's capsules is a reason that justifies Pfizer charging a premium?"

And then we get a fairly long answer but it is an important answer:

"... it would certainly be a reason that you would expect them to be able to charge -- be able to charge a premium commercially, which is exactly why in my report I said I think it is very important to benchmark

the pricing that we are talking about here against the pricing of other AEDs, which do not benefit from this -- from this kind of protection because if you had found that the prices of Phenytoin sodium were well above the price of other AEDs which were not in category 1, for example, more obviously faced direct competition, interbrand competition, then that would be a problem but what I do observe when I make that comparison is that -- that is why I do all of this AED price comparison, I find that the prices we are talking about for the Phenytoin sodium capsules are not clearly out of line with the prices which have been charged for other AEDs which do not benefit from this element of protection from competition. So that is precisely why I think that is a useful exercise to do.

"I am certainly not saying that just because consumers are dependent on a product, therefore a supplier should be allowed to charge whatever they like. I explicitly deal with that -- twice actually because it was ignored the first time -- in my two reports. I am not saying that. I am saying that is a good reason to benchmark the pricing of Phenytoin sodium capsules against the prices of AEDs which do not benefit from this feature which could otherwise taint the comparison because it would simply be reflecting the

power that the supplier has over the consumer."

Then there is further questioning, and I will speed up a bit, but I would ask the tribunal to look at this passage. The answer at 200, line 20:

"I am saying that the -- a medicine which treats a set of patients, which couldn't be easily treated by a different medicine is intrinsically valuable. That happens to be the situation with these stabilised patients on Phenytoin sodium capsules, it works for them and there is some sort of risk that it might not work if they were switched to something else. It may be fine but there may be a risk. Therefore that just explains why it is not surprising that there is a value -- there is an intrinsic value to this product."

Then Mr Lomas asks the question about the price elasticity.

THE CHAIRMAN: So he switched from benchmarking to intrinsic value.

MR BREALEY: Yes. And basically there is an intrinsic value, and then how are you going to value it? And what Mr Ridyard is saying is, well, have a look at the prices of other AEDs. We will come on to that maybe after coffee --

MR LOMAS: Could you just clarify: do we have evidence which says which ones of those other AEDs that are being used

as comparators are subject to continuity of supply constraints?

MR BREALEY: Yes. None of them.

MR LOMAS: None of them, okay.

MR BREALEY: And that is why Mr Ridyard regards them as a good comparator. Because if we were having comparison with other products, we would be met with the same problem.

MR LOMAS: That is why I asked the question.

MR BREALEY: There are two points. The first is -- and this is what Mr Ridyard says in his first and second reports. He has chosen non-category 1 products. But also after the coffee break, when one looks at generics, the generics, three of them are in Scheme M, a fourth generic is subject to competition. And therefore as we know from Scheme M, and category M, the prices are supposed to be reflective of competition on the market. There are several manufacturers, generic manufacturers, and therefore when one looks at the generic prices they are supposed to be reflective of the market price. And so when you are comparing the price of Phenytoin to the generics, you are comparing the price of Phenytoin with a competitive price.

THE CHAIRMAN: So these AEDs are good comparators because they are subject to generally competitive conditions and

treat the same illness.

MR BREALEY: Yes.

THE CHAIRMAN: So they are comparable in that sense. And you are going to tell us that Phenytoin tablets are a good comparator because they are the same product.

MR BREALEY: In the words of Professor Walker, they are identical.

THE CHAIRMAN: The considerations are different for those --

MR BREALEY: Yes.

THE CHAIRMAN: -- potential sets of comparators.

MR BREALEY: They are exactly the same molecule, the same patient.

MR LOMAS: Subject to continuity of supply.

MR BREALEY: Bar the continuity of ... yes.

Maybe we -- I do not know whether it's --

THE CHAIRMAN: There's never a good time and always a good time.

MR BREALEY: I have just prepared -- I will get them stapled actually --

THE CHAIRMAN: Are you on to the price of AEDs now?

MR BREALEY: I am going to look at the price. I can finish the fourth --

THE CHAIRMAN: If you finish AEDs and then we can have a break and then think about tablets. Is that not possible?

MR BREALEY: What I could do, if I could just finish the fourth proposition, and then I will get to the fifth, which is the price of AEDs, and then I will get to the tablet, or in my notes it says the "table", and then I will go on to the law.

Just picking up from what this cross-examination does, with the greatest respect to Mr Hoskins, I am not sure what the purpose of the cross-examination was because one does not need to be an eminent economist to state what most sensible people would say which is that medicines that treat very serious medical conditions may be more valuable to the patients than to society.

Also very little of the evidence, if at all, was challenged as regards the relevance of a price comparison. The only thing I can think of that the CMA is trying to tee up is its totally and utterly bizarre zero value case which I can finish before coffee by going to the closing. So if I go to our closing at paragraph 129.

Mr Ridyard was saying that if there is a continuity of supply, maybe there should be a premium. The CMA for some inexplicable reason say that it should be zero. At 129 we have set out an exchange between Mr Hoskins and Mr Lomas.

THE CHAIRMAN: I think it was me, actually.

MR BREALEY: Both. Yes, sorry, it was the chairman. The tribunal will be well aware of this, but it is an absolutely astonishing proposition that you can have a pharmaceutical drug which treats a serious medical condition which can have a value and then when it becomes so effective its value collapses. That just does not make any economic or common sense. So it may well be that that cross-examination was going to that point. But we would say that that approach, and the CMA do not shy away from it because they repeat it in paragraphs 322 and 324 of its closing. They still pursue this line at 322 and 324 of its closing that Phenytoin should be given no value whatsoever because it is such an important drug.

We say that that exchange between the chairman and Mr Lomas, that the CMA on this point has lost all objectivity. I will then after the coffee break go to the fifth issue and then to the tablet and then to the law.

THE CHAIRMAN: We will break for ten minutes.

(11.35 am)

(A short break)

(11.45 am)

THE CHAIRMAN: Mr Brealey, I know you have your scheme of the day. At some stage during it we would quite like it

if you would address those areas of the law on unfair pricing where there is still disagreement between you and the CMA. There are a couple of areas which I am sure you will have identified.

MR BREALEY: Yes, I will do that in about 15 minutes.

THE CHAIRMAN: It is up to you when you do it but we would not like you to rise for the day without having done so.

MR BREALEY: So the fourth point, I was looking at intrinsic value. As you picked up, sir, we were transgressing into essentially the fifth issue which is the price comparison. That was essentially what Mr Ridyard was saying on Day 5, page 198, which is it is relevant to benchmark Phenytoin against other AEDs. That is, as I say, Day 5, 198. I cannot see that was challenged, the relevance of looking at comparators was not challenged.

What I have done, and you should have it in front of you. This can go behind our closing submissions. It is a bit of a crib sheet. (Handed) Some of this is --

MR HOSKINS: Can we have one?

MR BREALEY: Yes, sorry. (Handed)

This is the cross-examination, just to assist the tribunal, on Phenytoin compared with other AEDs, comparison with the Phenytoin tablet which we are going to come on to in a moment. Page 3, the

cross-examination of Mr Ridyard on value. And then the last page is to pick up the point Mr Lomas was essentially putting to me which I regard as highly relevant.

I have tried to establish so far that epilepsy is a serious medical condition, that Phenytoin is an important AED in treating that, and that there are other AEDs which are comparable to Phenytoin. They control seizures, et cetera, et cetera. And what I have done on this table here at the back, this is the table showing a pricing comparison of other important AEDs, I will not go through this in great detail, but this is clearly something I was starting to do in opening.

If one looks at the cost, six month 2012, the Pfizer Phenytoin capsule, that is £268. £268. We will come on to the tablet in a minute, that is £588. If you adopt the ROS 6 per cent, all that Pfizer can do is charge £31. You compare that to Topamirate, the generic. The generic is not in category 1, it is in Scheme M, therefore this is supposed to be a competitive price. Topamirate generic is 291.

The branded Topamirate, Topamax, is 667. And one will have picked up from Mr Harman's evidence that there is a brand attached to the Epanutin. But we continue with the generic, so Levetiracetam, the generic, 232.

The branded, the Keppra, which is down here, 471. The Oxcarbazepine, 296. Actually the branded, Trileptal, is slightly cheaper at 249. The Ethosuximide is 625.

As I understand from the expert evidence of Mr Ridyard when he deals with these in his report, this is a price that was agreed between the supplier and the Department of Health. So Ethosuximide is a price, as I understand it, that was agreed by the Department of Health and the suppliers. Then you get Lamotrigine generic 77, the branded 710.

All these AEDs I have referred to this morning, they have been used as comparators in modes of action, they have been used as comparators when it comes to efficacy, they control seizures. And it is astonishing that Pfizer should be limited to £31 in the light of Professor Walker's evidence. And all the other AEDs, we are not even talking about the tablets here, I am going to come on to the tablets in a moment, but these very popular AEDs that are dispensed and prescribed in very large quantities have prices which are the same if not more than Pfizer Phenytoin capsules.

PROFESSOR WATERSON: Can I just ask about the date.

MR BREALEY: Yes, it's the six month 2012.

PROFESSOR WATERSON: About the choice of the date.

MR BREALEY: The choice of the date is when it was launched

basically. Mr Ridyard gives I think other prices but I chose this date because this was when they fixed on the price, when essentially Pfizer benchmarked the capsule by reference to the tablet, but these prices were in the market at that time.

MR LOMAS: I do not think it takes the force away from your point, but just for clarity, is this really apples and kumquats as I think we now have to make the comparison? These are at different levels in the supply chain, aren't they, though, because you are quoting a Pfizer price as what is essentially the transfer price and then comparing it with the price to wholesalers of the others.

MR BREALEY: I am.

MR LOMAS: So we need to be alert to that distinction.

MR BREALEY: I am alert. And in opening I did mention the Flynn price, that is on the record. But since -- and maybe I should have put the Flynn price here but it is in Ridyard and I mentioned it in I think 588 in opening. But there are two separate abuses here, and Pfizer is the manufacturer of the product, so in my submission, I do take the point, but if you are going to have a certain mark-up, whatever mark-up you say that Flynn could have, again in my respectful submission the Pfizer price is still not an outlier.

THE CHAIRMAN: It could be twice as high and your point would still be valid, you would say.

MR BREALEY: Yes. They put 10 per cent, 20 per cent, 30 per cent, whatever. So when one looks at the Pfizer price, and when one looks at Advocate General Wahl, the price has to be disproportionate. I understand, as I said in opening, there was a price increase, but when you look at the prices on the market, and these are not category 1, bar the tablet, several them are category M, Scheme M, they are supposed to reflect competitive pricing, bar the one I mentioned, Ethosuximide, which was a price agreed between the Department of Health and the manufacturer/supplier.

THE CHAIRMAN: Since you mention category 1, could we just take you to footnote 213 of your written closing on page 80.

MR BREALEY: 213?

THE CHAIRMAN: Yes, which is in the section where you are dealing with the before and after argument and the PPRS. I accept it is in a slightly different context but there is this almost throwaway footnote and we just want to understand clearly what you are saying. It says:

"... the prices of other category 1 AEDs ..."

Category 1 AEDs.

"... in Scheme M are a far more reliable benchmark."

I think you have been emphasising that these are not category 1 products. Or have we just misunderstood what you are saying?

MR BREALEY: I think it is a typo. It should say 3 I am told:

"Despite the difference between products ..."

Yes, it should say "category 3".

THE CHAIRMAN: It is a misprint. Well, it shows we are here for some purpose at least, Mr Brealey.

MR BREALEY: So that is the impression I would like to give the tribunal. I know it has been a slow process but that is where I get to economic value. If these AEDs are comparators, they are similar modes of action, they are compared frequently as to whether they are efficacious, they control seizures, is the Pfizer price so disproportionate as to be an outlier? There can only be one answer to that and that is no if the AEDs are a comparator.

Can I then go to the tablet. I will do this more quickly. We have obviously majored on the tablet, we regard the tablet as an extremely important comparator. It is a category 1 but we have the situation, as we will come on to in a moment, where we say the price was imposed by the DH. So that is what makes the tablet such a good comparator in the sense of it is the same

molecule, it is in category 1, and yet the DH, we say, put a value on Phenytoin.

If I go to the tablet, because I do want to tackle the law, as you rightly say, sir. Can I pick this up in the closing at page 30. I know the tribunal has read this because you have just mentioned the footnote --

THE CHAIRMAN: We have read this all right.

MR BREALEY: But I want to emphasise the points. The tablet has the best benchmark. The first point to note is that as a matter of expert evidence, which is unchallenged, the tablet and capsules are identical. They are two bioequivalent medicines, same active ingredient, supply the same patient groups, same medical condition.

We have Professor Walker's evidence on this. He was not challenged. This is paragraph 76. In the sheet that I have handed up there is also a reference I would ask the tribunal to note which is Walker 2, bundle D, tab 10, paragraph 2.12:

"There is no clinical or medical difference between the capsule and the tablet."

As we see in Walker 1, he says:

"They are identical drugs."

They are identical drugs. So that is the quote on the top of page 31, "They are identical drugs". This is, as I say, unchallenged expert evidence and we are

trying to work out whether the tablet is a comparator. If it is relevant to look at comparators one could not conceive, in my submission, of a better comparator than the tablet.

The second point, it is the same purchaser, the DH. So that is the second point. Advocate General Wahl said it is important to look whether the product is similar and whether the economic context is similar. Well, yes is the case with the Department of Health paying prices for these AEDs, in particular the tablet.

The third point, which is a critical point, and the tribunal will be obviously on to this, we say that in the light of Mr Beighton's evidence, with the greatest respect, the tribunal can only conclude that the price was imposed.

The Department of Health has not challenged the evidence of Professor Walker, but nor has the CMA or the Department come to challenge the evidence of Mr Beighton. It is silent. There is something quite wrong here. Obviously the tribunal can read paragraph 79. But I think this must be put in: the timeline of the tablet is not unimportant. If I could just digress on the timeline. So if we can go to J1 -- we need J1 and J2. This issue relates to what did the Department of Health do about the tablet, the Beighton

evidence.

J1 is at tab 31. Again this is really for the tribunal's note but it is not unimportant. Tab 31, J1 is a statement of objections. J1, 31, this is dated 15 September 2015. This is the statement of objections. It's a lengthy document, you do not get any discussion of the tablet until page 316 where you get five paragraphs. With the greatest respect, all of the paragraphs are meaningless in the sense of rejecting the tablet as comparator. But the tablet is essentially at the tail-end of the statement of objections.

What then happened was that there was the response and the oral hearing, and Pfizer started to say, well, the tablet is right at the back of the statement of objections. The tablet is actually a very important benchmark. That is how the parties perceived it at the time. They benchmarked the capsule against the tablet. And, by the way, the Department of Health intervened in the price of the tablet.

So one sees that, again for the note, at tab 32, page 36, paragraph 125. In response to the SO, it was at paragraph 125. Pfizer said, look, you cannot just ignore the tablet because the DH negotiated it down.

What then happened in this timeline was that one will see from, we do not need to go to it, but bundle A,

the Section 26 notices, the CMA issued further Section 26 notices to the pharmacies about the tablets but also met with the Department of Health, and that is at J2, 64, which is this famous note of the meeting. So J2, 64. This is the note of the meeting, I referred to it in opening, because paragraph 3479 of the decision gave a wholly misleading description of what was said at the meeting. So in opening I referred to this meeting of 23 February 2016 and I took the tribunal to paragraph 31. This is where the CMA sought the Department of Health's views on the price of the Phenytoin sodium tablets. And if one remembers from the opening, I had a submission to make about the inaccurate description of paragraph 31 in the decision. As I say, it was paragraph 3479.

But if one flicks to the front of the note, the purpose of the meeting was the Secretary of State's powers to intervene in view of the pricing of Phenytoin tablets. Paragraph 2.1 sees that the state of the meeting was that it was proposed and agreed it was possible that the CMA may request that the DH provide a witness statement further to discussions.

So the possibility in 2016 of there being a witness statement relating to this meeting was on the table and nothing has happened. The CMA and the Department of

Health have been on notice of this for some years now, and still today neither the CMA nor the Department of Health have engaged with what was said at the meeting.

This goes back to the third point as to why the tablet is the best benchmark. We say the evidence is all one way, that the Department of Health specifically intervened to fix the price of the Phenytoin sodium tablet.

Then the last point is at paragraph 84, page 34 of our closing. It is a reliable comparator because Professor Ridyard says it is not actually in direct competition with the capsule. So that is the fourth point.

I am skirting over the tablet but I do not want the tribunal to think we do not regard the tablet as important. We regard it as an extremely specific fact in this case. Whether the CMA bring other cases on excessive pricing, that does not relate to whether the Department of Health intervened in this case to fix the price of Phenytoin tablets which we say is the most logical comparator.

PROFESSOR WATERSON: Mr Brealey, could you just remind me which element of the United Brands are we in at the moment in looking at this comparison?

MR BREALEY: I will come on to that now.

MR LOMAS: Before you do, can I clarify a couple of points. You said earlier that the tablets represent the same product, and we heard your submissions on that. Then you said that as a Advocate General Wahl said, you not only look at the product, you look at the market conditions, and you went on to the DoH side for reasons I understand.

Can we step back for a second. I asked you I think when you were opening how many other manufacturers there were of tablets, as I recall, and I had the answer there were two or three.

MR BREALEY: Yes.

MR LOMAS: I think the evidence from Mr Beighton as I understand it, perhaps Mr Poulton, was when the new capsules were launched by Flynn, as I understood it there were no other competitors. Has the competitive position for the tablets changed across time, do we know?

MR BREALEY: Yes. As I understand it, when they launched I think there was only one -- in the decision they refer to several tablet manufacturers. I would have to check whether in 2012 there was only Teva, I will find out. Certainly after launch there was I think -- I will also dig that out, I think it is in G1 -- there was another tablet manufacture that came on board.

MR LOMAS: But as continuity of supply applies to tablets, presumably you would have the same debate in the tablet market that you would have in the capsule market as to whether that defines separate markets effectively because people are stabilised on it.

MR BREALEY: Correct. That is one reason why we say this principle of continuity of supply is just not as rigid as the CMA would have the tribunal believe. Because if it was as rigid as they say, you would never get any new market entry.

THE CHAIRMAN: Does that mean that the five paragraphs in the statement of objections that you mentioned, which effectively say that tablets cannot be compared because they also are subject to continuity of supply, therefore they have characteristics where their price is not related properly to their cost, is that covered in your fourth point?

MR BREALEY: Yes, what Mr Ridyard --

THE CHAIRMAN: You say that is a good thing?

MR BREALEY: Yes, he says it is a good thing, because actually you are -- particularly when the Department of Health has valued the tablet.

THE CHAIRMAN: So provided that the Department of Health has valued the tablets, then the slightly rigid, if you like, prescribing and dispensing features that attach to

the product make it a good comparator rather than a bad comparator. It's slightly counterintuitive.

MR BREALEY: Yes. But then we also get into this murky area which is how rigid is this continuity of supply?

THE CHAIRMAN: Yes, understood. But I was just referring to the statement of objections which says that because of continuity of supply, therefore price does not relate to cost, therefore you cannot use it as a comparator. And you say that is not correct.

MR BREALEY: It is a red herring because of the DH. I do not believe -- in the statement of objections, whether they knew or not it is certainly not apparent, but that is why they -- I think it may have come as a surprise to the CMA that the Department of Health had intervened in this way. That is why in February 2016 they had another meeting with the Department of Health and then it was this, with great respect, rather wishy-washy, well, we doubt whether there would have been this, it is likely this, likely that.

There has never actually been any getting under the skin of this issue. It has been left to Flynn to a certain extent to adduce Mr Beighton as a witness and again the Department of Health simply has not engaged on it.

So it is a specific fact to this case that there is

a benchmark out there where, on the evidence, the Department of Health not only intervened but said what the price should be. And that is why I asked Mr Beighton the question, I gave him the opportunity to say no, whatever. Because he had said £40 was tabled. I said: let us be clear -- if one looks at the evidence from him and the questions, I asked him: let us be clear, and he could not have been clearer.

THE CHAIRMAN: Is it right that you are putting this in terms of the burden of proof on the CMA?

MR BREALEY: We will come on to the law right now. The burden on the CMA is to show that the price is excessive and our overriding submission on that, whether it is limb one, limb two, Advocate General Wahl, classic United Brands, if there is valid comparators out there the CMA should look at them. And it is "inappropriate" to use the court's words, "insufficient" to use the Advocate General's words, for them to ignore it.

Question 2 in the copyright case, Latvian Copyright case, asked: is it sufficient, is it appropriate for the Competition Authority to just do this, do that? So although there is a margin of appreciation to a certain extent, it has to do a thorough job. And shutting its eyes to -- just saying, well, these are the margins, and then shutting one's eyes to all these AEDs and

comparators out there which have similar prices, which the Department of Health seems to be paying, is a flawed approach.

THE CHAIRMAN: Are you saying the CMA should have done this anyway of its own accord?

MR BREALEY: Absolutely.

THE CHAIRMAN: Or just because you have raised sufficient reasons as to why these comparators should be examined?

MR BREALEY: Both. The first is the burden of proof is on the CMA to prove an excessive pricing. If it only does half a job, and it ignores relevant considerations, it has not discharged its legal burden. In answer further to the question I would say that if it is unaware of comparators, and we discharge an evidential burden that comparators are out there, the evidential burden shifts back to the CMA and it bears the legal burden of showing the comparators are not good enough.

So the ultimate, as Lord Denning called it, or the legal burden is always on the CMA. It has to do a thorough job, it has to rigorously examine the allegation of excessive pricing. And that is all factors, not just margins, it is demand side, and demand side carries with it comparators and it has not done it. If the defendant does raise the issue of comparators then the CMA should look at it and either reject it or

accept it. But what it cannot do is say it is irrelevant.

THE CHAIRMAN: To be fair, I think what they said was they had looked but they did not find any that were suitable.

MR BREALEY: That is their kind of back up case. They said --

THE CHAIRMAN: It is in the decision.

MR BREALEY: It is. But their primary case, and be under no misunderstanding, their primary case is that we lose simply because of cost plus. They do go on to look at the comparators --

MR LOMAS: And unfairness in itself.

MR BREALEY: And unfairness in itself. But they say they can stop there. That is their legal approach and the approach in the decision.

THE CHAIRMAN: And this is an interpretation of the legal test which is why we asked you all to address it.

MR BREALEY: Yes.

MR LOMAS: Before you go on to the legal test, can I test one relatively simplistic point about how you use those comparators. If we take a hypothetical example of a comparator that is priced at 100, and the all up cost including a cost of capital of producing that comparator is, say, 80, so the return on sales of 20. Assume that is a good comparator for Phenytoin but in a different

market. Suppose the cost, to make the example extreme, of producing Phenytoin all up including cost of capital is, say, 10. Are you saying that the use of that comparator is that somebody should be able to price Phenytoin at 100?

MR BREALEY: Yes.

MR LOMAS: Your proposition is as simple as that.

MR BREALEY: Yes.

MR LOMAS: So you would put the economic value as 100 and say that the supplier of Phenytoin could pay up to 100 even though it is making a profit of 90 rather than a profit of 20.

MR BREALEY: Yes. Let us take that one stage further and let us assume there are nine players in the market selling at 100 with costs of 80, an ROS of 20. I come along in the market and I am so efficient that I do not do 80, I do 10. Why should I be penalised for being efficient?

MR LOMAS: I understand the point. I was just trying to understand what your submission was on the comparators.

MR BREALEY: Mr O'Donoghue says the cost of the tablets and capsules are the same. But taking the point, yes, that is what the market is bearing, that is what the purchaser is willingly paying.

THE CHAIRMAN: Does that apply even if you hold a dominant

position for your super-efficient product?

MR BREALEY: Yes, because the test of excessive pricing we say is that the price must be an outlier. And if comparators are relevant -- so if you are in a dominant position and you are more efficient -- well, I am not sure you can be -- in my example you have nine, you would not be dominant.

MR LOMAS: I think that is the point. That is why I said in separate markets.

MR BREALEY: Yes. Ultimately the price has to be disproportionate.

MR LOMAS: Again just taking it a bit further, one reason why I did not reference the tablets but other AEDs is we do not know what the cost structure is for those other AEDs.

MR BREALEY: No, we do not. We do not have actual data. Mr Ridyard --

MR LOMAS: You have some indicative --

MR BREALEY: Indicative, yes.

THE CHAIRMAN: It's another way of saying you do not accept cost plus as the be all and end all of assessing prices for dominant companies.

MR BREALEY: That is not how the world works.

THE CHAIRMAN: I am just trying to be clear what you are saying. I can probably work out how the world works.

MR BREALEY: So if I could go to the law. We can put bundle D away. You will probably need our closing and bundle C3, the authorities bundle C3 and the authorities bundle B1.

What I would like to do in the next -- I might have to go over just after lunch, I would like to make four propositions on economic value and comparators. I will define them and then I want to just show the tribunal the authority which I say supports the four propositions.

First proposition: there are several methods for determining whether a price is excessive or unfair and this includes comparators. So there are several methods for determining whether a price is excessive or unfair and this includes comparators.

The second proposition: the comparator product must be of a nature that a meaningful price comparison can be made. So second proposition, a meaningful price comparison can be made.

The third proposition is comparators are concerned with supply side and demand side considerations.

And the fourth proposition, which is probably the more contentious of the four, is that if valid comparators exist, the Authority should not ignore them as irrelevant. If valid comparators exist, the

Authority should not ignore them as irrelevant.

So if I just -- I will go to these comparators. So the first one is there are several methods for determining whether a price is excessive or unfair. At the moment I am not going to get hung up on whether this is limb one, limb two, we will probably come on to this. I want to just emphasise that whether you put comparators in limb two or excessive in limb one, there are several methods for determining whether a price is excessive or unfair. We can go to the questions a bit later on.

So if we just go to our closing to see where we say this. Clearly, just to flag it, Advocate General Wahl and the court appear to put the several methods in what has been called limb one, the excessive limb.

So go to our closing, paragraphs 41/42. 41, we say the CMA was wrong to suggest in opening that the court did not follow the Advocate General, and we set out various -- I will come on to the paragraphs in a minute.

Then at 46 we say:

"It is clear that a price cost analysis under limb one is neither necessary nor sufficient for the purposes of determining whether price is excessive. This conclusion is fortified by the opinion in the Latvian Copyright case. A variety of methods should be

deployed when determining an excessive price under limb one."

So the emphasis is on limb one but I do not believe that the unfairness can be excluded either.

Where do we get the support for those submissions? If one goes to Advocate General Wahl, so we will be looking at this in some detail, that is C3, tab 39A. I know the tribunal will have poured over this but I am going to give the paragraph numbers.

So this is where the Advocate General is saying there are several methods for determining whether the price is excessive. As the tribunal notes, the starting point is paragraphs 16 to 24 because the Advocate General at 17 says that the first step is to determine whether there is an excess. 18, the court has acknowledged there may be different methods of determining whether the price is excessive.

So clearly the Advocate General is looking at what Mr Hoskins would call limb one, but certainly, whether you call it limb one or not, whether the price is excessive and there are different methods.

One could also go to paragraphs 32 and 33. 32, just as an aside, but paragraph 32, note what the Latvian court is asking the CJEU: was it appropriate and sufficient to do the following exercise? We see that is

the thrust of question 2. Yes, the Authority has a margin -- has room for manoeuvre. Was it sufficient or appropriate for it to have done that exercise? We would say there is a similar question to be asked in this case: was it appropriate and sufficient to look at cost plus in itself and ignore comparators? But that is an aside, we will come on to that. That is paragraph 32.

Paragraph 33, again reference to methods relating to whether an excess exists.

So that is clearly what the Advocate General is doing. We will go to the court in a moment. Just if we go back to the transcript, Day 3, because we are still not quite sure what the CMA's position is as regards -- we know that there seems to be a submission that the court did not follow the Advocate General. If we keep C3 open, but if we go to Day 3, page 93, this is Mr Hoskins' submission. Halfway down 11, Mr Hoskins:

"Okay, I am going to start with the Advocate General. Of course neither Pfizer nor Flynn took you to the court ..."

I did actually refer to a paragraph but anyway.

"... I will take you to the court but let us go to the Advocate General first.

"First of all, paragraphs 15 to 22 ..."

What we have just been looking at:

"... if I may respectfully say, with the Advocate General opinion, is that he takes United Brands as being a two limb ... in particular the copyright cases ... he puts them into the United Brands excessive ... That is the problem."

And then over the page:

"That is why we are having all this debate ... Advocate General ... he is trying to bring it all together and put it under one rubric, but the court does not follow him. So what you have ... in particular ... paragraph 17 ..."

So there is a submission there that the court is in some way not following the Advocate General. Whether this carries through into the closing we will find out. It may well be that comparators are still in limb two or limb one. We will get some clarification. We can put that away. But there is a kind of a submission that the court is not following the Advocate General.

If we go to the court, which is obviously at tab B, and to the -- which are probably the most important paragraphs, we know, paragraphs 35 to 37. So we can put the transcript bundle away and we just need bundle C3.

There is some confusion, there is no doubt about it, and it's still ... 35, 36 and 37, this is to a certain

extent trying to meet a point that the court has not followed the Advocate General. 35, the abuse of dominant position might lie in the imposition of a price which is excessive in relation to the economic value of the service provided. So this is paragraph 35. Paragraph 28, which I do not believe is in the bundle, but that is what the court said in that case.

Then we get to 36 which we know. Then 37 which is important because it refers back to point 36 of the Advocate General:

"Nonetheless, as observed in essence by the Advocate General in point 36 of his opinion ..."

And we know what that is: no single method, et cetera et cetera:

"... also recognised ..."

This is referring to United Brands:

"... there are other methods by which it can be determined whether a price may be excessive."

So at least the court there is saying, well, as the Advocate General said, there are other methods by which it can be determined whether a price may be excessive. That is not just cost plus, that is comparators and all sorts of things.

It is not clear-cut because, as again the tribunal will know, the court there is referring to paragraph 253

of United Brands, and when you go back to 253 of United Brands the court does not refer to the word "excessive", the court refers to the word "unfair". But nevertheless you do have the CJEU agreeing with the Advocate General, paragraph 36. We saw this time and time again in opening. 36 of the Advocate General:

"It can be safely stated that in the current stage of legal thinking there is no single method, test or set of criteria which is generally accepted in economic writing or across jurisdictions for that purpose if authorities as well as lawyers, economists suggested a number of methods of analysis as well as a variety of criteria, tests or screens to that end, however in point of fact each of those methods reveals some inherent weaknesses."

I will come back to this when we come to the fourth proposition.

MR LOMAS: You say paragraph 36 is a limb one paragraph, do you, which would be consistent with this introduction?

MR BREALEY: Absolutely. It is all limb one, yes.

35:

"As I have explained in points 18 and 19 above ..."

And 18 and 19 are all about his first step which you see from paragraph 17.

So again what do we draw from this? There is

an issue, or a proposition as we say in our closing, that limb one is not just about cost plus, there are several methods open to the Authority to determine whether a price is excessive. And really at the end of the day that should not be a major issue because -- and we will come on to it, but to determine whether something is excessive should not just be about a supply side consideration, it is common sense. To determine whether something is excessive really you should be looking at all the circumstances.

But that is the first proposition. There are several methods for determining whether a price is excessive or unfair and this includes comparators. So the thrust of the Latvian Copyright case is on excessive. Even if you call it unfair, there are undoubtedly several methods and I do not actually believe the CMA to disagree with that too much. They say they are entitled to adopt the one, but they recognise that there are others.

THE CHAIRMAN: I think they rely on the margin of manoeuvre in paragraph 35.

MR BREALEY: They do. And then I reply in reply to that -- that is why I took you to paragraph 32, which is although you have the margin of manoeuvre is what they have done appropriate and sufficient? Because the

Advocate General, at 138, said they have to undertake a rigorous analysis. That is what he says. They have to undertake a rigorous analysis. If you are going to fine someone £84 million for excessive pricing, and you just do it on cost plus basis and in itself and ignore what the market is bearing, the purchaser is paying for the same or other similar drugs -- we will come on to it, but you are going to end up with type 1 errors all the time.

So that is the first proposition, several methods.

The second proposition is that the comparator product must be of a nature that a meaningful price comparison can be made. We do not have to turn to it but we make that point at paragraph 65 of our closing. And at paragraph 51(b) as you will have seen of our closing we give some examples of comparators.

But where does the tribunal get a sense of what is a meaningful comparator? Again, I will just refer to the paragraphs in the opinion and the judgment. Paragraph 32 of the Advocate General, is it appropriate and sufficient? 61 is where we really get into it, paragraph 61. This is something that the court does adopt. 61:

"... should first select the member states of reference according to objective, appropriate and

verifiable criteria."

So the comparator should be objective, appropriate and verifiable.

62, we see reference to "relatively similar", so there is a test of relatively similar.

The court, if we go to paragraph 39, again I am trying just to -- when the tribunal comes to decide if the comparators are relevant, are they valid comparators, at 39, the very last couple of words:

"... is it sufficiently representative ..."

That is repeated in 40:

"... a comparison cannot be considered to be insufficiently representative because it takes a limited number of member states into account."

So the court is looking at whether it is sufficiently representative to be a meaningful comparison.

And then 41 again refers back to the Advocate General, point 61:

"Such a comparison may prove relevant on condition, as observed by the AG in point 61, that the referenced member states are selected in accordance with objective, appropriate and verifiable criteria. Therefore there can be no minimum number of markets to compare and the choice of appropriate analogue markets depends on the

circumstances specific to each case."

I thought it was going to be -- it's translated into "analogous", but there is the word "analogue". An analogue market, it just means is it sufficiently similar. So the choice of an analogue market depends on the circumstances of the case.

Again are the other AEDs that I have referred to down here, the tablet, is it sufficiently similar to the Phenytoin sodium capsule to be a meaningful comparator?

So that is the second proposition.

The third proposition, as I say, comparators are concerned, not only with supply side, but with demand side. Again, that is a common sense -- and we will come on to the case, but it is such an obvious proposition. If one is looking at demand side, what you willing to pay, it does not take very much more to say, if you are willing to pay for that X product, which is the same, X and Y, then those are comparators on the demand side.

But can I go to paragraphs 30 and 31 of our closing where we make this point. This essentially replies to one of the questions put by the tribunal. This is paragraphs 30 and 31 of our closing. United Brands is the correct starting point in unfair pricing cases. 31:

"United Brands established the legal test for an abusively high price is a price that bears no

reasonable relation to economic value. Economic value is the overarching test. The Commission calls it the decisive test."

That is in Scandlines, paragraph 102. So that is the test. What is the economic value of this product and does the price bear any relation to this economic value?

I would like to go back to the Victor Chandler case, just so the tribunal has it in mind. I know it will. That is at B1, tab 2. Because Mr Justice Laddie, a very experienced Chancery judge, makes the obvious proposition that value is not only about cost, value is about perception; how consumers value it, consumers who use it, consumers who pay for it. If it is anything, the English courts have emphasised that the economic value cannot be determined simply by supply side consideration.

I took obviously Mr Harman to this. This is paragraphs 47, 48, and 49. Clearly, as we saw quite briefly with Mr Harman, the starting point is the first couple of lines of paragraph 47 and then Mr Justice Laddie at 48:

"It appears that this approach is based on a number of doubtful propositions ..."

And he just makes the obvious point that there are

sellers' markets and buyers' markets. So B1, tab 2, paragraphs 47, 48, and 49. I will not go over it but I would ask the tribunal to bear what he says in mind. And it was endorsed by the Court of Appeal in Attheraces, and we saw this, if one goes to tab 4. If we just start at paragraph 186, this is under the heading "Economic Value". This is, as I said in opening, where Mr Roth is criticising the judgment. So this is about economic value. At 195 the passage I took Mr Harman to, but this is the passage where the Court of Appeal is specifically referring to Mr Roth's submissions and what Mr Justice Laddie has said; there are buyers' markets and sellers' markets, you just cannot ignore the buyer in this analysis.

I will ask the tribunal to note again paragraph 198, where the criticism is failing to have regard to a range of comparators. Then paragraph 203 over the page, you have the Court of Appeal, having set out -- the Court of Appeal has not set out the arguments for no reason. They have set out these arguments and then they say:

"We are in broad agreement with Mr Roth's submissions criticising the judge's approach."

So the tribunal can get some comfort from having set out what the criticisms are, when the Court of Appeal

says we are in broad agreement with them, the tribunal gets some comfort there. Particularly at paragraph 208 where the Court of Appeal does endorse what Mr Justice Laddie said in the Victor Chandler case cited above.

The last paragraph I just want to emphasise is essentially the conclusion on economic value at 218:

"For all the above reasons we conclude in holding that the economic value of the pre-race data was the cost of compilation plus a reasonable return. The judge took too narrow a view of economic value in Article 82. He was wrong to reject the contention on the relevance of the value of the pre-race data to Attheraces in determining the economic value of the pre-race data and whether the charges specified were excessive and unfair."

So the whole thrust, as we know, is one has to look at what -- how do I pray this in aid? One has to look at what the Department of Health is paying for comparable products. That is a demand side consideration.

If we go to Advocate General Wahl. Just for the tribunal's reference, the Scandlines decision is similar and I will just give the reference: bundle E1. This is Scandlines: bundle E1, tab 11, paragraphs 214 to 248.

Scandlines is to the same effect. You have to look at what the consumers are paying.

But if we go back to Advocate General Wahl at paragraph 63, and he makes a similar point. So at 63 he has found the analogue markets to be objective and verifiable:

"They appear, in addition, relevant ..."

So they appear relevant:

"... insofar as they are meant to ensure that the markets are homogeneous ..."

So again homogeneous, similar:

"... on both the demand and supply side."

Emphasising the comparator. Then:

"It is indeed crucial in this context to take into account the following two factors which, in my opinion, could affect the economic value ..."

He emphasises "economic value":

"... of the service provided by AKKA/LAA (i) the capacity and willingness of AKKA/LAA's customers to pay for the service received and (ii) the economic benefit that AKKA/LAA's customers may derive from that service when in turn they supply products or services to their own customers."

So, in my submission, this is a clear steer to showing the tribunal that, when one is looking

at economic value, the CMA should be looking at what the Department of Health is paying for comparable products. That is a key ingredient in ascertaining the economic value of the Phenytoin capsule.

THE CHAIRMAN: Are you going to deal with Albion Water at some stage? That is cited against you.

MR BREALEY: I will deal with Albion Water, probably after lunch. But Albion Water, we say, is not against us at all. Had there been comparators in Albion Water, Lord Carlile would have referred to them. But it was impossible. If there are no comparators, you cannot take into consideration the comparators. The whole thrust of Albion Water was essentially on cost and allowing third parties to enter the market. So to adopt a phrase that, sir, you mentioned early on, it is very context-specific. It was a regulatory case. It was all about cost, margin squeeze and whether a third party could enter the market. And, as I say, the passage that is relied on just for a cost plus -- and I will come back to this as you have mentioned it, but the tribunal says there are no comparators out there. It is as simple as that. If it is impossible to have a comparator, you cannot take them into consideration.

THE CHAIRMAN: I think those were my words, but you have to look at the context. I suppose that could be applied to

the Latvian Copyright case as well, because also the context of that is a legal monopoly and the need to look at other countries' comparable monopolies.

MR BREALEY: Absolutely, and I would pray this in aid as well because one of the things, just standing back from it all, on the excessive pricing, in my submission, things are becoming a little bit too pigeonholed, too rigid. It is either limb one, limb two, you tick one box and go on to another box. As the Court of Appeal flagged in Attheraces, this is about the price of a pharmaceutical product and that is the context in which we are here today; the price of a pharmaceutical product. As I said, it is absolutely crazy in an allegation of excessive pricing of a pharmaceutical product for the authority in its closing submission not to refer to the serious nature of the condition, not to refer to the treatment, how the condition is treated by the same or similar medicines, and that is the context that we have here. It is the price of a pharmaceutical product, where other products are fulfilling the same or similar function but are being priced and paid for at a far higher price.

THE CHAIRMAN: Just to pursue my point, if you will indulge me. In a case like Latvian Copyright, a geographical comparison method is appropriate.

MR BREALEY: With all the caveats that they give.
THE CHAIRMAN: Yes. There must be cases where a cost plus method would be appropriate. Can you give me one?
MR BREALEY: Albion, where there are no comparables and the whole thrust of the regulatory regime is looking at the cost that is going to be borne by the new entrant and whether that new entrant is going to be squeezed out of the market by the incumbent.
THE CHAIRMAN: So that is utility.
MR BREALEY: Utility.
THE CHAIRMAN: Previously nationalised and subject to a privatisation programme. Your submission is that, where there are other elements, they ought to be looked at? That is your fourth proposition.
MR BREALEY: Yes. Shall I finish that --
THE CHAIRMAN: I think Mr Lomas has a point.
MR LOMAS: One point, just to understand what you are saying. Does Pfizer disagree with Mr Harman's fundamental, albeit theoretical, proposition that in perfect market conditions, leaving aside that that is theoretical for the moment, over the long-term the margin earned by the supplier will be on a cost plus basis, taking costs and the cost of capital. Are you actually attacking that as a theoretical proposition or are you saying that is a theoretical proposition, we

have to live in the real world and, in the real record, in real markets, you have to take account of the demand side?

MR BREALEY: I think it must ultimately be the latter. But I do it with some hesitation. Because when one has to accept a proposition about there being perfect competition, one is always very nervous about doing that. One can have a highly competitive market but my product just happens to be better than my competitors' and I charge a bit more for it. But in a perfect world where there are no unique features, probably. I will discuss it with my team, but I can see that in a perfect competitive world it could go down to cost plus.

MR LOMAS: But your point is that is not the world we are in.

MR BREALEY: As Mr Justice Laddie mentioned, in the real world that is not what happens. And in the real world we have a pharmaceutical drug which treats a very serious medical condition and the Department of Health is paying prices for similar drugs to treat that medical condition and, when one looks at that table that I referred to, why on earth should Pfizer be limited to 30p-odd and the others are receiving ten times more?

Maybe I will deal with the fourth proposition after lunch.

THE CHAIRMAN: We will reconvene at 2 o'clock.

(1.00 pm)

(The short adjournment)

(2.00 pm)

MR BREALEY: Before I go to the fourth proposition can I just mention two things. The first is in answer to the question of Mr Lomas on the number of tablets.

MR LOMAS: Manufacturers.

MR BREALEY: Tablet manufacturers. Pre-launch -- I will give the reference, pre-launch there are at least three.

MR LOMAS: Pre-launch of ...?

MR BREALEY: The capsule. So we are not sure what was around in 2007. Pre-launch Teva -- and all these are just references to these. Teva is G1, tab 3. There is a reference to Hillcross which is G1, tab 23. And then there is a reference at G1, tab 40, this is a Pfizer email pointing out that Actavis has recently launched a tablet at £30, so that is at G1/40. So in June 2011 Actavis launched a tablet at £30.

Then by June 2013 there is another one called Wockhardt and that is I1, tab 62. And lastly Aurobindo is I1, tab 57. So those were the references to the tablet manufacturers.

MR LOMAS: Thank you very much, and to whoever did that over

the course of lunchtime.

MR BREALEY: Mr O'Donoghue reminds me, it's footnote 73 of our closing that the tablet approval was basically piggy-backed on our bioequivalence of the capsule. So that is page 30 of our closing, footnote 73.

"The MHRA granted a marketing authorisation to Aurobindo Milpharm for 50mg Phenytoin sodium tablets. This approval was granted pursuant to the abridged procedure and the applicant cross-referred to Pfizer's Epanutin capsules."

The tribunal will know that is something we pray in aid as to why it is such a good comparator.

That is the first thing I wanted to draw the tribunal's attention to. The second thing before I go to the fourth proposition - Albion Water. I wanted to deal with that first. That is at authorities bundle A2.

THE CHAIRMAN: This is Albion Water II.

MR BREALEY: Albion Water II, so that is tab 15. I think on my feet I mentioned two points. One was -- so this is at tab 15. One was there were no comparators, and I will not go over old ground, I did that in opening, but that is at paragraph 251 onwards. The other point I made was this was in the context of regulation, encouraging new entrants, and on that point I would draw the tribunal's attention, if one goes to

paragraph 220, page 68, this is A2, authorities bundle, tab 15, page 68. This is under the heading "Economic Value of the Services to be Supplied". And we can skip to page 74. I just want to put it in context. Paragraphs 234 to 236 really put Albion Water in its context:

"If as envisaged by the guidance, common carriage is to be an important means of introducing competition to the water industry, it is neither possible nor desirable to divorce the economic value of the common carriage from the fact this is a vertically integrated market."

So this was a vertically integrated market:

"In contrast, the position in Scandlines where the dominant firm was not present on the downstream ferry services market, in this case Dwr Cymru is not only present on the upstream market for the transportation, it is active in the downstream market for the supply of non-potable water. Whereas in the upstream market Albion act as customer and supplier, Albion are actual or potential competitors in the downstream market. An excessive upstream price charged by vertically integrated dominant undertakings to customers who are also its competitors in a downstream market may have an exclusionary effect."

And then 235. And 236 is not unimportant:

"The common carriage proposal in this case only has economic value to Albion if it means it is thereby able to provide water to Shotton Paper at a retail price that can effectively compete with a retail price offered by Dwr Cymru. In the tribunal's judgment it is the fact that Dwr Cymru is a competitor of Albion in the downstream market and therefore in a position to lower its own retail price to the level of its import costs which means the economic value of the service, here common carriage, to its downstream competitors may be equivalent to the costs reasonably attributable to the transportation and partial treatment of non-potable water where otherwise common carriage in the present case would be virtually unattainable, thereby frustrating the various attempts to introduce a degree of effective competition in relation to the supply of water to large users."

So that is the context of why the cost was important, because obviously if it was too much then the person was going to be excluded.

So that was Albion Water. Can I then go back to the fourth proposition which is, as I say, the most -- probably the most contentious. The fourth proposition: if valid comparators exist, is it appropriate that the authority should ignore them as irrelevant? If

valid comparators exist, is it appropriate that the Authority should ignore them as irrelevant?

We obviously say it is not appropriate. Clearly the CMA say it is appropriate. They stick to their limb one, limb two in itself. We say it is not appropriate and I would like just to go to the Advocate General and to the court just to highlight certain passages where we say in the most recent authority it is appropriate. And we would say it was appropriate even before the Latvian Copyright case. If you look at the Attheraces it is just common sense, if you are going through an exercise of supply and demand side in order to look at economic value, to shut your eyes to the relevant comparators which would actually inform you as to the value that customers put on it, is only doing a partial job.

But I think in my submission the Latvian Copyright case does actually nail this point. So with that could I go to C3, which is the authorities bundle, tab 39. And I will just again -- I know the tribunal has read this, but I will just highlight the passages which in my submission support the fact.

The Advocate General, paragraph 32. I have already referred to this, that this was a question from the referring court asking the CJEU whether what the

Authority had done was appropriate and sufficient. So it is important to look at the question: is it appropriate and sufficient for the Authority to have done what it did?

So that is 32. 36, we know there is no single method or test. I do rely on the last line because the Advocate General is saying there are some inherent weaknesses. So again it is a logical step. If there are some inherent weaknesses, is it appropriate and sufficient that you just pin the whole thing on one test and exclude your mind to other methods when you are being told there are some inherent weaknesses?

Paragraph 42, what is the danger of not doing a more comprehensive examination? The answer is that you run the risk of producing type 1 errors. A price is mistakenly considered to be abusive when it is not. So again you just do a cost plus analysis. The margins are high. As Mr Justice Laddie in Victor Chandler said, you take no account of demand side or comparators and everyone else in the market is paying it. You have to inform yourself. So paragraph 42 is the type 1 errors.

Paragraph 43 clearly, and we rely on:

"In the absence of a ubiquitous test and given the limitations inherent ... it is in my view crucial ..."

It could not be more plain:

"... in my view crucial that in order to avoid, or more correctly to minimise, the risk of errors Competition Authorities should strive to examine a case by combining several methods among those which are accepted by standard economic thinking and which appear suitable and available in the specific situation."

And it is, in my view, crucial. This is a -- he is making a general point here. We say as the Court of Appeal in Attheraces said, this is the pharmaceutical industry where pharmaceutical companies, it is their business model, they benchmark their prices by reference to other companies. They do not price their products simply on a cost plus basis. It is the whole business model.

Paragraph 43, it is "crucial", and we would say it is even more crucial when you are looking at the pharmaceutical ...

Paragraph 44, he says that is what happened in Napp. I am not sure he would necessarily agree with what is happening in this case.

Paragraph 45, why is it that it is better to avoid the risk of type 1 errors? 45, again, if you combine the methods you are likely to end up with a more rigorous result. Again it is common sense.

Paragraphs 52 to 54. 52, often people refer to the

presumption of innocence but it does apply in competition cases and you do have a presumption of innocence. If you are just going to apply a very strict test and ignore all other relevant factors, there is a risk that the person who is presumed innocent is going to be found guilty.

And 54 is important because if you are looking at the various methods, the Advocate General is saying here that there must be a sufficiently complete and reliable set of elements which point in one and the same direction. So 54. So again avoiding the risk of type 1 errors, the Advocate General at least is saying, well, if one is against you, one is in favour of you, then actually presumption of innocence, the price is not excessive. That is obviously not a golden rule but that is an approach.

THE CHAIRMAN: Just remind us what the Advocate General meant by "hypothetical benchmark prices". I think paragraph 17.

MR BREALEY: Yes, it is. It is 17. What I understand him saying -- and I think from memory it is paragraph 138, yes. If one goes to paragraph 138, he is referring to -- he there refers to "higher than the competitive price", and essentially his benchmark price is the price it would obtain in a competitive market going back to

paragraph 249 of United Brands. So when one sees "benchmark prices", he is referring to a competitive price.

THE CHAIRMAN: I am not sure Mr Hoskins agrees with you on that.

MR BREALEY: I am sure he does not agree with me on many things, but that is how --

THE CHAIRMAN: That is one of the points of disagreement which we would like to be clear about as to who is saying what and who thinks what. You are accepting paragraph 17 effectively?

MR BREALEY: Yes, we are accepting paragraph 17, we are accepting that you need a benchmark, and in order to get to the benchmark you will look at comparators. So there are other manufacturers of other AEDs, as Teva and all the other tablet manufacturers selling the tablet and that is a benchmark price. As I said before lunch, in particular as regards the generic AEDs, that is Scheme M, category M, they are competitive prices, those prices are supposed to be the prices that pertain in a competitive market.

MR LOMAS: Just to be consistent. If you are taking Advocate General Wahl's opinion as valuable to you, you would say that you cannot just look at cost plus, you cannot necessarily just look at competitors either. You

are looking at a variety of factors of which you would say competitors would be one, and possibly a heavily weighted one, to establish an appropriate benchmark price from which you then work.

MR BREALEY: Correct.

THE CHAIRMAN: Comparators.

MR BREALEY: I go further. If you look at Scandlines, for example, or Athens, it would appear that benchmark competitive prices, prices in other ports, airports, are key. So if you win on that you should win on no excessive pricing. So that is the ratio of those cases. And one of the reasons that is so is because paragraph 54 of the Advocate General, you are entitled to a presumption of innocence, and if you are going to fine someone 84 million for excessive pricing the methods you choose should broadly go in the same direction.

So the answer to that question, the comparators being a demand side, basically very much a demand side -- they can be obviously supply side, but very much demand side are key, are relevant. And if you show that there are people out there paying a price then it should point -- that points in the direction of no excessive pricing.

Paragraph 138, we just saw -- paragraph 138, not

only is the reference to benchmark pricing a competitive price, to that end the Authority was required -- and there is the Advocate General almost putting a legal obligation:

"... was required ..."

Because there is an obligation according to the Advocate General to determine what is appropriate and sufficient:

"... to take into account during an objective and thorough investigation all the relevant facts in order to determine the correct benchmark price."

Again, it is startling that we are here disagreeing over this because what he is saying is pretty blindingly obvious, with the greatest respect.

Just on the court, the court is not as cogent as the Advocate General, we know that. But I pray in aid two passages of the court. Paragraph 37, which we have been to time and time again, but the reason I rely on that is because -- this is paragraph 37 of the court, is because the court is specifically referring to the Advocate General in point 36. And at point 36 the Advocate General is saying there is no single method due to inherent weaknesses.

At paragraph 49 the court says:

"It falls to the Competition Authority concerned to

make the comparison and define its framework although it should be borne in mind the Authority has a certain margin of manoeuvre and that there is no single adequate method."

So one asks oneself: if I am going to refer a question to the European Court and say is it sufficient for a Competition Authority to adopt a single method that you refer to in United Brands, that is to say cost plus and excessive and unfair in itself, and to stop there, and to shut the eyes to relevant comparators which would inform one as to the competitive prices, the prices out there on the market; given those two paragraphs, the court saying there is no single method and there are inherent weaknesses in the methods, I cannot believe that the court would say it is okay to adopt one single method.

THE CHAIRMAN: You are not suggesting we need a reference in this case, are you, Mr Brealey?

MR BREALEY: No, acte clair I think one could say. So that is the -- I am conscious I have -- because Mr O'Donoghue needs to deal with ground four and fines. That is all I was going to say on the law for the moment. I will come back to anything Mr Hoskins submits in reply. But those are my four propositions, and the four propositions are all designed to show to the tribunal

that as a matter of law it is right for the Authority to look at these comparators, it is wrong for them to shut the eyes to the comparators, and hopefully this morning I have shown the tribunal as a matter of fact the AEDs and the tablet are valid comparators. And that table I showed, the table shows that the Pfizer price is not out of all proportion to the prices out there.

Unless --

PROFESSOR WATERSON: Can I just check. So you have dealt with the first three of your grounds of appeal, you say. I do not think you have said anything particularly explicit about ground one, about Pfizer not being dominant. Obviously you cover that in your written submissions. But you are not adding to that?

MR BREALEY: Yes, I had a piece of paper somewhere. Orally in closing I do not intend to say anything about ground one, dominance.

THE CHAIRMAN: Can we just be clear what Pfizer's position is on ground one.

MR BREALEY: As set out in the closing.

THE CHAIRMAN: In relation to the break in the period as it were.

MR BREALEY: Yes.

THE CHAIRMAN: You have a footnote I think.

MR BREALEY: Our approach has always been there is certainly

no dominance for the whole period, and one of the key reasons for no dominance is because we say the DH had the power to regulate. I made that submission in opening and I --

THE CHAIRMAN: That is buyer power.

MR BREALEY: Buyer power. And if there is a stand-off between two people, and one has the power to regulate you, you cannot act independently.

THE CHAIRMAN: So that is nothing to do with other capsule suppliers.

MR BREALEY: No. So on market definition and dominance, and Ms Bacon will deal with this so we have tried to divvy it up.

THE CHAIRMAN: I do not want you to argue it at length.

MR BREALEY: Clearly on the first period, and it goes into 2014, there is a lot of competitive noise going on. NRIM takes almost 50 per cent of the market.

THE CHAIRMAN: It goes beyond November --

MR BREALEY: November 2013. And in circumstances where you get a new person come in taking between 30 and 50 per cent of the market, and to say that they are in separate markets, again there has to be some compelling reason why that is so and, in my submission, the CMA do not get close to showing that it is -- I mean NRIM is in its own market, Flynn is in its own market.

THE CHAIRMAN: Assuming Flynn and NRIM are competing with each other, just assume that.

MR BREALEY: Yes.

THE CHAIRMAN: Are you saying that Flynn is not dominant and also Pfizer is not dominant in that market in that period? Leaving the Department of Health argument on one side.

MR BREALEY: Correct.

THE CHAIRMAN: What about afterwards?

MR BREALEY: Afterwards there is still noise and again then one has -- then it gets a bit more complicated because clearly there is a bit of stickiness, and we get that from Professor Walker. He does not get as many stories about patients being switched after the MHRA guidance. But there is still a lot of noise going on, and ultimately it still depends on the interpretation that pharmacists put on the guidelines. So the whole market definition story and dominance story depends on pharmacists' interpretation of guidelines, guidelines which say you can dispense, and nothing happens.

THE CHAIRMAN: But again on the assumption that Flynn and NRIM were competing in some way or other, perhaps less aggressively than before or whatever, your position is that there is no dominance.

MR BREALEY: There is no dominance.

THE CHAIRMAN: You do not accept the argument a company can be dominant even though there is lively competition in the same market.

MR BREALEY: Certainly if there is lively competition there has to be some compelling case why one of them is dominant.

THE CHAIRMAN: Continuity of supply, I suppose.

MR BREALEY: That is what I am going to come on to. The evidence on continuity of supply is wafer thin, it really is. Obviously we have the Boots story after -- but this mantra that we are told that eight out of ten, it's like some advert, eight out of ten before 2013 adhered to the continuity of supply and then afterwards ten out of ten did. I want to come on to this in the next half an hour. Actually when one looks at it objectively, dispassionately, the evidence, the CMA does not prove its case.

It all hinges, the whole case, what Mr Hoskins called the crux hinges on pharmacists' interpretation of the guidelines and remembering that the guidelines say if it is written generically, you can dispense the cheapest brand. That is what the guidelines say. So the whole CMA case on this is an interpretation that all these pharmacists throughout the whole of the UK have interpreted the guidelines beyond what they need to in

circumstances where the majority of doctors are telling the pharmacists they can prescribe the cheapest brand.

THE CHAIRMAN: We do not want to squeeze Mr O'Donoghue so you had better get on and deal with what you need to deal with.

MR BREALEY: Just one last point. There are these two periods. And no one has really addressed this too much but there is a serious issue here. Let us divide it into two periods, period one and period two, and let us assume that there is healthy competition in period one, and Pfizer is not dominant, and ignore 2012 because as Mr Ridyard says, if there is a threat of entry there can still be a single market and you are not dominant. So simply because you are the only one on the Monday when you know someone is going to come in on the Wednesday does not mean to say you are dominant on the Monday.

So let us assume you have period one and period two, and let us assume there is no dominance period one but as a result of the Government's guidelines, and the MHRA guidelines essentially stem from the government.

As a result of government's guidelines, they put -- as a result of the Government's guidelines and the interpretation that the pharmacies put on them, which is beyond the guidelines, Pfizer is now dominant because it is dominant in its own very narrow product market. CMA

accept it is a very narrow product market. So you weren't dominant before, and then because of the guidelines that the government issue and the interpretation the pharmacies put on them you become dominant. But the price that you launched was the price you that set upon when you were not dominant.

There is a really interesting legal issue here as to what the person who does not know they are dominant because of what the pharmacies are -- in how they are interpreting them, whether all of a sudden the company that does not know it is dominant has to now say, right, well, I benchmarked the price by reference to all the competitors, I have now got to look at cost plus 6 per cent.

THE CHAIRMAN: It would not be the first anomaly in competition law.

MR BREALEY: But it is still an anomaly and whether that goes to fines or it goes to a substantive application of Article 102 is something to be debated. But clearly you can be dominant because of the actions of third parties, but here you have a circumstance where you are being put in your own market by the purchaser, so the purchaser -- and I am taking the government as a whole, as the CMA often takes companies as a whole. I am taking the government as a whole. It issues the guidelines, and

as a result of it issuing the guidelines it then says the price is too high.

There are some dense legal points here which the CMA have not addressed, if there is no dominance in the first period but they say there is dominance in the second period. Particularly when we reduced our price by 20 per cent.

MR LOMAS: Mr Brealey, at the risk of going back to another dense legal point, and conscious of time, paragraph 49 in your written closings which deals with this question of unfettered limb two.

MR BREALEY: Sorry, sir?

MR LOMAS: Unfettered limb two, paragraph 49 of your closing, "Genuine Alternatives?", last sentence:

"... they are alternatives in a more narrow sense. Where on the facts there is no relevant or useful data available, one or other of limb two may be used."

Is that a sufficient answer to the problem? Because if there is no relevant or useful data available you cannot really use limb two, can you? So is what you are really saying they are not alternatives; you should use limb two when data is available, and if it is not you should use limb one? And if that is what you are saying how do you square that with the various comments from the ECJ?

MR BREALEY: "The two approaches identified in limb two are not genuine alternatives in the sense there is an unfettered freedom, they are alternatives in a more narrow sense. Where on the facts there is no relevant ..."

I think all we are saying there, for example, that is the Albion Water case. So we are taking the CMA's case at face value, so that you have the unfairness in itself or by reference to competing products. And we say, well, even adopting that approach you have to look at them together, you cannot just say either/or. But what we are saying in 49 is if on the facts there are no comparators, then --

MR LOMAS: You cannot use it.

MR BREALEY: You cannot use it.

MR LOMAS: But what you are also saying is if there are comparators you should use it.

MR BREALEY: Yes, absolutely. Again whether you regard it as limb one, limb two, classic United Brands, Advocate General Wahl, the European Court in the Latvian Copyright case, putting several methods in limb one. Ultimately the test is economic value, and economic value as we have seen from the Court of Appeal plays great store on demand side, and once you get into demand

side comparators are extremely relevant. But that is what we are saying in limb two in paragraph 49. But if there are comparators then it is not a rigorous approach, it is not "appropriate" to use the court in Latvian Copyright to disregard them.

Could I then go to continuity of supply. I majored on this to a certain extent in opening. We have obviously put an annex in which sets out the bits in the decision and then the bits in the Section 26 notices. What I would like to do in the next 20 minutes is mop up on continuity of supply and make some general points.

On the Section 26 notices themselves, as a result of our opening, then Mr Hoskins followed, he made two points which I think broadly everyone can agree with. The first point on the Section 26 notices is that you, the tribunal, will give such weight to them as necessary, remembering that a Section 26 notice which is being advanced as evidence of a primary fact in our submission should carry little weight. Clearly if it is giving data or documents then it is more persuasive, but if a Section 26 statement is being used as evidence of primary fact we say it should be given little weight. But that is the first point where we agree, Mr Hoskins says the tribunal should give it weight.

The second point which is actually quite important as a matter of evidence is that if you are relying on a Section 26 notice, the tribunal should be looking for corroboration. The CMA should be -- the CMA should realise, well, we have done a Section 26 notice, we are putting forward this as evidence of primary fact, where is the corroboration? That is a point that Mr Hoskins accepts in his opening and that is what the case law says.

So those are the two preliminary points I would like to make by way of opening.

The mantra, the kind of -- we see at paragraph 19 of the CMA's closing, this is the eight out of ten cats prefer it. So paragraph 19 of the closing, page 11. And it is as if you just copy and paste this without more. It is just put in the starkest possible light.

So:

"In order to obtain evidence of pharmacists' dispensing practice, the CMA contacted ten pharmacy groups covering approximately 50 per cent ... The responses to the Section 26 notices showed that eight of the pharmacy groups followed continuity of supply throughout the relevant period, two of the pharmacy groups, Boots and Lloyds, did not, however after publication they did."

And it is put in those terms. As I say, it is all dependent on all the pharmacies in the UK interpreting the MHRA guidelines in a way they are not drafted. They are drafted in a way that if the prescription is written generically you can dispense the cheapest brand. So all the pharmacies have gone beyond that.

MR LOMAS: Does that matter? Surely it is a question of fact as to what they did do?

MR BREALEY: Correct, it is a matter of fact. But this is put forward as some sort of -- it is put forward as a factual statement and therefore the tribunal in this hearing has got to test it. And we have done it in opening, we have done it in the closing and we have done a schedule on it. But I would like just to draw a few points to the tribunal's attention, just to see where this goes.

So the first point I would like to make is the timing of the Section 26 notices. We are looking at a period of infringement, 2012-2016. The Section 26 notices they rely on is mid-2014. And that is it. So what have you done -- so some of them were asked what they did in the previous year. But the point is that these are a snapshot in time. So that is my first point, the Section 26 notices are a snapshot in time. If there was a pharmacy witness here I could ask them:

what are you doing in 2015? What did you do in 2016? There is no evidence adduced by the CMA in Section 26 notices what they did in 2015 or 2016. It is a snapshot in time.

That is not a hollow point, it is a real point. I will make it good by reference to both Morrisons and Superdrug. So if we go to the decision. We will need the decision -- there are three bundles. We will need the decision, bundle A, and we will also refer to bundle I. So this is the first inadequacy of the Section 26 statements, it is the timing of them. It is a snapshot in time.

So we will deal first with Morrisons. We will need the decision, bundle A, and bundle I. So on Morrisons, if we go to the decision at page 223, so we are testing the assertion eight out of ten. Morrisons, 223. There we have at paragraph 4116, Morrisons' pharmacist is focused on ensuring continuity of supply. Only dispense in limited circumstances. And they set out that passage.

So if we go to bundle A, tab 4A. We had a look at part of this in opening but it does nail the point. So bundle A, tab 4A. This is the graph of Morrisons. At tab 4A there is a graph. So continuity of supply, paragraph 4116, this is the evidence that is relied on

for -- they have interpreted this and they have shut the door.

The first point so note is, well, actually Morrisons' sales of NRIM have gone up and Flynn have gone down. So that immediately suggests, well, why are you, CMA, in the decision saying would only be dispensed in limited circumstances? When Flynn is going to rock bottom and NRIM is going up, how can that data possibly support that paragraph?

PROFESSOR WATERSON: Remind me, Mr Brealey, ADHL is one of the wholesalers.

MR BREALEY: It is.

PROFESSOR WATERSON: Was it affected by the Flynn reduced wholesale model?

MR BREALEY: That I do not know. I know Superdrug was, unless I am told --

MR HOSKINS: It was. Alliance was one of the companies that was no longer supplied.

MR BREALEY: That is -- yes. But I am not sure where that takes one. Clearly if they changed the preferred supplier -- but the point is that Flynn is going down, NRIM is going up. The CMA have not adduced -- so this comes to the corroboration point. We have this data and we are being told they only do it in limited circumstances. The CMA has this data, we do not. We

have not been given the other wholesaler data. But the data that we do have shows that the CMA is not right. We keep on coming back to the burden of proof, but there is only so much the defendant can do.

And it does get worse, because when one goes to bundle I, tab 46 -- and please keep the decision open -- I am trying to test the robustness of this single paragraph in the decision relating to Morrisons which says that they focused on ensuring continuity of supply.

So I have looked at the data, and the data that we have does not support it, whether there is other data out there we have not been given. If we then look at the Section 26 statement, this is tab 46. If one goes three pages in, so three full pages, so the sixth page, the first bit in blue is the bit quoted in the decision, so:

"If a patient was ..."

It is the bit quoted in the decision. But Section 26, if anything, is in Pfizer's favour. At worst it is internally inconsistent. Because if you look almost at the bottom:

"If a prescription is written generically ..."

That is clearly not consistent with focusing on no switching. This is the sort of danger that one gets if you just have a Section 26 statement and then one makes

a bold assertion about what it means. It is not even made, as I understand it, from memory by anybody with direct knowledge of what was on the ground. A Section 26 statement is internally inconsistent, if anything it is in our favour, and the data that we have been given does not support it. So there is no corroboration.

Very quickly if we go to Superdrug, so that is 4116, that is Morrisons. 4117, Superdrug. So:

"... would only be dispensed where ..."

And then sets out the -- again, this is eight out of ten adhere to this continuity of supply which we understand is do not switch.

So again back to the graph in tab 4A. Over the page. We do know this coincided with the switch of wholesaler, so ADHL did become the preferred wholesaler to Superdrug. But the data that we have clearly shows Flynn going down and NRIM going up.

So again Mr Hoskins in opening says, well, I understand that you have to attach the weight to these Section 26 statements and you have to look for corroboration. There is no corroboration in the data that we have.

MR HOSKINS: Sorry, I think this graph is not about supplies. Alliance ceased to be supplied with Flynn's

product, that is the point.

MR BREALEY: Mr Hoskins can make submissions and then we will come back to them.

It is sales of 100mg sodium to Superdrug, so the wholesaler is supplying to Superdrug, and there is Flynn and NRIM, and the graph is going up, and we can go back to the reply if you want but we do not need to. That is the data.

Then we go to the Section 26 notice which is at tab 7. I will just go to these two. So paragraph 4117, Superdrug quote in the decision. Again this is my snapshot in time point. The CMA says -- so this is tab 7, bundle I1:

"The only time NRIM would ..."

So that is the bit they cite in the decision. They do not cite the answer to 3:

"Whether or not we purchase NRIM in the future would depend on availability and patient needs including the nature of how the prescription is written, cost and the patient's individual requirements."

Again that is not in the decision.

"But whether or not we purchase NRIM will depend on ..."

The tribunal can read it.

It is not consistent with a pharmacist saying: come

what may, I will not switch -- it is not consistent with a pharmacist saying: the guidelines say I can switch a brand to the cheapest brand if it is written generically, but I am not going to do that, I am not going to switch.

It is quite clear it is not consistent with adherence to a continuity of supply.

So that is -- I made certain observations in opening. If one goes back to the decision, one of the things I got criticised for -- so in the decision we looked at Morrisons and Superdrug. Mr Hoskins said I was cherry-picking because the Section 26 notices, they start off with purchasing, and they have dispensing and then whether it is in stock, there are various questions. And I was told, well, I had referred to the purchasing parts rather than the dispensing parts.

Then have a look at paragraph 4.119. This is the basis upon which we are being told that Day Lewis and the Co-op did not purchase NRIM's product. So where is the hard dispensing? And again in opening I referred to the two Section 26 notices in for Day Lewis being inconsistent with one another. I referred to the Co-op and the reasons for the Co-op not purchasing NRIM. And then -- so that is purchasing.

Then Rowlands, 4.120. It is not dispensing, it never

purchased NRIM's, to which we have always made the point, and it has never really been satisfactorily answered for all these eight, if you only stock one and someone comes -- if you only stock Flynn and you come in with an NRIM, what is going to happen?

But all I am doing is meeting Mr Hoskins' point because he criticises me for relying on purchasing data and in the decision they do exactly the same thing.

Then we struggle around for corroboration. So these are statements relied on, inconsistent statements, and Mr Hoskins accepts that there needs to be corroboration. For the eight out of ten, where is the corroboration? Where does one find any corroboration in this decision to support the eight out of ten point?

In the decision we get paragraph 4.123, the Co-op and Day Lewis' submissions have been corroborated by NRIM. That is in a Section 26 notice. So that is salt on the wounds. And also again if we really are testing this rigorously, we know the story behind the Co-op, and what the Co-op then told NRIM was probably not the truth. But there is no hard data corroborating a strict adherence of continuity of supply.

THE CHAIRMAN: Are you putting to us that the CMA ought to have obtained purchasing and dispensing information from all the pharmacies, the major pharmacies certainly, for

this period of infringement?

MR BREALEY: Yes, absolutely. 2013, 2014, 2015, 2016, and then the tribunal would have had a full picture. These are basically Section 26 statements made in mid -- basically June and October 2014, and then we do not know what happens after that.

THE CHAIRMAN: And you would have wanted a couple of pharmacy witnesses so you could ask them what they were actually doing.

MR BREALEY: Absolutely.

THE CHAIRMAN: More than a couple.

MR BREALEY: And the reason for that is that if the Competition Authority is going to bring a case based on primary fact, it knows from the Durkan case and the Tesco case that the evidential weight of notes of interviews, Section 26 notices by analogy, they are not evidence of primary fact, and the tribunal has already said that. You have to be able to test them.

THE CHAIRMAN: And the cases where the tribunal has relied on Section 26 notices, they are distinguishable?

MR BREALEY: You can rely on Section 26 notices. It depends for what purpose. Clearly in the LME case it was kind of interim injunction purposes. Clearly you -- but the question is what weight do you attach to them? And my simple proposition is that if you are adducing the

Section 26 notices as evidence of primary fact, what the pharmacists did on the ground, how they interpreted the guidelines or went beyond the guidelines, you have to do a little bit better than a single paragraph taken out of context.

Mr O'Donoghue rightly tells me at paragraph 202, 203 we say what they should have done. Sorry, of our closing, we say what they should have done.

THE CHAIRMAN: And this goes to dominance and to economic value.

MR BREALEY: It goes to quite a few things. Continuity of supply feeds into many issues in the case. It goes to market definition which is switching, it goes to dominance, it goes to Mr Hoskins' -- the bizarre submission on complete dependency and therefore Phenytoin should be given zero value. So paragraphs 202/203 of our closing is where we say what they should have done, and paragraph 199 is where we refer to the LME case, but we deal with this in our closing.

Five minutes and then I shall finish.

So again we have taken head on, and we have always done it, throughout the whole process we have complained about the Section 26 notices, the CMA has adduced no evidence before the tribunal as to the pharmacies'

practices, but we have, so the very last piece and then I shall finish.

Professor Walker, if I can go to Professor Walker which is bundle D, this is Walker 1. Tab 9, paragraph 614. This is evidence from someone on the ground who is meeting patients:

"As mentioned above, the evidence indicating ..."

Yes:

"Prior to the MHRA guidelines, it was my experience that it was commonplace for patients to have their Phenytoin brand or formulation changed."

So:

"... it was my experience that it was commonplace for patients to have their Phenytoin brand or formulation changed."

He sees 1,000 patients a year and he runs a clinic I think of 11,000 patients. So he sees 1,000 patients a year and he is head of a clinic which has 11,000 patients a year.

Walker 2, paragraph 2.8(a) and (d) but I will just go to 2.8(a). This is bundle D, tab 10. The last sentence of the second paragraph of 2.8(a):

"This supports my clinical observation that the so-called principle of continuity of supply of Phenytoin sodium was being ignored for many patients with

epilepsy. The NICE guidelines did not have, in my experience, much impact on prescribing practice for AEDs ..."

So it was being ignored.

THE CHAIRMAN: But that is prescribing practice.

MR BREALEY: It is.

THE CHAIRMAN: We know that because of the open prescriptions.

MR BREALEY: Then ...

THE CHAIRMAN: There is something about prescribing practices in 2.8(b). Perhaps that is what you want us to look at?

MR BREALEY: Yes, there is. He refers:

"The MHRA guidance on dispensing practice is highly specific and only advises pharmacists to ensure continuity of supply ... my experience prior to the MHRA guidance was that patients frequently reported they had been switched from one brand to another."

So when he says "frequently reported that they had been switched", this must refer to the pharmacists. Because he has a patient, it has been written generically, obviously they have gone to a pharmacy and the patient has reported they have been switched.

We do not get anything like this from a CMA. And the last thing is, again we tried to come up with

an independent survey, obviously the Kantar report, Mr Goosey. This is the sort of thing that the CMA could have done, but it does show that 56 per cent only stocked the Flynn product. And when asked what they would dispense if a patient came in, they would say, well, I would dispense what is in stock.

So again the CMA can try and downgrade it, but we have put forward evidence which militates against a hard continuity of supply, and the CMA simply has not done its own survey, it has simply relied, as I say, on the Section 26 notices as evidence of primary fact of pharmacists' individual dispensing behaviour in circumstances where they are often internally inconsistent and not corroborated as Mr Hoskins says they should be.

The last thing I would say, sir. I think you mentioned in our closing, where are errors, how do they relate to the grounds?

THE CHAIRMAN: We can probably work that out for ourselves. I do not think we need your help on that.

MR BREALEY: If I just do it. In our closing we have errors one, two and three, they relate to economic value which is ground 2. In our closing we refer to error four, that relates to ground three, which is the cost plus. And the error five we refer to in the closing, that

relates to market dominance, market and dominance, that is ground one. Then after tea we will hear ground four and penalties.

THE CHAIRMAN: Do you want to break now or does Mr O'Donoghue want five minutes before ...

MR O'DONOGHUE: I am in your hands but maybe this is a natural break.

THE CHAIRMAN: We will break now.

(3.10 pm)

(A short break)

(3.20 pm)

Closing submissions by MR O'DONOGHUE

MR O'DONOGHUE: Sir, as has been indicated I will cover ground four and fines for the remainder of afternoon.

On ground four, it of course comes chronologically fourth in our substantive grounds, but I want to emphasise that does not mean that it is last in terms of thinking or importance. In fact logically it is a distinct point and there is a logical case for it coming first, rather than fourth. But therein lie the problems of drafting by committee. So it is a separate point and it is an important point, in my submission, for the reasons I will develop.

What ground four goes to is really the fundamental theory of harm in this decision. In my submission, the

CMA has consistently struggled to nail down a coherent theory of harm, it has chopped and changed, tried a bit of one on one, tried a bit of circumvention, and landed on successive abuses. My core submission is that the final landing spot, if I can call it that, is wrong in law and wrong in fact.

The investigative history of these proceedings has been somewhat airbrushed from the trial so far so I want to go back and put this in context. If I can ask the tribunal to get out bundle N, which I think is a rarely visited bundle, and it is towards the back at N22.

THE CHAIRMAN: It is a rarely visited bundle for a rarely visited ground, you would say.

MR O'DONOGHUE: Indeed. At 21 and 22 we have Request for Information under Section 26 by the CMA. And I want to turn to page 2 and 3 of tab 22. Starting at the bottom if you see it says:

"First ..."

At the bottom of the page, does the tribunal have that?

THE CHAIRMAN: Yes.

MR O'DONOGHUE: The CMA, in teeing up its Request for Information, says:

"First, the OFT ..."

THE CHAIRMAN: Office of Fair Trading.

MR O'DONOGHUE: Yes:

"... has reasonable grounds for suspecting there is or has been at some time in the past one or more agreements and/or concerted practices between Pfizer and Flynn."

Then over the page this is articulated in a bit more detail:

"More specifically, the OFT has reasonable grounds for suspecting there are agreements and/or concerted practises between Pfizer and Flynn involving the transfer of the UKMA of Phenytoin sodium with a view to increasing the price thereof. As a result of these agreements and/or concerted practices, the price of Phenytoin sodium capsules has increased to a higher level than would have been the case absent these agreements and/or concerted practices."

So in my submission what the OFT is clearly teeing up there is an effect case under 101 because there is a clear reference to the counterfactual in the last part of that paragraph. So a higher price than would have been the case absent the agreement but that is classical counterfactual.

Just to complete this idea, this is not a one-off. If one looks at tab 21, another Request for Information, essentially the same text has been reproduced. So in my

submission certainly at the outset of this investigation Article 101, an effects case, was front and centre of the theory of harm.

We can pick this up again in a bit more detail in a state of play meeting and this time it is J1, tab 4. And this time it is internal page 9, paragraph 56. It says at the bottom of the page, if the tribunal has that?

THE CHAIRMAN: Yes.

MR O'DONOGHUE: "JH ..."

Who was I think an OFT team leader:

"... said the case team is currently examining the issues under both Chapter I and II. There is a possibility that even if the OFT decides it does not meet the requisite standard of proof/does not have enough evidence to continue its investigation under Chapter I, it may meet the requisite standard of proof/have enough evidence to continue investigating Pfizer under Chapter II."

JH noted that the Chapter II investigation may still have implications for the Pfizer/Flynn arrangement. So at this stage --

THE CHAIRMAN: A bit of an understatement there, is it not?

MR O'DONOGHUE: As it turned out, yes, significantly so.

THE CHAIRMAN: Nicely put.

MR O'DONOGHUE: But the point again at this stage is that it was Chapter I, Article 101 first, see if they could ascertain sufficient evidence to prove the effects case I have just shown you, and then, and it seems only then, Chapter II, 102.

THE CHAIRMAN: Are you going to take us to paragraph 57? I have been reading that.

MR O'DONOGHUE: I am very happy to while we are here. So CF, who --

THE CHAIRMAN: It's the elusive concept of doing something wrong. At that stage the OFT were not saying anyone had done anything wrong.

MR O'DONOGHUE: No. But indeed --

THE CHAIRMAN: That probably does not take us very far.

MR O'DONOGHUE: No, but it does actually highlight an important point which is it was only in February 2014 that Flynn was added into the mix, and that was a Chapter II case only.

THE CHAIRMAN: It was 16 July 2013, that meeting.

MR O'DONOGHUE: Yes. Sir, I am afraid we are back to bundle N again and this time it is the very last tab, tab 25. This time the CMA, a letter to Pfizer in December of last year, and this letter essentially closes the case in relation to two of the three suspected infringements and obviously followed the

decision which picked up on one of the suspected infringements. So you will see on the first page the three suspected infringements are listed, so there is the agreement, the 101, Chapter I case, object or effect, which I have just shown you. Then there is the abuse which is the second one. And then there is the circumvention or avoidance case which is transferring the MA via the agreements was part of a strategy to avoid PPRS and so on.

Then over the page the CMA says:

"We have decided to close our investigation on the first and third suspected infringements ..."

About a third of the way down.

And then in the penultimate paragraph the wording is interesting. They say:

"The primary reason for this decision is that the CMA anticipates that the infringement decision which CMA has issued today to Pfizer in relation to the second suspected infringement ..."

So the unfair pricing:

"... will address any competitive harm and any subsequent detriment to consumers which may be caused by the first suspected infringement and/or the third suspected infringement."

So in a nutshell, in my submission what they are

saying is, well, we do not need to bother with suspected infringements one and three because two can get us to the same end.

In my submission, that is the fundamental problem with the theory of harm in this case.

THE CHAIRMAN: It is on administrative priority grounds, the decision.

MR O'DONOGHUE: Well, in part. But in my submission the reason they gave was quasi-substantive in that they thought the second suspected infringement in the decision --

THE CHAIRMAN: So it's a prioritisation decision taken on those grounds.

MR O'DONOGHUE: On those grounds, yes, that is quite correct, sir.

In my submission, the circumvention here is not Pfizer, it is the CMA trying to circumvent the inability to bring an Article 101 case due to lack of evidence by the back door of Chapter II and Article 102. And fundamentally, in my submission, that eventual theory of harm is bad in law and is bad in fact for the reasons I will develop.

Can we start with the decision, just to see how this case is put, and this is at 5328 on page 371.

So the CMA says:

"Although Pfizer has no control over Flynn's prices, its own prices have an impact on the end customer and the price paid by CCGs because they set a minimum price floor which Flynn cannot price below."

The point I want to make here is that in terms of evidence evidencing the minimum price floor allegation, which, by the way, is completely unexplained, because we are led to believe that there is a situation of no control over Flynn's prices but nonetheless a minimum price floor. That distinction has never ever been explained by the CMA either in this paragraph or anywhere else.

But the point I wish to make here is there is no evidence whatsoever which goes to the allegation of a minimum price floor. The reason I mention that is from the state of play meeting I showed you, the reason the Article 101 case hit the skids on effects we strongly infer is due to a lack of evidence in terms of a counterfactual causative effect. In my submission, what they are trying to do through 102 and Chapter II on an evidence-free basis is to make essentially the same case on a manifestly weaker basis and, in my submission, that simply does not work.

We can go through the pleadings, because it continues to be an evidence-free allegation, and in all

of the pleadings and even in openings there hasn't been a shred of evidence advanced to evidence this minimum price floor allegation. The first and only time they have deigned to refer to any evidence is in paragraph 333 of their closings. That is obviously unsatisfactory for reasons I will make plain.

MR LOMAS: Was it not picked up by the witnesses on the basis that if the Pfizer price was 10, Flynn were not going to price at 8? I think that was picked up.

MR O'DONOGHUE: It was, sir, in a slightly accidental way, if I may say so. There are four pieces of evidence which have finally emerged in closings and I will deal with each and every one of those individually. I am not ducking this point. I will come to it but let me telegraph the point: where at 5328 you have an apparent distinction between no control over pricing but something called a minimum price floor which is not explained, I would in fairness have expected the words "minimum price floor" to appear somewhere in cross-examination and they did not. The point came up essentially accidentally and in a sort of shadow-boxing way.

I am going to tackle these head on, I am not running away from them, but a point I am going to make is the real case in paragraph 5.328 simply was not put in any

way that was direct or cognisant.

On the defence, again not a shred of evidence evidencing the so-called minimum price floor, and in fact at paragraph 59 of the defence the CMA says:

"Flynn had a sufficient margin to reduce its own prices in any event. It was not dependent on first agreeing a price reduction with Pfizer."

So not only no evidence, but on the face of it evidence going in the other direction.

If we can pick up the defence because I want to be very clear about this. This time it is at bundle A, tab 3, paragraph 234. It's internal page 80 of the defence. The CMA essentially makes three points there. 234 says:

"This is a false premise because the decision does not directly address whether Pfizer's price and the supply market of Flynn was unlawfully high ..."

And so on. Then it says:

"For the sake of completeness ..."

And there are two points. 235(a) is that Flynn would not set its prices below the price charged to it by Pfizer. That's Mr Lomas' point. And 235(b) is a point which was briefly referred to in openings, the circumvention point. So in terms of concrete evidence, beyond the rather general assertion in 235(a) there is

essentially nothing in the defence.

In openings, as I indicated, despite some promptings from me we did not get a response to the points that we had set out in detail addressing each and every point made by the CMA. This is paragraph 234 of our skeleton for trial. I made the point when I was on my feet, and I made the point when Mr Hoskins was on his feet, that we simply hadn't had an answer. And as I indicated in closing, for the very first time in paragraph 333 we got four pieces of evidence said to go to the minimum price floor point.

I am going to deal with these four pieces of evidence but I first want to deal with the evidence on our side which, in my submission, is overwhelming and shows that this minimum price floor allegation, and it is just an allegation, is completely unsustainable.

So the simple point is this: this is a situation in which the conditions in the downstream market were driving the supply price, and not the other way around. That is the simple point. The CMA of course says the opposite.

On the Pfizer side we rely on seven pieces of evidence to support our factual position. I will set these out very quickly and then I will deal with the CMA's four points said to go in the other direction.

The first one is in bundle G1, tab 16. This is the Flynn proposal from June 2010. It is about four slides in, headed "Phenytoin capsules: potential price as generic". It is the second indent:

"It is suggested that the price is pitched at half of the price for Phenytoin tablets ..."

And so on. So the point we get from this document is the idea on the Flynn side was to peg prices to tablets from the outset.

Then if I can ask the tribunal to turn up J1, tab 3.

THE CHAIRMAN: Are we coming back to G1?

MR O'DONOGHUE: Yes, I may have to come back to it briefly.

This is a state of play meeting with Flynn, and if I can ask the tribunal to turn to paragraph 26, which is on page 5, at the top of that page it says:

"Flynn said that the benchmark would be the tablets. Flynn saw this as reasonable as capsules cost more than tablets to produce. If the product was going to be introduced as a brand, then Flynn would look to set the price at ..."

A certain percentage less than the tablets:

"... and if it were to be generic, then it would look to set the price at ..."

A lower percentage than the tablets.

"In a responsive proposal from Flynn regarding a

one-off price increase above the permitted level, the Department explained it would need to go to its pricing committee but noted the DH would be concerned about setting a precedent for such a large increase outside the PPRS."

And so on.

And then a similar point at paragraph 53 on page 8:

"CB queried how Flynn had modelled the value when approaching negotiations. DW said Flynn began by looking at the market and estimated what 50 per cent of the revenues would give Flynn allowing for changes due to parallel imports et cetera. Then DW explained that Flynn ..."

And this is redacted, I do not know why, it is essentially the same point as I have read out at 26.

But again you see here very clearly that the benchmark for the price was the tablet.

The third piece of evidence on the same point is Mr Walters' cross-examination, and this is on Day 4, page 155. It starts at line 9:

"We benchmarked them against the tablet price and we had every reason to believe that the tablet price, every reason, was accepted by the DH as being fair. Everything available to us told us that the price had been set by the DH. Everything. The definition

of category end product says specifically that the Secretary of State determines the price based on information from the suppliers."

So again a clear recognition of the downstream tablet price driving the price rather than the supply price.

The fourth piece of evidence is from Pfizer, another state of play meeting at the CMA. This time it is J1, tab 5. Sir, there are two tabs, there is J5 and an A has been added, the A is the unredacted version, and it is paragraph 42. I think because it has been redacted I should not read it out. It is not clear why that is. But if I can ask the tribunal to turn to paragraph 42, and about two-thirds of the way down where it says:

"Pfizer took a view ..."

Can I ask you to read to the end there. (Pause)

So the overwhelming expectation on the Pfizer side was that the retail price, if I can call it that, would be pegged to the tablet.

Mr Poulton picks up on this in his evidence and I will quickly give you the references.

MR LOMAS: That last sentence, without reading out the numbers, says that "Pfizer took a range by reference to" the range that you can see there "and ended up with a supply price of" X.

MR O'DONOGHUE: Yes.

MR LOMAS: Does that not rather make the point that was being made, that the floor price was set at X because within the range you would not go the £5 or £6 per packet beneath that? In other words, the price that was agreed upon was actually in the middle of the range that was anticipated for the sale price.

MR O'DONOGHUE: Sir, in my submission that is consistent with what I have read out, which is the initial heads of terms looked at a 50/50 split.

I think the point I am trying to make here is that the reason the supply price was set at this particular level rather than, say, £5 was that there was a clear expectation that the capsule price would be pegged to the tablet, and therefore if the supply price was abnormally low, if I can call it that, it would simply be a windfall.

MR LOMAS: Yes. But we are looking at the other side, are we not? We are looking at whether the supply price is set sufficiently high that it excludes some of the pricing options that would be available to Flynn, and this paragraph seems to be suggesting that.

MR O'DONOGHUE: Sir, let me continue because there are a number of pieces of evidence. Mr Poulton picks up on I think this very point in his evidence. This is the

point about headroom. In his witness statement, and this is at paragraphs 69 and 70, the point he makes, this is in bundle B, I do not think we need turn it up. The point he makes is that:

"Pfizer pitches supply price some way below what it understood Flynn's price would be at in order to leave Flynn what he calls sufficient headroom to allow them to make a good commercial return. And crucially -- and this is important and may go some way to explaining what we have just seen in 42 -- he stated in very clear terms that Pfizer did not know the actual precise downstream price that Flynn would charge and did not discuss that end price with Flynn.

For the tribunal's record, in our notice of appeal at page 80 we set out a table showing the exact extent of the headroom between the supply price and the retail price. The tribunal can see the extent of the headroom there.

A fifth very important piece of evidence in my submission is Pfizer's internal financial modelling. We can pick this up in bundle G2. This time it is tab 108. Just to put this in context, this is the established products business unit within Pfizer which was the unit responsible for the capsules. This is an internal report dealing with various matters including the

Phenytoin. If I can pick this up at page 11, and it is about halfway down before the redactions:

"Key to note is the ongoing discussions between Flynn and the DoH on the pricing of the generic with a possible significant price cut a strong possibility. Pfizer would have to mirror this price cut to maintain the deal and required market volumes and this price cut was included in the budget for AP2 ..."

And so on.

So in my submission what one gets very, very clearly from this is that it was already factored into the budget that if the retail price reduced, that would have to be mirrored with an equivalent reduction on the supply side price. And in my submission that confirms very clearly that this is not a case where the supply price is driving the retail price, it actually seems to be the other way round.

A couple of final points, and I will not ask you to turn these up. I will quickly give you the references.

So the sixth point is that in Flynn's original heads of terms there was a suggestion that the market price would be split on a 50/50 basis with Pfizer. Ultimately we know that did not happen, but I do make the point that this form of revenue share based on the retail price was part of at least the initial discussions. We

know in the final agreement that the supply price is set on an arm's length basis, so it is somewhat different.

And the seventh point I wish to make -- well, there are two points really. First of all, in the exclusive supply agreement itself there is a contractual provision allowing for periodic and, as necessary, reductions in prices. One of the factors that would justify such a discussion and reduction is the net prices after deducting any rebates or trade related discounts at which comparable products are supplied by other suppliers in the open market.

We infer from that that Flynn was entitled to request a price reduction to reflect changes in the conditions of competition on the retail market, and we know that in late 2013, early 2014, when Flynn requested a price reduction it got a 20 per cent reduction in the supply price.

In my submission, what these seven pieces of evidence show very clearly is that the price was essentially built from the bottom up, not the other way round. The parties at all stages factored in the possibility that prices would change downstream and they would need to react, and in particular on the Pfizer side, in terms of changes to the supply price.

I do emphasise the fifth piece of evidence which is

contemporaneous internal modelling where actual budgetary reductions were factored in to the internal modelling. That, in my submission, is a highly significant piece of evidence in the real world.

PROFESSOR WATERSON: By "bottom up", you mean what?

MR O'DONOGHUE: The retail being the bottom. I appreciate it is --

PROFESSOR WATERSON: The downstream price.

MR O'DONOGHUE: The downstream. You are quite right, conventionally you would think it would be the other way round, so it is an unusual situation. So when I say bottom I actually mean from the retail back.

In terms of CMA's evidence, I have made the point that the three words "minimum price floor" were never uttered in this courtroom until I said them. This point was not put in any direct fashion to any witness. In my submission, what happened was basically forms of shadow boxing or things put in an oblique way in the hope that something might emerge that they could then say in closings, aha, there you go.

So at paragraph 333 of the closings they set out four pieces of evidence that in their view make good the case on the minimum price floor. The first I think is a point that Mr Lomas has adverted to and this was an answer given by Mr Poulton in cross-examination, so

it is Day 5, page 75. It starts:

"Is it fair to say that your negotiations with Flynn ..."

Sorry, I think it is Day 4. Forgive me. Day 4, page 75, line 21. At the bottom of the page Mr Hoskins says:

"Is it fair to say that your negotiations with Flynn proceeded on the assumption that both you and Flynn would be making a profit from your respective sales of Epanutin? Flynn wanted to make a profit, that is why you did the deal?

"Answer: Yes, we expected that both companies would make a profit, certainly."

In my submission, this rather oblique way of putting the case does not get CMA very far at all. In fact in my submission it is either neutral or helpful to my case.

The first point is a point I mentioned which is the supply price allowed Flynn a substantial degree of headroom. So in that literal sense there was headroom to make a profit so it really goes nowhere.

But the critical point is if Flynn wanted or needed to reduce the price, the exclusive supply agreement allowed for that to occur. And in fact, as we saw, that is what happened. So in my submission, what one gets

from this is something prosaic which is a supplier expects a customer to make a profit, and this does not tell you anything about the dynamics of the supply chain in terms of whether it is the retail price driving the supply price or vice versa. It simply does not bear, certainly in any direct sense, on that issue.

We even had a very bizarre line of cross-examination from Mr Hoskins that, oh well -- this was to Mr Walters, that Flynn could have got by on 1, 2, 3, 4, 5 per cent ROS. That is a hopeless point for other reasons. But I want to make the point that the tenor of the cross-examination by the CMA on a different issue was that there was headroom. So in my submission, this point of Mr Poulton does not really go anywhere.

The second point relied on by the CMA at paragraph 333 is evidence from Mr Williams, again in cross-examination. I will give you the reference, I do not think we need to turn it up. So Mr Williams said:

"The price that Flynn pays to Pfizer does inevitably impact on the price that Flynn is able to profitably sell the product to the NHS."

This is Day 6, page 32, line 25 and page 33, starting at line 2.

Again, this piece of evidence in my submission does not take the CMA very far at all. If one looks at the

context of the discussion, it was about the allocation of common costs. It is surprising that the CMA sees fit to rely on this because of course Mr Williams is a chartered accountant giving expert evidence on the operation of the PPRS. To extract or excavate from his expert evidence a factual point about the internal workings of the Pfizer/Flynn deal, to which he was not frankly privy, is in my submission quite bizarre.

Again he is talking about, in my submission, something quite different. He is not talking about the dynamics as to whether there was a retail price driving the supply prices or vice versa, he is making a more general point which is if you have an input cost, all else equal if you do not cover it, you will lose money, and therefore you would probably not agree to a supply price that was axiomatically going to lose you money. But that does not bear on the more important point as to what is driving the supply price.

The third piece of evidence was the cross-examination of Mr Walters, and again I will give you the reference, I do not think we need to turn it up. Day 4, page 195, lines 5 to 17. Mr Hoskins asked him, and I am quoting.

"Question: If Flynn had not been able to sell the product at a price higher than the price you paid to

Pfizer what would you have done?

"Answer: We would never have gone into an arrangement with them we did make a provision in the original supply agreement in case that actually happened.

"Question: Do you want to explain that further?

"Answer: I believe there was a provision to return the product to Pfizer in the event that the pricing -- because they were concerned, as was talked about earlier, as to whether the DH would simply force the price down to a point where it would not be viable for us."

Again, in my submission that evidence really does not bear in any direct sense on the minimum price floor point and, in my submission, it is something neutral or perhaps supportive of our case. The point which we have seen from the Pfizer evidence is that Flynn was not constrained by the Pfizer supply price. As we have seen from the internal modelling, if it was the case the Department of Health forced the retail price down the first resort of Flynn would be to seek a reduction in the supply price. So again retail driving wholesale, not the other way round.

The final point the CMA relies on is another strange one. This time it was Mr Fakes' witness statement, and

this was a witness statement given in the context of the interim measures application which the chairman will remember very well, I am sure.

If one looks at the CMA's reference, it goes to a heading which is headed "The Escrow Account". And the chairman will remember this, there was a particular issue in the context of interim measures where Pfizer had suggested something akin to an escrow arrangement in respect of a reduction in the Flynn price, and for reasons that do not concern us now that ultimately --

THE CHAIRMAN: It was actually in the Pfizer price, no reduction in the Flynn price. So the difference was going to be paid into an escrow account.

MR O'DONOGHUE: Indeed. And for various reasons that was not relevant.

So to take an extract from this interim measures statement dealing with the escrow account as speaking in any direct or useful sense to the minimum price floor in my submission does not bear scrutiny. So in my submission when one looks at the weight of evidence, the seven pieces of evidence I have shown you on the Pfizer side and the four pieces of evidence on the CMA side, there is no doubt, in my submission, as to what the true position is. This is a case where the parties had determined the supply price essentially as a function of

the retail price, and if the retail price was reduced then the supply price would in one way or another be reduced correspondingly. So it is a situation where the retail is driving the wholesale and not the other way round. Therefore, on the evidence there simply is no minimum price floor. It does not exist.

I want to pick up on a couple of points which I think I have already shown you Mr Hoskins picked up on in opening.

THE CHAIRMAN: Before you do, can you help us to decide where this might go. Are you saying that in circumstances where you are otherwise dominant, I know you disagree with that but let us assume you are, and your customer is an independent company that buys product from you and sells it in a dominant position to consumers and abuses its dominant position, and you are charging them a price which is a proportion of the final price that they have arrived at through one means or another, you are simply not abusing your dominant position, is that where this takes us? Or is it something less than that?

MR O'DONOGHUE: It is something less than that.

THE CHAIRMAN: Would you share it with us because it is not clear at the moment.

MR O'DONOGHUE: Sir, I am very happy to. There are

a number of general principles which I think are important to articulate in the context of this point. The first general principle is that Article 102 protects consumers rather than competitors.

THE CHAIRMAN: That was not always so but it is nice to hear it. Keep going.

MR O'DONOGHUE: I think certainly following Intel it is quite clearly so, but it is correct it was not always so.

What one gets very clearly from that is that if the only issue is the transfer of resources between two suppliers, that without more is not a violation of Article 102, because in crude terms whether producer A or producer B gets a bigger or smaller part of the cake, that is not a valid concern under Article 102.

THE CHAIRMAN: Are you saying the upstream company does not hold a dominant position then?

MR O'DONOGHUE: It may or may not. My point, which you get very clearly from Attheraces, is that the allocation of resources between a dominant supplier and its customer who is not a consumer is not, without more, a valid concern on under 102. So that is the first general point.

The second general point which we get from Attheraces paragraph 215, and also from the Latvian

Copyright case at paragraph 63 of the Advocate General's opinion which we saw this morning, is that it is in general lawful for a dominant firm to set its supply price as a function of the conditions of competition faced by its customer on the downstream market. So in the case of the Latvian (inaudible), they are at least as a general matter entitled to set their --

THE CHAIRMAN: I see that. But it is all a bit circular, is it not? If you take the contrary assumption, which is that the downstream or towards the bottom company is not operating in competitive conditions but is somehow shielded from competition, then where does your argument take you then?

MR O'DONOGHUE: That is why the minimum price floor finding, if I can call it that, is crucially important. Because if it is the case as I have submitted on the evidence that Pfizer's supply price does not set a minimum price floor in the downstream market, then the pricing you observe in the downstream market, even if it is uncompetitive, is not caused by the supply price, it is caused by the conditions which set the price in the downstream market. So that really is a point of causation.

THE CHAIRMAN: So it leaves poor old Flynn on the hook and you off the hook. Is that what you are saying?

MR O'DONOGHUE: It may do, it may do.

THE CHAIRMAN: But assuming we accept all these other parts of the argument.

MR O'DONOGHUE: There is a factual component and there is a legal component.

THE CHAIRMAN: Are you aware of this argument ever being advanced before in any other case?

MR O'DONOGHUE: In a sense, sir, I think the outcome of Attheraces is fairly on my side. Why do we not turn to --

THE CHAIRMAN: Before we do, this is an interesting discussion so let us pursue it. If you can clarify our thinking it may be very useful. It may not on the other hand.

Am I right that the Hoffmann-La Roche case many years ago, and after all we are looking at United Brands which was many years ago, also started out as an Article 85 and 86 combined case?

MR O'DONOGHUE: I think there were a mixture of both 101 and 102 issues in this case.

THE CHAIRMAN: As the articles were, yes. So these major pharmaceutical companies were buying vitamins from Hoffmann-La Roche, and Hoffmann-La Roche was being accused of abusing its dominant position in relation to its supply to them. Are you aware of anything like this

argument being advanced at that time?

MR O'DONOGHUE: Until Attheraces, I do not think this point has been raised squarely in any judgment that I am aware of.

THE CHAIRMAN: The point against you in Attheraces is that the downstream market conditions are competitive so you cannot draw any comfort from it for this case, I think.

MR O'DONOGHUE: If we can quickly look at that. In my submission, that is a misreading of paragraph 215. It is in bundle B --

MR LOMAS: Are you going to come on to circumvention as well?

MR O'DONOGHUE: Yes, I will. The two points I want to deal with before moving on to fines are the circumvention and the competitive market point.

THE CHAIRMAN: Tab 4.

MR O'DONOGHUE: Court of Appeal, tab 4.

The CMA's competitive market point comes from paragraph 214 of the Court of Appeal's judgment. As you will see from that paragraph, that paragraph is actually dealing with a different point which is externalities. They say:

"The expert witness has agreed economic theory recognises the relevant externalities to price. The judge rejected BHB's argument that the benefit of the

system to overseas bookmakers was a relevant externality, but it was incontestable that the overseas bookmakers were paying ATR in a competitive market amounts which afforded a handsome profit which it wanted so far as possible to keep, and the facts found by the judge do not suggest that anybody is going to go out of business as a result of the alleged abuse. And despite its elaborate legal economic arguments and the high levels of moral indignation, this case is about who is going to get their hands on ATR's revenues from overseas bookmakers ..."

And so on. So the first point I wish to note is that -- so the CMA has excavated the word "competitive market" from this paragraph and says, well, there you go, there is a general principle that when the market is competitive, the argument being run by Pfizer is invalidated. It is simply impossible, reading this paragraph dealing with externalities, to read it in that way.

I am going to show you very clearly why that is because what the CMA seems to have forgotten is the Court of Appeal goes on at 215, and they say:

"... there is moral force in ATR's position. It adds value [and so on], it is taking risks [and so on]. This may be thought to be unfair but it cannot alone

make it an abuse of BHB's dominant position. As Advocate General Jacobs said in Bronner, the principal object of Article 82 is the protection of consumers, in this case the punters, not of business competitors, and in our judgment this is correct. Even if it is the competitors not the consumers who are alleging the abuse of dominance, we need to look beyond ATR's immediate interest in the market served by ATR and there is little, if any, evidence that competition in the market has been distorted by the demands made by BHB upon ATR."

The critical point is 216 and 217. 216, in my submission, is addressing something more closely analogous to this case:

"Mr Hollander's response to a hypothetical case put by the court - a monopoly wholesale supplier of a delicacy to a supermarket who charges to his supermarket his cost plus a moderate margin but finds that the supermarket is marking up his product by 500 per cent - was that the supplier would be abusing his dominant position if he raised his price to more than he could get in a competitive market, if there was one, however much the supermarket was charging the public for it. Mr Roth's answer was that the supermarket had established the economic value of the product and was there nothing to stop the producer securing as much as he was able to.

The consumer might well need protection, albeit from the supermarket rather than the producer, but if neither solution is going to provide it, the central purpose of Article 82 would not be accomplished and courts would not be justified in intervening. The control on the monopoly producer [here the supplier] would be the wholesale price: if he raised the price too high he would lose his business."

In my submission, far from paragraph 214 supporting what the CMA says, if one reads on to 216 and 217 the Court of Appeal clearly confirms that the supply price in such a situation is not a valid concern under Article 102.

MR LOMAS: But this market is rather different, is it not, because in this case continuity of supply means the consumer has to buy this particular delicacy. So you have a linear relationship which would not have applied in the example that Mr Roth or Mr Hollander was taking there.

MR O'DONOGHUE: First of all we say that as a matter of fact that --

MR LOMAS: I know you dispute that. But the assumption, looking at this point, if you win on that then this may be a somewhat nugatory argument. But assuming you have lost on that, this example is in slightly different

circumstances, isn't it?

MR O'DONOGHUE: Sir, in my submission, no, because if one looks at the exclusive supply agreement, and one sees this from the actual price reductions in the internal modelling, the way this operated was that if there was a need for a change in the retail price, that would inevitably be factored back to the supply price. So there were mechanisms by which the competitive conditions in Flynn's market would be effectively blown back to the supply price. So it was always the downstream market driving the supply price rather than the other way round.

THE CHAIRMAN: Your argument is that the downstream price is set by reference to the price of tablets, that is nothing to do with abuse of dominant position, and what price you choose for your supplies to Flynn does not really matter because the economic value, as you put it, has been fixed at the downstream level by the downstream operator.

MR O'DONOGHUE: And to that extent the consumer is protected.

THE CHAIRMAN: I think you had better get on to circumvention.

MR O'DONOGHUE: I had better get on to circumvention.

THE CHAIRMAN: The point against you is that this enables

you to drive a coach and horses through the application of Article 102, yes?

MR O'DONOGHUE: Sir, that is said. There are a number of responses to that. The first is there is no circumvention in this case. There was an Article 102 case which was available to the CMA and which was not pursued.

THE CHAIRMAN: 101.

MR O'DONOGHUE: 101 case which was available to the CMA. And I do reiterate the point that it is not good enough for the CMA to recycle the 101 case they failed to make on the agreement through the back door of 102. If the evidence was lacking in the context of 101, then the evidence cannot in my submission be good enough to make a case under 102.

To that extent it is the point I started off with. If there is circumvention here it is by the CMA and not by Pfizer or companies in the position of Pfizer.

MR LOMAS: That is a sidestep, is it not? You still have to deal with the frontal allegation that by interposing a party, if you are right in your theory, the supplier avoids an abuse of dominance position.

MR O'DONOGHUE: I do. The simple answer to that question is that if the consumer is protected in the downstream market by a lawful price, cost plus 6 per cent, then

there is no reason under 102 to interfere with the supply price charged by the supplier. Because if the consumer is protected by cost plus 6 or whatever is determined to be the lawful price in the downstream market, there is no reason to interfere upstream in the bargain struck between Pfizer and Flynn. And that comes back to my point that if you do that in a situation where consumers are protected. That is protecting competitors for no good reason.

THE CHAIRMAN: At what level of trade is Pfizer's dominant position, if it has one?

MR O'DONOGHUE: It is effectively as a wholesale supplier in this context.

THE CHAIRMAN: So you would put it similar to the wholesaler in Mr Hollander's example.

MR O'DONOGHUE: Yes.

THE CHAIRMAN: So Pfizer does not interface directly with consumers, retail customers, commissioning groups, it just supplies --

MR O'DONOGHUE: It also comes back to the circumvention case that the CMA initially pondered but rejected. Because you will remember one of the three suspected infringements was an attempt to circumvent the PPRS. And that was a case which they considered and which they seemed to think was open to them and, in my submission,

having dropped 101 and having dropped their circumvention case, it is not open to them under 102 to resurrect the same case through the successive abuse construct.

MR LOMAS: Can I just take what I think you said a moment ago a little further. I think what you are saying was if Flynn had held its prices to cost plus 6 per cent and had met the CMA test, then what? They could price up to tablets -- or, rather, Pfizer could increase its supply price to just Flynn cost plus 6 per cent and scoop the whole of that benefit?

I think legally what you are saying is even if that net price in the market bore no relationship to economic value, because the direct supplier, Flynn, was only supplying at cost plus 6 per cent Pfizer would be protected.

MR O'DONOGHUE: Yes, that is the logic of my argument.

MR LOMAS: It's quite a strong proposition.

MR O'DONOGHUE: One needs to deconstruct it. Because if the consumer is protected through a lawful price of cost plus 6, and if Flynn is profitable at cost plus 6, then there is absolutely no reason under 102 why the cutting of that cake between Pfizer and Flynn has anything to do with the protection of consumers.

THE CHAIRMAN: Would there not be a risk of discontinuance?

MR O'DONOGHUE: Sorry, sir?
THE CHAIRMAN: If the deal was not attractive to Flynn, presumably they would --
MR O'DONOGHUE: Indeed. The point in Attheraces is there is a market out there for companies like Flynn who will partner with you in terms of genericisation and fostering, and if your supply prices are unattractive the market discipline is that you will struggle to find partners to partner with you.
THE CHAIRMAN: So you are asking us to leave aside considerations of whether Pfizer wished to discontinue or to continue supplying the product to the UK market.
MR O'DONOGHUE: I am going to come on to that in the context of fines.
THE CHAIRMAN: I mean in this context. You're asking us to put it on one side?
MR O'DONOGHUE: Yes, for these purposes, yes. In any event, my core submission is that on the factual evidence as heard by the tribunal this minimum price floor point has not been made out by the CMA.
MR LOMAS: I understand that. But can I come back to the question I was asking, because the assumption behind that is that the Flynn output price bears no sensible relationship to economic value, otherwise presumably we have a different set of issues to deal with. If you

accept that assumption, so you would have something that was prima facie United Brands infringing because the price bore no relationship to economic value, I think what you are saying is if Flynn's own position is they take your input price, add their other costs, add on 6 per cent so they meet the CMA test, Pfizer's position is entirely protected.

MR O'DONOGHUE: Everyone is protected. The consumer is protected by a lawful price of cost plus 6, Flynn is profitable at 6, and if those two conditions are met there is no reason under 102 why the divvying up of the supply price or that cake between Pfizer and Flynn is a competition law issue, it is simply a transfer of resources between two producers, because everyone further down the chain is protected.

MR LOMAS: Even though you have a price in the market that bears no relationship to economic value?

MR O'DONOGHUE: Yes, because the general principle which I adverted to, which we get from Attheraces and Latvian Copyright, is that it is lawful for the supplier to take into account the revenues achieved by the customer in its market. So again if the consumer is protected by a lawful Flynn price, and Flynn is making a living margin, there is no reason under competition law why the cutting of that cake has anything to do with 102. If

one takes that view when there are protections down the chain, one is protecting competitors for no good reason and that is expressly contrary to Attheraces.

THE CHAIRMAN: Have you dealt with circumvention or not?

MR O'DONOGHUE: That is all I wanted to say on circumvention.

PROFESSOR WATERSON: When you say Flynn charges cost plus 6 per cent, those costs are themselves determined by the price that Pfizer charges to Flynn. So if Pfizer chose to charge an extremely high price to Flynn, then a price, say, which was already in excess of the tablet price, then what would be the position? Because clearly the capsules would then be substantially higher in price than the tablets, so how would that protect the consumer?

MR O'DONOGHUE: I entirely accept that the CMA's decision establishes the lawful price in the downstream market, which is taking Flynn's costs as a given and adding cost plus 6. So that is my benchmark for a lawful, compliant Article 102 price. Therefore I must accept that if the price on the retail market is above that level, there is an issue and the argument collapses. But as long as the retail price is at or below that level, in my submission what we get from Attheraces is that a supply price which allows Flynn to essentially remain whole is it

a prima facie lawful price because otherwise one is protecting competitors for no good reason. That is the logic of the argument.

So in a sense there is no circumvention because the only people who need protecting under 102, the end consumers and Flynn in terms of living profit, are protected. And once those objectives are achieved or acquitted there is no basis on which to interfere with the supply price.

MR LOMAS: I am sorry, I do not want to take up time but it is a critical part of your argument. How is the consumer protected or the NHS budget protected if, on this assumption, the market price, the ex-Flynn price, is materially above economic value?

MR O'DONOGHUE: In my submission it is not. Because the retail price in Flynn's market, if it is at or below cost plus 6, that is something which is lawful, and any sub-component of that which can be garnered by Pfizer is a prima facie lawful price.

I entirely accept if the price goes above cost plus 6, that would be an unlawful price in the downstream market and Pfizer cannot justify its supply price on that basis. But once Flynn stays within cost plus 6, that is on the logic of the CMA's decision a lawful price. Because the way the CMA has calculated

Flynn's excess is to take its costs including Pfizer's supply price as a given, add the 6 per cent ROS, and that is the lawful price.

THE CHAIRMAN: We understand what you are saying. Thank you.

MR HOSKINS: Can I raise a timing point. I do not mean any disrespect, but I obviously have to prepare for Thursday and I am not dealing with fines. I mean no disrespect but I am going to leave now if you will let me.

THE CHAIRMAN: Mr Hoskins, of course you may leave.

MR HOSKINS: I am obliged.

THE CHAIRMAN: Please continue.

MR O'DONOGHUE: Let me move on to fines. But I think the essential difference between us is a factual point about whether the supply price is truly driving the retail price. And in my submission, the core factual point in this case is that Pfizer's price was not, because the retail price was being set essentially as a function of tablet and other conditions of pricing in the downstream market. That is the essential point. Once that is understood, in fact the supply price is not driving anything, it would be set at the level of tablets come what may.

THE CHAIRMAN: We understand the argument. Thank you.

MR O'DONOGHUE: Let me move on very quickly to fines.

I have five points make. The first point: we set out in our closings six points to do with general legal contexts, that is at paragraphs 257 and 265. The only point I wish to add here is it is fair to say in the written pleadings and in the oral openings that the CMA's position on the legal principles under unfair pricing has been somewhat shifted.

We were told, for example, in openings there was a genuinely free-standing alternative available to the CMA outside of United Brands. We were told that was within the decision. We then learned in this note from the CMA that that is not the position and we have a somewhat different set of legal principles now set out in the closings which Mr Brealey dealt with.

The only point I want to make here by way of general legal context is that the changes and, in my submission, contortions on the legal test from fair pricing, they do have a varying in terms of foreseeability and culpability for Pfizer and Flynn as to whether this was an infringement that they could reasonably have foreseen. That is the point on general legal context.

The second point I wish to make is the analogy with cartels and a point made by Mr Bailey in relation to the Intel judgment. The CMA's position as set out in the decision of paragraph 7.70 is that unfair pricing is

worse than a cartel. They say, and I quote:

"The prices resulting from unfair pricing can, and the CMA considers are likely to, be considerably higher and more certain than those which might ordinarily be achieved through many forms of exclusionary conduct or the cartelisation of a market."

So we were very surprised on this side of the room when Mr Bailey said in his openings that this sort of comparison is simply uninformative. It was their comparison, not our comparison.

The bottom line, which is the point I made in opening, is that in the real world it is simply absurd to suggest that unfair pricing is as bad if not worse than a cartel. That is entirely lacking in realism and common sense. Apart from anything, if one thinks about the type 1 errors in the context of unfair pricing, and compares those to the type 1 errors that arise in the context of cartels, they simply bear no comparison. To suggest that these are the same or worse is, in my submission, untenable.

In Intel Mr Bailey made the point, well, the general court's judgment was overturned on substance but not on fines, and therefore when the general court said that you cannot compare a cartel with an abuse of dominance that is something the tribunal should rely on.

In my submission, if one analyses Intel on a basic level that is simply unsustainable because the whole point of the Court of Justice judgment in Intel was that it was wrong of the general court to treat the rebates as an object, the correct analysis was an effects analysis.

We will have to see what happens with the remittal, but if the analysis has shifted from object to effects, it seems to me virtually impossible to imagine that the treatment of fines in the context of a pure effects analysis would be identical to an object. So that point is either neutral or actually positively unhelpful for the CMA.

The third point I wish to make is on the facts. I was very clear in openings that the CMA's case was put very much in terms of superintent. We have the highest ever individual fine, we have the highest ever multiplier for deterrence, we have the maximum 30 per cent gravity multiplier; a whole series of unprecedented figures and, in my submission, that sort of extremity can only be justified by something akin to superintent.

At least until cross-examination that seemed to be CMA's case as well. For example, at 5.434 of the decision, the CMA says that the language Mr Poulton used

"fleecing the NHS" is consistent with the belief that the NHS would have been overcharged. They say it is consistent with them believing that a price increase on the scale that was implemented in September 2012 was not fair.

So the two central pillars of the CMA's intent case were the allegation of fleecing the NHS and the supernormal profits and, in my submission, when it came to cross-examination, the CMA's case was a dog that barked but did not bite. Because the case of intent or deliberate intent in respect of these two key pieces of the CMA's case, these were the two pieces of evidence recited at length in all of their pleadings, a case on intent in respect of those two pieces of evidence was simply never put in cross-examination.

I will give you the references. So in respect of "fleecing", Mr Hoskins, he did not put to Mr Poulton that Pfizer intended to fleece the NHS, what he said, and I quote, and this is Day 4, page 60, lines 5 to 7:

"So you were anticipating what the criticism would be. You knew that Pfizer would be, rightly or wrongly, criticised for fleecing the NHS, did you not?"

In my submission, the addition of the words "rightly or wrongly" really takes the wind out of it being an intent case. Our position was always that this was

a reference to the perception of third parties, and Mr Hoskins seems to concede in using the words "rightly or wrongly" that that may be a misplaced perception. So the superintent case in respect of this email was never put.

Equally in respect of the supernormal profits allegation, no allegation of mala fides was put in cross-examination and at one stage Mr Hoskins suggested to Mr Poulton that what Pfizer had done was bring about "a nice little earner", and we make the simple point in closings that, if you are going to justify the highest ever fine in competition law in the UK, "a nice little earner" simply will not do.

So in my submission, on these core intent allegations and CMA's case on fines, they were simply never put to the witnesses in the way they had been articulated for the last 18 months, and that does, in my submission, have a bearing on fines.

A couple of other factual points and then I can wrap up pretty quickly. The tablet, in my submission, is a critical factor in the context of fines as well. Because, even if the tribunal decides as a technical matter in terms of comparators that the tablet as a matter of substance, for whatever reason, is not sufficient, that does mean in the context of fines that

the tablet ceases to be of any relevance. Because, in my submission, what one gets overwhelmingly from the evidence and from the cross-examination is that the parties genuinely believed at the time, because this was the available market intelligence, that the tablet was the benchmark.

I have shown you the cross-examination evidence of Mr Walters. He said everything pointed to the tablet, and Mr Poulton said exactly the same thing. Let me just quickly give the references. It is Day 4, page 31:

"That was the benchmark we had all through the project as the value to the Department of Health."

And a similar statement at Day 4, page 37, and I quote:

"So the prime reason was our interpretation of what had happened in the market. We couldn't think of any other credible reason why Teva would treble their price and then, within a month or two, bring it back down to the price it was at before without the Department of Health intervening. And that was clearly also the opinion of both Tor and Flynn. So as I say, that was confirmation of our conclusions."

Mr Brealey mentioned in opening that NRIM, who do not have any skin in the game, reached exactly the same conclusion; that the tablet was the benchmark. So when

one looks at the contemporaneous evidence as it was tested in cross-examination, in my submission it is clear based on the market intelligence that the parties genuinely benchmarked the prices to the tablets. Again, it may turn out that, as a technical matter under 102, it is not a sufficient defence on the substance but, when it comes to fines, in my submission it is highly relevant.

One final point on the factual evidence as it came out in cross-examination, this is the discontinuance point, so in the decision again it was put very, very high in terms of Pfizer's intentions at 5318 the CMA said:

"There is no evidence to support the proposition that Pfizer ever seriously considered discontinuing the product."

Then in cross-examination Mr Poulton, this is Day 4, page 26, said:

"So that was at the point ..."

This is in 2010:

"... where I believe there was an extremely serious threat that Epanutin in Europe would be discontinued."

Then at Day 4, pages 51 and 52:

"I do not believe it would have been discontinued in 2012. I believe it would have been discontinued as part

of the implementation project that I referred to earlier and I am convinced and remain convinced that, if we had not entered into the deal with Flynn, it would no longer be on the market in the UK now. It would have been discontinued by now."

That evidence was never seriously challenged by Mr Hoskins. Again, in my submission, that is relevant when one comes to calibrating seriousness and intent because there is no doubt, as the evidence has emerged, that discontinuance was a real issue.

Two final points, one on deterrence and one on market interventions. On deterrence I think the tribunal essentially has the point from openings. So we had a £67 million, 400 per cent deterrence uplift, entirely unprecedented, and the question is who or what is being deterred? We simply do not understand the CMA's position on this. Because if one thinks of the regulatory scheme, so for branded products in the UK we have the PPRS, for generics it is now common ground that, with the new primary legislation in 2017, the so-called gap, which we say never existed anyway, has been plugged and, for your reference, that is decision 3158. Similar regulations exist in other EU Member States and, of course outside the EU, there is either regulation or, in some countries, there is no

offence of unfair pricing. So when one asks oneself, and looks at the regulatory regime in this country and other European countries, what is being deterred, it is very, very difficult in my submission to see any gap for which deterrence would be required.

The CMA comes back to this closings at 402 and they say, well, we were trying specifically to deter Pfizer from infringing competition law in the UK. You have my point that there was nothing left to deter but, even in terms of Pfizer, it is a bizarre argument because of recidivism, Pfizer would be far more disincentivised to re-offend than any new offender. So it simply does not work on any level.

The CMA also contradict themselves because they say at 388 of the closings there was also a need for general deterrence of dominant undertakings imposing unfair prices if they are unavoidable trading partners for captive customers. But again, if one looks at the regulatory regime, where is the gap?

A very important aspect of deterrence of course is over-deterrence, and one of the fundamental criticisms of the 400 per cent uplift and £67 million is that the CMA has had no regard as to whether that level of deterrence in terms of uplift and absolute amounts will lead to over-deterrence and, therefore, to type 1 errors

in other contexts. Because one cannot in the same breath talk about general deterrence and specific deterrence without also considering the question of type 1 errors for general deterrence, and the CMA has simply not addressed its mind to this question in any shape or form.

One final point, and it is something that Mr Brealey touched on. We make the point in closings that, on the CMA's version of events in relation to the MHRA guidance, there was an intervention by the state that had an impact on the market. On the CMA's case, they say it led to a reduction in switching. We disagree with that on the facts. That is something the tribunal will have to determine. But, on any view, if the state in the form of guidance has intervened, with good reason they would say, to reduce the possibility and scope for switching, it is relevant in the context of fines to ask yourself whether the blame for that effectively anti-competitive intervention is something which should be laid fairly and squarely at Pfizer's door.

This actually links into the point that Mr Brealey mentioned, which is one of the oddities in this case is that you have a very competitive market in which NRIM is capturing a significant share in a short period. You have Pfizer and Flynn setting their prices during that

period. There is then the intervention in period 2 of the guidance and, not only do Pfizer not do anything to take advantage of the state's anti-competitive intervention in effect, but they actually reduce their prices. So the case certainly during period 2 and also under period 1 for criticism in the context of fining of Pfizer's actual conduct, it does seem very odd. Because the state has intervened in a way that seems to have been anti-competitive and Pfizer has done nothing to exploit or take advantage of this position. In fact, all of its actions were the opposite in terms of the 20 per cent price reduction.

One final point. The intervention by the MHRA was undoubtedly adverse, and you will have seen from the documents that NRIM had developed a new generic product other than Phenytoin sodium capsules and, because of the guidance, it had to shelf the development of that product. So that is a very vivid example of the adverse effects brought about by this guidance and, in my submission, that is something in the context of fines the tribunal can and should wish to bear in mind.

That is all I wish to say about fines, unless you have further questions.

THE CHAIRMAN: Do you think we are obliged to take account of the CMA's guidance on penalties or should we step

back and look at the situation in the round?

MR O'DONOGHUE: Sir, we dealt with this in closings. Why do we not have a quick look at it. Essentially, sir, the point is you have a free hand. We pick this up at the back end of our submissions at 255.

THE CHAIRMAN: You quote the Napp --

MR O'DONOGHUE: The point is very familiar. You have full jurisdiction. You are not bound by the guidance. But logically, if you have full jurisdiction, that must include the jurisdiction, if you wish, to go down the route of the fining guidance.

THE CHAIRMAN: So you would encourage us to look at the guidance and apply it better, in your view, but also to step back and take --

MR O'DONOGHUE: In my submission, any way you look at this fine, it cannot be justified. You can do this one of two ways: you can look at the 30 per cent gravity multiplier, you can look at the 400 per cent deterrence multiplier, you can look at the mitigation factors I mention and do this line-by-line analysis. But the big question in the context of fines is whether £67 million just for deterrence of Pfizer is justified. It is unprecedented on every level and, in my submission, would require overwhelming justification and, based on the case as put in cross-examination, the

gravity of case required to justify that sort of outcome has never been put. They have pulled back from putting the case they would need to put to justify that level of seriousness and deterrence. It simply never transpired. It was telegraphed in openings, but it was never put. They have skirted around the emails they rely on and what we have is "a nice little earner" and "rightly or wrongly" and, with respect, that cannot possibly justify a fine of £84.2 million.

THE CHAIRMAN: Thank you, Mr O'Donoghue. Tomorrow?

MS BACON: It is me tomorrow. I will need the whole day.

THE CHAIRMAN: You can have the whole day.

MS BACON: Just one point, in case you were reading our closing submissions overnight, there are a couple of incorrect references and I thought it might be best to give those to you now. Four actually. They are all in footnotes. At footnote 71, the reference is to Day 4. That is right, but the page numbers are wrong. It should be page 136, line 22 to page 137, line 12. The next one is footnote 86. The second reference is to paragraph 80 of our skeleton argument. It should be 80 to 81 and it is actually 81 which is the main paragraph from which the proposition in the main text is drawn. It is a small point. The third reference is in footnote 279. It refers to Day 6, it should be Day 8.

That was Mr Harman. The fourth is in footnote 300, the reference to Scandlines, it refers to paragraph 169, it should be 179.

THE CHAIRMAN: Well, if we had not been going to read them overnight, we certainly shall now.

MS BACON: I am just showing you that I mark my own homework. Tomorrow I will mark Mr Hoskins'.

THE CHAIRMAN: 10.30 am tomorrow.

(4.45 pm)

(The hearing adjourned until 10.30 am on Wednesday, 22 November 2017)

INDEX

1

2