IN THE COMPETITION APPEAL TRIBUNAL

Case No: 1524-1525/1/12/22

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Monday 6th November – Wednesday 13th December 2023

Before:

The Honourable Mr Justice Marcus Smith
Eamonn Doran
Professor Michael Waterson

(Sitting as a Tribunal in England and Wales)

BETWEEN:

Appellants

Pfizer Inc. and Pfizer Limited & Flynn Pharma Limited and Flynn Pharma (Holdings) Limited

V

Respondent

Competition & Markets Authority

A P P E A R AN C E S

Mark Brealey KC, Robert O'Donoghue KC & Tim Johnston (Instructed by Clifford Chance LLP) on behalf of Pfizer

Jemima Stratford KC, Tom Pascoe & Alastair Richardson (Instructed by Macfarlanes LLP) on behalf of Flynn

Josh Holmes KC, David Bailey, Jennifer MacLeod, Julianne Kerr Morrison & Conor McCarthy
On Behalf of the Competition & Markets Authority

Monday, 11 December 2023

(10.02 am)

Closing submissions by MR BREALEY

THE PRESIDENT: Mr Brealey, good morning.

MR BREALEY: Good morning.

Sir, the parties have allocated the time, I believe. I am going to kick off. Mr Johnston is going to follow me on the medical, then Mr O'Donoghue. Ms Stratford wants us to finish around about 2.30 or 3.00, so we have that in mind, but that is the way we are going to play it, so Ms Stratford will be on some time this afternoon, maybe about 2.30, 3.00.

Obviously we have put very detailed written submissions in.

THE PRESIDENT: Yes, thank you. We have read them all I think probably a couple of times. So we are very grateful to the parties for the very considerable work they put in and we have been considerably assisted by those.

MR BREALEY: Thank you. On that basis, I will not read it out then.

What I would like to do, though, is deal with three matters. I'd like to address the Tribunal on three matters.

First, I wish to address the Tribunal on the law,

and I appreciate the Tribunal is well acquainted with the law, but I feel I must set out certain principles because they constitute the critical legal framework, and in our submission, with the greatest of respect, the CMA has not applied the correct legal framework yet again, so it is important to see that.

Second, I wish to address the CMA's focus on the supply side evidence, and I want to show how the Pfizer cost plus factors have been skewed to achieve a low price, and I also want to show how the CMA applies more favourable evidential standards to limb 1 than to limb 2, and that is something that we do see from the CMA's closing.

So the second point is essentially the supply side evidence, and lastly, I would like to explain economic value. I want to highlight certain evidence concerning the demand side factors. I will not, obviously, have time to go through the whole of the demand side factors, but I will explain or try and deal with the Tribunal's ceiling, its floor and I would like to add a roof. So that is the three matters. Essentially we kick off with the law, supply side and how the CMA applies more favourable evidential standards to limb 1 than to limb 2 and then economic value, the ceiling, floor and roof.

So going to the law, on the law, I want to draw

attention to four key issues, four key issues.

First, the relevance of the workable competition and cost plus, so first the relevance of workable competition and cost plus.

Second, the relevance of workable competition and comparators, so that is workable competition and comparators.

Third, the relevance of demand side factors and economic value, so third the relevance of demand side factors and economic value.

And fourth the relevance of willingness-to-pay, willingness-to-pay, and economic value.

So just to recap: workable competition and cost plus; workable competition and comparators; demand side factors and economic value; and willingness-to-pay and economic value. They are the four areas of law I would like to cover.

Going first to the first area, the first, we call it legal principle, workable competition and cost plus, and we start -- I hope we have the right reference because they came in over the weekend -- with the CMA's closing at annex 3, and can we go to {XL/9}, please, and every time we do that, can we blow it up a little bit.

This is the annex 3 to the CMA's closing on fairness, and if we go to page {XL/9/2} paragraph 4.1

here we see the CMA saying:

"At a conceptual level, Ms Webster and Mr Harman made three key points about the conditions of [normal and sufficiently effective competition] or workable competition."

I will call it "workable competition", and they say:

" ... [workable competition] typically produces an outcome in the long run whereby prices tend to converge to a level that is reflective of costs and those costs (including a reasonable rate of return) are reflective of value."

So that is quite an important foundation for the CMA's case, and if one looks at the footnote 12, just go down a little bit, it cites in support Ms Webster on Day 11. So we should just go and have a look at that, this is the transcript {Day11LH1/81:18}. This is Ms Webster in cross-examination which the CMA refer to:

"So in the long run, my sense is that prices, even under workable competition, will come down to a level which is reflective of those costs and where those costs are reflective of value."

So that is essentially the key proposition, and there are many, many references to this. We can also go to the transcript on Day 7, this was an answer to the President's question, this is on page 108, so

{Day7LH1/108:7}, the President says:

"If you are coming to it later, do say ..."

At line 12:

"... does that mean that you have an a priori view as to prices converging to cost in a case where there is normal and sufficient competition? Is that your premise?"

And she says:

"Yes..."

So this is a pretty important foundation for the CMA's cost plus approach.

Now, despite this being an important foundation, in truth there was very little evidence to support it. It tends to be, with the greatest of respect, the economists saying it is an obvious proposition, but when one drills down, where was the evidence to support this, and I come then to the law because the law quite clearly shows that this proposition is dubious and overly speculative, and with that we need to go to the *Victor Chandler* case, the *BHB v Victor Chandler*. That is {XN3/7} at page {XN3/7/16}, and blow it up. It is paragraphs 47 to 48 and 49, really, are -- I mean, I know the Tribunal will have these well in mind, but this is Mr Justice Laddie saying that -- we get the Mr Turner submitting, which is very similar to what the

CMA is submitting in this case, and then we get at 48:

"Even before one considers the case law, it appears that this approach is based on a number of doubtful propositions. It assumes that in a competitive market prices end up covering only the cost of production plus the cost of capital. I am not convinced that that is so. Sometimes the price may be pushed much lower than this so that all traders are making a very small, if any, margin. Sometimes the desire of the customer for the product or service is so pressing that all suppliers, even if competing with one another, can charge prices which give them a much more handsome margin. In other words, even when there is competition, some markets are buyers' markets, some are sellers'. I do not see that there is any necessary correlation between the cost of production and the cost of capital and the price which can be achieved in the marketplace. Furthermore the question is not whether the prices are large or small compared to some stable reference point, but whether they are fair."

Then given the time I will not go over because I know the Tribunal will go back to this, but at paragraph 49 he says:

"In addition, this rule breaks down as soon as one applies it in the real world. What happens if there are

only a few customers? Must the cost of production, including all research and development, be recovered from them? If so, does that mean that the price varies depending on the number of customers one has?"

This sentence is quite important for this case.

"Does it also mean that the price must go down once all the [R&D] costs have been recovered?"

So he gives some reasons why he believes this cost plus approach is dubious, and I would ask the Tribunal to look at what Mr Justice Laddie is saying when considering the CMA's case.

We should -- this is not just Mr Justice Laddie, I do not know if one remembers Mr Justice Laddie, I can well remember him saying this sort of thing with some gusto, but if we go to the *Attheraces* case at {XN3/10}, clearly the appellants on this side rely on *Attheraces*. I would ask the Tribunal to note this is a fairly strong Court of Appeal. We have got Lord Justice Mummery, Sedley and Lloyd, and at page {XN3/10/16} -- sorry, at page {XN3/10/37}, at paragraph 195, we see here -- sometimes with this case one is not quite certain whether the Court of Appeal is citing its own view or what Mr Roth is submitting, but I think this paragraph 195 is the Court of Appeal citing what Mr Roth was submitting, and he is referring to the judgment of

Mr Justice Laddie in *Victor Chandler*. Halfway down:

"The cost [plus] test has the attraction of being simple, but the reality is that it is not easy to establish what the price of a product would have been under different and competitive conditions. As Laddie J observed, even in competitive markets, there is no necessary correlation between the cost of production and the cost of capital and the price that can be achieved in the open market: there are buyers' markets and there are sellers' markets."

It is absolutely common sense.

We then go on to page {XN3/10/39}, para 208, and we see the Court of Appeal here essentially endorsing what Mr Justice Laddie said:

"ATR argued that, if the indicator of abuse is a presumptive competitive price, cost [plus] is what a competitive price should be. This seems to us to be at best a rule of thumb. Competition may drive price below cost for a time or in a part of the market. Where profit is obtainable, the margin of profit will be as great as the market will yield, reflecting such factors as elasticity of demand. Thus, even a hypothetically competitive market may yield a rate of profit above, as well as below, the reasonable margin represented by cost [plus]. Those and related issues were usefully

discussed by Laddie ... in ... *Victor Chandler* ... It seems to us that the most that a successful challenge under Article 82 can achieve in a case like this is a renegotiation, not a cost [plus] limit on prices, for whatever else Article 82 does it does not create a European system for determining prices."

So this is a very strong Court of Appeal giving a very strong steer about this presumption that competition will just bring prices down to cost.

I draw two main principles from these passages.

First, it is a doubtful proposition that workable competition will typically reduce prices to a cost plus level. The Court of Appeal approved Mr Justice Laddie's reasonings. Dr Majumdar also said this, and I will just give the reference for it, but he said the same thing, and that is at {XE6/3/19}, we do not need to go to it, but he was consistent with that.

So in this case the Tribunal must be very astute to a similar argument run by the CMA, and it should probe the CMA why this would be so.

The second point I want to make is that the Court of Appeal did not interpret section 18 as containing a prohibition against high prices. As the court said there, we live in a market economy, so, again, the Tribunal must be very astute to a claim that

says prices are too high when the case is based on a proposition that has not even attracted judicial support. So that is all I want to say on workable competition and cost plus. One must be very, very careful.

PROFESSOR WATERSON: Could I just ask what is meant by "European system for determining prices" here?

MR BREALEY: Well, all he is saying, that was an Article 82 case, it is basically saying that the competition rules of the treaty are not there to determine prices, equally section 18, and what the Court of Appeal undoubtedly said in *Attheraces* is that you have to be very careful that you do not use the competition law to regulate prices.

PROFESSOR WATERSON: Thank you.

MR BREALEY: That is what is meant, a European system.

You can have a regulator, but you have got to be very careful you do not apply competition law to regulate prices. I come to the next area of law which is workable competition and comparators.

Now, we have been through this with the experts to a certain extent, but it is absolutely critical and we do need to address it. Here it is important to recognise the length that the CMA has gone to dismiss comparators for the last ten years.

It marginalises any demand side factor and in my submission, the history of this matter shows that the CMA has not, with the greatest of respect, looked at comparators as objectively as it should.

So if I go first to the law, and I will just look at the law on the comparators, can we go first to the judgment of Green LJ, but it is {XN1/4}. This is the judgment of Lord Justice Green in *Phenytoin* allowing the CMA to amend its notice of appeal, and as the Tribunal will remember, Professor Waterson will well remember, at the previous hearing, the CMA first said the comparators were irrelevant, then before the Tribunal the CMA conceded the comparators were relevant, then, having lost, it sought to contend before the Court of Appeal that they were irrelevant again, so the CMA flip-flopped on the issue of comparators.

If we just go to page {XN1/4/10}, please, and blow it up, it is paras 41 and 42:

"... as to the argument that the CMA has failed to proffer any sort of explanation for its change of position, Mr Hoskins ... explained that the short answer was that the CMA has decided that its earlier position was wrong and the position it now advances is correct. He says that a good faith change of position by a public authority reflects responsible, not bad, administrative

practice. In terms of ordinary public law principles this is correct. A public authority should not persist in applying a policy that, on reflection, it considers to be wrong in law. If that means, as here, seeking to withdraw from a stance formally adopted in earlier legal proceedings, then that is an appropriate course of action to adopt. Whether the 'new' position turns out to be good or bad in law will, of course, depend upon the final assessment of the Court."

We know the Court of Appeal said that comparators were relevant.

I would also ask the Tribunal to note -- Mr O'Donoghue is going to deal with penalty -- what Lord Justice Green had to say in paragraph 42 about penalty and negligence.

He said:

"... in relation to alleged prejudice arising out of the impact of the concession upon fines, I have already observed that granting permission does not wipe the slate clean. If the appeal is allowed, and assuming that the Court then remits the case to the Tribunal for a consideration of any outstanding issues ... then it seems to me that in deciding whether Pfizer acted negligently it remains open to Pfizer to refer to the CMA's position, and to uncertainty in the law as

evidenced by changes in that position, as relevant and significant mitigation."

So that is how the situation stood then, but in my submission things have just got worse.

If we then go to the *Phenytoin* Court of Appeal judgment at {XN1/5} and to page {XN1/5/29}, this is the famous paragraph 97, but I do -- if we look at -- we will come later to (v), but if we just look at (vi) to (viii), so if we go down a bit, this is Lord Justice Green, and this is the Court of Appeal, giving the approach:

"In analysing whether the end price is unfair a competition authority may look at a range of relevant factors including, but not limited to, evidence and data relating to the defendant undertaking itself and/or evidence of comparables drawn from competing products and/or any other relevant comparable ..."

I ask the Tribunal to note that:

"... or all of these."

I ask the Tribunal to note:

"There is no fixed list of categories of evidence relevant to unfairness."

"If [the] competition authority chooses one method (... Cost Plus) and one body of evidence and the defendant undertaking does not adduce other methods or

evidence, the competition authority may proceed to a conclusion upon the basis of that method and evidence alone.

"If an undertaking relies, in its defence, upon other methods or types of evidence to that relied upon by the competition authority ... the authority must fairly evaluate it."

So fairly evaluate it, but in the context of there is no fixed list of categories of evidence relevant to unfairness, and Lord Justice Green says -- refers to:

"... evidence of comparables drawn from competing products and/or any other relevant comparable, or all of these."

Now, as Professor Waterson knows, we rely on *Liothyronine* for this -- sorry, if we just go to page {XN1/5/39}, paragraph 123, which is obviously a critical paragraph relating to comparables:

"... I note that in paragraph [249 of *United Brands*] the Court says that it is only 'advisable' to ascertain whether the undertaking had exploited its dominance in a way which it could not have ' ... if there had been normal and sufficiently effective competition', these being the words said to create the requirement for a hypothetical benchmark price. There is no specific reference to price in the paragraph and in any event the

expression 'advisable' is inconsistent with the Court intending to provide anything more than guidance as to best practice. It would have used more directive language had it intended to lay down a fixed rule."

Now, I ask the Tribunal to note that last sentence:

"It would have used more directive language had it intended to lay down a fixed rule."

So we then proceed to the *Liothyronine* case, and remember the reason I am doing this -- we will come on to it in a minute, but the CMA says you can only have a comparable if it is a product of workable competition, and we will see that in a moment, but that is why it is so important for me to take the Tribunal through the law.

So if we go to *Liothyronine* judgment at {XN2/28}, that is *Liothyronine*, then we go to page {XN2/28/48} at paragraph 132:

"... the submission that the CMA's starting point should have been workably competitive prices was not well founded. As Green LJ held, there is no rule that the competition authority must establish workably competitive prices at any stage ..."

And then goes on to cite 123 of the *Phenytoin* judgment.

So this is in the context of the CMA trying to look

at comparators which were not the product of workable competition. The appellants were submitting there, well, that is the test, the CMA were saying, no, it is not, and we will see what the Tribunal said.

At page {XN2/28/82}, paragraph 236:

"The Decision also compared the current price of Liothyronine ... with drugs with a similar market size to Liothyronine Tablets ... reproduced [at] Figure 4 ..."

Now, we do not have figure 4, the Tribunal may obtain it, but figure 4 compared 13 Scheme M drugs.

THE PRESIDENT: Well, Mr Brealey, I think you can proceed on the basis that we would not be seeking to obtain figure 4 without actually having it first before the parties, so --

MR BREALEY: Well, the CMA obviously know it.

THE PRESIDENT: Well, indeed, but you can hardly make submissions and we can hardly entertain the point without everyone seeing it.

MR BREALEY: Well, I do not think it is a huge point, but --

THE PRESIDENT: No, no, what I am saying is for our purposes we should be proceeding on the basis of a non-confidential judgment.

MR BREALEY: I do not actually understand what is confidential about it.

THE PRESIDENT: Well, nor do I, and it is not a matter that is before us.

MR BREALEY: I do not believe I am giving any secrets away, what I can say: this figure had 13 Scheme M drugs and they were completely unrelated.

THE PRESIDENT: Yes.

MR BREALEY: Again, I am not giving any secrets away, this was -- the data point is liothyronine, is it priced fairly, and one of the products was an anti-seizure medicine, like in this case, not phenytoin, but another one. So the CMA were comparing the price of liothyronine for thyroid issues with an epilepsy drug, and that is what figure 4 was showing, 13 Scheme M drugs.

If one goes to page {XN2/28/94} at paragraph 264, you see here -- and I think this was Mr O'Donoghue who was cross-examining, and I think it -- well, it was one of us:

"In cross-examination ..."

This is in cross-examination of the CMA's expert Professor Valletti.

"... he accepted that he had not defined the markets for the 13 Scheme M drugs used for comparison in Figure 4 ... that he did not know how difficult these drugs were to make or how many suppliers there were for

each one, or what the manufacturing costs or specific market characteristics were. He nevertheless defended the use of these drugs for comparison purposes, pointing out that the large size of the data set such as that used in Figure 5 ... would mean that the information disclosed was meaningful despite the effect on the numbers of unobserved factors."

So again, this is the CMA adducing evidence to the Tribunal, a comparator that has not been subject to any workable competition analysis, and we go lastly to page {XN2/28/98} at para 277, and this is where the Tribunal, two-thirds of the way down, accepts the evidence of Professor Valletti and the Tribunal says the comparisons were "meaningful".

Last, sir, again, I am just looking at the law on comparators and what the law says and how the CMA until today or until this Tribunal, has been dealing with the matter.

We go to the *Hydrocortisone* abuse case which obviously, sir, you will know very well. That is {XN2/29}, and it is page {XN2/29/164}. If we blow it up again we have paragraph 330:

"There is no single method ..."

331:

"Any appropriate method is likely to be informed by

that which is being valued: identifying costs and linking them to a particular product is a problem in almost every case ..."

Then in (1):

"Comparators are of particular importance, even where they may not be clear or compelling. Comparators can include: (i) comparators on different markets; (ii) comparators on the same market at the same time; and (iii) comparators separated by time. In all cases, the critical question for the court is whether anything probative can be derived from the comparator in question."

Now, again, the Tribunal could not be clearer, in my respectful submission, and I know the President, you are familiar with this, that we are not seeing a sense there that comparators must be the product of workable competition.

Let us just see what the CMA does in this case, contrary to its approach to the law in *Liothyronine*, because in my submission, the CMA has misunderstood the law on comparators yet again.

We go to {XE6/8} which is the position paper of Ms Webster, we see page {XE6/8/1}, we went through this with her, but it is important that we see this again. At paragraph 1.2 and 1.3, if you blow it up, please:

"I have been guided by relevant case law ... I have also been directed to the Tribunal's recent judgments in *Liothyronine* and *Hydrocortisone*. Where appropriate, I include references to aspects of the Tribunal's [judgment] ..."

None of the paragraphs which we have just been referring to.

"Given this guidance, in my view, for comparator analyses to show that the Parties' prices were fair they would need to identify a comparator that:

"(a) is sufficiently similar ..."

"(b) has prices which reflect sufficiently effective competition."

Now, that was the guidance to her as to the law, that anything outside those two conditions would not be relevant, and we see that if one goes to page {XE6/8/16} which is -- again blow it up -- section 5:

"Relevance of the £30 Drug Tariff ...

"I note that the Parties' experts do not advance well developed arguments as to why the £30 DT price should be considered as a relevant comparator ..."

I will come on to this later.

"Dr Majumdar suggests that 'the £30 DT price is a potentially relevant metric to be considered in the round when assessing the fairness of Pfizer's price'.

"In my view, the £30 DT price for Tablets is not a valid comparator as it does not meet the criteria that I set out in paragraph 1.4. Specifically, the £30 DT price was not a price consistent with the outcome of sufficiently effective competition."

So again -- so that is her evidence, and we can marginalise her evidence, but that is the guidance that she has been given by the CMA.

Then if we look at how she deals with the AED data set at page {XE6/8/17}, this is all she says on it, we know and we will come on to it in a moment, we will get Mr Ridyard's reports:

"Relevance ..."

It is a legal question:

"Relevance of the reimbursement prices of Other AEDs.

"The Pfizer Notice of Appeal also argues that the reimbursement prices of Other AEDs are relevant comparators. On this, my position is as follows.

"... the prices of Other AEDs that Pfizer puts forwards for comparison with the Parties' Capsule prices are not ones that, in my view, are consistent with sufficiently effective competition."

Then if we go down to 6.2, the last sentence:

"The price benchmarks put forward by Pfizer are

therefore not appropriate for assessing the fairness of Capsule prices."

Lastly on this, if we just go back to the CMA's closing at {XL/9}, this is its annex 3, page {XL/9/3}, paragraphs 6 and 7.

This is the CMA's closing submission on comparators:

"Aside from the need for a proposed comparator to be workably competitive, the question of how similar the comparator is to the product under investigation goes to the weight to be given to the comparison ... the mere fact that a product is similar to the reference product is not, in itself, a good reason for including it as a benchmark. A valid and meaningful benchmark must also be anchored in what would have been obtained under [workable competition].

"It follows that the touchstone for comparisons is not (as was suggested during the cross-examination of Ms Webster) any comparator that might provide some possible indication of whether the disputed price is unfair, regardless of whether the margin or price of the comparator would have been obtained under [workable competition]. Where comparators do not help to answer the question as to whether a dominant undertaking reaped trading benefits that would not have been earned in conditions of workable competition, it is not

appropriate to give them weight in the overall assessment of fairness."

In my respectful submission, that is just plain wrong as a matter of law, in the light of what the Tribunal said in *Hydrocortisone* abuse, what the Court of Appeal said in *Phenytoin*, what Mr O'Donoghue is telling me now. It is just plain wrong, and there were some other data points in *Liothyronine*, but I have not gone to them, but it was figure 4 and figure 5, but the simple point is (a), it is a misunderstanding of the law and there is a degree of cherry-picking or double standards in the approach to what Pfizer has put forward on comparators in this case.

That is comparators. The third legal principle --

THE PRESIDENT: Mr Brealey, is the difference between your position and the CMA's really the difference between admissibility and weight? You are saying that they have got an admissibility filter which you say is not reflected in the case law in that comparators are just excluded because they do not meet certain legal requirements, whereas you say, well, let all the comparators in and it is a question of the weight that should be attached to them looking at the similarities and the differences in terms of what they are comparators for?

MR BREALEY: Well, it is, it is, but we have Mr Ridyard's reports, we have just seen the CMA, because of relevance, does not even deal with it. So we have before the Tribunal evidence on a data set of other AEDs, and it is important for us to say, well, that is our evidence, and there is no evidence in response by the CMA. It criticises it in the Decision, but there is no evidence in response.

So it does go to -- I mean, the Tribunal put such weight on AEDs and the £30 drug tariff as it deems fit, but it is important for the Tribunal to note that in dismissing the relevance of our AED data point, the CMA has committed an error of law, and in dismissing the £30 drug tariff benchmark, the CMA has committed an error of law, and if the CMA adopts an error of law and excludes consideration of relevant evidence, that is highly relevant to whether this appeal should be successful or not.

It is deeper than that. That is why I went to Lord Justice Green to begin with, because this is the second time, and there is only so much that Pfizer, we should have to deal with in trying to get its demand side factors before the court. The CMA said it was irrelevant/relevant/irrelevant last time, now they say, wrongly, it must be the subject of workable competition.

If the CMA adopts a Decision and comes to this Tribunal saying that comparators are not relevant and that is an error of law, it needs to be recorded.

It goes to the whole mindset -- it is more than that, it goes to a mindset, we say, of excluding comparators. I will come on to it later. We rely, obviously, heavily on the £30 drug tariff price as a willingness-to-pay and I will come on to that later on. We rely on the prices of other AEDs. That is evidence as to what the Department of Health was prepared to pay for other anti-seizure medicines and just to dismiss it as irrelevant and then we are left to -- if the question to me is it is just a question of weight, well, it goes more to the question of weight, it goes to the whole approach in this case.

So that is the comparators. It is important to recognise, if one goes back to paragraph 6 {XL/9/3}.

7:

"... the touchstone for comparisons..."

Now, if the touchstone -- the touchstone normally means this is a very important part of a case, the touchstone. If that touchstone is wrong as a matter of law then it is more than just a question of weight, there is an issue as to whether the appeal should be allowed for that purpose because the CMA has not

properly addressed its mind to it.

I move on to the third legal principle: demand side factors and economic value.

Can we go back to the *Victor Chandler* case again at {XN3/7}, page {XN3/7/17}, what I want to deal with here is demand side factors and economic value.

So page 17 at paragraph 51, Mr Justice Laddie:

"I do not accept that this supports the proposition advanced on behalf of VCI. On the contrary it appears, particularly from the paragraph 252 of the judgment [that is *United Brands*] that all the ECJ was saying was that comparing prices with costs determines the profit margin. Once that has been achieved it is necessary to go to the next stage to determine whether the price is unfair. What it did not do was suggest that high prices or high margins are the same as unfair prices. Indeed, were Mr Turner right, it seems to me that the law reports would be full of cases where undertakings in dominant positions would have been found guilty of abuse by simply charging high prices. As Mr Vaughan says [he was obviously a great advocate], the reality is that there are no such cases."

Then if we go to page {XN3/7/19} at 56:

"It seems to me that Mr Vaughan is right. The message of [*United Brands*] is that we still live in

a free market economy where traders are allowed to run their businesses without undue interference. What Article 82 and section 18 of the Act are concerned with is unfair prices, not high prices. In determining whether a price is unfair it is necessary to consider the impact on the end consumer and all of the market conditions. In a case where unfair pricing is alleged, assessment of the value [and the judge underscores 'value'] of the asset both to the vendor and the purchaser must be a crucial part of the assessment. VCI's approach does not take into account value at all. It simply relates prices to the cost of acquisition or creation."

So let us finish, then, we will go on to *Attheraces* which is {XN3/10}, and I do appreciate that the Tribunal has demand side and value well in mind, but it is important to see the framework for this.

If we go to page {XN3/10/24}. Paragraph 116, we are very familiar with these, 116 to 119. I rely in particular on 117:

"... the central concept in abuse of dominant position by excessive and unfair pricing is not identified as the cost of producing the product or the profit made in selling it, but as the 'economic value of the product supplied.' The selling price of a product

is excessive and an abuse 'if it has no reasonable relation to its economic value'."

Then if we go to page {XN3/10/35}. Obviously we have paragraph 119, the Tribunal will know this well. Page 35 at paragraph 189 we should just look at this. Again, this is Mr Roth emphasising:

"... that the economic value of a product was a different concept from its cost, as it reflects its revenue-earning potential to the person who acquires it."

We can leave that there. We can go to page {XN3/10/38} at para 203, because the Court of Appeal there agrees with the submissions of Mr Roth.

If we go to paragraph 209 at page {XN3/10/39}, in the middle, again, the Tribunal will be familiar with this:

"But, to the extent that he sought to make charging above cost [plus] the principal criterion of abuse of a dominant position, we do not agree."

Then lastly, the one that we had some difficulty with Ms Webster as we will see, is page {XN3/10/41}, paragraph 218. This is a very, very important paragraph for this case:

"For all the above reasons we conclude that, 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 [/section 16]. In particular he was wrong to reject BHB's contention on the relevance of the value of the pre-race data to ATR in determining the economic value of the pre-race data and whether the charges specified by BHB were excessive and unfair."

I know the Tribunal has that in mind, but clearly we rely on this paragraph because we do say that phenytoin affords benefits to the NHS.

Lastly on the law, can I just then go to the Court of Appeal in *Phenytoin* at {XN1/5}, two paragraphs which relate to paragraph 218. If we go to page {XN1/5/29}, we have seen this before, but here I just want to emphasise, if we blow it up, (v):

"If a Cost-Plus test is applied the competition authority may compare the cost of production with the selling price in order to disclose the profit margin. Then the authority should determine whether the margin is 'excessive'. This can be done by comparing the price charged against a benchmark higher than cost such as a reasonable rate of return on sales (ROS) or to some other appropriate benchmark such as return on capital employed (ROCE). When that is performed, and if the price exceeds a selected benchmark [and we will come on

to our benchmark in a moment], the authority should then compare the price charged against any other factors which might otherwise serve to justify the price charged as fair and not abusive."

Again, a further paragraph which shows that the CMA is wrong on its approach to comparators.

If we go to, lastly, on page {XN1/5/28} and paragraph 96, I rely on paragraph 96 because, as the Tribunal will know, Lord Justice Green goes through the case law and what is the critical paragraph he relies on? *Attheraces*, we see that, paragraph 218.

So that is the paragraph of the *Attheraces*, 218, I have just shown the Tribunal.

So in short, we have a ringing endorsement by the Court of Appeal on two occasions, one in this case that the value to the purchaser is critical, and in our submission, the CMA in this case has not properly analysed the demand side factors and the value of phenytoin to the NHS. That is the third legal principle.

The fourth I just want to touch on is the law on reasonable willingness-to-pay.

THE PRESIDENT: Just to identify exactly the place in which this point fits in, I noted that there was some, I think, definitional pushback on our use in our guide

to closing submissions to the term "ceiling", and you very helpfully indicated that that was a term that might require more careful articulation if it was to be used as a term of art, and is the concern with the use of the word "ceiling" which is intended to refer to the price actually charged the fact that it might be said to cause there to be a failure to look at the consumer surplus that subsists above the ceiling, in other words, that which would have been paid or the willingness-to-pay that exists in most cases above the demand curve and that ceiling rather implies that there is nothing above it?

MR BREALEY: 100%, sir. So, yes, we have the floor, which we, actually in this case, we say is a basement, but let us keep it as a floor, then we have the ceiling, and the trouble we had with the ceiling is because that is the price charged -- that now is excessive and in one's head can you go above excessive and that is a ceiling, you cannot go above the ceiling. That is why I would prefer, if we are going to have floor, ceiling, I want a roof, and the roof is what the consumer is reasonably willing to pay.

Now, if the ceiling goes above the roof we know we are in trouble. The roof could collapse to the floor, then we know that it is cost plus, but we need some room

above the ceiling because the price charged, as we have just seen, the price charged, although one might call it a ceiling, it is a bit of a loaded term unless you have got something above it and that is why we kind of push back on it.

THE PRESIDENT: I am grateful.

PROFESSOR WATERSON: The attic.

MR BREALEY: The attic. Well, you could take it because -- that could be the attic because again can you not abuse your dominant position -- is there a headroom, because it has to have no reasonable relation to the economic value, so we could go further, but attic, roof, yes, but we do need something --

MR O'DONOGHUE: Sorry, we might put dormer bungalow into the mix.

MR BREALEY: But we do need something above the ceiling if we are going to continue with whether it is attic or roof, because it is so important. This is why I wanted to concentrate on this because the courts have time and time again said it is not just cost plus, it is not just the floor, it is not just the price it is charged because excessiveness is just the start. You have got to really look at the economic value which is very much the demand side, whereas the cost plus is all supply side, really, and this is where we really part company.

The case presented by the CMA is very supply side, it is all very high, but then that is not the whole picture.

THE PRESIDENT: No, indeed. I think the point that you make that it is a question of definition is helpful. The reason I think ceiling has its attractions is that the price charged is the price charged, and it is that which is under attack. Whether it is rightly or wrongly under attack is neither here nor there, but no one is actually interested in prices above the prices actually charged because they were not actually charged and presumably there are some factors as to why the price stayed where it was.

What we are interested in, and I would be grateful for your pushback on this, what we are interested in is how far, if at all, the price actually charged, the ceiling, is too high. Now, one factor in determining whether the ceiling is appropriately located or not is the consumer surplus that subsists above it.

MR BREALEY: Yes.

THE PRESIDENT: So we are not pushing back on the irrelevance or otherwise of what is above the ceiling. If there is a large amount of consumer surplus above it then that might be a factor to say that the ceiling is appropriately located, but in terms of the enquiry, it is the location of the ceiling that we are all focusing

on.

Now, we may have some pushback from the CMA who may be saying: no, the appropriate starting point is in fact the floor or the basement and one sees how much higher the price that was charged can be justified by reference to the floor, and that is an important way of colouring the enquiry that we are undergoing, but it does seem to us, subject to being very clear about what one is talking about, that it is really a choice between a starting point of cost or a starting point of price actually charged and then a determination of where a fair price subsists in that range, accepting that the ceiling, the price actually charged, cannot presumptively be regarded as unfair simply because it exists at above cost.

MR BREALEY: Two points on that. The first is that I do need my roof, which is the consumer surplus which is defined by the economic value, and the ceiling obviously -- I mean, you could have -- the analogy can go further, you can have kind of a three storey house, because you could have the third floor, second floor and first floor because the price can come down and it can come down towards the floor and you get more consumer surplus, and that is what we say happened here, and I will explain that in a moment.

The big answer to that question is that, yes, the CMA has a margin of appreciation as to how to approach unfair pricing, we see that. It can start off with the cost and excessiveness and then go on to look at unfairness, but the courts have also said that it is not a rigid and fixed way, there are all ways of doing it, and the only thing I would submit in reply to that is that if we are going to go down -- if we are having to meet a two-limb *United Brands* case, one has to be ultracareful that we are not fixated on the cost plus and we forget that there is a lot more out there.

So one could say forget cost plus, the Department of Health absolutely 100% sat down and said this is a fair price, this is the price I want, this is the price I am paying for all the other anti-seizure medicines, it is saving us a lot of money and £30 is the right price.

Now, you could say forget the cost plus bit, the evidence for economic value is so clear, and everybody else is pricing above cost plus -- we will come on to that in a moment -- we just go straight to what is the economic value of this.

So I think one has to be very careful that we just do not get fixated on the approach of: well, look at cost plus and then all of a sudden, because it is a 50% ROS or a 60% ROS it must be bad and there needs to be

some really good justification for it.

THE PRESIDENT: The problem -- and it may be ameliorated by your roof or further storeys -- is that normally in a market of workable competition, economic value equates to price. Where one has a dominant situation, that may be the case, but it is not the case where one has a case of an abuse of dominance and that is, of course, the allegation or the finding here.

So how, when the very question is whether there was an abuse of dominance in terms of pricing does one attach value or meaning to economic value independent of the price charged, given that --

MR BREALEY: It is really easy. It is difficult, but the answer is really easy.

THE PRESIDENT: Well, I'm pleased to hear that, Mr Brealey. That is all right, then.

MR BREALEY: It is easy because clearly workable competition is a good test for deciding what is value. We do not say it has to go down to cost plus, but that is a good test, but it is not the only test. See what the CMA submitted to the Tribunal in *Liothyronine*. See the Athens airport case. See all the PRS cases about royalties.

One looks at a whole range of factors to determine whether this consumer values this product, and it may

well be that the consumer, as basically you said sir in *Hydrocortisone* abuse, is getting a good deal because competition is bringing the prices down, but it may well be six months ago it was more than happy to pay a higher price because look at the comparators, look at what it has admitted.

Again, we say that the factual evidence and the clear evidence is that phenytoin saves the NHS a lot of money: hospital care, inpatient care. Now, where do you factor that in? It is not factored in just because prices have come down because of competition. All it means is that the consumer, the NHS, is getting a much better deal, and that is the nub of -- that is why I say it is quite easy.

So if --

THE PRESIDENT: Assuming -- and it is a big assumption -- that these factors could be absolutely calculated with a high degree of precision, in other words, one could ascertain and knew exactly what the prescription of sodium phenytoin capsules had saved in terms of non-visits to hospitals, you would say that it would be a fair price to price up to the level of the savings to the NHS because, provided there is a margin that could be very small, but a margin which represents the fact that the NHS is paying even marginally less for the

benefits of not having all these epilepsy sufferers coming into hospital with seizures that need treatment and cost money, then that is a reason why the price does not shift very far down from the ceiling, assuming the ceiling is equated to that cost saving, irrespective of what the costs are in terms of production of the drug.

MR BREALEY: Correct. The straight answer to that is yes. I mean, I noted down you had that debate with Ms Webster, I think, and you could have some argument that if the supplier took all of the cost savings that the NHS obtained, so your example to me is it is right almost at the level of the cost savings, so the supplier is taking all of the cost savings, you may have some argument that it is unfair to take all of the cost savings, I do not know, what I can say -- but I would say the answer is you can, but I do not think that anybody is remotely saying that here.

Again, we have had no one from the Department of Health. We do know that the daily cost of phenytoin is £2, £2.41 in 2012 prices. We know that the annual cost therefore is around about £600 for phenytoin for one patient. We know that the hospital visit, if one has an epileptic fit is several thousand pounds.

The Tribunal has that evidence here that there is a significant gap between the cost of the product and

the saving to the NHS, and it is something I want to remind the Tribunal of. It is the Department of Health's letters, and I may do that out of turn because I do want to -- it would maybe flow logically -- I do want to refer to the Department of Health's letters which rejected the CCGs' complaints about the price increases. It is a very, very important piece of evidence because the Decision says the Department was not willing to pay, look at the CCGs evidence, they complained.

One looks at the opening submissions, one looks at the closing submissions, one looks at the Decision: you do not get any sense whatsoever that the Department of Health rejected those complaints because phenytoin produced cost savings to the NHS.

Now, that is right in -- we have it in front of us -- paragraph 218 of *Attheraces* endorsed by the Court of Appeal in this case.

So we are focused on cost plus, we are focused on prices coming down because of competition, and yet one of the critical demand side factors, that is to say the saving to the NHS, just gets left out of account, and that is where we say there is a problem here.

THE PRESIDENT: How much weight, if at all, are you attaching to the human benefit of avoiding seizures,

irrespective of the savings to the NHS, to what extent is that a relevant factor in justifying the price charged? I continue to refer to it as a ceiling but --

MR BREALEY: The answer to that is I think if you were to ask any pharmaceutical drug company there should be a benefit. We see in *Hydro* abuse, we see in *Liothyronine* where the Tribunal has given very little credit for the therapeutic benefit to the patient, and that is why we have, as a result of the Tribunal's judgments in *Liothyronine* and *Hydrocortisone* abuse, have focused on the savings to the NHS because the Department refers to both. In its letters, the Department refers to the benefit to the patient and the savings to the NHS.

My honest and straight answer is that when one is trying to value a pharmaceutical product, it has a greater value -- if it is having a -- sorry, I have lost my train of thought now.

A drug that treats a very, very important clinical condition in my submission should not attract necessarily the same value as a drug that, for example, cures a headache or a skin rash or whatever, no matter how serious that might be, the more serious the condition -- personally I see no reason why the drug should not attract a greater value, but we are

concentrating on the cost savings to the NHS, that is the purchaser, because we are straight in paragraph 218 of *Attheraces*.

THE PRESIDENT: That is very helpful because the differentiation between savings to the NHS and patient benefit has this advantage in terms of analysis. The savings to the NHS, leaving on one side the difficulties of computation, are essentially like for like, we are look at money spent, money saved. Whereas patient benefit carries with it the very difficult question of the more valuable the pharmaceutical product, in a sense, the greater the health benefits it delivers clearly is valuable, but equally the more pressure there exists on the health service and on the patients who will demand the drug because there is not merely a desire to have it but a need.

MR BREALEY: Again, this word "need" has been kind of thrown around as if it should devalue the drug, when in my respectful submission it should not, but the answer is we have concentrated because of paragraph 218 on the savings to the NHS, the savings of the healthcare. To a certain extent -- and those are the Department's letters, the savings to the NHS.

The beauty of Mr O'Donoghue's QALY submissions and the evidence is that that also -- that has a twin

approach: it has patient benefit and it has savings to the NHS. So the QALY which is the standard way of trying to value a drug, new and to a certain extent old, does embrace both cost savings to the NHS and patient benefit.

It does not calculate an inability to drive or losing a job which is the social -- the wider social costs, but it does look at patient benefit. It does look at, we saw, the clinical trials. So the QALY is the Department's way of combining these two approaches, cost savings to the NHS and patient benefit, and that is why Mr O'Donoghue went through all these clinical trials, but paragraph 218, we say we are squarely within that. Was there a benefit to the NHS? Yes. Has the CMA taken it into consideration? No.

Can I go on to the fourth principle and then I may take -- well, we will see.

The fourth principle is the reasonable willingness-to-pay, readiness to pay. I just want to give the Tribunal the framework for this.

Can I go to the Court of Appeal in *Phenytoin* again. We already have it open. It is at page {XN1/5/51}, paragraph 171. This is where it is dealing with where does economic value come in:

"... the Tribunal observed that this was clearly

a legal test. The categorisation of this as a 'legal' concept seemingly led the Tribunal to treat economic value as a discrete component of the test in law to be applied. It is 'legal' in a strictly limited sense that it has been ascribed a meaning in a court judgment but, at base, it is an economic concept which describes what it is that users and customers value and will reasonably pay for and it arose in the *United Brands* judgment as an economic description of the abuse of unfair pricing ..."

I ask the Tribunal to note that economic value is a concept which describes what it is that users and customers value and will reasonably pay for. That is my roof, and on this I think Pfizer and the CMA are ad idem because if one go to the Decision at {XA1/1/381} at footnote -- it is buried, but it is at footnote 1564, we see there the CMA agreeing that:

"The Court of Appeal held that 'in broad terms the economic value of a good or service is what a consumer is willing to pay for it' and that economic value 'is an economic concept which describes what it is that users and customers value and will reasonably pay for'."

Citing paragraph 171 of the Court of Appeal's judgment.

Again, I hesitate to go back to it, but *Hydrocortisone* abuse at {XN2/29}, page {XN2/29/157}.

Again I know, sir, you know these paragraphs well, but in my submission, these paragraphs of the judgment are all concerned with the roof and what consumers are reasonably willing to pay, and I was particularly -- I will ask the Tribunal to read it. I was particularly taken by the footnote 399, if one goes down below and blows it up:

"In the real world there is no single Product, but competition between different products which meet -- to different extents -- the same demand. Unsurprisingly, the Seller who taps closest into what Buyers value will accrue a demand that may be quite inelastic, and will be able to price accordingly."

So this is not just something -- economic value is not just something that a consumer has when there is workable competition. You may be an innovator, you may be the sole supplier of a product, and you tap in to what the buyer wants, and that is the roof, and then one has to look for evidence to determine objectively is that a price which the buyer was reasonably prepared to pay?

I will just finish and then maybe the shorthand writer wants a break, with one more reference which is I was very surprised by Ms Webster's evidence and we go to her cross-examination on Day 11 at page 72,

cross-examination {Day11LH1/72:11}, because we tried to explore this with her. I said:

"Question: I am asking you a different question, and I think you know the question, so let us try again.

"We have the cost of the phenytoin capsule; yes?

"Answer: Yes.

"Question: £2.41 a day at the 2014 price, £2.41, and my simple question to you is this: as an economist, do you believe that that cost of acquiring phenytoin should be balanced against the cost savings to the NHS that that drug affords, as a matter of simple economics?"

She says:

"Answer: My view is I do not feel that as an economist sitting outside of the Department of Health and National Health Service that I am qualified to take a view on that. I see from the documents that that is what is described as happened. It is not for me, I think, to say whether that is -- I mean, it seems sensible that they might do that. That is not what I am instructed to look at."

I was surprised that she could not offer any economic evidence as to how you would -- a cost benefit analysis. She said it is sensible, so I will take that,

but she has put it to what the Department of Health says, and that is what we shall come to after the coffee break.

THE PRESIDENT: I am grateful. In that case, we will resume at 11.30, in ten minutes' time, thank you very much.

(11.22 am)

(A short break)

(11.38 am)

THE PRESIDENT: Mr Brealey.

MR BREALEY: Thank you. I am going to take it slightly out of order, because we were doing so well on willingness-to-pay that I just want to go on to the evidence which we say -- you know, was this a price that the Department of Health was prepared to pay, and I just want to pick it up in our closing because it is quite a way in.

I think it is {XL/5}, I appreciate the Tribunal -- and it is page {XL/5/74}, but I am -- clearly the Tribunal have read it, but this is an important passage in the closing, obviously we refer to it in the introduction, and I do really emphasise these paragraphs:

"The costs avoided by the [Department of Health] ..."

So paragraphs 223, 224 and 225, it is not just --

this is showing it is not just our case, this is a Europe-wide, worldwide, UK-wide issue which is the healthcare costs for epilepsy far outweigh the spend. This is important.

So the healthcare costs, 2.8 billion, compared to 400 million, and that is set out in Professor Walker's evidence. That is paragraph 224.

Then at 226, 227, 228, we set out some of the evidence with the three witnesses of fact, Mr White, Mr Green and Ms Smith where, again, they agreed that there is significant cost to the NHS with treating epilepsy, A&E visits, inpatient, outpatient, nursing support, etc, etc. We set that out at 226.

Then 227, Ms Smith estimated that one hospital visit alone will be several thousand pounds.

Then 228 it was put to them -- and these are the people from the CCGs -- is there a cost benefit here, and in 228(a) and (b) they agreed:

"Question: I think you ... agree, you may quibble with the increase, but you agree that the cost of phenytoin must be balanced with the cost savings it affords to the NHS?

"Answer: There is a cost to keeping people epilepsy free.

"Question: A cost to the NHS, yes?

"Answer: Yes, absolutely."

Said Mr White.

"Question: You would accept, logically, that phenytoin as a drug produces benefits to the NHS because it avoids the costs we have just been talking about?

"Answer: Yes."

Said Mr Green.

I would ask the Tribunal to look at the Day 5 evidence of the factual witnesses because they do confirm that you should balance this off, but it is more than that, because I do want to take the Tribunal to the letters that I took them to, but it is important to remind ourselves what they say. So there are several letters, but I will go to three.

If we go first to {XD1/5}, this was attached to the statement of Susan Smith, and if we go to page {XD1/5/24} this is a letter dated 5 November 2012, and I ask the Tribunal to note the 5 November 2012 because I will be coming to the note of a meeting between a Susan Grieve and Flynn of 6 November, and so the date is actually not unimportant.

This is in response to the complaint by the CCG about the increase in the price of the capsule, and it is from the Department of Health, it is a response to the Nene Clinical Commissioning Group, and note that it

is a letter written on behalf of Dr Keith Ridge. I do not think any of these are -- what we agreed right at the beginning of this trial, that this would not be confidential.

This is Dr Keith Ridge. He is the chief pharmacist, and it said -- he is writing on behalf of Dr Keith Ridge:

"The Department fully understands your concerns.

"The new supplier of phenytoin capsules..."

They refer to.

"The Department is in discussion with the company ..."

Then we get:

"The cost of any medicine has to be balanced with the potential additional costs to the NHS through adverse reactions and reduced patient outcomes if [the] supply is interrupted.

"Whilst any price increase is unwelcome [because they were complaining about the price increase], especially at a time of financial restraint such as this, systems are in place to ensure, in the main, the NHS obtains the best value from medicines. For example, we were able to move quickly, earlier this year to reduce the cost of atorvastatin to the NHS when it came off patent."

I just ask you to note that there is the Department of Health, this is the first letter, 5 November, that the cost of basically phenytoin has to be balanced by the additional cost to the NHS.

Can we then go --

THE PRESIDENT: Just pausing there, could you help me just to locate this evidence in the structure of excessive prices that we are talking about. What you are saying is that this is evidence going to comparables, is that right?

MR BREALEY: No, it is going to economic value.

THE PRESIDENT: Economic value.

MR BREALEY: It is paragraph 218 of *Attheraces*.

THE PRESIDENT: So what you are saying is that economic value is something which is relevant independently of the fact that it is not the outcome of a market process; it is simply a justification that one can charge more.

MR BREALEY: Yes, and that has been the way of life for thousands of years and, as I said earlier on, if I value my Aston Martin, I do not have one any more, but if I had one -- sadly -- and I got it at a much lower price, I would be very, very happy, but I value that brand, I value the -- so it is not to do with workable competition as such.

It can be. Clearly economic value is related to

workable competition because competition does provide you with a certain value, but that is not the sole answer.

THE PRESIDENT: I think that is the basis of my --

MR BREALEY: Sorry, as *Attheraces* specifically. Attheraces specifically said that: you have a competitive market, but the judge did not take into consideration the benefit to the purchaser.

THE PRESIDENT: Yes, it is back to the operation of markets that I am reaching for.

In an effectively competitive market with workable competition, you have the price mechanism which determines value, and let us take it as agreed for the sake of argument that the equilibrium price in that situation subsists well above cost. So you have, through the operation of aggregate supply and demand in a competitive market an outcome that gives you what economic value is, and therefore courts do not need to worry about what economic value actually means because the answer is provided to them.

Where one has a situation where the position is not necessarily a competitive market, there is a detachment between what price tells you about economic value, and my point is to what extent is the Department of Health's view about economic value of assistance in terms of

just -- all it tells us is what the Department of Health was prepared to pay, but it does not really --

MR BREALEY: Full stop.

THE PRESIDENT: Okay, that is as far as it goes?

MR BREALEY: But that is what demand side is to a certain extent all about, and that is why my fourth point is economic value, so says Lord Justice Green at paragraph 171, so says the CMA in the Decision, economic value is what the customer is reasonably willing to pay.

THE PRESIDENT: In a competitive market.

MR BREALEY: No, it did not say competitive market in paragraph 171.

THE PRESIDENT: Right.

MR BREALEY: It did not say competitive market in that footnote.

THE PRESIDENT: Okay.

MR BREALEY: It can be clearly in a competitive market, but logically why should it be limited to a competitive market?

So, for example, in this case -- let us just leave aside the tablet price for the moment -- the capsule comes along, debrands, now in a generic market. Pfizer and Flynn sole suppliers of the capsule in a generic market.

The CCG says: I do not like the price increase. The

Department of Health says: ah, but you will be disappointed by my reply, that is the next letter, I am rejecting your complaint because phenytoin provides cost savings to the NHS. We are prepared to pay that, we are prepared to live with that. That is our £22, that is the drug tariff when Flynn goes in.

Now, when NRIM came in in 2014, it went down by 20%, so competition started to bring the price down, but because competition brought the price down to £18 does not mean to say that the Department did not value it at £22.

THE PRESIDENT: So this goes to the level of your attic, not the level of the ceiling at all?

MR BREALEY: Correct. I can see we have gone for attic now rather than roof, but --

THE PRESIDENT: Roof -- Mr Brealey, I am very happy to stick with roof if that was your terminology.

MR BREALEY: Just an aside, I only came up with roof when I went to the nativity play on Friday and it was Bethlehem Builders. It just dawned on me there must be a roof, but I will live with attic.

But seriously, that is the benefit: the benefit to the purchaser is not necessarily dependent on competition.

That was from Dr Keith Ridge.

Can I then go to the -- because this response comes from the top. If we go to {XD1/4/28}, I have gone to the end, but this is from the minister for medicines and pharma policy:

"I realise that this reply may be disappointing but I hope that it clarifies our position on the matter."

Now that is a very, very important statement when we are trying to meet a case advanced by the CMA that the Department was not happy to pay because all they do is refer to the letters from the CCGs. They do not refer to the response by the Department to the CCGs, and the response by the Department:

"I realise that this reply may be disappointing but I hope that it clarifies our position on the matter."

Now, let us see why the response may be disappointing, if we go to page {XD1/4/27}.

This now is, from the first paragraph you see this letter is coming essentially from the top:

"I am replying from the Minister responsible for medicines and [pharma] policy."

Again we see at the bottom:

"The cost of any medicine has to be balanced against poorer patient outcomes and the potential additional costs to the NHS from adverse reactions if supply is interrupted."

Again it quotes:

"... the best value [for] medicine..."

Now this is clearly a ministerial decision that is being made here, and I do remind the Tribunal that no one from the Department has come to give evidence at the Tribunal, notwithstanding the Tribunal told the tribunal last time it was quite disappointed with them because they could have given evidence on relevant issues.

My solicitors, Clifford Chance, have spent literally years trying to get disclosure from the CMA and the Department of Health, and they managed to get the disclosure about the statutory powers and Matt Otton-Goulder, but we have had no disclosure from the Department of Health which is underpinning this policy decision. But I do pray in aid the fact that this is the stated position by the Department to the CCGs: you have to pay the price because it is giving benefit to the NHS.

THE PRESIDENT: Mr Brealey, could you help us on this. Given the point you have just made that the Department of Health have not appeared before us, presumably you are saying that it is not open to anyone to suggest that there were not savings of the sort adverted to in this letter because if Earl Howe is mistaken then we would need someone from the Department to explain that those

savings did not exist --

MR BREALEY: Yes.

THE PRESIDENT: -- and that therefore what is said in this letter needs to be taken at face value?

MR BREALEY: Absolutely.

THE PRESIDENT: Yes, I see.

MR BREALEY: Absolutely. In the last hearing, as Professor Waterson will remember, we made a point about the Department of Health not coming to give evidence and we said adverse inferences should be drawn. That was rejected, so we are slightly surprised second time round, but the letter should be treated at face value and it is supported by the witnesses of fact, the CCGs -- I have just read the evidence -- who say: well, yes, the benefits should be, and that is why I -- it was at paragraph 228.

So both Mr White and Mr Green accepted that the cost savings should be offset against the drug.

PROFESSOR WATERSON: Can I just check, Mr Brealey, the previous letter was 5 November --

MR BREALEY: Yes.

PROFESSOR WATERSON: -- and you said that there was a meeting on the 6th, I think.

MR BREALEY: Yes.

PROFESSOR WATERSON: But this letter is dated the 28th, so

it does not talk about the outcome of that meeting.

MR BREALEY: Well, sorry, I have got three letters.

PROFESSOR WATERSON: Okay.

MR BREALEY: The very first letter we referred to was dated 5 November. This letter from the minister is on the 28th. If we go to the next letter -- and there are others, but the next letter is {XG/243} -- this is 20 December 2012, and again, this is now -- if one goes to the next page {XG/243/2}, this is actually from Dr Keith Ridge, the chief pharmaceutical officer, and I ask the Tribunal to note the chief pharmaceutical officer, and I also ask, as we are on this page, the Tribunal to note that the chief pharmaceutical officer, he is the head, the boss, is in contact with a person called Susan Grieve who is the principal pharmacist.

I just ask the Tribunal to note Susan Grieve and Keith Ridge, the chief pharmaceutical officer.

If one goes back, again we have the same language, the same policy decision, the same rejection of the complaint, the same stance that the price increase has to be paid because it is providing a benefit to the NHS.

Again, I make the point about there has been no disclosure, no one coming from the Department to gainsay what is said in these letters, and that is why I put these letters to the witnesses of fact and they agreed

that there has to be this trade-off.

Now, why have I referred to the Susan Grieve? If one goes to {XG/226}, this is a note of a meeting that Flynn referred to in its -- because it is the CMA's case that the Department was not happy with the price increase, and they rely on the CCG letters about the price increases and I have dealt with that, and they also rely on the note of the meeting dated 6 November with Susan Grieve, and if one goes to page {XG/226/2}, more or less at the bottom, we have a kind of -- you can see the paragraph:

"We felt that the discussion with [the] DH ..."

And then:

"We [that is Flynn] should not (in [Susan Grieve's]) view, assume that the DH and NHS are happy with the price of the tablets."

So this was all about the capsule prices and the CMA rely on this as some sort of evidence to say that the Department was not happy with the price increase of the capsule.

So I am sure Mr Holmes will come on to it, he referred to it in spades in opening, it is in the closing, but we should not -- and it is in her view, Susan Grieve's personal view.

Now, the reason that I have referred to that is

because the CMA use this against -- this is a Flynn document -- use this against Pfizer as evidence that the Department was not willing to pay a price increase of the capsule, and what I say to that is: well, all that is her personal view. We have seen letters giving the ministerial department's policy view and this is 6 November and the first letter I referred to was 5 November, and I would submit that it was highly likely that the chief pharmacist, who wrote basically on the 5th, would have been in discussion with Susan Grieve and she did not disclose the Department's position on the 6th, the day after.

All I am trying to do is put some jigsaw together to show that when she said this is her view, her personal view, it may well have been her personal view, but she should have known or would have known that a day before her boss had sent a letter saying: well, there has to be this trade-off.

We say this is evidence which shows the Department of Health was willing to pay the price increase of the capsule, and we say it is bolstered, and I will take this very briefly, it is bolstered by the evidence on the £30 drug tariff. So Flynn came in at £22. It is important to realise that Flynn's £22 was basically a third less than the £30. Pfizer's price was

two-thirds, essentially two-thirds of that particular -- 2014 prices.

I just remind the Tribunal of two documents we rely on, we have been through this before. The first is {XH/152}, page {XH/152/6}, answer 6(a). We have seen this a few times, but it is very, very important. This is an answer by the Department of Health, this is at the end:

"It is not possible to determine precisely how the fixed price of £30 was maintained ... A spot check of each quarter's model from July 2010 to January 2013 confirmed the Category M calculation model had a £30 value for phenytoin [100mg] tablets hard-coded in relevant cells ..."

Again, we have had no one from the Department of Health, we have had no disclosure, and we are entitled to rely on this as an admission that phenytoin 100mg tablets had a £30 value attached to them. When we are looking at economic value, that is evidence of economic value. That is what the Department was prepared to pay, reimburse, for the tablet.

It says "value", "£30 value", and we know why this was so, because if we go to {XG/25} and go to page {XG/25/3}, this is the email exchange after the Teva meeting that was not disclosed to the Tribunal before.

So this was not disclosed to the Tribunal before, and if we blow it up, please, again, we have seen this before, this is the day after -- this is basically a contemporaneous record of what was agreed at that meeting:

"Dear John [that is John Beighton]

"Very many thanks ..."

This is from Mr Mat Otton-Goulder who is responsible for the price of the tablets.

"Very many thanks for coming to see us yesterday: we appreciate the effort you have made to help us reach a conclusion which is of value to NHS patients.

"Just to summarise our agreement ..."

He summarises the agreement.

If one goes up, please, if you blow it up, please, at the bottom {XG/25/2}:

"It was good to see you both ..."

That is the two officials.

"I am sure that we have reached an agreement on this though Richard [John Beighton's colleague] ... remember the £30 reimbursement price kicking in ... [we were] furiously writing what you [had] said word for word."

Given, as I said in opening, this is an indication that the Department was basically dictating what was going to be done. They say they may not have heard

correctly because they thought the £30 was going to come in a bit later, and then we go up, please:

"I cannot but smile at [a colleague] writing furiously ..."

He goes on. He agrees to 1 October and that -- and then the last paragraph:

"And that is as far as I am prepared to go in this matter ..."

That is coupled with the -- we will not go to it, but the document {XG/284} where Mat Otton-Goulder told Susan Grieve that he had the power to impose a maximum, and that supported what Mr Beighton had said, and Susan Grieve did not disclose that document.

We say that these documents evidence a clear willingness on the Department of Health to pay £30 for the tablet which it did for several years, it is "of value to [the] NHS". We are entitled to take that at face value, the price of £30 was insisted upon, threatened with a statutory maximum if they did not agree. So we put all this together and we say there was a ready willingness-to-pay by the Department to pay in the round £30 for the tablet, £22 for the capsule.

I finish this little section with the question: is this seriously evidence of the £2.40 that the CMA say Pfizer and Flynn should have paid, should have

charged, £2.40? This is evidence of the Department's readiness and willingness-to-pay for phenytoin.

Can I just -- what I would like to do is finish because we will run short of time. Can I finish with a couple of points on the supply side. I said that I had three -- we are going to deal with the law, supply and demand. I have done law and demand now, and I would just like to draw the Tribunal's attention to certain failings, we say, in the supply side cost plus as well.

I will try and do this in half an hour and then I will let Mr Johnston kick in around about 12.40, 12.35.

So the last issue I wish to address is limb 1, and the CMA at paragraph 8 of annex 2 -- we do not need to go to it -- but paragraph 8 of annex 2 on excessiveness submits that we, Pfizer, do not seriously challenge the finding on limb 1, and that is not correct. So it is important for me to deal with this so that Mr Holmes can deal with it if necessary.

Go first to our Notice of Appeal at {XB/1} and page {XB/1/81}.

Now, ground 3, if you just blow it up, please, and go to the bottom, we say "The CMA's cost plus model is not fit for purpose". Now, I appreciate that is an extreme submission, the Tribunal might think, because we

have had so much evidence on the cost plus, but I will show you the frailties of the cost plus model so far as it applies to Pfizer, and my main point is when the Tribunal comes to balance all the range of factors, the demand side and the supply side, it is important that the Tribunal is aware of what we say are the frailties of the cost plus model. It is not to say you cannot have a cost plus at all, but in this case, it is on shaky ground, the floor is on shaky ground.

So this is page {XB/1/81}. We say the preceding grounds 1 and 2 -- this is page 81, paragraph 210:

"The preceding Grounds 1 and 2 are based on the exculpatory comparator and value-based indicators pointing away from the conclusion that Pfizer's ASP was unfair. This Ground explains why the only metric pointing in the CMA's desired direction, and the only one on which it chooses to rely, its desktop cost plus model, is unfit for purpose."

Now, we set out various reasons there. If one goes to paragraph 211 we say:

"The CMA's alleged non-abuse distributor-level price of £2.40 has been calculated by reference to an unrealistic hypothetical benchmark far below the actual prices that have prevailed in conditions of real world competition."

We say that the cost plus is -- the CMA has arbitrarily prioritised its cost plus model over the reasonable real world metrics and that is where our complaint is when one is balancing the range of factors, it is important to see what is going on in this cost plus model.

There are two main factors I want to emphasise on the supply side. The first is that this cost plus is an artificial construct for a generic drug, and we do need to recognise that. It is an artificial construct for a generic drug. Second, I just want to draw the Tribunal's attention to the far more generous way that the CMA looks at limb 1 to limb 2. So why do we say it is an artificial construct? There are two reasons for this. First, the cost plus is skewed in favour of a regulated price, and, second, it is not grounded in the real generic world. So we say it is skewed in favour of regulated price, this floor is skewed in favour of a regulated price, and second, it is not grounded in the real generic world.

Dealing quickly with the regulated price, if we go to the Decision at {XA1/1/181}, this is the section in the Decision on Pfizer's excessiveness and why is it excessive, and it is important to see paragraph 5.144, 5.145, 5.146, and we see there it is based primarily on

the EPBU, and we see that is the -- it is the Established Products Business Unit. We see in these paragraphs that the CMA uses the products supplied by the EPBU and uses a return on sales product but it is important to remember that these products have been regulated under the PPRS for some considerable time.

So one is looking at the ROS of 10%, but it is based on products that have been in the PPRS for some considerable time, and they are the ones that are basically coming off-patent or are off-patent, so they are the tail-end products, the lower profitability products. It is important to remember this: this is essentially a regulated business.

We then go to page {XA1/1/184} at 5.163, and the next metric is, well, the allowable ROS under the PPRS. Well, again, that is a regulated ROS, it is low. Then we go to page {XA1/1/185} at paragraph 5.170, and under ROCE the CMA is looking at Pfizer UK's WACC.

Well, again, it is all based on regulatory prices. This is not market -- you are not looking at returns in a competitive market, and why do I say that? I took one of the witnesses to it, but if one goes to {XG/20} I remind the Tribunal of what the CMA OFT said about the PPRS.

This is the CMA Office of Fair Trading

Pharmaceutical Price Regulation Scheme. If one goes to page {XG/20/5} at the bottom, if you blow it up, I tried to take one of the witnesses to this:

"The workings of the scheme are complex, but at a broad level it comprises two main components:

"Profit controls, which set a maximum level for the profits that a company may earn ..."

So we know that.

If one goes over the page {XG/20/5}, we have "price controls" at the top. So essentially you have a price control, you cannot increase the price, and over time the price will get cut. So it is not being increased, it gets cut.

This is the basis upon which you are benchmarking the floor, and then I also just remind the Tribunal that the last paragraph above "Assessment of the Scheme":

"... despite its name, we do not consider the scheme to be a regulatory mechanism in the true sense of the word. It is best thought of as an attempt to exercise buyer power in the purchase of prescription pharmaceuticals by the NHS across the UK ..."

That is not our language, that is the CMA OFT's language, so it is somewhat ironic that Pfizer is being found guilty of an abuse by charging above a regulated level, a level achieved by the Department exercising its

buyer power and, moreover, by reference to a business unit that is responsible for products that have been regulated under this price control system for some considerable time, but I do want just to urge upon the Tribunal, to note that a lot of the ROS that is said here, the floor, is skewed to the regulated price.

Now, the second point I wanted to make is cost plus, that is not how generics work.

If we go to page {XA1/1/183} of the Decision, I ask the Tribunal to note paragraphs 5.155 and 5.156. This is relevant for the next point about the difference in treatment as well.

5.155:

"For these reasons, the CMA considers that it is reasonable to use the average ROS earned by the EPBU ... as one benchmark for a reasonable ROS for Pfizer's Products."

Remember, this is all regulated under the PPRS.

This is an important paragraph:

"While the CMA recognises that returns across the EPBU will vary, with some products earning in excess of the average and some below, the CMA considers that average profitability provides a useful input for the purpose of assessing what would be a reasonable ROS for Pfizer's Products. The CMA considers this to be one

data point which provides useful insight for the purposes of its assessment and has sought to corroborate its reasonableness by reference to various other data points as follows."

So two points here: first, it is not at all clear why a company should be guilty of an excessive price when it is pricing above an average, we see that at 156, but, second, this is a comparison between the notional cost of one product against a portfolio of products, and that is important to realise, that Pfizer is being accused of excessive pricing by reference to one product, by reference to a portfolio of products, and my main point here is that it is clear and it is plain as a pikestaff that in the real generic world, suppliers price a single product far in excess of cost plus.

If we go to Mr Ridyard's report which is at {XE1/2}, this is Mr Ridyard's report. Page {XE1/2/17}, it is under the heading "Topiramate". If you blow that up:

"Topiramate is an AED that is sold in significant volumes in the UK ([about] 800 thousand prescription items of Topiramate were dispensed in 2016). It lost patent protection and faced generic entry in 2009. It is listed under Scheme M ... readily available ... following generic entry the market for Topiramate is characterised by both the availability of multiple

competing suppliers and the clear ability of customers to switch ... I understand that it is increasingly being used as a third line adjunctive treatment.

"Generic prices of Topiramate reduced substantially following entry, as illustrated by Figure 1."

It goes on to talk about the brand.

If we have a look at figure 1 {XE1/2/18}. So that is what happened to the price of topiramate. So you have the brand at the top and you have the price of the generic coming down.

Now, I am not at the moment comparing -- we say a fair comparison is to have an average weighted price which the CMA says: no, you cannot do. All I am doing at the moment is I am asking you, the Tribunal, to look at the period of time from 2009, and we see, for an initial few years, the generic supplier is pricing well above cost. The market -- essentially what the generic suppliers have done, they have benchmarked by reference to the NHS list price, and the market is taking a top-down approach and not a bottom-up approach. That generic supplier is not pricing at cost plus, and that is not how the market operates. So why would Pfizer not get the same treatment? Why would it not get the same temporal leeway? The CMA then have a construct on a cost plus -- it is coming down to cost plus.

This is how the generic market works. You start at a higher price and it comes down, but the notion that on day one you are pricing at cost plus is pie in the sky, and this was a conundrum for the experts and given the time we can just go to our closing at {XL/5}, para 9. I am not sure what page that will be. {XL/5/5}. Thank you.

So we have just seen that figure 1, and there is a temporal, so we say:

"There is also a further temporal issue [with this cost plus]. Mr Harman said that he would expect returns to hit cost plus based on conditions of workable competition in the 'longer term.' Ms Webster recognised that there would be 'temporal factors', meaning that a supplier should not be expected to price at cost plus immediately. She was taken in cross-examination to the example in the Decision concerning the ASM, lamotrigine..."

That is figure 2, so we have just seen topiramate. That is figure 2:

"The purpose was to show that generics ... may well be priced well above cost plus for some time. She accepted that the suppliers might lawfully price at this level for an 'extended period'. Yet when asked by Mr Doran 'how long' one waits before a price becomes

unfair, she immediately fell back on this being a policy question which economics could not answer."

All this in our submission shows how far removed from the real world the CMA's sole yardstick for fairness really is, and how uncertain the yardstick of cost plus can be. I want to make those two points, to just put the floor in context.

That is all I want to say about the floor. We say it is a rather uncertain, shaky and indeed, moving floor, and to say on day one Pfizer should have priced at cost plus is essentially basing that on the PPRS regulated prices and is not looking at the real world generic market.

I just want to finish by making a few points about the comparison between limb 1 and limb 2, and this is the double standards that the CMA adopts when looking at the evidence for limb 1 and the evidence for limb 2, and I will mention three key differences: workable competition, data points and averaging.

So firstly on workable competition, can I go back to the Decision at {XA1/1/181}, just to identify what we are talking about. We are talking about in bold the EPBU, so we are talking about the average ROS of this Established Products Business Unit.

Then if we go to page {XA1/1/182} at paragraph 5.154

at the bottom, I am talking about workable competition here, the CMA at 5.154 says:

"Finally, as regards costs and competitive conditions, the CMA has not seen evidence to suggest that the costs associated with the production and supply of phenytoin sodium capsules differ materially from those of Pfizer's other established products, and [I emphasise this] has no reason to consider that the remaining products managed by the EPBU were not subject to a reasonable degree of competitive pressure."

One only has to read that again "has no reason to consider that the remaining products managed by the EPBU were not subject to a reasonable degree of competitive pressure" is a wholly different standard of workable competition in limb 1 and limb 2. In limb 2 we had 60% fall in prices, we have more intense competition, and what we have here is "has no reason to consider that it was not subject to a reasonable degree of competitive pressure", and here we are looking at a portfolio of products, and it is almost an assumption that there is workable competition to ground the unfairness.

The next point on data points. Again, on 5.156:

"... the CMA recognises that returns across ... will vary ... the CMA considers that average profitability provides a useful input ... The CMA considers this to be

one data point which provides useful insight for the purposes of its assessment and has sought to corroborate its reasonableness by reference to ... other data points as follows."

So here in limb 1 it is quite permissible for the CMA to refer to data points, prices, priced data points for completely different products and yet when we try and have a data point for anti-seizure medicines which treat the same clinical condition, we are told you cannot have it.

The two reasons are advanced: one the data point is not a product of sufficiently workable competition, and the characteristics between the ASMs are not the same, and yet here we have on limb 1 a data point which covers a multitude of different products serving a different clinical need.

Lastly, we see at para 5.156 the CMA is quite prepared to average out certain data points, and yet when Pfizer wants to -- when Pfizer through Mr Ridyard wants to average out the branded and generic versions of AEDs we are told we cannot, so we saw that figure 1, you have 19% of the market is branded, 21% is generic, we say let us have a weighted average, we set it out in our closing, we cannot, you cannot average it out.

When it comes to a comparison of the tablet ASPs,

you cannot average it out, you have to exclude Teva. Teva was the obvious comparator in the proceedings previously. We are now told in the Decision in Ms Webster's you cannot average out Wockhardt, Milpharm and Teva, and yet at paragraph 5.156, averaging out everything.

So in conclusion we say that the evaluation of the supply and the demand side criteria has not been fair, and what I have tried to do is at least show the Tribunal that there are some frailties with the calculation on the supply side and ultimately what the Tribunal has to do is evaluate both the supply side and the demand side and work out whether the price is unfair.

Those are all the submissions, I had lots more, but we have shorter time and thank you for not interrupting too much, but Mr Johnston is going to deal with the medical evidence.

Unless -- obviously, if you have any questions, sir.

THE PRESIDENT: Well, just one, and it relates to the last two topics that you have covered, and it is, I suppose, a contrast between static and dynamic visions as to how cost and price relate.

You have taken us to points made by both Mr Harman and Ms Webster that prices on their view of the world

trend towards cost in the medium-term.

MR BREALEY: Or long term.

THE PRESIDENT: Well, indeed, we can label it how we like, but what they are saying is there is a temporal aspect to the movement of prices towards cost.

MR BREALEY: Yes.

THE PRESIDENT: I do not think we need worry about the extent of that temporal aspect. Let us just take it that they are both saying that there is a temporal question in terms of the relationship between price and cost. Mr Harman was, in his evidence, focusing on the excessive limb, and Ms Webster was on the unfair limb, but they both made the same point.

MR BREALEY: She trespassed on his ground; he did not really trespass on hers.

THE PRESIDENT: Fair enough. So let us suppose we have an infringement found across a relevant period of zero to 100 and we have a constant price -- sorry, a constant cost, so we do not need to worry about variance in cost, it is a cost of 10, but one has a price that is varying over that relevant period, and let us say the price moves downwards from a very high price at the beginning of the relevant period on day zero to a price that is just above cost at the end.

To what extent ought we to be looking at the average

across period in answering both the question of excess and the question of unfairness given that both Mr Harman and Ms Webster have been saying that the mismatch or the gap between cost and price is something that has a temporal factor to it?

MR BREALEY: Well, I think in answer to that -- so if one goes -- can we go back to that figure 1? I will answer it by reference to that figure 1 which is at {XE1/2/18}. Thank you.

In our unfairness, Dr Majumdar has averaged out, so we cannot necessarily complain about the averaging; Ms Webster does. She says Dr Majumdar cannot average and she takes two small months or whatever. So we have averaged out. Obviously the infringement has averaged out the prices, and there is no reason why if you are looking at excessiveness you should not say: right, well, average out those three years there.

If one looks at that graph, there is a temporal aspect. In three years it goes from the peak to 200. It is quite clear that even the first three years or whatever is above cost plus, and one is then starting to get closer to how the generics work.

Probably either you average it out or you give Pfizer a period of three years, and I would mention one point on this: remember, this generic supplier priced by

reference to the peak, the NHS list price. Pfizer did not, Flynn did not. It is a substantial discount from the drug tariff price for tablets. So you could even shift Pfizer and Flynn's temporal thing along because it started at a low -- a high discount from the drug tariff, but, yes, you could do, but all I am attempting to establish here is it is not grounded in the real world to say cost plus should be the floor.

THE PRESIDENT: Thank you very much.

MR BREALEY: Thank you.

Closing submissions by MR JOHNSTON

THE PRESIDENT: Thank you, Mr Brealey. Mr Johnston.

MR JOHNSTON: Sir, rather than the normal box shuffling I am going to step into Mr Brealey's shoes to save a little bit of time.

As with opening I am going to be addressing you briefly in relation to the clinical evidence that we heard at trial but before I come on to that I am going to touch briefly on the evidence in relation to continuity of supply. I have a relatively small time window before I start to squeeze Mr O'Donoghue's time and if Mr O'Donoghue overruns he is going to squeeze Ms Stratford's time, so in an act of co-appellant solidarity I will try to be to the point. So starting with continuity of supply, this is addressed starting at

paragraph 51 of Pfizer's written closing.

What that section of the closing does is draw out really the distinction between three different kinds of continuity of supply that we have heard about at this trial, and I just want to touch on those briefly and elaborate on them.

So the first of those is continuity of supply as regards formulation of phenytoin. So this is the difference between Pfizer-manufactured capsules and capsules manufactured by somebody else or Teva-manufactured tablets and tablets manufactured by somebody else.

The clinical evidence was that the clinicians took this into account, were aware of it, but did not feel totally constrained by it. Professor Sander memorably said he would not take the MHRA guidance to a desert island with him, and that is consistent with the fact that we know that most of the prescriptions in this period were open, they did not specify a particular formulation.

We also heard that there were nonetheless clinical consequences to switching as between one formulation of capsule and another, or one formulation of tablets and another, and Professor Walker explained that from his perspective, if a patient moved between formulations

what he would begin doing was the blood concentration measuring that he described, this is the process where the patient has blood samples taken periodically, the concentration of phenytoin sodium in the blood is measured as a way of making sure that this switch has not given rise to a change or a material change at least in concentration.

We also heard from both of the experts they are likely to receive more phone calls, more emails, more communications from patients who are anxious about switching. In fact one of the things that they were telling us was that just receiving a parallel import of a Pfizer-manufactured product with different writing on it is likely to trigger some of that and that is doubtless going to lead to additional appointments.

There is also a real, but we have to be clear, a modest risk of loss of seizure control, and that is precisely why the blood concentration measurement is undertaken.

So there are real costs, there are real downsides to switching, but equally it is not an absolute barrier that cannot be overcome and that was not on occasion as we know from the data something that happened.

From the patient's perspective, there are both clinical and psychological consequences to switching.

Professor Walker's evidence was that the majority of the pressure for the MHRA guidance actually came from patients. Clinically, in terms of the relatively modest risk of loss of seizure control, also the need to go back to the GP to start blood concentration monitoring again, and psychological in terms of the anxiety that can follow for patients about this kind of switching, and that is consistent with what we know and what the Tribunal explored in some detail at the previous trial which is that at the point of prescribing when the prescriber -- sorry, at the point of dispensing, rather, where the dispenser is talking to the patient even though a high proportion of the prescriptions, the scripts are open, we know that is the point at which continuity of supply had a considerable effect.

So that is the first kind, switching between formulations of a capsule or a tablet. The second is switching as between capsules or tablets, and this, I think, is relatively straightforward.

The clinical consequences of doing so are similar to switching between formulations, so there is going to be additional monitoring, there is going to be additional patient contact, and so on and so forth, and some, albeit relatively modest, risk of loss of seizure control.

Overall, if necessary, we know it can be done. If Pfizer had withdrawn its capsule from the market, patients would have been switched to tablets. There would have been all of the processes that I have just been describing, there would have been a considerable increase, of course, in blood concentration measuring, the NHS would have paid £30 rather than the Pfizer price for the phenytoin prescriptions, and ultimately if there was not sufficient capacity in the market for tablets then some patients might have had to switch to a different anti-seizure medicine altogether.

The third form of continuity of supply that we have heard about is as regards switching between ASMs, and both of the clinicians agreed that the risks of doing that can be very severe indeed. You will remember Professor Sander's moving evidence actually about a patient of his who was a CEO, they had been seizure-free for a number of years, he had persuaded them, he said, early in his career to change ASM because he was concerned about some of the side effects and said to them you might have been Prime Minister rather than a CEO, I think that was how he put it. Eleven days later that patient had their first seizure for several years and died.

The risks of seizure outbreaks when patients switch

ASM are around 20%, so really very considerable, and that is far too high for most patients to accept, and it is worth saying that that is what the Decision says. The Decision says that remaining on phenytoin sodium when you are stabilised on it, is, and I quote "essential to maintaining quality of life".

So that is the clinical evidence on continuity of supply. In very brief terms, Pfizer submits that three things follow from this. The first is that there was a real and measurable clinical benefit to patients and to the NHS derived from keeping patients stabilised on Pfizer manufactured phenytoin sodium, and that is important for two reasons.

First, it goes to the economic value of the product. Pfizer-manufactured phenytoin sodium provides some unique and identifiable benefits, and that is a factor that has to be taken into account when valuing the product.

Pausing there for a moment --

THE PRESIDENT: Just pausing there, though, are you rolling up in that real and measurable clinical benefit all three of your different strands of continuity of supply?

MR JOHNSTON: That is a very good question. I was careful to say Pfizer-manufactured phenytoin sodium because the index question is of course Pfizer-manufactured

phenytoin sodium.

Now, there is not a complete boundary between the two, because if you take Pfizer-manufactured phenytoin sodium out of the market in 2012, then you have all of the switching to tablets at that point, so you have, as it were, categories 1 and 2 rolled in together, and you also, to the extent that there were capacity issues in the tablet market, you have category 3, though I recognise that we have not got direct evidence on that and it is very difficult to get that kind of evidence, but that is why I am focusing and using the language specifically of Pfizer-manufactured phenytoin sodium, but you are right to ask the question.

The nub of it is rooted in 1 and 2, though doubtless as of 2012 if Pfizer had stepped off the market we would have had elements of 3 as well. So that is how I put it, I hope that is helpful.

Just pausing here for a moment, because the CMA's closing argument devotes quite a lot of time to describing stabilised patients as steady-as-you-go patients, is one of the terms, or locked-in patients, as if this was some kind of factor that might be a downside to phenytoin or might be something that caused it to have less value to the NHS and to patients, and frankly we just do not understand that submission.

On the CMA's logic, if a patient tried every other anti-seizure medicine on the market, they have all failed, and then they try phenytoin and it worked, on the CMA's account that is a reason to downgrade the value of phenytoin sodium because they are locked-in or they are steady-as-you-go patients where we do not know, we do not know whether another ASM would work.

Candidly, we struggle on this side of the room to understand the logic of that submission, and connected to this of course is the question that has been canvassed with the experts in various contexts which is whether or not continuity of supply is something that moves phenytoin from case 3 to case 2, and so on and so forth. Ms Webster was content to say that it was, the CMA's closing says that it does not. You will anticipate Pfizer's submission that if we are thinking about this through that lens and using that typology, clearly this is one thing that would indicate that phenytoin sodium manufactured by Pfizer is a case 2 product, and I say that, sir, mindful of all of the other points that follow from it, which is that this does not automatically justify any price, but if we are looking through that typology then it would be one factor that would lean towards or point towards, rather, a case 2 outcome. So that is the first consequence that

follows from it.

Secondly, Mr Brealey has already touched on this, in relation to the tablet ASPs, continuity of supply obviously is engaged there. Taking it in stages, prior to November 2013, we know there is market entry in the capsule market, we know there is market entry in the tablet market, we know there is considerable price and volume shifts. We also know after November 2013 there is some additional stickiness possibly, but that does not stop in Pfizer's case the price fall in 2014.

So in Pfizer's context, at the point at which continuity of supplies come into play, that might be the point at which you would expect a now supermonopolist, if that were the true position, to start to ratchet up the price. Quite the contrary: that is the position at which Pfizer's price falls in 2014, at the beginning of that year.

So we say it does not prevent price falls and volume shifts. That was what Dr Majumdar's evidence was. He was saying: if I want to know how this works in practice on the tablet market, look at what happens on that market, and so it does not support the conclusion that there was no workable competition in that market.

The third consequence of continuity of supply, we say, is relevance as regards Pfizer's culpability and

I am treading on Mr O'Donoghue's turf here relation penalty, but this was a point that Pfizer pressed in some detail at the previous trial. The Tribunal in that case decided that Pfizer was dominant in the market for the manufacture of Pfizer-manufactured phenytoin sodium tablets and it rested that conclusion in material part on continuity of supply.

So in simple terms, an external force, the MHRA, had intervened on the Tribunal's analysis to put Pfizer into its own market. Prior to that, NRIM had been gaining very considerable market share very quickly.

The point is a simple one: if Pfizer was dominant because of a factor outside of itself, that is a very significant factor to take into account when it comes to culpability and when it comes to the need for specific deterrence, and I labour specific deterrence because you will be familiar, having read the submissions, that when looking at the very large £66.5 million penalty almost all of the weight of that comes from step four and comes from specific deterrence, but if it is right that Pfizer has been placed into this market and indeed coming back to what I said a moment ago at that point has cut its prices in any event, then we say that is very significant when it comes to culpability and it is very significant when it comes to deterrence.

So that is continuity of supply. I have rattled through it, but I am mindful of the time.

Moving to the medical evidence more generally on phenytoin sodium, the medical evidence was from Professors Walker and Sander and it played an important role, we say, in setting the parameters for this appeal, and we have dealt with that evidence in some detail at section A(d) starting at paragraph 66 of our closing and I am not proposing to repeat obviously all that is there.

What I want to do briefly today is work through that evidence focusing first on what was agreed, secondly, on what was not agreed, and thirdly, what were the consequences of that for the Tribunal, but before I get started I want to really just crystallise our submissions on this evidence so you know, as it were, where I am going, and our submission is a simple one.

First, the CMA in the Decision made a number of serious, clear and hard-edged mistakes in relation to phenytoin. So, in summary, they exaggerate the difficulties with it and they undervalue the benefits of it, but that is not just the theoretical point of medical intellectual interest because the errors that the CMA made are right at the heart of its analysis of economic value, and I will show you that in a moment

probably after lunch.

When the CMA comes to ask itself the question: what value does this product have above cost plus, we say part of the reason it says phenytoin sodium has no value above cost plus is because it has grounded that analysis in mistakes, actually, about the nature of the product, and that is a major problem for the CMA and it is a major problem for the Decision itself.

So that is the punchline, as it were, but to start out with the foothills and to start with what was agreed: so there was a helpful high degree of common ground between the parties. There were four key points of agreement.

First, they agreed that uncontrolled epilepsy is devastating for patients. That is a strong word. It is a word that both experts used or agreed with. The risk of having a seizure prevents somebody with uncontrolled epilepsy from driving, from swimming, but more importantly, it overshadows all aspects of their social, personal, economic lives. Patients with uncontrolled epilepsy have a 1% to 2% chance of dying every year from a seizure, and that is why the experts described it like having a sword of Damocles hanging over you.

Second, it was common ground that at the start of the alleged infringement about one in ten of all

prescriptions for anti-seizure medicines in the United Kingdom were for phenytoin. Now, adding capsules and tablets together that means around 75,000 people for whom phenytoin was absolutely critical to maintaining their quality of life.

Third, the experts were also of one mind about the importance of keeping patients on an ASM when they were seizure-free. Now, it is fair to say Professor Sander probably had a slightly lower threshold for which he might suggest changing anti-seizure medicine if there were adverse side effects present, but the difference was not that material between them, and that comes back to the point I was making earlier, and that is why in fact Professor Sander told the story about his patient who had shifted and had died eleven days later.

THE PRESIDENT: I think where we ended up with on both experts on this point in particular was that neither was characterising the other's position as one that could not reasonably be held.

MR JOHNSTON: Precisely so.

THE PRESIDENT: So translating what Professor Sander thought of his colleague, he had no difficulty in accepting that a fairly stringent adherence to the same regime was one that was entirely proper --

MR JOHNSTON: Indeed.

THE PRESIDENT: -- and that he would not criticise, and for our part, I think that is where we want to --

MR JOHNSTON: That is absolutely right, sir, and actually, the difference between them on this particular point was pretty slender and that is why for my part they are really agreed on this. There may be some spectrum between them but the nub of the point is agreed.

The fourth point that the experts agreed on was that phenytoin is an effective anti-seizure medicine, it works. Not in all cases. No anti-seizure medicines work in all cases, but when it is used as a third line anti-seizure medicine it will work in a small but significant number of cases, and both experts ballpark that at around 5% of the total universe of patients, and that is why it has been recommended by NICE in 2012 and in 2022, and neither expert suggested that it should not be a third-line drug. So that is the common ground.

Moving on to the areas where the experts disagreed, it was clear, as you have just said, sir, that they place phenytoin higher or lower in their personal batting order of drugs, if I can put it that way.

Professor Sander in particular explained that he had a number of what he called bees in his bonnet about various ASMs.

So, for example, he is firmly against the use of

enzyme-inducing ASMs, and that is very important to him, and it includes not using carbamazepine where possible which was the first-line treatment for focal epilepsy in 2012. So it might have been recommended as a first-line treatment by NICE, but he avoided it if he could.

He also had -- and again, it was his words -- a powerful bee in his bonnet about oxcarbazepine which is a second line ASM because of its potential to cause hyponatremia which is reduction of sodium in the blood which can lead to brain swelling.

So they might place phenytoin sodium at a different point, but both of them accepted the other's position, as you said, was reasonable and Pfizer's position is that these personal differences of opinion about the batting order are not that important, they reflect the spectrum of legitimate clinical expertise. So that is where the experts agreed.

How did they differ? Because there were a number of important respects in which Professor Sander's views differed markedly from those of Professor Walker that went beyond just the question of clinical preference, and those differences are important to come back to the submission I was highlighting earlier, because at various points in the Decision when expressing the conclusion: this is why phenytoin has very limited or

low value or no value above cost plus, the CMA in effect expressed views that were contradicted by Professor Walker at this trial, and this is addressed in some detail in our written closing, but I just want to focus on four key points and then I will stop after I have rattled through those and I will come back and deal with the Decision.

So the first of those. Professor Sander was very clear in his witness statement that phenytoin was a third-line drug because of its efficacy. So in his position paper when explaining why phenytoin is a third-line drug he underlined the word efficacy, placing particular emphasis on it, and you will find that -- I do not propose to turn it up -- at {XE6/9/12}, and Professor Walker did not agree with him on that, and it is clear having heard the evidence that Professor Walker was right on that point, and that is because in cross-examination Professor Sander accepted that phenytoin was just as efficacious as the first-line drugs off the rack in 2012, and you will recall we went to the Cochrane study and we talked about sodium valproate, we talked about carbamazepine and again, to anticipate the submission, the reason this is important is because in the Decision the CMA says: we are not really affording much value to phenytoin, and part of

the reason is it is not very effective.

So that difference between the experts finds its way into the Decision not just as sort of contextual interest, but it finds its way into economic value, and that is why we say it is significant, though it is fair to say that in written closing the CMA does not seem to be relying on efficacy in particular, so it may be that they have quietly now abandoned that point.

Secondly, in relation to side effects, we had the paper very helpfully written by Professor Sander himself in 2013 where he looked at the side effects of the ASMs on the market at the time and the key thing that was clear from that paper was that carbamazepine and sodium valproate, and if we think right back to the opening of this trial these were the two drugs that I was stressing in opening, the first drugs off the rack were associated with more long-term side effects and more strongly associated with long-term side effects than phenytoin or very, very similar and Professor Sander agreed that that was the case.

Now, again, this is important because of the emphasis the Decision places on side effects as going to value.

Third, Professor Sander's evidence was in writing, and I quote:

"I do not think any neurologist would recognise phenytoin to be used by their family or friends."

But he accepted in cross-examination that Professor Walker does recommend it, as do others, and with respect, that is a very bold statement given that NICE recommend it for friends, foes, enemies and family alike, and in fairness to Professor Sander, he did accept that.

The fourth and final point is that in Professor Sander's written evidence, he stated, again, very clearly "phenytoin is not relevant and not valuable any more", and again this is precisely the kind of language that we find feeding its way into the Decision, but in cross-examination he accepted it is relevant and it is valuable to patients who are stabilised on phenytoin, and it is relevant and it is valuable to patients who have uncontrolled epilepsy, try phenytoin and secure seizure-freedom as a result.

Sir, before I come to the Decision, I have one more short point, if I can trespass five minutes into the break that would be very helpful.

THE PRESIDENT: Of course.

MR JOHNSTON: So to close for now, two more things that Professor Sander accepted in cross-examination that we say are very significant contextual points for the

Tribunal to bear in mind when it comes to reading the Decision.

The first is that Professor Sander accepted that his written evidence to the Tribunal, which was squarely consistent with what he told the CMA, and is squarely consistent with what is in the Decision, reflected his views now in 2023 rather than his clinical views and practice in 2012, and this is a point that is developed at paragraph 71 of our closing.

Professor Sander created a very impressive impression, actually. He is a horizon-scanner, he is clearly a horizon-scanner, he is somebody who wants to anticipate what is coming next in clinical practice, what do we need to be thinking about stopping or starting doing ahead, but that is also consistent with the evidence that he gave in writing, and he was very helpful and very clear at points that what he said in writing was a reflection of his views now looking forward, not the position in 2012.

Connected to that, but perhaps more importantly, Professor Sander accepted that his views as expressed in his written reports were an outlier, and in particular, an outlier as regards 2012, if I can put it that way, and that is why right at the beginning of his evidence I said to him: I am going to be asking you to sort of

put yourself in a metaphorical time machine and think back to the time of 2012.

Professor Sander had strong views, it is fair to say, about a range of drugs, including phenytoin and including some first-line drugs, but those views were an outlier, and I mean no criticism of him in that respect, that is the kind of clinician he obviously presented as, but some of them are an outlier now, they were certainly not the mainstream views of clinicians in 2012, and that is important, so I am going to come back and address you after lunch on how those views feed into the Decision and we say have distorted the CMA's assessment of the value of this product to patients, to the NHS and to society more widely.

Sir, I propose to stop there. I hope to be reasonably brief, so I do not get daggers, metaphorical or literal from my right, or my left in fact, after we come back. Thank you.

THE PRESIDENT: I am very grateful, Mr Johnston. We will resume then at 2.00. Thank you very much.

(1.04 pm)

(The short adjournment)

(2.02 pm)

THE PRESIDENT: Mr Johnston.

MR JOHNSTON: Sir, I am grateful. Before lunch, we were

talking about the clinical evidence.

What is the significance of all of this or where does it go? We have set out in paragraph 76 of our written closing various points in the Decision where the CMA describes phenytoin and its characteristics. I am not proposing to go back to any of those now.

What I want to do with the time that I have available now is to focus on the CMA's reasoning at the point in the Decision where it decides that phenytoin is not worth more than cost plus or at least certainly not worth the prices that were charged.

So if we could start at {XA1/1/267}. So to put this into context -- sorry, thank you, Mr O'Donoghue is making sure I am being picked up on the audio -- this is part 6 of the Decision, so it is dealing with value, it is in part 5, so it is the part of that section that is dealing with the features of the product and whether they justify the price.

So starting with 6.88:

"Notwithstanding this, the CMA has also considered whether the features of the Capsules resulted in 'additional benefits' or any 'particular enhanced value' for customers and might nevertheless explain or justify the significant price increases and the ... very high prices."

So what's being tied together here, as I say, are the features of the product and the prices, and there are four points that the CMA relies on in respect of this question.

The first is at paragraph 6.90 which is just at the bottom of the page. Just taking it line by line:

"First, as a treatment for epilepsy, Capsules have long been superseded by other AEDs as a first-line treatment ..."

So the reason that phenytoin does not provide any value to the NHS or to patients materially above cost plus is because it is a third-line treatment.

Pausing there for a moment, and I have prefigured this to some extent, with respect, that finding makes no sense at all because the fact that phenytoin is a third-line treatment means that it will only be prescribed to patients who have not managed to secure seizure control from other AEDs. They have tried the first-line treatments, they have tried at least some of the second-line treatments, not necessarily all of them, depends on the patient, they are looking at third-line treatments, and they are likely at that point frankly to be desperate to secure seizure control, and a small but significant percentage of the total patient population are going to secure seizure control at that point from

phenytoin.

So the value of phenytoin to the patients for whom it works in the third line is unbelievably high, and the fact that it is third line is not, we say, rationally connected to the question what value does it provide when it is prescribed and when it works.

Reading through the paragraph towards the end:

"[The] other AEDs were preferred to Capsules due to their greater overall benefits for patients. This was recognised in NICE guidance ... which identified ... [it] as a third-line treatment. This reflects an assessment of the drug's therapeutic benefits by an expert body based on a significant volume of evidence, and which categorises AEDs based on the benefits they provide to patients. Phenytoin's categorisation by NICE as a third-line treatment reflects the fact that other AEDs have greater efficacy ..."

Wrong. We know that is wrong, because we know that phenytoin is as effective as the first-line treatment recommended by NICE.

"... fewer side effects..."

Wrong. We know that is wrong because Professor Sander's own paper from 2013 associated the first-line treatments with a similar number of serious, long-term side effects.

"... fewer adverse drug interactions..."

Yes.

"... greater ease of clinical use."

Yes. And this was Professor Walker's evidence: his evidence was the reason it is third-line is not because it does not work, it is not because of the side effect profile of it, it is because it is more difficult to use. That is the blood concentration measurement that we have been talking about earlier.

So that is the first reason. That is the CMA's first justification for explaining why this product, looking at value, does not have value materially above cost plus, and we say at the heart of that reasoning there are clear, hard-edged analytical mistakes.

So moving down to the second reason now on page {XA1/1/269} and paragraph 6.94, so just over the page, if we can zoom in at the top:

"Second, evidence gathered by the CMA on remittal from Professor Sander, a clinical expert, does not suggest that Capsules had previously been hugely undervalued, or that the drug has 'additional benefits' or any 'particular enhanced value' related to any therapeutic advantages of the product. Indeed, Professor Sander's view is that phenytoin sodium exhibits a combination of unique therapeutic

disadvantages which do not benefit patients or customers or enhance the value of the product for them."

So here is what I was referring to earlier, the downplaying of the benefits of phenytoin tied directly to the evidence of Professor Sander which he describes himself as reflecting a series of bees in his bonnet.

So let us take them as they come.

First:

"Its NTI and non-linear pharmacokinetics."

Absolutely agreed. That is the point which means you need to be careful to titrate the dose of phenytoin, and we heard evidence on that:

"The combination of them makes it difficult for practitioners to regulate the dose ..."

Yes.

"... can lead to toxicity and irreversible problems for patients."

All anti-seizure medicines can lead to toxicity. What is meant by toxicity is the acute side effects that derive from having too high a concentration in the blood and if we think right back to the opening we looked at that table and within the acute side effects they were similar vis à vis phenytoin as other drugs and Professor Sander agreed with that as well.

Moving to the next paragraph:

"Potential[ly] serious side effects. It is an enzyme-inducing drug, which are recognised as having potential[ly] serious side effects which are not a concern for non-enzyme-inducing [drugs]."

Now this goes right back to what I was addressing you on earlier. Professor Sander, and I mean no disrespect to him by this at all, described this as a bee in his bonnet in relation to enzyme-inducing drugs. His view is enzyme induction bad, non-enzyme induction significantly better, and that is why he does not like to use carbamazepine, but it is also fair to say carbamazepine is the first drug recommended by NICE in 2012 for focal epilepsies, and at no point in the 2012 guidance or indeed the 2022 guidance is there this analysis that says enzyme-inducing AEDs do not go here or touch with great care. Non-enzyme-inducing AEDs, completely different, much better. So what we have here is Professor Sander's horizon scanning as of 2021, 2022, written into the Decision when discussing economic value and what we have here is not consistent with the perspective of -- let me put it just at this level, not consistent with the perspective of NICE as of 2012 at the relevant time.

"It is also the worst enzyme-inducing AED currently in use in terms of side effects."

Just to take that sentence as well, wrong, again, because carbamazepine, it was agreed in cross-examination, is associated with as many, in fact more side effects and more strongly associated with the listed side effects and it is the leading enzyme-inducing AED.

So what we have here, all through this reasoning, are these important principles or propositions about the nature of phenytoin that we say are mistaken.

Turning over the page {XA1/1/270}:

"Potential drug interactions, which makes phenytoin ... very difficult to use ..."

Again, we have covered this. It is notable that the same points are coming back again and again, so within each of these categories, within each of these listed reasons, we are seeing, it is fair to say, a high degree of repetition.

"Third [so that is paragraph 6.96] the ... majority of patients treated with Capsules during the Relevant Period were legacy patients..."

So pausing there what is being said is phenytoin has less value because the majority of patients are legacy patients and there were significant barriers to switching these legacy patients to alternative treatment options.

In fact, rather than hearing my voice constantly, if you could zoom out a little and have the rest of 6.96 and then all the way through to the end of 6.97 and then I will make my submissions. (Pause)

I am not going to put my submission any higher than to say that this is muddled. The conclusion seems to be that because switching patients away from phenytoin might cause them to have a seizure outbreak with potentially devastating consequences for the patient as well as, if we are going to take this into account as well, as well as all of the economic consequences for the NHS. That means that it has limited therapeutic benefit to patients, and that means that it has limited value.

The barriers to switching that are being described here are clinical barriers. You do not want to risk the patient experiencing the story that Professor Sander told us near to the end of his evidence, and the Tribunal will anticipate the submission before I make it, which is that this is a point that goes the other way.

If a patient is stabilised on a drug and there are very considerable risks to them from switching away from that drug, that is not consistent with its low value, that is consistent with the fact that that product

provides good value to both the patient and to the NHS.

Paragraph 6.98, you have it just there at the bottom:

"This does not mean that Capsules have zero therapeutic benefit for patients ... treated with the drug."

With respect, that is not a contentious statement, but it is surprising that the CMA felt that it needed to put that in. It has got itself and it has reasoned itself to the position where it has to reassure the reader that there is some therapeutic benefit to phenytoin, and we say that shows quite how much the CMA has lost its way in the course of its analysis. If we could go over the page now to 6.99, this is the fourth and final reason {XA1/1/271}:

"Fourth, the evidence put forward by Pfizer relating to supply prices of other AEDs ..."

Mr Brealey has already addressed you on this this morning. You will have very clearly in mind what the Tribunal said last time about the other AEDs, and what the Tribunal said was that they provide an indication of what the NHS is prepared to pay for seizure-freedom. It did not put it any higher than that, Pfizer does not put it any higher than that, and I will not address you on it any further. We have set out our reasoning in full

in writing, but that is the reasoning. That is why the CMA has decided this product does not have any material value above cost plus, and we say it is riddled with mistakes. We say that it is quite clear that the CMA's analysis is flawed and, as a consequence, the conclusions that it has reached about the economic value of this product are not sustainable. It has been materially understated, and if that is right, then we say the Decision has to be set aside.

Members of the Tribunal, unless you have any questions I am going to hand over to Mr O'Donoghue to address you in relation QALY.

THE PRESIDENT: No, we have no questions, Mr Johnston. Thank you very much for sticking so closely to the timetable.

MR JOHNSTON: I am grateful.

THE PRESIDENT: Mr O'Donoghue.

Closing submissions by MR O'DONOGHUE

MR O'DONOGHUE: Sir, thank you. Sir, I am going to, as Mr Johnston said, address QALY and also briefly penalty, although, sir, you will understand Pfizer's primary position today is not to seek clemency.

So starting with QALY, obviously, sir, that is an issue of some granularity and technicality in these proceedings. It spans, I think, 20 pages in our written

closings and in the next 30 or 40 minutes, I cannot hope to cover all of that terrain.

What I want to do instead, sir, is focus on three points, if I may. First, to start with what does the Decision say on QALY, and in truth as we will see there is not very much, and we submit, as we will see in a moment, that what is set out in the Decision on QALY is wrong, and at the very least inadequate as a response to that issue.

The second point I want to focus on in a bit more detail is really the CMA's leitmotif when it comes to QALY which is that that method has nothing to do with economic value as used in a competition law sense.

Now, that is of course a legal question on which the experts could not really assist. We say this assertion on the part of the CMA is inaccurate and that, as I will develop, QALY does speak to a number of the essential factors in any proper assessment of economic value in the context of this particular pharmaceutical product, given the unusual context in which phenytoin sodium arises.

Then finally on QALY before we turn to penalty, I want to pick up on a couple of short points in Dr Skedgel's model. We continue to submit that his model is at the very least a helpful and reasonable

piece of work and that it shines light on a key question in this case, and indeed, it is very conservative from a number of perspectives.

We do say that he deserves credit in developing such a model within the constraints of the deadlines of the appellate process, that he was conspicuously fair to avoid overstating his position and we say he is exactly the type of independent expert who came to assist the Tribunal again for which he deserves credit.

So starting, sir, with my first point on the Decision, QALY of course is not a new point in this case. The Tribunal may recall from my openings that Mr Ridyard covered, albeit briefly, the concept of QALY in his evidence, and I will come back to that in a second, and, as we will see in the Decision, the QALY concept was something that Pfizer in particular advocated for during the administrative phase and suggested it was something the CMA should investigate.

So can we start by looking at the Decision, what it says on QALY? It is at {XA1/2/59}. If we can start at E.87 at the top of the page, the CMA says:

"... a QALY analysis is generally used to assess new treatments and concerns whether a drug should for the first time be made available for prescribing on the NHS, not whether a drug should continue to be available."

Now, sir, as I think will be very clear from the evidence we have heard, that is simply wrong. QALY equally applies to a range of existing medicines and indeed, the guideline process for the most part is concerned with existing medicines, and indeed, the guidelines on ASMs in 2004, 2012 and 2022 were only concerned with existing ASM drugs, so it is simply wrong to say that QALY is even generally about new products, and this of course is the point made sotto voce in a number of respects in this case: well, phenytoin is old and why would it be assessed by anyone.

Now, as I said, sir, in fact it has been assessed successively in guidelines for the last 20 years, so this first point is plain wrong.

Indeed, sir, even on its own narrow terms it is wrong, because of course you will remember the exchange with Professor McGuire that in relation to a new medicine undergoing the TA process, that medicine will be compared to existing treatments. So even within a TA context and confines it is at best incomplete. So that is a wrong statement as a starting point.

The second point then is at E.88 you will see a reference to Mr Ridyard's evidence, and if the Tribunal can quickly scan the quotation which is set out there. Rather comically in the footnote it is referred

to as a cross-examination of Professor Waterson.

I think it was the other way round, but I can assure the Tribunal it is Mr Ridyard.

PROFESSOR WATERSON: I am still waiting for that.

MR O'DONOGHUE: If we look at what Mr Ridyard actually said, if we go to his report it is at {XE1/1/36}, it is at 105, and again, if the Tribunal could quickly scan that. What I would suggest he is saying there is that if pharmaceutical companies can charge a premium of up to £20,000 to £30,000 according to the QALY thresholds, then a supplier of a drug, the CMA itself, suggests is essential non-substitutable should be allowed to charge a premium to reflect those benefits. So he is making an analogy between the QALY premium and the premium for an important medication such as phenytoin sodium.

I would suggest that with respect to the CMA, all one gets from Mr Ridyard's evidence is something which we have seen in spades in this case, which is that health economics is a distinct branch of expertise to competition economics. So Mr Ridyard in my submission is saying: well, there is something important to investigate here, I am not the man for that job, but we have the two professors and we have seen what the health economics evidence has shown.

So we say that the point in the Decision on

Mr Ridyard with respect does not really go anywhere.

Then if we go back to the Decision, please, the previous document {XA1/2/59}, you will see at E.89 at the bottom of the page, the CMA says:

"... a QALY analysis does not assess what is the economic value or a fair price for a particular technology or medicine."

They say:

"The concept that underlies QALY ... is that of the opportunity cost of existing health interventions that could be displaced by the introduction of new technologies."

Then you see the footnote 2076 -- well, 2075 is the cross-examination of Professor Waterson. The next footnote, you will see there is a single reference to a NICE Guide from 2013, and what is strikingly absent from this brief paragraph is there is no reference to the guideline manual, no reference to the technology appraisal manual, there is no reference to NICE's work at all, and there is no record of the CMA discussing this with NICE, the Department of Health, the National Health Service, or any of the stakeholders you would expect them to engage with. There is a single footnote referring to a guide from ten years ago.

So we do say as a starting point these two and

a half reasons in the Decision are either wrong or at best inadequate as a response to the QALY question. This is a complex question, it cannot be fobbed off in the manner we have seen. We say it is a recurrent theme in these proceedings that the CMA simply did not engage with the Department of Health, the NHS and its auxiliaries such as NICE on issues that were potentially exculpatory in relation to the defendants or the appellants. It did not, in our submission, adopt an open and neutral and inclusive approach.

So that is all I want to see in the Decision. In my submission it is an unpromising starting point for the CMA. I accept that things have moved on, we have the witnesses now, but as a treatment of QALY, the Decision, in my respectful submission, is inadequate.

The second topic is the question of triangulating QALY and economic value in a competition law sense, and, as we saw in the Decision, one of the CMA's consistent criticisms has been that NICE in its QALY work is not assessing economic value in a competition law sense, or indeed otherwise evaluating the fairness of the price for medicine in a competition law sense.

We say that is only true in a reductionist sense and is superficial or we say inadequate as a response. We say that when one looks at the basis for the remittal in

these proceedings, the evidence that the CMA does accept is relevant to economic value and the practical context in which QALY is applied, the QALY methodology does offer useful evidence in the present case, including, we say, on aspects of economic value.

Now, I want to build up this point, sir, in cascades or layers. The starting point, I think, is common ground, which is we need, as best we can in these proceedings -- and this picks up from Mr Johnston's submissions -- to try and calibrate as best we can the therapeutic benefits of phenytoin sodium, and indeed, that was one of the main reasons for the original remittal.

If we can quickly go to the judgment from 2018, it is at {XN1/2/133}. It is at paragraph 419 it says:

"... the Decision was defective in its treatment of the economic value that may be derived from patient benefit. Placing a ... monetary value on patient benefit is not straightforward but it appears to us that a qualitative assessment would be possible and should have been attempted by the CMA rather than simply assessing this value as nil."

So one of the main reasons for the remittal was a defective approach to the question of patient value, and of course, the only reason the evidence of

Professor Sander has been put forward is that the CMA says that that informs the question of the effectiveness and therefore the patient value of phenytoin sodium.

Now, it cannot be right to claim in the same breath that having put forward Professor Sander on evidence of therapeutic benefit that looking at therapeutic benefit under the lens of QALY is somehow objectionable. It is the same issue, so we make the sauce for the goose/sauce for the gander point.

So the first point as a starting point, it is common ground in this case that therapeutic benefit is something that is critical to economic value and that the QALY analysis at least in part addressed that question in a systemic manner, so that is the first point.

The second point in my cascade is the Decision accepts based on the Court of Appeal judgment that we need to consider the value of the medicine, not only to the patients who are for these purposes the users or consumers, but to the NHS as the end customer underwriting the entire social insurance system, and we can again pick this up in the Decision, the previous document, {XA1/2/60}.

It is at E.94, at the bottom:

"... the Court of Appeal noted that economic value

is what 'users and customers value and will reasonably pay for.' In this case, the end customers are CCGs and the NHS, and the users (or consumers) are [the] patients."

So the value to the patient is obviously critical, but in a world where the drug is therapeutically valuable, perhaps even uniquely so, but neither the patient nor the prescriber pays for the medicine or indeed even typically takes the cost into account, it is vital, we say, that the person who is footing the bill, the NHS in this situation, has some method of working out from its perspective whether a medicine is actually a good use of its finite resources.

Now, of course, in a very real and certainly individual sense, this sounds quite distasteful. Who is to say that one person's life is worth more or less than another's. But since the NHS budget is finite and there are competing priorities, public policy has to grapple with hard decisions using some reasonable and consistent method, and in particular, NICE must consider the value to society in terms of how the same money could be used to help a different patient within the NHS. So there needs to be a method from the perspective of the end customer, the NHS, as to how to spend its budget wisely.

My third point of the cascade is that for the last

25 years, the most widely used method the NHS has decided upon in terms of recommending use of new and continued treatment of existing drugs is the QALY method, and we say the QALY method is important because it captures the key elements of interest in terms of benefit, and we therefore say value, to the NHS and the end user.

Now, just to unpack that, it obviously looks at the clinical and observational evidence on efficacy in enormous detail. These clinical observation studies are the bedrock or the first step in the QALY analysis, and indeed, the data-gathering, if I can call it that, on a QALY, it involves ferreting out any reasonably available study of a clinical observation nature that is available, in particular in English, but not exclusively in English. So it is a highly inclusive approach as indeed Mr Hawkins made clear. It is a data driven, insofar as possible, empirical and clinical-based approach. So they are looking at therapeutic benefit to the patient in a systematic way, we say.

It obviously takes into account the price of the medicine, the price of the medicine is an input into the cost calculation under the QALY method. It is one of a number of costs taken into account.

It takes into account all of the direct costs to the

NHS, in addition to the drug acquisition costs, and for these purposes and critically to Mr Brealey's point it takes into account the costs avoided by the NHS in purchasing this particular medicine.

Now, only the QALY analysis does this. The qualitative evidence we had from the medical professors does not do so, and nor does the CMA include these avoided costs anywhere else. We say it is obviously important and relevant that these benefits are considered. We have of course seen the evidence that the costs associated with a loss of seizure-freedom are an order of magnitude higher than the drug's acquisition costs, and we would submit that it would be quite extraordinary if these costs were completely ignored in the analysis of economic value.

Now, as Mr Brealey showed you, in Attheraces the Court of Appeal overturned the High Court because the revenue earning potential of the product in that case, as part of its economic value, had been disregarded, but we say the other side of that coin is that the cost savings generated by product are also part of economic value. I mean, just to take an example, suppose you had a piece of machinery that allowed a factory to reduce its costs by 90%. We would suggest that it could not be seriously argued that those cost savings generated by

the machinery would be irrelevant to its price or that a seller who reflected the capacity for the machinery to generate substantial cost savings in its price would be guilty of unfair pricing, or that it should be pricing at the same level as a seller of an inefficient piece of machinery.

We say if Attheraces says revenue earning potentially is part of economic value, then by parity of reasoning, so is cost-saving potential.

These are either two sides of the same coin or indeed the same coin, the same side of the same coin, because cost is obviously related to price.

The fourth point in my cascade is that the QALY analysis does assess value in a way we say that is consistent with the notion of economic value.

If we can go to Dr Skedgel's teach-in, it is at {XE7/8/9}, these are the four quadrants as the Tribunal may remember.

So at its most basic what the QALY analysis is asking is whether the cost incurred, which includes the price of the drug, is justified by reference to the effectiveness or benefits in terms of the QALYs gained, and the process as we saw is inherently a competitive one: one drug costs less and/or is more effective than one or more other drugs, and if one looks at the

quadrants, the south-east of course, less costly, more QALYs, that is ideal, but the south-west and north-east are also positive outcomes, and the north-west is bad all round, because it costs more and has fewer QALYs.

In a stylised, and I accept basic way, what the four quadrants show you is that what the QALY does in its basic and essential form is work out whether one drug is better value in cost, which again includes price, and/or in terms of QALYs gained compared to another drug, and indeed, it is the only metric in this case which is trying to address the fundamental question for the NHS as end customer which is how do you balance potentially infinite patient need on the one hand and the willingness-to-pay against a constrained budget on the other using a method that is reasonably consistent.

Now, as we know --

THE PRESIDENT: Mr O'Donoghue, just so that I am clear, the way in which QALYs work -- and do correct me if I am wrong about this -- is that you have an existing way of dealing with a given malady which entails certain costs and results in certain benefits to the patient, and what you do is when a new form of treatment comes along, you assess it in comparison with that old form to see whether it is worth undertaking or not using this sort of grid.

In other words, it is a very narrow exercise. It does not operate to justify a completely new form of treatment, but it does operate to act as a control in respect of new forms of treatment where the cost is already being incurred.

Have I got that right in a broad summary?

MR O'DONOGHUE: It is partly correct. Now, sir, your example I think is most apt for a technology appraisal. So a technology appraisal typically is for a new product comparing it to some existing product.

In the guideline context, as we see in 2004, 2012 and 2022, they are not looking at new products at all, they are looking at a range of existing ASMs and seeing whether the ones that have been recommended or funded to date are still worth the candle, and it is a discerning process because you will remember the point I put to Professor McGuire, we have seen the cenobamate study from 2020, that out of a total of 30 ASMs, only 18 are recommended by NICE. So there is a culling or at least a non-recommendation if I can call it that.

Now, the third piece of the jigsaw, sir, is the QALY process does not just apply to medicines, it also applies to medical technologies.

THE PRESIDENT: Yes.

MR O'DONOGHUE: Sir, you may have quantum-leaped surgical

diagnostic equipment or surgical equipment, and that technology looked at as an integrated whole generates substantial savings over something that is the current state of the art and that of course may be a sort of apples and pears assessment. So there are different types of assessment, sir, if that makes sense.

THE PRESIDENT: Well, that is helpful, Mr O'Donoghue. Sticking then to the guidelines as opposed to the TAs, to what extent is it the case that development and understanding and development in available drugs means that some old established drugs drop off, as it were, the perch, to use your phrase, simply because they have been overtaken by other forms of treatment which render these older forms redundant? I mean, is that the process that we are looking at when one is --

MR O'DONOGHUE: In part, sir, yes.

THE PRESIDENT: In part.

MR O'DONOGHUE: I think it goes back to my point that of the total of 30 ASMs, only 18 are recommended.

THE PRESIDENT: Yes.

MR O'DONOGHUE: So there will be drugs that historically have been used and suddenly fall off the cliff, if I can put it like that, and of course, the most obvious reason is that there is something more effective and/or cheaper out there, but it may also be that there is a more

detailed up-to-date economic cost utility study done and it turns out the conventional wisdom of describing X for many years does not have a good empirical basis. So there will be a range of different scenarios why something might fall out of favour, and again, the critical point is phenytoin has consistently been recommended.

THE PRESIDENT: Well, indeed, though we do not know, because we do not have the detailed consideration of the committee that considered this, precisely what weighed with the committee in terms of the continuation of sodium phenytoin. It may have been the clinical benefits to the existing cohort of patients and the inadvisability of changing. It may have been a more psychological question of wanting to ensure that patients were not concerned by effectively a mandatory change in their treatment, even if that was medically neutral. We just do not know what the position is there, all we know is that the continued deployment of sodium phenytoin was approved by NICE. That is as far as it goes.

MR O'DONOGHUE: Well, I think, sir, for 2022 there is some truth in that.

THE PRESIDENT: Yes.

MR O'DONOGHUE: Because you will recall that in essence the

clinical opinion overrode or at least took a different view to a cost effectiveness study, but of course you remember we had this discussion about a week ago. I mean, the conclusion in 2022, it was based on what we say was a rather rigid set of criteria in the sense that unless NICE could find third-line efficacy evidence bang-on point and in relation to complete seizure-freedom there was no such clinical study given the age of phenytoin, that is why at least in terms of complete seizure-freedom the cost effectiveness in 2022 was considered something more marginal.

Of course, Dr Skedgel has done something different which we also say is consistent with what NICE itself has done, which is to say we know in the first line from studies that phenytoin is effective, we can extrapolate from the first line to the third line, and if you look at efficacy in those terms, then it is cost effective, so there is a bit of apples and pears about these assessments.

Sir, I am sure the Tribunal has this point, but it is important, I was going to come back to it, but I will deal with it now, the guidelines are looking at the question from the perspective of a new patient.

THE PRESIDENT: Well, indeed.

MR O'DONOGHUE: Of course, Dr Skedgel's model therefore does

the same thing. Now, about the one thing in these proceedings everyone agrees on is that for existing and legacy patients, phenytoin sodium is extremely valuable and extremely effective, and from that perspective, Dr Skedgel's analysis is about as conservative as could have been imagined.

THE PRESIDENT: Because it leaves out of account the continuity of supply point.

MR O'DONOGHUE: The main event, the main event, and the guidelines of course do the same, so in a sense, sir, the point is a fortiori because we know that for new patients, phenytoin has been consistently recommended, even after 100 years, but we also know above all that for the existing patients this is the best drug that they could be on, and from that perspective, Dr Skedgel's model is, we say, unbelievably conservative.

PROFESSOR WATERSON: Can I just check on that? We know that these patients are on -- the existing patients are on this drug; we do not actually know whether it is the best drug for them or not because they continue on it.

MR O'DONOGHUE: Well, Professor, in a sense, that is putting the cart before the horse, but what we do know is that if they are stabilised on phenytoin about the last thing you would want to do is switch them to another ASM.

PROFESSOR WATERSON: I am just making the point about, or questioning the assumption that it is a conservative assessment because it is difficult to assess those who have always been on it.

MR O'DONOGHUE: Well, indeed, sir, but the one thing we know is that for those patients in particular this is effective and that the risks of switching are very substantial indeed.

THE PRESIDENT: Well, yes, it may be that the point can be put in several different ways, but you say Dr Skedgel's assessment is conservative, and I can see why you say that, but on another view, it is also failing to take into account a significant piece of value, if I can use that unfortunate word in that context, a significant piece of value to the cohort of patients who are stabilised on sodium phenytoin which according to the medical evidence we heard, and they certainly agreed on this, patients do derive significant benefit in remaining seizure-free.

So a very important aspect is left out of account in both the NICE assessment and Dr Skedgel's replication of that assessment, and --

MR O'DONOGHUE: Sir, that is true, but of course if as we say it is within threshold for new patients, the intuition -- what we know about existing patients, that

is a very powerful and frankly uncontested, we say, piece of evidence. I mean, in a sense, as Mr Johnston said, the CMA seeks to make a virtue for its case on the importance of this drug for legacy patients, so we say if we are within threshold viewed from the lens of a new patient in relation to existing patients it must be a fortiori, because think about this in terms of avoided costs: if the risk of seizure for coming off phenytoin sodium for an existing patient is something like 20%, we heard about these costs of thousands of pounds for hospital visits and so on, it is not very difficult, we say, to then understand why the intuition of the value for existing patients is a very powerful one.

PROFESSOR WATERSON: Just to come back on that, supposing you are with a particular broadband provider and that broadband provider increases the price a great deal at the end of your contract. Then you have to make a decision to do the easy thing, which is to stay on the same broadband contract, or to search around for a new one.

So some of these people, the existing legacy patients, will have been put on the product when it was very cheap, so the decision was made at that time, as it were, that it was sensible for them to be put on it. Then, when it becomes more expensive there is this

trade-off in the same way as with the broadband provider.

MR O'DONOGHUE: Yes, yes, well the virtue of Dr Skedgel's analysis of course is that he conducts the QALY assessment at the level of the challenged 2012 prices, so he is asking the question: if the price increased to this level, would it still remain within threshold. So we say he is meeting that challenge head-on and based on his evidence we are still well within threshold.

So we say he has answered that question by way of a proxy with the new patients. It is not a ransom price, in other words, it is well within threshold.

Now, just to move on, on the thresholds of course there was some discussion as to the origin of the thresholds and there was some obscurity as to the genesis of the 20,000 and so on. Now, I do not cavil with that, but in my submission, what matters is not the origins of the thresholds but rather the fact that the threshold has existed for 25 years and is being applied consistently in the real world in relation to multibillion pounds decisions by the National Health Service in relation to funding.

Now, we would respectfully suggest that if the NHS via NICE is content to see the QALY threshold set at £20,000 or £30,000 the fact they do so is more important

than trying to divine its genesis or to ask whether some lower or higher or different threshold should have been applied instead.

NICE and the NHS live and breathe these methods and thresholds and use them in the real world to spend finite taxpayer money, and in our submission, we should be humble and respectful of these methods as a consequence and not iconoclastic.

Now, there is also one other rather obvious point that needs to be said. If, as the Decision says, the benefit to patients in therapeutic terms and the benefit to the NHS as end customer needs to be taken into account, the CMA's desktop cost plus model makes no effort to capture either benefit, so from that perspective we say that it is at least 2-0 to QALY.

Now, the final point is one of principle. The Tribunal will recall that I put to Professor McGuire a number of specific features of the pharmaceutical market that we said needed to be taken into account when it came to considering the economic value of the drug, and the point being put is there were certain peculiarities, if I can put them as neutrally as that, within the pharmaceutical sector compared to other unregulated markets, not subject to a social insurance model, and that these needed to be factored in somewhere

in the analysis.

Now, just to give you a legal basis for that proposition, it is the *Glaxo Greece* case. It is at {XN5/19.1}.

This is a pre-Brexit judgment of the Grand Chamber of the Court of Justice, so it is something the Tribunal can have appropriate regard to.

The case was about whether the restriction of sales to wholesalers who were parallel importing was an abuse of dominance by the manufacturers, and if we can then go forward to paragraph 20, please {XN5/19.1/10}. Sorry, jump forward to 59, please {XN5/19.1/22}. You will see it says:

"It is clear that, in the majority of Member States, medicines ... are subject to regulation ..."

Then you see a reference to the scale of reimbursement of the cost of the sale of prescription medicines in the relevant social health insurance systems. So that was the point being argued that these are regulated markets subject to price control with social insurance models.

If we then look at what the court -- so the manufacturer was saying: well in the context of these regulated markets they actually had an extreme case whereby they said competition law should not apply at

all, and if we then look at what the Court of Justice said, it is at 66 and 67 {XN5/19.1/24}, you will see in the second sentence:

"In the light of the abovementioned ... objective there can be no escape from the prohibition ..."

So the argument they were exempt from competition law did not find favour, but the next paragraph is important, they say:

"Although the degree of price regulation in the pharmaceuticals ... cannot ... preclude the Community rules on competition from applying, the fact nonetheless remains that, when assessing, in the case of Member States with a system of price regulation, whether the refusal of a pharmaceuticals company to supply medicines to wholesalers involved in parallel exports constitutes abuse, it cannot be ignored that such State intervention is one of the factors liable to create opportunities for parallel trade."

Now, the upshot of the case in terms of the court's finding -- this was a preliminary ruling -- was that these abnormal features of the pharmaceutical market, they needed to be taken into account and the practical consequence was that the Court of Justice was content to find that the wholesalers could be restricted to not making orders that were disproportionate to their past

ordinary orders so as to at least minimise the scope for parallel trade.

So there in my submission you have quite a stark example: parallel trade, a sacred cow under competition law and EU law, and the court saying that because of the features of the pharmaceutical market, price regulation and social insurance model, they had to be factored into the analysis of abuse and the consequence was there could be a tangible upper limit placed on the obligation of manufacturers to make sales to parallel importers, in this case in Greece.

So that is the legal principle.

Now, mapping it on to this case, we say a number of things. First, the QALY analysis is a well-established method where the NHS seeks to capture the value of the drug to the patient, the direct cost to the NHS in terms of the price of the drug and cost savings associated with that drug, and how in comparative terms different ASMs rank for these purposes in terms of their respective QALY scores.

These assessments are done within the context of a social insurance model in which the budget is finite, and relative value needs to be worked out in some reasonably consistent fashion using the QALY thresholds.

Dr Skedgel's evidence seeks to use a QALY method

commonly used by NICE in a TA and guideline context to see if phenytoin sodium at its challenged price of 2012 is below the NICE QALY thresholds. We say that is a relevant and useful piece of analysis and evidence when it comes to assessing abuse under Chapter II.

We say it would be quite wrong as the CMA suggests that we ignore the QALY method entirely when it comes to abuse, that is not the approach we see in *Glaxo Greece*, you take into account the context and the features of the pharmaceutical market, and we say the correct approach is to factor it into the abuse analysis as we propose, and we say the evidence of that of the challenged prices, phenytoin sodium was below the NICE QALY thresholds is a probative piece of evidence that speaks to the economic value of phenytoin sodium.

Finally, sir, I want to pick up on a couple of short points on the model itself.

The first point. In all modelling of course the challenge -- and, sir, you will know this very well from follow-on damages and other contexts -- the challenge is whether the model and its assumptions accord with reality in the market at hand. We say from this perspective the basic conclusion that phenytoin sodium is an effective third-line drug is valuable to the NHS and is cost-effective is actually quite an intuitive

one.

We know it has been recommended for the last 20 years on three separate occasions by NICE. It is common ground, as Mr Johnston said, that it is an effective third-line medicine.

Dr Skedgel's assumed efficacy percentage for phenytoin 6.8% is in the ballpark, around 5% figure that the medical experts essentially eyeballed. It is also important to note that the concern, if I can put it like that, in relation to phenytoin sodium, it is not to do with its efficacy; it is to do with things like tolerability and retention. In efficacy terms, it is actually one of the better anti-seizure medicines from a comparative perspective. We know that phenytoin sodium in particular because of category 1 in the 2013 MHRA guidance is distinctive in the sense that keeping patients on the same formulation of phenytoin sodium, ideally from the same plant, is considered important to maximise stability.

And in this way phenytoin sodium continuing to be available will result in large amounts of avoided costs to the NHS. As Mr Brealey said more than once in these proceedings, that was the very point being made by Dr Keith Ridge when he responded to the CCGs when they complained about the price increases.

As I noted earlier on, it is important to note that phenytoin sodium is in select company. There are at least 12 ASMs, as I indicated, which are not approved or recommended by NICE, and for all these reasons we say the conclusion in the model that at 2012 prices phenytoin sodium is a good use of NHS resources is hardly a surprising one.

Now, one final point: a point made in the CMA's written closings is, well, phenytoin was not approved by NICE at the challenged prices, because of course in 2022 they were looking at a somewhat lower price.

Now, of course, in a sense, we say it is hard to see where that point goes because the whole point of Dr Skedgel's analysis is to look at phenytoin sodium at the challenged prices, but, as Mr Hawkins made clear, and perhaps we can bring this up, it is quite important, and it goes, sir, I think to a question -- it partly addresses a question you had as to what do we get from the 2022 guidance, so if we go to {Day14LH1/21:23}, at the bottom of the page, you will see, sir, there is a reference to a figure of £11.08. So that was effectively the price at that time that NICE looked at in terms of phenytoin.

If we then go to Dr Skedgel's table, it is in our closings in {XL/5/80}, this is cut and paste from

Dr Skedgel's teach-in slides, and we need to divide by three, these are packs of 84. So the 19,557, so that is the highest price at any point, but of course as you will see in the third line, if one takes the Flynn ASP, the reduction in 2014, which is about £16, that gives you 18,418, and if you take the Pfizer price, even in 2012, it is obviously lower still.

So the reason I took you to the £11.08 is one can see at prices not dramatically different from £11.08 that phenytoin sodium is, we say, well within threshold. So we say to some extent one does get something useful even in pricing terms from NICE in 2022, because the price level at which they assess phenytoin, £11.08, is proximate to at least some of these prices in 2012.

So we do say that for that reason as well one does actually get something from the 2022 guidelines, even though they were not assessing these exact prices, so we say it does tell you something.

We know, of course, the 2012 guidelines, they were in early 2012, so pre-dated the price rise in September 2012, but what we do know is that the £30 drug tariff price was a public price for many, many years by that stage, so at least in relation to phenytoin at that stage that would have been one of the prices which was publicly available. So we do say that

the NICE guidelines, although they have not directly assessed the 2012 prices, at least indirectly one gets something useful from them, quite apart, of course, from the overriding point which is it has been consistently recommended for the last 20 years.

Sir, I was going to spend a few minutes on penalty, but I am anxious not to trespass on Ms Stratford's time.

THE PRESIDENT: I understand.

MR O'DONOGHUE: Perhaps, sir, we could pick it up in reply.

THE PRESIDENT: Very good. That would be helpful, Mr O'Donoghue, thank you very much.

Ms Stratford.

MR HOLMES: Sir, can I very quickly check, I don't think it would be possible to pick up any points in reply that have not been developed in the first round of closing submissions, so I just wanted to make absolutely sure that there was no expectation that Mr O'Donoghue would return to penalty by way of reply.

MS STRATFORD: Then they will have to do it now.

MR O'DONOGHUE: Can I spend ten minutes now?

THE PRESIDENT: You had better spend ten minutes now.

MR O'DONOGHUE: Well, sir, what I was proposing to do was to quickly run through the headline points in our written closings and I can do that very quickly indeed.

It starts on page 95 of our closings which is in

{XL/5/95}.

THE PRESIDENT: Yes.

MR O'DONOGHUE: If we can go on to paragraph 285, please {XL/5/97}, thank you.

Sir, there are three points I want to quickly rattle through.

First on the threshold question of intention or negligence, second, a very brief word on the gravity multiplier, and third, on step four in particular where we focus quite a lot of our fire.

So, sir, starting with the threshold question of intention or negligence. Obviously it is trite that without intention or negligence there cannot be any penalty, and we do say, sir, this is an unusual case which has lasted for a decade, and we do say this is a case in which the Tribunal should be open to the possibility that there is not a proven intention or negligence and therefore --

THE PRESIDENT: This is why I felt it might be more appropriate in reply, because we will have some questions for the CMA on this. What actually does intention mean in this context?

I mean obviously there was an intention of charging prices which were charged, but that is presumably not enough to get you over the line because that is true of

any price.

MR O'DONOGHUE: Every case is intentional.

THE PRESIDENT: Indeed. So I am slightly concerned that we do not actually have a clear handle on what is being said in terms of --

MR O'DONOGHUE: Can I just give you my headline points and then Mr Holmes can respond as he thinks appropriate tomorrow or the day after.

THE PRESIDENT: Yes, of course.

MR O'DONOGHUE: So sir, on intention we say first of all it was not put to Dr Fakes that he intentionally infringed competition law, it was not put to Mr Poulton back in the original trial that he intentionally infringed competition law, and, indeed, the one thing which is crystal clear from this case is that what both Pfizer and Flynn did was they looked at the public tablet price, discounted by, in Pfizer's case, I think 60% from that price, in Flynn's case something like a third or a bit more, and we have heard a lot in this case about the alleged oversight on the part of the Department of Health in keeping the drug tariff price at £30.

Now, you have heard what Mr Brealey said about that, we do not think that is remotely credible, it is backfilling, but even if one took that at face value, you have a public facing price that has been in place by

the time Pfizer and Flynn are setting their prices I think for four years, and for the Department to say, well, on our part that was an oversight, but when a rational manufacturer, doing the thing that every manufacturer does, which is looking at the drug tariff and pricing with that in mind, that they should be found guilty of intentionally having infringed competition law, that seems to us rather upside down.

Now, just to show you, sir, what was -- I mean, a great deal was made by Mr Holmes of various documents which he put in prejudicial terms. Can I just show you one document in relation to Mr Poulton because this is very important on the question of intention.

It is at paragraph 88 of our closings which I think is page 31 {XL/5/31}.

You see at 88 this was cross-examination by the CMA in the first trial. We say it was not put to Mr Poulton that Pfizer ever actually intended to fleece the NHS. He was read the relevant email and it was suggested to him:

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

I ask you to underline the phrase "rightly or wrongly". So that is why we say, in spite of the

rhetorical excitement of Mr Holmes in openings, the crucial point of intention was not put to Mr Poulton in the original trial. We had Dr Fakes for Flynn who gave evidence, he was not cross-examined on anything to do with intention, and we say it is quite wrong when two of these witnesses show up at a tribunal that the key point on intention is not actually put to them.

So that is what I want to say on intention.

Then, sir, on negligence, if we can go back to the quote from Lord Justice Green which Mr Brealey showed you in part, it is at {XN1/4/10}, it is the second half of paragraph 42. It says:

"... it seems to me that in deciding whether Pfizer acted negligently it remains open to Pfizer to refer to the CMA's position, and to uncertainty in the law as evidenced by changes in that position, as relevant and significant mitigation ... And if and insofar as the CMA was then to adopt another decision to address and remedy defects identified in the Judgment, Pfizer could at that stage still pray in aid changes in the earlier position of the CMA as relevant."

So this is on the negligence point.

Now, Mr Brealey has explained to you the chopping and changing of the CMA's case. They started with two potential Chapter I issues, they were abandoned. We

then had the position on comparators initially to be disregarded, then at trial to be included, on appeal to be excluded, and so on.

We have Ms Stratford's points on the flip-flopping on ROCE and ROS, and in a variety of respects and important respects the CMA's case has chopped and changed over the last several years.

So we make the basic point that no undertaking could in any reasonable sense ex ante have predicted any of these twists and turns. To suggest, therefore, that the undertakings were negligent in infringing we say would be quite wrong.

Finally, sir, on step four, so the step four multiplier in percentage terms is 275%, which is pretty chunky, and in relation to that, if we can go to our closings, it starts at 293 {XL/5/101}.

So, sir, as you may be aware from the other pharma cases in 2017 there was new legislation which brought in express price control powers in relation to products where the firms concerned were also members of a voluntary scheme, so the 2017 legislation, and you will see at the bottom of the page, at 461 the Tribunal in 2018, they made some reference to that in the context of penalty. They said:

"Having listened carefully to submissions made by

each party ... we make one specific point ... Had we upheld the CMA's findings on abuse, we would likely have regarded the very substantial uplift for deterrence applied to Pfizer as, on its face, difficult to justify and not required by the CMA's own penalty guidance ... If we had needed to come to a decision on the level of penalties to be applied to Pfizer ... we would have given the appropriate uplift for deterrence close scrutiny, particularly having regard to the new price control powers ... the [Department of Health has] recently been passed into law."

You will then see a reference to the legislation in the next paragraph.

Now, of course at the time one of the main reasons that the Department of Health trumpeted in terms of the need for this legislation was this case was said to be the poster child for why these powers were required, and yet we are now to believe that having got the powers that they sought -- and we say of course there was no gap to begin with -- but having got the powers they advocated for, then being in force to say that when it comes to deterrence those additional legislative powers do not amount to a hill of beans in terms of deterring, we say is an extraordinary submission.

You will see in the next paragraph in *Liothyronine*,

493:

"... the Tribunal considers that the powers available to the DHSC to control prices under the Costs Act are a further reason to conclude that a deterrence uplift is unnecessary."

You will see that they make the point that those powers now apply to a voluntary scheme. So we have the Tribunal on two occasions saying this new legislation is material when it comes to specific deterrence and the CMA in its Decision cocked a snook at the Tribunal's original ruling. That is the first point.

Two further points, if I may. Second, in relation to, again, specific deterrence on Pfizer, you will see at 296 this was primarily imposed because Pfizer has unrelated turnover, particularly outside the UK. Now, we make the point that in most jurisdictions, particularly in the United States where Pfizer generates most of its turnover, unfair pricing is not an infringement at all.

We do not understand why an undertaking in relation to non-UK activities and non-UK turnover needs to be deterred to the tune of 275% in relation to an infringement that does not exist on the statute book in those jurisdictions, so we say there is a mismatch there in terms of looking at unrelated activities.

Then over the page, sir, in relation to specific deterrence {XL/5/103} we make a series of points there as to essentially the novelty of this case and the unusual features, and you will see:

"Pfizer had to establish a de novo price for phenytoin sodium once it exited the PPRS. It paid careful attention to the only public price ... [the £30 DT], a price that stuck for 4 years by the time Pfizer was setting its price. Pfizer, acting responsibility and proportionately, set its price at below half of this published price, thus guaranteeing plenty of headroom for Flynn and the other stakeholders ..."

Then as Mr Johnston said:

"Even when the MHRA Guidance came into force, Pfizer never increased its price and in fact reduced its price to Flynn by ... 20% in February 2014."

And:

"Flynn made similar price cuts ..."

We say:

"These are not the actions of a company intent on flouting the law that needs a 275% deterrence uplift so that [they] can 'get it'."

Again we make reference to *Liothyronine* where a frankly, we say, a weaker point than the one I have outlined was accepted by the Tribunal when it came to

step four and specific deterrence.

The final point, sir, is over the page, again it is an important point {XL/5/104}. A key element of step four deterrence from the CMA's perspective was to disgorge what they termed the gain from the infringement.

Now, if one looks at what they did in the Decision, they assumed that every penny above their cost plus calculation was an improper gain. There was no allowance for pricing above cost plus but still within the confines of a fair price. They essentially assumed that every single penny above cost plus was the fruits of some ill-gotten gain.

Now, if one looks at what was done by contrast in *Liothyronine*, there the cost plus figure I think was something between £1 and £6, but when it came to assessing the gain, there was a headroom of £20.48 given to the undertakings, and the gain was not every penny above cost plus, was on the something above the headroom.

So we say in this case to assume that anything above cost plus gets counted as part of an unlawful gain is simply wrong in principle. There has to be some headroom, some allowance, some margin of tolerance above that, even on the CMA's own case.

So we say at the very least the starting point in terms of that metric is wrong, see *Liothyronine*.

THE PRESIDENT: Mr O'Donoghue, that was also the case in *Hydrocortisone* where there was no argument about the cost plus level save that it was, for administrative reasons, adopted by the CMA at a level above cost plus.

MR O'DONOGHUE: A high level, yes.

THE PRESIDENT: But if one is to go further than that, given that you are submitting, understandably, that it is no function of this Tribunal to locate the mezzanine between the ceiling and the floor -- I hope I can be forgiven for using those words again -- how does one, if one is to depart from cost plus, actually work out what the gain was for purposes of penalty?

MR O'DONOGHUE: Well, sir, we have put forward, I think five or six demand side benchmarks. Now, some of those like the £30, the tablet ASPs, they are hard numbers. If the Tribunal says: well, we think 30 is a bit high but that some other figure is in the ballpark, then one can at least triangulate that with the cost plus figure, and on an admittedly approximate basis come up with something approaching the delta, but of course, sir, you are right, you need a number to compare it to.

Of course the Tribunal will have to work out whether the challenged prices were fair or whether the

benchmarks we have put forward, most of which have specific pounds and pence numbers, whether they are meaningful, and there may be a halfway house whereby the numbers are probative to some extent and with some rough adjustment can tell you something, and it is in that context, which I admit is not perfect, that a handle can be got on the gain. But we do say loud and clear, it may be the point was not taken in *Hydrocortisone*, but it is being taken now, but we do say loud and clear that starting with an approach that every penny above cost plus is up for grabs, that is wrong in principle, because as the Tribunal, you will see in the closings at paragraph 443, in 2018 said, there has to be some headroom. We are not in a central planning world where every penny above cost plus is illegal. That is simply wrong in principle. The CMA makes no attempt to grapple with that frankly rather basic point.

Now, of course, we have points of principle that the CMA is not a claimant in a damages case, and in a way that one would not in a cartel case, should not really be in the business of trying to pinpoint the exact gain, but that is a separate point of principle, but we say if we are to go down the route of the gain it has to be something which is in a sense the true gain and not any deviation from cost plus in any shape or form. We say

that is simply a wrong approach.

Now, I do not think that point was taken in *Hydrocortisone*.

THE PRESIDENT: Well, it may have been because there were lots of points, but it did not arise because we allocated *Hydrocortisone* into case 3, and therefore did apply a cost plus approach to what was an excessive price, but that is, of course, up for argument here.

MR O'DONOGHUE: Of course it was taken in *Liothyronine* and was essentially accepted, we say.

Sir, that is all I want to say on penalty, but I may need to come back on that.

THE PRESIDENT: I am very grateful, Mr O'Donoghue, thank you very much.

Ms Stratford, you are on now.

MS STRATFORD: Thank you, sir, good afternoon.

Closing submissions by MS STRATFORD

MS STRATFORD: So, I want to begin where I started in my opening submissions and to ask how one goes about advising a company that wishes to avoid abusive pricing.

The Tribunal said that it wants to set out a test that is realistic for businesses, so we need a test that is realistic for businesses to apply and does not require the input of wall-to-wall experts. With respect, we agree, and this case seems to us to present

a good opportunity to lay down the law, particularly on the gateway requirement of excessiveness.

It has been very interesting, I suggest, to listen to more than a week's worth of evidence from economists, each with their own theory of how one should, in an academic sense, approach the question of what is a fair and non-excessive price for a product.

One could, I suspect, fill an economics textbook with the issues that have been canvassed, but that will be, frankly, of little comfort to the average business person who needs to make these sort of decisions on a day-to-day basis and in a practical way.

Companies are rightly wary of straying on to the wrong side of the law. Abusive pricing is a serious matter, quasi-criminal conduct, that can result in your business becoming tangled up in litigation with the CMA for years, in our case for over a decade, and facing millions of pounds of penalties.

So businesses need reassurance that they can and will know in advance if they might breach competition law by setting their price at a particular level.

Unfortunately the CMA's approach in this case gives none of that reassurance. It has applied a benchmark for excessiveness which is both very complicated, and I will come back later if I may to why, but it is also

a benchmark which sets the bar for excessive pricing very low, meaning that many businesses will be guilty of excessive pricing and, therefore, into the realms of unfairness without even realising it. The reason this has come about is, we submit, the CMA's fixation on cost and finance theory as the basis for abusive pricing.

Mr Harman's test for excessiveness with all its complexities and subjectivities boils down to a simple but frankly rather striking proposition that a company should not price above its costs -- he called them "economic costs" as you will recall -- and that if it does so, it is at risk of being called upon by a competition authority to justify its price as a fair one.

I think I have got time before we break for the shorthand writer just to show you, please, one place where Mr Harman said that, he actually said it multiple times, but if we could please go to the transcript at {Day8LH1/20:} and focus near the bottom of that page, line {Day8LH1/20:24}. We are going to read over the page, please, on to page {Day8LH1/21:}.

We can see here -- I am looking really at the very bottom of page 20 from line 24 and over to page 21, line {Day8LH1/21:14}, I will not read it out in the interests of time, but Mr Harman says very clearly that:

"... if you looked at the average prices [and I am quoting him now] ... and you found that they were above cost ... then it may bring you ..."

Then he corrects himself:

"... it would bring you under limb 1, the excessive limb, it would say there is an excess."

Then he goes on to say that an excess is not the same thing as an abuse, and the question then would be whether there is a justification.

So Mr Harman is very clear that on his view of the world a seller satisfies the gateway requirement for abusive pricing and excess as soon as its prices exceed its costs.

At that point, he says, you are in the realm of having to justify your price, and it is important to remember that this is being put forward as a universal test. It is not said to be limited to the facts of this case, or even to this specific industry. The logic of Mr Harman's model is that it can tell you whether any product is excessively priced.

Ms Webster said something similar in her teach-in, if we could maybe just go to that before we break, at {XE7/4/11}, please. This is in Ms Webster's slides from her teach-in, and the red box -- you will recall this -- is the total of direct costs plus a reasonable rate of

return, including what Ms Webster refers to as "investment costs". The grey box at the top is described as the "range of prices above costs but not abusive" which she says is likely to be "case specific... and dependent on policy considerations", and if you could just note that this box represents prices above costs.

So by necessary implication, Ms Webster sees everything below the box, including the reasonable rate of return, as representing a cost. So the logic being presented here is the same as that of Mr Harman: once you price above your costs, you are into the rather amorphous territory of unfairness and what Ms Webster called policy considerations, and the consequence, if this were right, would be to expose a huge number of products to the risk of abusive pricing, subject to the whims of how the CMA applies its case-specific policy considerations to each one, and that is the sniff test which I objected to in my opening submissions.

Sir, I do not know if that is a convenient moment to break.

THE PRESIDENT: Halfway through the afternoon.

Ms Stratford, I think it is. We will rise for 10 minutes and resume then. Thank you very much.

(3.27 pm)

(A short break)

(3.40 pm)

THE PRESIDENT: Ms Stratford.

MS STRATFORD: Thank you, sir.

Just to wrap up on my question of how one advises a business person how to price without breaking the law. In light of what the CMA, Mr Harman and Ms Webster have said in their position, this would all lead to rather startling advice, we say. You would need to advise the business that if it prices above its costs, it had better watch its back. So why do I say that on the CMA's case excessiveness, the gateway requirement for abusive pricing, comes down to cost and no more? And the easiest way to unpack the point, and I will come back, if I may, later to the detail of the table I am going to take you to, but I would like to show you now our floor/mezzanine/ceiling table which is annex 1 to our written closing submissions, so that is {XL/4/88}, please, and the top blue box contains Flynn's costs. These are the CMA's own figures, just to be clear, and taking the 100mg capsule as an example, Flynn's total cost per pack we can see there is £39.84.

That comprises a variable cost of £38.12 which is essentially the input price paid to Pfizer, the CMA's allocation of fixed costs of £1.05, and a capital cost

of 68p.

Moving down the table, the next blue box shows our competing cost plus calculations, and for now I want to focus on the CMA's cost plus figure, so that is the first entry in this box, and you will immediately see it is identical to Flynn's total costs, and that is because the CMA sees the purpose of the reasonable rate of return as being to cover Flynn's costs, including its capital costs of 68p per pack and no more.

So in the simplified example that I explored with Mr Harman in cross-examination, that is the equivalent of the 10% interest rate that Flynn pays to the bank to obtain its working capital.

The President, in an exchange with Mr Harman, described the CMA's approach as involving, and I quote:

"... an inevitable and ineluctable elision between cost and cost plus..."

That has always been at the centre of our appeal, and I am going to keep coming back to that phrase because it is, with respect, a very good way of putting it.

One might ask how the CMA has backed itself into this rather extreme corner of saying that an excessive price is one which exceeds economic cost. The reason is that the CMA faced a cross-roads in both this appeal and

the previous one: either it could build its own model of excessiveness by formulating an economic theory, or it could look at what levels of return are earned in the real world.

The real world path, while messy, provides a more moderate answer to the question of what is a normal rate of return, because we all know that, contrary to Mr Harman's model, many companies price their products above cost, and that is perfectly normal behaviour, but once one takes the real world out of the equation and goes down the theoretical path as the CMA has done, the only place to look for a benchmark is cost, and a repeated theme that I will be coming back to is that the CMA's finding of excessiveness in the last appeal was set aside in essence because it took a wrong turn at the cross-roads, it went down the theoretical rather than the empirical path, and what is rather surprising is that the CMA has made the same wrong turn in this appeal. So that is the CMA's approach.

What is ours? We have taken the other path of looking at empirical evidence. We say that what a company should be asking itself when setting a lawful price is two things: first, what is a normal competitive margin for the product based on what actually happens in the industry, and, second, what is a normal competitive

price for the product based on comparators? We will be the first to admit that those questions will not always admit of clean, easy answers. More often than not, they will identify a range of what is a normal return and a fair price rather than a single specific figure, but this process at least has the benefit of corresponding with how one would expect a company actually to go about setting its prices rather than applying rather abstruse economic theory.

It also provides some meaningful guidance to businesses, unlike the CMA's model, which simply says if you price above cost, you are at risk. With that in mind, I would like us for a moment to put ourselves in Flynn's shoes in mid-2012. So it has acquired Epanutin from Pfizer which was selling at a loss and needs to set a price. What should it do? There are only two possibilities. Either it ought to have looked to the market for comparator prices and margins, which is what it in fact did, or it should have applied Mr Harman's finance theory in order to calculate what he referred to as its economic costs of supplying the product and priced at that level.

Now, unsurprisingly, we say that the former is the correct, indeed, the only realistic approach. Flynn was entitled to ask whether the price it proposed to charge

for phenytoin and the margin it proposed to make were in the ballpark of the prices and margins being achieved by other companies around it.

Unless one were to assume that the entire market is anti-competitive, Flynn ought to have been able to take comfort that it was pricing in line with how the industry actually and normally behaves. As we understand it, Mr Harman says that Flynn ought to have done things very differently when it acquired the product in 2012 if it wanted to make sure that it was pricing lawfully.

First, he would say it ought to have calculated its capital that would be employed in supplying phenytoin. Now, as we saw in the course of cross-examination and the coffee shop example, that is not going to be a straightforward exercise, or one that will produce the same objective answer across businesses. It is also perhaps for that reason not an exercise that people setting prices at least in the pharmaceuticals industry actually do. You may recall that Mr Williams rather frankly said that his industry contacts would not have a clue what their capital employed was for a product.

Second, Mr Harman says that Flynn ought to have calculated its cost of capital. In the simplest scenario, that might just mean the interest rate it pays

on its bank loan, but in the real world things are likely to be more complex and will involve a blend of debt and equity finance. So, again, a rather complex exercise.

Third, Flynn then ought to have set a rate of return that was not materially above the return needed to pay its cost of capital, and we are not told what is meant by "materially". Mr Harman, at one point, mentioned that a business might be forgiven for going 1% above, so it seems we are talking about a small margin of error.

Just for your note, the reference for that is {Day12LH1/138:7} of the transcript.

Then if Flynn had wanted to price above its total costs, including what it has assessed to be its cost of capital, it has to turn its mind to whether there was a justification for that, and that is where Mr Harman hands over to Ms Webster, and Ms Webster tells us that Flynn should have been thinking about what she called her policy considerations.

Now, Mr Harman might say that Flynn is free to set its prices as it wants, this is just an ex post facto analysis for deciding whether a price is abusive, but that misses the point that companies need to be able to know in advance whether or not their prices might come within the cross-hairs of abusive pricing and it bears

emphasis that between our two competing positions, ie pricing by reference to industry data which in our case means the tablet, and pricing at cost, there is very little else.

There is no other reference point or benchmark that the CMA has identified as an intermediate position where Flynn could have charged more than its costs but less than the tablet price.

As we have said in our written closing, had Flynn chosen to ignore the tablet as a comparator and had it not followed the CMA's lead in pricing at cost, it would, quite frankly, have been sticking its finger in the air.

PROFESSOR WATERSON: Can I just raise a couple of points and go back a little bit?

MS STRATFORD: Of course, yes.

PROFESSOR WATERSON: The first one is you said that -- and this is perhaps a point as much for Pfizer as for Flynn -- you said that the product was unprofitable for Pfizer. I don't think we have had that established, have we?

MS STRATFORD: Well, it has been said, and I think recognised, that it was -- at points made a loss and at best break even. We can dig out references for you if that would be of assistance.

PROFESSOR WATERSON: Yes, and the second point is when you were talking about a company and thinking about this you presumably recognise that there is a special duty on a company which finds itself in a dominant position or potentially dominant position to think carefully about what it is doing?

MS STRATFORD: I do, I do, but as perhaps, Professor, you know even better than me, dominance -- we cannot assume that Flynn knew it was going to be found to be dominant, indeed, it was certainly not Flynn's expectation that it was going to be found to be dominant, so whilst I of course accept that as a matter of basic law --

PROFESSOR WATERSON: I am just saying it in the context that Pfizer was the only producer or the only source for the drug, and Pfizer and Flynn engaged in an agreement of exclusivity.

MS STRATFORD: Well, Professor, I am going to come back to the question about the extent to which there was an agreement and what that means for this case.

PROFESSOR WATERSON: I did not say it was an agreement on price at all, but simply an agreement on the supply.

MS STRATFORD: I am grateful, I am grateful, but of course we know that -- well, I will come on, if I may, if it is not inconvenient for you, to deal with those points and the fact that obviously, notwithstanding that the CMA

originally opened a Chapter I investigation, that was not pursued. There can be, we say, no legitimate basis for any adverse implications of any sort, and I do stress that for a company in the position of Flynn there is a real danger here that we are applying a lot of hindsight, perhaps inevitably after ten years and a case that has been not only to the Court of Appeal but even to the Supreme Court, this territory is now well traversed.

PROFESSOR WATERSON: That was not the implication at all.

MS STRATFORD: I am grateful, but even a company that is dominant, in my submission, does need predictability in knowing how it can price and how it can lawfully conduct its business.

Is that sufficient for now?

PROFESSOR WATERSON: That is fine, thank you, yes.

MS STRATFORD: I am grateful.

I would like, then, to move on to show you a document which the Tribunal may not have seen before, which is a note of an early meeting between Flynn and the CMA in the early stages of the investigation in 2014. If we could please go to {XH/38/4}, just to orient the Tribunal, I believe this is the CMA's meeting note with Flynn's tracked changes, but the changes do not affect the part I want to show you in any event.

If we could look, please, focus in on paragraph 26, we can see, WR, that is one of Flynn's directors, Mr Roiter asked whether the CMA's case came down to whether the margin of 30% is reasonable, and he noted that Flynn was buying at a fixed price, and he said that the -- I am quoting now:

"[The] industry would be surprised to hear that a margin of 30 per cent was excessive..."

Especially on a relatively low cost product compared to treatments that cost thousands of pounds. Then you will see Mr Roiter puts the critical question:

"This begs the question of what is a reasonable margin."

At paragraph 27, AP, that is the CMA, Ann Pope of the CMA:

"... acknowledged that the reasonableness of the margin is the heart of the issue, but there are lots of issues before one gets to that stage. AG [that is someone else at the CMA, then] acknowledged that it is a fair question to ask what is a fair margin and these are issues which the CMA is considering internally and has not yet concluded on."

The CMA has since then spent nine or ten years pondering on that question, and the only answer it has been able to come up with at the end of that process is

that a reasonable margin is one that covers Flynn's costs.

The fact that it has taken so many years to come up with that answer, with all of the CMA's twists, turns and U-turns along the way suggests we are a long way from a test which is something that businesses can apply on a day-to-day basis to price their products.

A final topic I wanted to deal with just by way of introduction is the Tribunal's structure guide. Flynn's team thought long and hard about the Tribunal's guide to structure documents and the questions that it poses, and you have seen how we addressed them fully in our written closing submissions whilst trying to keep the document to a manageable length, and we have also, you may have seen, provided a crib sheet which we hope is useful, but I wanted to explain quite candidly why we have taken the approach we have.

We of course want to be as helpful as we can be to the Tribunal in providing what we submit are the answers to the questions raised, but we also need to balance that with covering Flynn's grounds of appeal which challenge the Remittal Decision that the CMA actually took, and it is the Decision which the CMA took on which it must be judged of course.

So with the greatest respect, we do urge the

Tribunal alongside addressing the structure guide issues to give, in addition, detailed consideration to Flynn's cost plus excessiveness appeal ground and also, as Pfizer has already stressed, to the legal implications of the £30 agreed price for the tablet comparator.

THE PRESIDENT: Ms Stratford, I do not think there is any question but that we will do that.

MS STRATFORD: I am grateful.

THE PRESIDENT: I mean, the guide was at a level of a high level of generality, and frankly, both of the points that you have mentioned seem to me to slot in quite nicely under two of the broad heads that we had.

I mean, the question of what is excessive and the relevance of comparators obviously matter whether one adopts this structure or not.

MS STRATFORD: I am very grateful, and that was how we saw it as well, but I just wanted to be, as I say, quite candid about the fact that we have slotted them in, we have given them perhaps more airtime than some of the other issues, but there is a reason why we are doing that, and it has been thought about.

THE PRESIDENT: That is understood. In a sense, it was easiest for the CMA to adopt the structure because they have to deal with a whole range of points that are run, whereas we do understand that Flynn and Pfizer major on

somewhat different points and that therefore affects the structure of their submissions, and also we found the tension between the way you have put your case and the structure that we articulated actually quite helpful. I think Mr Brealey's submissions this morning demonstrated that there is real assistance to us in the pushback from the parties on the guide. It was never intended to be more than a guide.

MS STRATFORD: Thank you. That is very helpful.

So I wanted then to move on to the law.

I think all parties are agreed that *United Brands*, so far as it goes, is still good law, and this means there are still two separate stages of the analysis: excessiveness and unfairness, and the Tribunal's structure guide has asked us to explain the meaning of those terms in the abstract and to state whether they involve working up from a floor down from a ceiling or something else.

As regards excessiveness, we think the position is relatively straightforward. The excessive limb involves measuring the difference between cost and price. That is *United Brands* paragraph 252 which I do not think we need to turn up.

By its very nature, therefore, excessiveness involves working up from the floor. That is reflected

in the CMA's cost plus approach which starts with cost, ie the floor, and then adds a reasonable rate of return.

Unfairness is a more nebulous concept, and that is why we are concerned that the CMA has set the bar for excessiveness at the level of cost. It loads almost all of the analysis into the unfairness limb.

We saw from Ms Webster's slides that she sees the role of the unfairness limb to be identifying a mezzanine price which is calculated from the floor upwards by reference to what she described as policy considerations. Now, I say candidly: we are doubtful that Ms Webster is correct here. First, it is unclear to us how policy considerations could ever translate into a monetary value and therefore could ever in practice locate the mezzanine.

Second, and importantly, in most cases we would expect the battle lines on unfairness to be drawn around the prices of comparators. It is important here to recall that the test in *United Brands* is whether the price is unfair in itself or compared to other products. So comparators will always need to be considered, if, of course, they are raised by the company under investigation.

Once one is in the realm of comparators it is not particularly informative, in our submission, to speak of

moving up from a floor or down from a ceiling; one is simply assessing the validity of the comparator and then plotting its price against that of the product under investigation. So rather than moving up or down, one is, if you like, moving across.

In many cases, comparators will have a higher price than the focal product at which point, as to some extent has been canvassed this morning, the terminology of ceilings and mezzanines begins to break down, and our reading of the CMA's skeleton, closing skeleton, is that they agree with us on that, but of course we will hear from Mr Holmes.

That brings me on to *Hydrocortisone*. The Tribunal has asked us to comment on how the case 1, 2, 3 analysis might apply in our case.

The first point I want to make is that on our reading of *Hydrocortisone*, the judgment does not on its face apply the case 1, 2, 3 analysis to the excessiveness limb of the test, and that is because excess was taken as a given in that case, so the words used by the Tribunal were that the excess was "plain to the point of irrefutability", for your note that is paragraph 333 of *Hydrocortisone*.

The case was, therefore, about what more beyond an excess was required to establish an abuse which, in the

traditional scheme of the *United Brands* test, would be referred to as the unfairness limb.

Now, we can see that the case 1, 2, 3 analysis could -- I stress "could" -- play a role in relation to excess, and we have dealt with this at paragraph 53 of our written closing and we have said there it is conceivable that if the Tribunal concluded that a product was more than just a commodity and produced some economic value beyond its cost of supply, that is something that could be recognised when the Tribunal is assessing the evidence on what is a reasonable rate of return.

In essence, the Tribunal could take a more generous approach to that evidence in a case 2 scenario than in a case 3 one, but we do not think that the existence of cases 2 and 3 removes the need to identify a reasonable rate of return and, therefore, to assess on the evidence before the Tribunal what is a normal competitive return for the product under consideration. We do not understand -- again, we do not understand the CMA to take a different view on this.

As regards the application of cases 1, 2 and 3 to the unfairness limb, that has been, of course, the focus of Pfizer's appeal and I am not going to repeat their submissions on it which are developed in quite a lot of

detail in their written closing.

One point I do want to make clear because it matters on the facts of our case is that we do not see the analysis in *Hydrocortisone* as removing the right of the undertaking to show that its price was fair by reference to comparators.

The case 1, 2, 3 distinction might inform what is and is not a good comparator in the sense that if a product is a differentiated one in category 2 you might say it is not a good comparator for a commodity product in category 3 or vice versa, but it does not remove the need to look at comparators at all.

I am not going to deal with *Liothyronine* at this point, although of course I will cover it at various points as we go through, but I cannot resist observing the extent to which the CMA seems intent on trying to use it as a sort of nostalgic crutch in their written closing. All I would say now is that, like *Hydrocortisone*, it was a very different case from Flynn's appeal here and the CMA are praying it in aid in ways that we submit is often misplaced.

The other point I just need to deal with on the law, because it is perhaps easy to lose sight of, is the burden of proof.

It is common ground that the CMA bears the burden of

proving the infringement against us. The corollary of that was set out by Advocate General Wahl in the *Latvian Copyright* case, and could we perhaps just turn that up briefly. That is at {XN5/36} and I want to go to page {XN5/36/4}, please.

I am going to take this at quite a lick, if I may. Of course I can introduce the case but I am sure the Tribunal is very familiar with it and the facts, and we can see at paragraph 52 I wanted to look at, please, the Advocate General makes the point there that the authority bears the burden of proof and conversely that the undertaking under investigation is entitled to a presumption of innocence.

The key passage for our purposes is paragraph 53 where the AG says:

"As a result, in my view, a lack of reliable data or the complexity of the operations involved in the calculation of the benchmark price ..."

Just pausing there for a moment, read "benchmark margin" for the purposes of our appeal.

"... cannot justify an incomplete, superficial or dubious analysis by a competition authority. In other words, difficulties encountered by an authority when carrying out an assessment cannot be to the detriment of the undertaking being investigated."

The reason this matters is that we say that in our case the CMA has carried out an "incomplete, superficial or dubious analysis", so it approached what I have termed the cross-roads and chose to take the path of economic theory rather than real world evidence. That resulted in gaps in the evidence available to the Tribunal about what is a normal rate of return.

What the Advocate General is saying is that those gaps cannot be to the detriment of the company under investigation. It certainly cannot be assumed that the gaps, if they were filled, would prove the authority's case, quite the opposite, and I will come back to this, if I may, when I deal with -- probably tomorrow, tomorrow morning -- with the market evidence and questions of remedy.

So that is all I wanted to say about the law, although I will pick up, as I have said, some other discrete points on the authorities as I go along, and I would like now to move to what the Tribunal has rightly identified as the issue at the centre of Flynn's appeal which is the size of the gap between cost and price. The Tribunal asked whether it would be appropriate to apply the test of whether that gap is demonstrably immoderate.

We agree, but with some qualifications and

clarifications which we have set out at paragraph 58 of our written closing. I do not think there is any need to turn it up.

The main point we have made there is that the question of whether a gap between cost and price, ie a margin, is demonstrably immodest cannot be assessed in a vacuum or just as part of a sniff test, and that is because what might be immodest in one industry might not be in another.

In our written closing we have highlighted the example of the supermarket industry where Mr Harman told us a normal margin is around 3%. If a supermarket becomes dominant, perhaps by buying up all of the other supermarkets in the area, and begins achieving margins in the 30s or 40s of per cent that may well qualify as a demonstrably immodest margin, but where the normal margin in the industry, ie the normal gap, between cost and plus is higher, the same margin might not be immodest.

So unfortunately there is no shortcut which would enable the Tribunal to skip over the factual and expert evidence about what constitutes a reasonable rate of return for phenytoin.

THE PRESIDENT: No, I mean, I do not think that was the intention. It might be helpful if one could identify,

in broad terms -- I suspect you will be going on to do this -- the factors that one ought to bear in mind when considering whether that test has or has not been satisfied.

You have, I think, already touched on two: one is the inter-relationship between margin and volume sold in the sense that if you are selling in very low quantities then one would ordinarily expect the gap to be bigger, and the other one is what, for instance, in the pharma industry -- although I appreciate it does not really apply to Flynn, but would apply to companies producing or manufacturing drugs -- what does one do with the lost R&D costs of unsuccessful efforts at finding another drug? I mean, these are all things which need to be considered. How relevant they are must depend on any particular case, but I think I am accepting the point you are making that whilst one can frame the test briefly, if it is the right way of doing so, but that brevity does not provide a shortcut and say: well, a given percentage or a given absolute amount is the answer in all cases. That clearly cannot be right.

MS STRATFORD: Absolutely, yes. I will, if I may, come back to that, as you anticipated we might, if that is acceptable, because I just think it is going to proceed more logically and frankly probably more speedily if

I stick to my structure.

I would just observe that of course it is right that Flynn does not have R&D costs as such. Anyway, I am going to come back to it. It does have products as you know, sir, within its portfolio that are or have been at times loss-making, but you have the point. There is no shortcut. There has to be an objective yardstick to measure the size of the gap against. The CMA's yardstick is its ROCE theory. Our yardstick is the market evidence on what is a normal level of return in the industry, so in other words, part of what I am saying is that the disagreements between Flynn and Mr Harman about the correct approach to assessing Flynn's profitability do matter, but equally, we recognise that there may be more than one reasonable answer to the question of how to measure and assess a company's margins, and where that is the case we accept that any reasonable approach is eligible to go into the mix, and that mix is likely to produce a range of normal or reasonable returns rather than a single figure. That of course reflects the position in real life, so there is not a single normal rate of return waiting in the ether to be discovered.

That brings us to the question of whether Mr Harman's ROCE benchmark is a good yardstick for

measuring whether Flynn did or did not exceed a reasonable rate of return, and we need to remember that at this stage of the analysis the Tribunal is asking itself whether the analysis in the Decision which hangs entirely on Mr Harman's ROCE theory as far as Flynn is concerned, whether that analysis is wrong.

If it is, the Decision as against Flynn must be set aside. Whether the Tribunal is able to fill the void with a better benchmark is a separate question which, if I may, I will again come on to later, and I would like first, therefore, to spend some time explaining what Mr Harman's ROCE benchmark actually involves before moving on to explain why, in light of that, ROCE does not work as a benchmark for an asset-light people-intensive business such as Flynn.

The underlying theory is in Mr Harman's third report. If we could please go to {XE1/15/25} and zoom in on paragraph 3.2.16. I know the Tribunal has seen this probably more than once, but he says there:

"Based on the theory above [ie in his report], it is ... possible to test whether a firm's actual return (eg, as measured by ROCE), is above a competitive ... benchmark (ie, WACC), in percentage terms. The test can be summarised as follows:

"ROCE (%) [is greater than or equal to] WACC (%)."

The Tribunal is by now very familiar with the contours of this theory. Essentially Mr Harman, on his view, a price satisfies the gateway requirement for abuse, excessiveness, if its return on capital exceeds its cost of capital. In my simplified example, this is the 10% interest rate that it pays to the bank.

Just while we are here, I would like, if I may, to show you the equivalent statement from Mr Harman's first report. So that is at {XE1/13/40}. It is at paragraph 4.8 of his first report. This was the report of course served in the previous appeal or the first report served in the previous appeal. We need to recall that at this stage Mr Harman said that he did not consider ROCE was an appropriate metric but was using it as a cross-check, and I will come back to that if I may. For now, I just want to show the Tribunal that the fundamentals of his theory were exactly the same as they are now. So he said there at 4.8:

"The competition test for excessive prices considers whether the ROCE equals or exceeds the WACC, as follows ..."

And then we see the same formula. So it is exactly the same theory as is being put forward now, and it is the same theory that was rejected by the Original Tribunal as being overly theoretical and based on

idealised competition, both points I will return to.

So the assumption of Mr Harman is that a company's return on capital will, in a normal, competitive market, converge with its cost of capital. That is a proposition that we take issue with at a fundamental level, but it also turns heavily on what is and is not counted as capital.

To be clear, if something is not counted as capital, a seller is not, on Mr Harman's view of the world, entitled to earn a return on it. So we do need to understand what the CMA and Mr Harman have understood to be Flynn's capital base.

So on this, please, could we go back to the Decision at {XA1/1/199}. I want to start at 5.231, please.

It might be perhaps easiest if the Tribunal would be so kind as to read between 5.231 and 5.235.

THE PRESIDENT: Of course. We will let you know when to change the page.

MS STRATFORD: I am grateful. (Pause)

THE PRESIDENT: Yes.

MS STRATFORD: I am grateful.

So in short, the CMA finds that the value of Flynn's working capital is the value of its stock which it holds is £2.8 million, and the value of its net debtors estimated at £0.7 million, and that gives us a total

working capital of £3.5 million.

Going on, please, to page {XA1/1/202} and paragraph 5.250, this is where the CMA reaches its decision not to recognise any human capital in Flynn's business, so the value of its workforce simply goes down as wage costs and no more, and you can see that from that paragraph. I do not think I need to read it.

Moving on over the page to 5.257 {XA1/1/203} we see there the CMA concludes that, in the first sentence:

"... there are no intangible assets that are applicable to Flynn's Products."

Then at 5.258 at the bottom of the page, the CMA therefore concludes that Flynn's total capital is only £3.5 million which is its working capital and no more. So on the CMA's ROCE benchmark, the only thing driving Flynn's phenytoin business and the only thing on which it is entitled to earn a return is the cost of its stock and net debtors. The President had some detailed exchanges with Mr Harman about subjectivities that go into identifying a company's capital base, and we agree that this is a very subjective exercise which can produce wildly different excesses and, therefore, prices for different companies.

That became very clear from the three coffee shop examples that were canvassed with the experts. These

subjectivities are a particular issue for asset-light companies because they matter more than for capital heavy companies. If you are a company operating a power station, the majority of your capital will be accounted for in the value of the plant. The more subjective elements like human capital will be, for such a company, dressing around the edges.

THE PRESIDENT: What about something like goodwill, would that have to be calculated and if so, how would one do that?

MS STRATFORD: Well, for some companies that will need to be, yes. In this case, it was assumed to be zero.

THE PRESIDENT: I see.

MS STRATFORD: But my point at the moment is where you are an asset-light company such as Flynn, you have no concrete capital investments, and so a ROCE analysis turns almost entirely upon the kinds of subjectivities that you, sir, discussed with the experts, human capital, yes, could also be goodwill, brands in some cases, and so on.

What is clear is that amongst the many subjectivities that it faced in calculating Flynn's capital, the CMA has in fact taken the least generous possible approach to Flynn in every important respect. The only capital it has allowed is the cost of Flynn's

stock and its net debtors, so it has not recognised any value in Flynn's workforce, nor in any other aspect of its phenytoin business.

Just to complete the picture on the Decision, as the Tribunal knows the CMA applies a 10% WACC to Flynn's capital assets which comes out at £350,000 a year, so any returns above that level are treated as an excess and assessed for abusiveness.

On that basis, it may be just worth turning up in the Decision table 5.17 at {XA1/1/236}, please. It is a Decision we have seen many times before, you will be familiar with it, it finds that Flynn's overall excess is 47% and its excess on the 100mg capsules is 37% based on the CMA's 10% ROCE benchmark. Those figures obviously stand or fall with the correctness of the benchmark.

That brings me to the inappropriateness of ROCE as a metric. I already have showed the Tribunal and Mr Harman the historical documents in which the CMA found that ROCE was an inappropriate metric for Flynn because it was an asset-light, people-intensive business, and you will probably at this point, especially at 4.30, be pleased to hear that I am not going to do a full trawl again, but I do need to deal with a point of principle as to whether it actually

matters that the CMA has changed its mind.

I hope I explained the position clearly in opening when the President asked about this point. We are not at this stage making some form of public law argument that the CMA was bound by the position it previously adopted, rather we are saying that the reasons the CMA and Mr Harman originally gave, presumably in good faith, for finding ROCE inappropriate were good ones and still hold true, and they undermine the credence that the Tribunal should afford to the new view.

So if we could, please, for one last time look at the document which shaped the CMA's approach to this issue last time around, this is {XA2/2/253} which is the original statement of objections, and I want to look at paragraph 5.92 which the Tribunal has seen before, and it said there that:

"The CMA considers that ROCE is challenging to apply for Flynn and has limitations given that its activities in supplying phenytoin ... capsules, namely ordering and managing customer relations, are people intensive ... As a result, the CMA considered that ROCE was not appropriate for assessing what a reasonable return would be for Flynn."

What the CMA is referring to here with the specific example of people activities are the subjectivities

involved in calculating the capital assets of a company like Flynn.

The problem, in short, is that people-intensive activities are much more difficult or even impossible properly to assess as a capital value, much more difficult than, say, the value of a power plant, to go back to my earlier example, and that means that any given company's reasonable rate of return and, therefore, non-excessive price is going to differ according to how the company calculates its own capital value.

We have seen that the CMA's view that ROCE was inappropriate for Flynn was then followed through in the original Decision and later in Mr Harman's reports where he said that it was -- and I am quoting from Mr Harman's second report, maybe it is just worth turning it up, it is at {XE1/14/39}, paragraph 4.32, where Mr Harman said it was common ground -- so it is four lines down, starting four lines down:

"It is common ground that a ROCE analysis is not appropriate for establishing excessiveness in this case."

So it may be worth noting that Mr Harman did not simply say that a ROCE analysis had not been done, he deliberately used the word "inappropriate".

While we are here on this second report, perhaps we could just go to page {XE1/14/38}, please, the previous page, at paragraph 4.29 where Mr Harman says that there are "difficulties associated with a ROCE-based approach for asset-light businesses" because total capital may be understated.

Now, that was obviously a reference to Flynn, but if we could maybe just split the screen now with the CMA's closing submissions. So if we could split it with {XL/8/16}, please, this is annex 2, and I want to look at paragraph 40 of the CMA's closing. We can see that the CMA is now taking the position that "Flynn is not genuinely asset-light". So we not only have Mr Harman disagreeing with the CMA but also now seemingly the CMA disagreeing with Mr Harman.

Do you see that, sir? I can see a puzzled look.

THE PRESIDENT: No, no, I am only trying to read.

MS STRATFORD: I am grateful.

When I cross-examined Mr Harman on this issue frankly he got himself into a muddle. He said for the first time in cross-examination that he disagreed with the CMA's view that Flynn was a people-intensive company such that ROCE was an inappropriate metric for it, but in doing that he contradicted his first and second expert reports in which he had given his independent

opinion that the CMA had made the right choice in using a ROS rather than a ROCE metric for Flynn.

Mr Harman tried to explain his way out of the contradiction by saying that the CMA simply had not, as a matter of fact, done a ROCE analysis for Flynn and, therefore, all that was left was a ROS approach which he endorsed, but that made no sense because the position was not that the CMA forgot to do a ROCE analysis; the CMA had reached a considered view with reasons for finding that ROCE was inappropriate.

If Mr Harman disagreed with that view, then it was his duty as an independent expert to speak up. The only proper inference is that in choosing not to speak up, he did in fact agree with the CMA's view that ROCE was inappropriate and for the reasons that the CMA had given.

For its part, the CMA had a go in its Decision at suggesting that some new evidence had come to light between the first and second appeals which caused its original concerns about using ROCE to evaporate, and I can take this quite quickly because Mr Harman fairly accepted that as far as he could tell there was no new evidence.

Just for your note, that is {Day12LH1/79:5-9} of the transcript. So he had always known that Flynn was an

asset-light company and that phenytoin had no major capital investment behind it.

So the suggestion that there has been a watershed moment which suddenly enabled the CMA to value what it described as Flynn's people-intensive business in a way that it was not able to do previously is frankly for the birds. It bears emphasis here that the CMA has not actually assessed Flynn's capital base any differently to how Mr Harman did it for his cross-check in the first appeal.

In both cases, they said that the only capital employed by Flynn was its working capital, meaning its stock and net debtors. In both cases, they have said that there are no intangible assets in Flynn's phenytoin business, so there has not been an epiphany between the first and second appeal in terms of the way that Flynn's capital is calculated.

So where does that take us? Quite simply, that the CMA was right for the reasons it gave that ROCE is not a meaningful metric for an asset-light business such as Flynn. The reason boils down to the subjectivities that the President identified during the trial.

If your business is driven by people skills rather than large capital investments, ROCE is not going to produce a reliable result because the company's people

skills cannot be easily quantified and fed into a cost of capital analysis. The CMA has sought to duck those difficulties by attributing no capital to Flynn at all except the sum of its stock and net debtors, but that inevitably produces a very high return rate because the amount of capital employed, the denominator, is tiny.

So I would like to move on now, please, to consider the problem with Mr Harman's ROCE WACC benchmark on its own terms by which I mean setting aside my threshold objection that ROCE is an unsuitable metric, I want to grapple with what we say are its key flaws, and there are two that I want to highlight.

The first is that it is purely theoretical.

The second is that it involves what the President called:

"... an inevitable and ineluctable elision between cost and cost plus... "

I said I was going to come back to that phrase. The consequence of that being that it does no more than identify the minimum price at which the product must be sold in order to break even.

I am afraid I am going to ask the Tribunal to turn up the original CAT judgment one last time because these are the same criticisms which led the Tribunal to reject Mr Harman's theory last time around, and the reason

I have had to go over these passages so many times is that the CMA has refused to acknowledge that they exist or say anything about them at all in their pleadings, skeleton arguments or orally, save for at last a single sentence in the CMA's written closing which I will deal with, and we are not prepared to let the CMA sweep these criticisms under the carpet in that way.

If we could please go to {XN1/2/105-106}, perhaps we could have them both up, because I know that the Tribunal is by now extremely familiar with these paragraphs. It is paragraphs 318 to 323. I do not know whether you would like an opportunity to remind yourself one final time?

THE PRESIDENT: Let us quickly read them over, yes. (Pause)

Thank you.

MS STRATFORD: Thank you.

So the two key points I want to take from those passages are, first, that the Tribunal thought that Mr Harman's approach was overly theoretical and ought instead to have been based on real life evidence, and second, that it modelled prices under idealised rather than normal competition.

Now, leaving aside the noise about whether the Tribunal's criticisms of cost plus as an approach were justified and whether one should seek to identify

a hypothetical benchmark price rather than a hypothetical benchmark margin, these were the two core criticisms of Mr Harman's approach, and they have never been disturbed or questioned, and of course, we need to remember that the Tribunal was addressing, in 2017, precisely the same ROCE WACC theory that has been put before you in this appeal, and that is -- again, I do not know if it is helpful to have it up on the screen -- Harman 1 at {XE1/13/40}, it is the paragraph 4.8 again.

I mentioned that the CMA has finally acknowledged these passages in a single sentence of their skeleton, and it is, for your note, paragraph 33 of their annex 2, but I do not think we need to turn it up, but what they say there is that all of these criticisms, criticisms of course of which Professor Waterson was one of the authors, were swept away by the judgment of the Court of Appeal which found that the Tribunal had been wrong to find, if it had, that the authority needed to identify a hypothetical benchmark price, so I would just like to deal with that point.

Perhaps the first and most straightforward answer to this point is that if it were right, then the Court of Appeal ought to have reinstated the CMA's finding of excess against Flynn which, as we know, it did not.

Digging a little deeper, it is important to appreciate that Flynn actually advocated in favour of the Court of Appeal's finding that if what the Tribunal had been insisting upon was a hypothetical benchmark price in every case, then that would be wrong.

One can see that very clearly from the Court of Appeal's judgment which, if we could get up {XN1/5/38}, and I just want to look at paragraph 122, where it says:

"... as to whether that benchmark must relate to price, I agree with the CMA and the Commission. I also agree with the submissions of Ms Bacon QC for Flynn (who ultimately did not support the reasoning of the Tribunal, if the Judgment was to be construed as requiring a hypothetical benchmark price in every case) that in both the law and in economics all that is required is that there be 'a' benchmark or standard against which to measure excess or fairness."

So we are actually all agreed on this point that there needs to be a benchmark but it need not be a price benchmark, and in fact, we are all agreed that the type of benchmark we are talking about under the excess limb is a margin benchmark because it is the reasonable rate of return.

Nobody, either on the court or counsel's side,

thought or said that this rather high level debate about whether the benchmark should be price or something else was really about whether the Tribunal's assessment of Mr Harman's expert evidence should be undone.

When one thinks about it, that cannot possibly have been the intention. Even if the Tribunal should have been focusing on a hypothetical benchmark margin rather than a price, its two key criticisms of Mr Harman were unaffected: that his evidence was overly theoretical and based on idealised rather than normal competition.

So the short point is that nothing that the Court of Appeal said in its judgment even touched on those two core criticisms. Leaving that legal point aside, Mr Harman's main answer to these passages was that he had not been instructed to respond to what the Tribunal had said in its judgment and, therefore, had not done so. With respect, that is not going to cut it.

If, as an independent expert, you put forward a theory which is subject to root and branch criticisms of this kind, you cannot just ignore what the Tribunal has said, it borders on the disrespectful.

Another point that Mr Harman made is that the *Liothyronine* and *Hydrocortisone* cases represent, to use his words, "the latest thinking" on excessive pricing and had therefore overtaken these criticisms of his

evidence. I do not think I need to labour the point that nothing was said or debated in those cases which would override the two core criticisms of Mr Harman's model, that it was overly theoretical and based on idealised competition.

Two out of the three members of our panel will be very familiar, more familiar than I am, with what was and was not in issue in *Lio* and *Hydro*. Respectfully, we imagine you might be quite surprised to be told that you had overruled the previous tribunal's careful assessment of Mr Harman's evidence in the phenytoin case. There is no reference to anything like that on the face of either judgment.

A related point that I wanted to deal with here is paragraph 154 of the *Aspen* decision. If we could turn up, please, {XN6/7/31}, and I want to look at -- it is this paragraph 154 of *Aspen* or recital 154, I should say, to the *Aspen* decision, and in his cross-examination Mr Harman put this forward as something that had overridden the Tribunal's previous judgment.

If we could note first the heading that this paragraph appears under, so it is:

"Aspen's claim that the price increases were necessary to recover its investment."

Oh, I am sorry, I am looking at a different screen.

Could you scroll down a little -- sorry, scroll up so that we can see the heading of this section, please, and maybe zoom in on paragraph -- thank you. Maybe make that heading and paragraph 154 a little larger, please.

We can see immediately under the heading from paragraph 153 that *Aspen* was running an argument that it was entitled to charge higher prices to recover the investment that it had made in acquiring the products from GSK, and then the critical paragraph is 154. I do not know whether the Tribunal would like a moment to read it or whether you are already familiar with it?

THE PRESIDENT: It is all right. I think do go on.

MS STRATFORD: I am grateful. We simply do not understand how the CMA can take from this that their model that a company ought to recover its cost of capital and no more is correct.

The Commission does say that a seller is entitled to recover its cost of capital and that Aspen will in fact be able to recover those costs based on its reasonable rate of return, but it does not say that it is limited to recovering its cost of capital, and those two are obviously very different things.

The critical words we suggest, respectfully, are in the middle of the paragraph where the Commission says that it has based its reasonable rate of return on the

industry's average performance, and we rely on that because it is similar to the approach that we have adopted.

So really the beginning and end of this case should be that Mr Harman's benchmark based on his theory that ROCE should equal WACC has already been considered and rejected by the Tribunal and there is no reason why this Tribunal should reach a different view, especially when one member of the panel, Professor Waterson, was one of the authors of the original criticisms, but in any event, the two core criticisms of being overly theoretical and based on idealised competition still hold true.

Sir, I am going to go on and develop those on their own merits, if I may.

So on the first of those points, we do not think it is actually in dispute that Mr Harman's benchmark is a theoretical one rather than being based on market evidence, and there is a telling passage of the cross-examination that I would like to turn up briefly. It is {Day12LH1/129:} of the transcript, please. I am putting here to Mr Harman that he has not obtained or referred to any empirical evidence of what level of returns pharmaceutical companies actually earn in the real world, and I want to look, please, at his response

at line {Day12LH1/129:12} which was very telling. He said:

"In the world in which I operate, it is generally assumed [I stress those words] that that is the average return that companies will earn."

So I want to focus on those words "generally assumed" because that is really what drives Mr Harman's theory. He assumes that companies do in the long run earn their cost of capital and no more because his theory tells them that it should -- tells him that it should be so. That is the theoretical assumption that the Original Tribunal called Mr Harman out for in the original judgment.

Mr Pascoe is reminding me of the time, quite rightly. If I could just use my final three minutes or whatever it is, could we please pull up {XE2/7/12}. This is in Mr Williams' seventh report, and what I want to do -- and obviously I am going to develop this tomorrow morning now -- is to look at some actual ROCE figures from the real world and we submit that once you start to look at those, Mr Harman's assumption begins to crumble.

So these are the ROCE rates that Mr Williams has calculated for his five comparator companies, but perhaps I should stop there because I have a few points

on those and come back to that in the morning.

THE PRESIDENT: Thank you very much, Ms Stratford.

We are doing fine for time. You are moving quite briskly.

MS STRATFORD: I am very grateful for your indulgence, not interrupting with --

THE PRESIDENT: Not of course, it is very helpful.

MS STRATFORD: But of course any questions the Tribunal has I am extremely happy to answer, but, no, I am making decent progress, I think. We have agreed that I will sit down by lunchtime and then Mr Holmes will begin his closing submissions.

THE PRESIDENT: Excellent.

Well, thank you very much. We are resuming at 10.00, I think, tomorrow morning.

MR O'DONOGHUE: Sir, can I give you one quick reference? Professor Waterson asked about the lack of profitability of Epanutin. It is covered in Mr Poulton's statement, paragraph 17, it is {XC2/6}. In the Decision it is footnote 1011 which is {XA1/1/248}.

THE PRESIDENT: Thank you very much. I am very much obliged to you all. 10.00 tomorrow morning, thank you.

MS STRATFORD: Thank you.

(4.58 pm)

(The hearing adjourned until 10.00 am on

Tuesday, 12 December 2023)