IN THE COMPETITION APPEAL TRIBUNAL

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

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Monday 6th November – Friday 1st 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

Tuesday, 7 November 2023

(9.30 am)

THE PRESIDENT: Mr O'Donoghue, good morning.

Opening submissions by MR O'DONOGHUE

MR O'DONOGHUE: Sir, members of the Tribunal, good morning.

Sir, we move to what I believe is virgin territory for the Tribunal: the fascinating topic of health economics.

I am conscious that there are seven substantial documents in this area, two reports from Dr Skedgel, one from Dr McGuire, two statements from Mr Hawkins and two position papers.

There is obviously then a teach-in to come later in the month and the cross-examination, so in the next 30 minutes or so my brush strokes will be, as a result, fairly broad.

I want to cover three topics: first to anchor this in the grounds of appeal, second to touch on the role of NICE generally since this provides the launch pad for the health economics modelling exercise, and finally to give you the outline of Dr Skedgel's analysis and to tee-up the main points in dispute.

So starting with anchoring this in the grounds of appeal, if we can go to our notice of appeal it is at {B/1/71}, and you will see, sir, this is part of

ground 2. It is set out at 185 of the original Decision and what it said about patient benefit. Then over the page {B/1/72}, 186 in the original Tribunal judgment, there was a finding:

"There is clearly some economic value to be derived from the significant contribution of phenytoin to treating epilepsy in a significant number of patients."

Then at 187, the CMA's position both in 2016 you will see at 188 in the remittal decision, is that any patient benefit is captured already in the plus element of cost plus and as we say in 188, the CMA, second sentence:

"... continues to point to an otherwise almost identical list of factors [in support of] the conclusion that the product offers no value to patients other than the cost of production ..."

You will see, sir, at 190 and following, they say that the drug is old, superseded and so on, so there's a shopping list of factors said to respond to the issue of patient benefit.

Finally, sir, just to anchor this more specifically in the evidence, over the page at 194 on page {B/1/74}, you will see, sir, there are two components to what I would call the evidence on patient benefit. The first, of course, is the medical or therapeutic evidence

which is Professor Walker and Professor Sander which Mr Johnson has outlined.

Then, sir, you will see at {B/1/76} paragraph 196, Dr Skedgel also supports this conclusion albeit by a different route.

Sir, I see you are looking somewhat quizzical.

THE PRESIDENT: No, no, not at all.

MR O'DONOGHUE: Is there a technical issue?

THE PRESIDENT: It is simply the jumping between focusing in on the page and the complete page which, when you are trying to localise yourself, is --

MR O'DONOGHUE: Forgive me for going like the clappers, but I am trying to give Ms Stratford a fair crack at the whip.

THE PRESIDENT: No, not at all.

MR O'DONOGHUE: But we will come back to this. This is just to tee-up the lie of the land.

So we have the medical and therapeutic evidence, the second piece of expert evidence in this case is from the health economists, and you will see at 196 Dr Skedgel has prepared an analysis of the value of phenytoin guided by NICE's value for money test and following NICE's approach to health technology appraisals and clinical guidance and development, and you will then see, sir, the rest of 196 and then over the page

{B/1/77} at 197 his high level conclusions, and you will see, sir, at 196(c)(iii), the incremental cost effectiveness ratio of phenytoin relative to the other comparators was £19,557. So again, this is at the 2012 challenge prices.

Then, sir, you will see at 197 there are various thresholds. There is a rule of thumb, if not presumption, that below a £20,000 threshold something is value for money and at £20,000 to £30,000 it may be depending on the circumstances.

Then I will unpack all of this, sir, in more detail, this is just to give you the high level points.

THE PRESIDENT: No, that is helpful, but just to respond with a sort of high level question and do deal with it as and when convenient: this QALY point is a relative point, not an absolute point.

MR O'DONOGHUE: Yes.

THE PRESIDENT: In that you are saying when you look at phenytoin as against other anti-epileptic drugs it is not out of line, if I can put it that way.

MR O'DONOGHUE: Better, we say, but, yes.

THE PRESIDENT: In a sense you only need, I would think --

MR O'DONOGHUE: In the ballpark.

THE PRESIDENT: -- in the ballpark, not out of line, not wantonly expensive, however you want to put it, but it

is a relative test.

MR O'DONOGHUE: In part.

THE PRESIDENT: Well, I suppose my question is to what extent is there an absolute element, because that is something I have not detected in the sense that the threshold, if one looks at paragraph 197, which we happen to have up, NICE applies a threshold of 20,000 or 30,000 per QALY drugs to produce one QALY.

There is no -- or at least as I understand it there is no attempt to justify that figure of 20,000 to 30,000 in terms of an absolute value, in other words, is it worth buying a drug in the first place and how does one work out whether it is on a cost benefit analysis worth spending that sort of money.

MR O'DONOGHUE: Sir. I have that well in mind. I think it will become clear as I proceed and maybe at the end at 10.00 when I wrap up I can give you at least the headline points in response to that question.

So, sir, you will then see at 198, just before you close N away, the punchline, the final sentence on the page:

"The results of Dr Skedgel's analysis therefore undermine the CMA's statements that phenytoin sodium should be afforded no economic value above cost ... on the grounds that phenytoin sodium is third line and so

of little value to new patients. On the contrary, [this] analysis shows that, at the £67.50 capsule ... price, phenytoin represented value-for-money."

So that is the punchline.

Now, sir, in terms of the headline points, and again, I will come back to this in more detail, but just to give you the headline points, we say there are a handful of things which at this stage should be borne in mind.

First of all, it is routine for the NHS to conduct a health economic valuation of a medicine or a treatment, for example epilepsy, and the health economic evaluation is concerned to understand the value of a medicine in the context of its costs and benefits. The greater the benefits relative to costs, the greater the value of that medicine.

Now, the NICE processes are practically important. Where a product which has undergone a technology appraisal under the NICE processes meets the relevant threshold, whether it is 20,000 or 30,000, the NHS has a statutory obligation to reimburse the product in question, and just for your reference, sir, that is Hawkins 2, paragraph 11. If we can get that up it is {XC1/6.1/3}.

THE EPE OPERATOR: I cannot see a tab 6.1.

MR O'DONOGHUE: It is Mr Hawkins' second statement. It is the last tab.

THE EPE OPERATOR: Oh, XC1.

MR O'DONOGHUE: Yes.

THE EPE OPERATOR: Sorry.

MR O'DONOGHUE: Paragraph 11. This of course is the CMA's witness, and we will see that the NHS is legally required to fund and resource medicines within three months of a positive recommendation by NICE technology appraisal, and you then see a reference to the guidance.

So the meeting of the threshold in a technology appraisal is of enormous practical significance because it gives rise to a statutory obligation to fund the medicine in question, and as we will see in Dr Skedgel's report, the processes used by NICE are widely used by other health authorities outside the UK, so this is something of a gold standard, if I can call it that.

The second point, sir, is that this is the concept of the QALY. The health economists measure the value of the medicine by reference to the quality of life adjusted years or QALY. This weights the years of life by the quality of those years, and if a treatment adds years to life or improves the quality of life or both, relative to some comparator, this, sir, is your comparator point, those health gains can be summarised

as a QALY unit, and as you say, sir, the exercise certainly in part is inherently a comparative one. Product A creates more benefits than product B, given their respective costs and benefits. Product A therefore has an incremental benefit over product B.

The third point is Dr Skedgel, we say, has used standard health economic modelling methods including in particular those used by NICE and well regarded health economic tests in this sphere.

His model concludes that applying a NICE standard assessment of units of economic health, the QALY, phenytoin at the challenged 2012 prices was, and I quote, good value for money and/or represented a good use of NHS resources compared to a number of other AEDs.

Now, we say in a sense his conclusion is not terribly surprising. As Mr Brealey told you yesterday, phenytoin has been prescribed for many decades, perhaps as long as a century. It has been repeatedly recommended by NICE as an effective treatment, including most recently in 2022.

The penultimate point by way of a headline point, the CMA does not have a competing positive case on the QALY in terms of its own model. Its challenge is essentially a destructive one aimed at critiquing Dr Skedgel's modelling, and finally we say it follows

from the penultimate point that the only evidence in this case, at least as a matter of health economics, quantifying the value of phenytoin to the NHS is Dr Skedgel's. The CMA, as I noted, has no positive quantitative case.

THE PRESIDENT: Just to understand exactly the nature of the attack, and I am sure Mr Holmes can correct us both if we have it wrong, but there are two lines of attack that one can contemplate as a destructive approach.

One would be that Dr Skedgel has simply got his modelling wrong. In other words, when he says on a comparative basis that phenytoin is in the ballpark, let us keep it neutral, he is wrong: it is out of the ballpark and his modelling is just bad.

Now, that I do not understand to be the attack. The attack is much more that the process of using QALYs in the first place to, as it were, describe the ballpark is in itself wrong. Have I got that right in terms of the attack?

MR O'DONOGHUE: Yes, they do say both. They say the health economics exercise is misdirected or I think they go further, of essentially no value when it comes to determining economic value, so that is certainly one line of attack. But secondly, sir, within Dr Skedgel's modelling, there are some critiques of the assumptions

he applies, and one or two other aspects of the model.

So they also say that his model is not robust for various reasons. My simple point at this stage is that it is not as if the Tribunal has been confronted with a better model coming from the CMA, so that is the simple point I make at this stage, which is that in my submission it is a somewhat limited attack, it is not to say that it is not one they are entitled to make, but it comes from, we say, a relatively narrow perspective.

Sir, I will come back in my final point to some of the key differences, but at a very high level of abstraction, those are the two lines of attack if I can call it that.

Then, sir, moving to my second point which is to understand a bit more at this stage on the NICE processes, if we can start with Dr Skedgel's first report. It is in {E3/1/6}. It is at paragraphs 20 and so on.

Sir, if we just jump back to page {E3/1/3}, please, just to quickly look at Dr Skedgel's credentials, you will see, sir, he has been a health economist for more than 20 years. His day job, if I can call it that, is health economic modelling and he has built quite a large number of these models over the last couple of decades, so he is someone whose core expertise is health economic

modelling.

If we can then move forward to page {E3/1/6}, please, so, sir, in your own time you can perhaps look at 20 to 29 in more detail, I can just quickly give you some of the headline points.

THE PRESIDENT: Yes.

MR O'DONOGHUE: First, NICE is an executive non-department public body of the DHSC. It publishes evidence-based guidelines in a number of areas, including in particular health technologies and clinical guidance, which are the ones of most interest.

In 21:

"The role of NICE in informing pricing of medicines ... is consistent with the principles of value-based pricing."

Then you see, sir, reference to the OECD:

"...'current thinking in many countries is that the price of medicines should reflect their clinical and therapeutic value for patients and society'. To this end, many countries in Europe and worldwide have created health technology appraisal bodies ... which perform assessments of value offered by pharmaceuticals and other forms of healthcare, in order to determine whether they offer sufficient 'value' to be financed by the healthcare system."

So, sir, that is my point. This is not some foible of the UK system: health economic modelling is the meat and drink of a number of Western European countries in terms of understanding whether something is worth paying for or not.

Then, sir, 24. So 23 you will see the QALY which we have touched upon. Then in 24:

"NICE defines costs as all of the monetary costs, or indeed savings, which are associated with the health technology, its infrastructure, and associated health service use ... Therefore, the economic value health technologies can generate for the NHS by averting healthcare service use (for example, if a patient is successfully stabilised with an [AED] and therefore needs to attend fewer outpatient appointments) is captured within this measure of the net cost to the NHS."

So it is capturing direct cost savings in terms of the input costs, but also wider cost savings that the drug or technology creates for the NHS as a whole. So, for example, reduced outpatient time, reduction in social care costs and so on. So it is capturing a range of direct benefits to the ultimate purchaser, we say.

THE PRESIDENT: Mr O'Donoghue, it probably would be of assistance for the health economists including

Dr Skedgel to assist us on how all these different values fit together, because I understand how relative value or the use of the QALY to assess relative value works, but you have to start somewhere with a form of treatment. In other words, if you have no comparator, you have got something which is completely new in terms of what it delivers, you have got to ask yourself: well, is it worth it or is it not.

MR O'DONOGHUE: Yes.

THE PRESIDENT: Now, it may be that you can say: well, we will just look at other drugs in unrelated areas and do a QALY assessment there, but it does seem to me you need a starting point somewhere in that whether you choose to buy or not buy a drug needs to have an absolute in order to get off the ground.

MR O'DONOGHUE: Yes.

THE PRESIDENT: So what we are really talking about is the value of a statistical life or the value of an improvement to the quality of a statistical life in absolute terms.

Now, you can measure that in a couple of ways. One you have just adverted to which is does the new treatment create a form of savings in the NHS relative to its price, in which case you will green-light the drug provided the price is up to or equal to the savings

to the NHS.

MR O'DONOGHUE: Yes.

THE PRESIDENT: Now, that is a rather unattractive way of looking at things because it is simply looking to the NHS economics, obviously relevant, but it is disregarding the main purpose of the NHS which is actually to make ill people better, and my question is how does that factor in, so if you have something which does not create any savings in the NHS at all, it actually costs more, but it improves quality of life in a manner that does not entail any form of a monetary saving to the health service but improves quality of life, how does one fix on a figure there?

MR O'DONOGHUE: Well, sir, we will deal with that in the teach-in later in the month.

THE PRESIDENT: Right, I am grateful.

MR O'DONOGHUE: Of course, sir, as in this case where one is talking about quite a large number of comparators, I can see, sir, the point you make has particular force where there is simply one drug and there is no back story, or sort of comparative basis at all, but here of course we are dealing with quite a large number of comparators, and unless it is suggested that each and every one of those comparators is itself unfairly priced, the fact that phenytoin is incrementally more valuable, at least

as valuable, as a bunch of comparators certainly gives you a level of comfort.

THE PRESIDENT: That is a fair point, Mr O'Donoghue. It may be that you get home on comparators alone, but if one looks at United Brands and the case law, what they are saying is comparators are a relevant factor to determining whether something is unfair in terms of price, but I do not think it is an absolute rule that if you are able to localise yourself in a range of comparable products that is in and of itself a total answer to an unfair pricing case, it is obviously relevant, but whether it completely ring-fences you from an abusive pricing allegation I would not want to be drawn now. It may be that you end up saying it is a complete answer, but I would not want that to be, as it were, built into your submissions.

MR O'DONOGHUE: At this stage I would say at least it is a good start.

THE PRESIDENT: It is certainly accepting that, but it does not -- at least I am not wanting to close out the possibility that it is no more than a good start, and you therefore need to do something more at the absolute level in order to make the point completely watertight.

MR O'DONOGHUE: Yes. Sir, I have well in mind your point on absolute versus relative and this is something we will

cover in the teach-in and in the cross-examination.

Sir, just to finish on the process point, if we can look at Dr Skedgel's position paper it is in {E6/1/1}, and it is 5.1 and 5.2. You see, sir, at 5.1 the guidelines, 5.2 the technology appraisals, and then you will see over the page:

"In simple terms, it ensures that costs (including price) to the NHS represent a 'good use of NHS resources'....Manufacturers submit a value dossier for their product, including an economic model. This dossier is reviewed by an Expert Review Group ... The [group] critiques the submission and may make changes to the model to produce -- in their view -- a more plausible (and typically more conservative) estimate of the value of the technology. The NICE Appraisal Committee receives the original dossier along with the ERG's critique. The committee then decides on the 'most plausible' estimate of value to inform their final decision. The [Health Technology Appraisal] process often involves resolving differences between the views and conclusions of the manufacturer and ERG in relation to methods, results and value."

So that is the basic process.

Now, just to wrap up my second point, sir, just to take you through the steps in Dr Skedgel's analysis, we

can pick this up in again his position paper. You will see, sir, at 2 in the conclusion -- it is XE6 -- if we go to page {E6/1/1} of what is open:

"... in my opinion, at its 2012 price, phenytoin ... provided expected value similar to or better than its adjunct comparators ... would have fallen within [NICE's] £20,000 ... threshold. It represented 'good use of NHS resources'."

So that is the overarching conclusion.

Then, sir, at 8 and 9 you will see the concept of QALY and the ICER unpacked in a bit more detail. We will obviously come back to that in a bit more detail.

11, sir, is important. That I think in part goes to one of your questions.

"NICE's guidance for cost per QALY analysis recommends, in most cases, only accounting for the direct financial impacts --"

Sorry, page {E6/1/3}, paragraph 11:

"NICE's guidance ... only accounting for the direct financial impacts to the NHS and ... Social Services ... and direct health benefits to the patient and their carers ..."

You see at 11.1 is the direct benefits to the NHS in terms of savings and so on, but at 11.2 is the patient benefit, if I can call it that:

"The direct clinical benefits to patients and carers typically focus on changes in mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The additional economic benefits of improved health, enjoyed by the patient, their carers, or employers are not typically concluded."

And the penultimate sentence:

"Therefore, a cost per QALY ... captures some, but not all, of the benefits of a treatment."

That is only a partial answer, sir, to your question, but at least it gets us some of the way.

Then, sir, 12, a point we have touched on already, at below £20,000 in principle should be good value, between 20 and 30 may be depending on the circumstances.

Then 14, the point we saw in Hawkins 2, there is a statutory requirement to fund a medicine which has passed a NICE technology appraisal.

Then at 15:

"... [the] QALY threshold is a key reference in manufacturers' 'value-based pricing' ... strategies. Under a [value-based pricing] strategy manufacturers seek to set a price that will secure a positive NICE recommendation but also maximise their profit. This is called 'pricing to the threshold' ... NICE's methods and thresholds play an important if indirect role in how

manufacturers set their prices."

That is something of course which is contentious, but that is Dr Skedgel's view.

Then, sir, a couple of final references. At 18 --

THE PRESIDENT: Just looking at 15 and really re-running the debate that we had with Mr Brealey yesterday about how far a price control is relevant to the question of an unfair price in competition terms, is the dispute between yourselves and the CMA with regard to NICE evaluations simply this: that you say there must be some sort of relationship, it may not be an absolute, precise correlation, but there is some sort of relationship between what NICE says is worth spending NHS pounds on and what the NHS spends and the unfair pricing question, whereas the CMA are saying these are two entirely separate exercises and one does not inform the other?

MR O'DONOGHUE: Yes, they --

THE PRESIDENT: Putting it crudely, that is the debate?

MR O'DONOGHUE: That is one of the battle lines.

THE PRESIDENT: Yes.

MR O'DONOGHUE: And I think the CMA -- Mr Holmes will correct me if I am wrong -- they go as far as to say it has zero value, and we say that is a very, very strong thing.

THE PRESIDENT: Zero economic value?

MR O'DONOGHUE: Well, zero relevance as a piece of evidence.
THE PRESIDENT: Well --
MR O'DONOGHUE: In this case in the context of economic value.
THE PRESIDENT: So they are not saying necessarily zero economic value, they are saying in terms of the understanding or the information we get from this sort of exercise is of no value in terms of the United Brands test.
MR O'DONOGHUE: Indeed. It is a strong submission.
THE PRESIDENT: Okay.
MR O'DONOGHUE: We say, sir, pausing there, to say that the predominant health economics assessment conducted by NICE as the basis for the fundamental decision whether to reimburse a medicine or not has zero value in this case we say is an extreme position.

It may not be perfect, but we say it is a benchmark of significance in this case, even if it is not clear and compelling in each and every single respect. It is a useful and important piece of evidence both practically and analytically.

Now, sir, I am conscious of the time. Just to run through in one minute the four steps in Dr Skedgel's analysis.

You will see, sir, starting at 17 of the position

paper, on page {E6/1/5}, step 1 is estimating the efficacy of ASMs or AEDs, so this is the review of the medical literature, and you will see, sir, over the page {E6/1/6} starting, for example, at 22, he has a proportionality assumption on page {E6/1/6}.

Then on paragraph 28, he has an equivalence assumption, and then over the page on page {E6/1/10}, there is a dichotomous outcome assumption. So these assumptions are attacked by Professor McGuire. And then you will see at 33 {E6/1/11} the results of the efficacy analysis:

"Estima concluded that the likelihood of complete response with phenytoin was greater than any of its adjunct comparators."

So that is step 1, the efficacy.

Then step 2, sir, at 34 you will see the price of phenytoin and its comparators in an adjunct setting, so this is the cost including the price.

Then at 35 and 36, this really is the core of the analysis, the cost effectiveness, and you see at 37:

"... I concluded that phenytoin would have met NICE's £20,000 acceptable cost per QALY threshold if it had been subject to a HTA in 2012."

Then 41 is you will see that one of the criticisms of Professor McGuire was that there was no sensitivity

analysis. In 41, that was done in schedule 2, and he sets out the contours in the sensitivity analysis there.

Sir, just to wrap up in five minutes, in terms of the key differences, if we can first go to the Decision, it is at {A1/2/59}, please, this is annex E to the decision, and you will see sir, at 87 to 89 there are a handful of points made.

You will see at 87, E.87:

"... a QALY analysis is generally used to assess new treatments..."

And so on.

So they make the point about new versus existing treatments.

Now, if we can go to {E6/6/2}, please. This is Professor McGuire's position paper, you will see at paragraph 5 he says it can be applied to new and old drugs. So on the first point on the Decision it is now common ground that it can be applied to new and old drugs, well, with respect that is a bad point for the CMA to make, so we can take that off the table.

We then go back to the previous document, the Decision {A1/2/59}. They say in E.88 it is hard to do. Well, given it has been done, that point does not really go anywhere in the sense it is the out-turn of the analysis of the expert health economic evidence which

will decide whether it has value or not. Then, sir, as you saw the three assumptions are attacked by Professor McGuire, so there is a dispute there.

There is a criticism which we say has been remedied on the lack of sensitivity analysis in schedule 1 which has been corrected in schedule 2, but there are some outstanding points still in relation to that, and if we then go back to Dr Skedgel's position paper, paragraph 44, it is at {E6/6/14}.

This is Professor McGuire's position paper. You will see at 44 he says:

"Dr Skedgel has stated that he considers..."

And so on.

So the basic point being made by Professor McGuire is contrary to what Dr Skedgel says, he says that Dr Skedgel has not followed the NICE processes and methods at least faithfully, so that is a point of dispute.

If we then go to {E6/6/5} at 15 you will see that a further point made by Professor McGuire is the distinction between the health technology appraisals on the one hand conducted by NICE and the guideline assessment on the other, as also conducted by NICE. We do not accept that, we say that is a formalistic distinction that in practice is not really of any

significance, at least in this case.

Now, sir, just to wrap up in terms of what we say are the headline points in terms of triangulating this within *United Brands*, five points.

First, we say the QALY measure is the predominant method used by the Department of Health to work out whether a drug represents good value to the NHS, and to say that it is irrelevant to working out the economic value of a medicine is an extreme proposition.

Second, it is common ground that you need in some way to work out the patient benefit of the drug. The CMA's position is that it is no more than cost plus but it at least accepts in principle that you need to capture the patient benefit in some way, and we say that the QALY analysis does this and does so in a way that involves a widely accepted and widely used and practically important methodology.

THE PRESIDENT: It is a matter for Mr Holmes, but just so that we have it out there, is it the CMA's position that all pharmaceuticals need to be assessed on a cost plus basis? In other words, the value is limited to cost plus, or is it simply a case in this case?

MR O'DONOGHUE: Well, sir, certainly in the case of unbranded generics their overwhelming rule of thumb is if it is not at the level of cost plus it is at least

very suspect. So that is something they seek to apply as a general matter. We will hear from Mr Holmes whether he admits of any exceptions, but that is their clear and unambiguous starting point.

You will recall, sir, that they place heavy emphasis on the life cycle of the pharmaceutical product, they say in the post-patent phase in the generic period if it is not at or approximate to cost plus there is something fishy, and we say that is also an extreme position.

Third, the QALY analysis is, we say, in many respects superior to what the CMA has done in qualitative terms, at least in the present case.

One of the oddities, of course, of pharmaceutical cases is that there are in reality two consumers: there is the ultimate patient who consumes the prescription medicine and there is the NHS which underwrites the entire system. The patients of course do not pay for the medicines they consume, at least typically.

So what the QALY analysis does, in a way, frankly that traditionally *United Brands* does not do is capture the benefits to both of these categories of consumer. That is why we say at least in a case like the present, the QALY analysis is meaningful and actually we say superior, because it nests the position of the two sets of consumers in a way that, on the CMA's analysis, you

simply look at one category of consumer which we say is too narrow.

The penultimate point. We say that for reasons of error cost and otherwise, of course, quasi-criminal penalties being one of them, it is important as a general matter that an inclusive approach is taken to benchmarks and comparators. In unfair pricing cases, the problem is that there is typically a dearth of benchmarks or comparators and we say that as a result, even if a benchmark or comparator is not clear, compelling or perfect, the benchmark should still be given some evidential value.

Finally, as we discussed yesterday with Mr Brealey, it is clear the *United Brands* is a flexible test, it is a case from the 1970s about bananas. Things have moved on, it is a test that can and should be adapted to the circumstances of the case at hand. As we saw paragraph 253 of *United Brands*, there is an express recognition that other economic methods may be devised in other cases, and here we have one such health economics method which has been used in practice for decades, and we say it fits fair and square within *United Brands*.

So, sir, those are the initial submissions on the health economics.

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

PROFESSOR WATERSON: Could I raise a question?

So in this QALY analysis, supposing -- is there an aggregation issue? What I mean by that is supposing the NHS were to in some way carry out this test on all the drugs it used, would that mean that the sum total of the drugs that would be supported in that way would exceed the NHS budget for medicines? It seems to me that is another way of thinking about this issue as to whether the NHS in a sense relies on some of the products being at markedly below the threshold in order to cover the total budget?

MR O'DONOGHUE: Well, sir, in theory I see the point there is almost a problem of infinite regress. Now, in practice we would say that, as we saw in *Liothyronine*, each market because of its volume and difficulty of entry would be a sort of tangible limit to the number of entrants that could be supported. So we say that in practice, that acts as a filter in terms of the proliferation of individual products. We say that in practice one does not end up with a situation where there are N number of products and therefore all or most of them have to be funded because they are incrementally better than the worst products.

We say that in practice -- in theory I accept your

point, sir, but we say in practice that seems a vanishingly unlikely concern for the reasons I have given, but it is something we will come back to, I think, in the teach-in and the cross-examination and in closings.

THE PRESIDENT: Thank you very much, Mr O'Donoghue.

Ms Stratford.

Opening submissions by MS STRATFORD

MS STRATFORD: As the Tribunal knows, I appear for Flynn with Mr Pascoe and Mr Richardson.

The Tribunal has already had the benefit of full opening submissions from Mr Brealey together with Mr O'Donoghue and Mr Johnston, and to a considerable extent, our appeal overlaps with that of Pfizer, and I am going to do my best not to cover the same ground. As should be clear from our pleadings and our skeleton argument, we agree with and adopt much of what Pfizer says.

Flynn, unsurprisingly, agrees with Pfizer in particular that phenytoin capsules have significant therapeutic benefits for the patients who take them and that they have economic value beyond what it costs to produce them.

We have not led our own expert evidence on these issues because, frankly, the Tribunal would not thank us

for making it listen to the same evidence twice, but the Tribunal should not mistake our attempts at economy for lack of enthusiasm for these points: we have adopted them in our pleadings and are entitled to take the benefit of them if they succeed.

THE PRESIDENT: Yes.

MS STRATFORD: While there is overlap between our appeals, there are a number of grounds that are specific to Flynn's position as the marketing authorisation holder of the medicine which purchased phenytoin from Pfizer and sold it on to the next person in the supply chain at what we say was a normal industry margin.

These grounds, as the Tribunal knows, revolve around the plus or the reasonable rate of return in the CMA's cost plus calculation, and this is a point that is in play for Flynn's appeal but less so for Pfizer, and Professor Waterson will recall this issue was debated at length in the first appeal. Indeed, a repeated refrain of our submissions is going to be that the CMA has done nothing to meet the criticisms made against it by the original Tribunal on the size of Flynn's plus.

I am going to structure my submissions in five overarching sections. First, I will deal with the architecture of the Decision as against Flynn, particularly in relation to the first limb of

United Brands, so excessiveness, and that is important because it will show that the Decision hangs on the CMA's plus, ie its reasonable rate of return for Flynn.

Second, I will make introductory remarks about our appeal and in that section I will also explain Flynn's version of the facts without, I hope, trespassing on any of what Mr Brealey already covered yesterday.

Third, I will do some historical excavation, if you like, into the basis of the CMA's original Decision in particular on excessiveness, what the Tribunal and the Court of Appeal previously found to be wrong with it, and what the CMA has now done or not done to fix it.

Fourth, I will deal with Flynn's plus and that section will encapsulate three issues in particular: one, the debate about the proper metric for Flynn, so that is the ROS versus ROCE debate; two, the battle between theoretical and empirical approaches to identifying the correct plus, and three, Flynn's empirical evidence on what is a normal rate of return.

So that is where our margin comparators or our margin market evidence comes in, and I will also deal under this fourth section, which I should say candidly now will be my longest, with cross-checks.

Fifth and finally, I will deal much more shortly with the tablet comparator.

Just for your note, I am not going to deal with penalties at this point since I do not anticipate that any of the evidence that the Tribunal will hear is going to relate directly to that issue. I will return to penalties in closing as appropriate, and the Tribunal knows we have already set out our position fully in writing.

You will have spotted, I am sure, that there is a bias in my submissions towards limb 1 of *United Brands* and excessiveness. I stress again that is not because we do not have good arguments under limb 2, so economic value and price comparators or perhaps as the Tribunal put it yesterday, price controls. It is simply a question of economy between Pfizer and Flynn and the fact that the points specific to Flynn do congregate around limb 1.

This is relevant to the CMA's allegation at paragraph 26 of its skeleton, and I do not think there is any need to get it up, but the CMA says there that because of the parties' supply arrangements Flynn's arguments have opportunistically focused on margins and Pfizer has focused on price.

Now, I can only speak for Flynn, but at least as regards Flynn, that is wrong. Our appeal is and always has been based on both margin and price comparators, and

we succeed on either.

So with that I turn to my first topic where I want to begin, you may say prosaically, with the Decision.

The Tribunal will be relieved I am not going to attempt to trawl through the Decision in its entirety. Instead, I want to focus on the structure of the Decision, particularly in relation to excessiveness, so that the Tribunal understands why our appeal on the plus really matters.

It involves a little bit of jumping around because of the way the CMA has organised the Decision which skips at points from Pfizer to Flynn and then back again, but I cannot stress enough that this is foundational and important.

Just beginning with the basics, if we could get up {XA1/1/4}, this is the Decision paragraph 1.3, where the CMA finds in summary that each of Pfizer and Flynn infringed the Chapter II prohibition and there are two immediate points I want to make here.

First, these are separate decisions against separate undertakings. There is no attempt to treat Flynn and Pfizer together. That is not the case we are facing from the CMA.

Second, the infringement is limited to the Chapter II prohibition. As the Tribunal may already

have seen, the CMA considered but abandoned an investigation that Flynn's supply agreement with Pfizer constituted an anti-competitive agreement under Chapter I and I do need to stress that investigation was dropped.

Moving on in the Decision at page 5 --

THE PRESIDENT: Just to be clear about the implications of that in terms of Chapter II, you say that we have got to assess Pfizer and Flynn as entirely separate economic actors in a single supply chain but we need to be looking at those parts of the supply chain in which each acted and so when one is considering either excess or unfairness in your case, in Flynn's case, we take as a starting point the charge to Flynn by Pfizer of the capsule and look at what you sold at, and in Pfizer's case, the process ends where it begins with Flynn and one looks at the cost, effectively, to Pfizer and the sale price to Flynn, and that is where the difference in case exists, because one is looking at a single chain but it is disaggregated in that way?

MS STRATFORD: Yes. Sir, I am very grateful. I am going to come back to this because I entirely agree it is very important, but that is the case that we are facing, that is the decision that the CMA has taken. They have looked at the cost stacks, built them separately.

THE PRESIDENT: Well, that is why we have got the four infringements by Flynn and four infringements by Pfizer which are differentiating between dosage but also differentiating between localisation in the supply chain, and it is not the case of either, as you say, Chapter I or indeed, a case of collective dominance. These are not points that are live before us. We are simply talking about two separate sets of self-standing Chapter II infringements.

MS STRATFORD: Yes. I am tempted to say I could not put it better.

THE PRESIDENT: Flattery will get you everywhere, Ms Stratford.

MS STRATFORD: Moving on, sir, you have already anticipated a point I was coming to, but at page {XA1/1/5} paragraphs 1.8 to 1.10 you have there the summary finding that Flynn committed an abuse by excessive pricing, and I do stress there that there were four separate abuses for four separate strengths of the drug and again, that is something I am going to come back to.

Then if we could skip ahead to page {XA1/1/148} of the same tab, this is paragraph 5.2 of the Decision, and this is the CMA's analysis of excessiveness, you have got the main heading at the top of the page there. 5.2 makes clear that the CMA assessed excessiveness by

applying cost plus.

5.3 then says that:

"After establishing the costs actually incurred, [that is in supplying phenytoin] a reasonable rate of return should be estimated and added to total costs, to determine Cost Plus."

And that makes clear a point which I do not think should be controversial that the reasonable rate of return for Flynn is an integral part of the CMA's cost plus analysis, and, therefore, its finding of excessiveness.

So the reasonable rate of return is the plus in cost plus. If the reasonable rate of return is wrong, the excessiveness calculations must be wrong.

THE PRESIDENT: Is there an ambiguity in what reasonable rate of return means? I am not talking about specifics, I am talking about the general question one must ask, which is this: we are talking about infringements which are, as we discussed, very specific: they are localised in dosages. So does one need to ask what is the reasonable rate of return for that particular product, or does one ask what is the reasonable rate of return for the undertaking that is producing, amongst other things, that particular product?

MS STRATFORD: Well, we say four separate infringements have

been found, and in relation to each of those, the CMA needs -- therefore, bore the burden of establishing that those prices for each of those four doses were excessive.

THE PRESIDENT: Yes, so you do not look, on that basis, at return on costs that have nothing to do with the manufacture of a particular dose of capsule. In other words, you localise the costs to the specific capsule, say 100mg and you say: okay, we have the costs now, this is what you need to spend in order to produce this capsule, now let us ask ourselves what is the reasonable rate of return in relation to that specific product. Is that the approach that we should be taking?

MS STRATFORD: In principle, yes.

Now, I accept that we need to be realistic about how granular you can be. Again, the Tribunal may, or Professor Waterson will recall and the Tribunal will have seen, for example, there was a considerable debate about cost allocation at the first hearing, and I will come -- it is not a freestanding ground of appeal now, if I can put it like that. One of our experts, Mr Williams, does still have things to say about cost allocation and we look at it for the purposes of testing the robustness of some of --

THE PRESIDENT: This is a question of by volume or by

revenue in terms of allocation of fixed costs?

MS STRATFORD: Yes.

THE PRESIDENT: Yes.

MS STRATFORD: So it is still in play in -- I only mention that because that is an example of where some of this may in practice go to.

THE PRESIDENT: I quite understand that I have in a very blasé way said you work out the costs of the product; I entirely accept that is in any multiproduct firm a difficult thing to undertake, but let us assume one has uncontroversially reached an outcome as to the cost of producing the product in question, let us take 100mg capsules sold by Flynn as an example of four.

When one has, having ascertained the cost, trying to work out the plus bit, the rate of return, what does one look at if one is not looking at the overall rate of return to the undertaking itself, given that the undertaking is producing many other things than just that product?

MS STRATFORD: If I understand, sir, your question correctly, I do not think we accept that you can look in some generalised way at Flynn's overall rate of return across all of its products.

THE PRESIDENT: No, indeed, that would be wrong given the localisation of the infringement in the excess of price

over the costs of this particular product.

MS STRATFORD: Yes.

THE PRESIDENT: What I am really saying is: are you saying that a measure that is based upon return on capital assessed generally would in principle be wrong?

MS STRATFORD: Yes, I think we are saying that.

THE PRESIDENT: Yes.

MS STRATFORD: In fact, if I may, I will come back to it.

THE PRESIDENT: No, of course.

MS STRATFORD: We may get a little bit of help later on from the *Aspen* decision of the Commission, just by way of example of the way the Commissioners thought it appropriate to approach these questions, because there, frankly, the Commission has not been as granular as I was referring to when talking about cost allocation and so on, but equally it certainly has not looked globally at an undertaking in that way, but I will come back to that, if I can, in due course.

I think I rashly said I was making a point that should not be controversial. I am going to go back, if I may, to the Decision and at page {XA1/1/160}, paragraph 5.62 of the Decision, the CMA says that it has applied a ROCE methodology to establish Flynn's reasonable rate of return and I am going to just -- at the moment I am just flagging that. I am going to, of

course, come back to that point.

Then page {XA1/1/208}, paragraph 5.277, the CMA says it:

"... uses a WACC of 10% in its base case calculation of the reasonable return for Flynn's Products, consistent with the cost of capital used in Jefferies' analysis of Flynn's business."

So in simpler terms what the CMA is saying is that it has determined Flynn's reasonable rate of return to be a 10% return on capital based on its cost of capital.

Then again, moving on, and I will of course come back to pick up all of these points in my submissions, but just sticking with the structure of the Decision for the moment, at page {XA1/1/236}, that is paragraph 5.396, the CMA calculates Flynn's excess by measuring the extent to which its returns exceeded cost plus, and the key figures there in the table are the ones at the bottom of the table, so the excess percentages, and the overall excess found across all four products is 47%, although the excess on the most popular 100mg product tablet capsule is 37%. The percentages are also expressed there in absolute terms, and that is again a point I will deal with later. These excess figures depend entirely on the CMA's reasonable rate of return for Flynn of 10% ROCE.

Moving on to page {XA1/1/239} of the Decision at paragraph 5.408 and following, the CMA applies what it refers to in the subheading here as a "rate of return cross-check", and this is a rerun of what will be particularly familiar to Professor Waterson, the 6% PPRS benchmark that the CMA put forward unsuccessfully in the first appeal, as the CMA itself fairly acknowledges at paragraph 409.

Over the page, page {XA1/1/240} at 5.414, one sees in the table a set of alternative excess calculations based on the 6% ROS return, which produces an overall excess of 41% and 31% for the most popular 100mg capsule.

Finally, still on page {XA1/1/240} at 5.417, there is the overall conclusion that each of the excesses set out in table 5.17, that is the 10% ROCE table we just looked at, is material and sufficiently large to be deemed excessive.

So where we get to is that the CMA has found Flynn's returns to be excessive based first on its primary basis of a 10% ROCE benchmark, which I will explain in more detail later is essentially designed to make sure that Flynn covers its costs, and second, on a cross-check of a 6% ROS derived from the PPRS.

Now, it will not be lost on the Tribunal, this is

the same analysis of excessiveness that the CMA sought to defend in the original appeal, albeit in reverse order with a superficially different ROCE figure, and I am going to come back to all of that, but I can now move on to my second section and make some introductory remarks about our appeal and then deal with Flynn's facts.

The reason I wanted to take the Tribunal through the Decision is to emphasise that the CMA's headline rate of return at 10% ROCE cross-checked by a 6% ROS is the only basis on which Flynn has been found to have priced excessively. If these are bad benchmarks, as we say they are, the finding of excessiveness must fall. That is the case the CMA has chosen to make, and it is the case to which Flynn has responded.

So either Flynn's returns were excessive based on those benchmarks or they were not, and this is not some roving enquiry into Flynn's pricing, and it is not open to the CMA, we say, to develop some other benchmark during this appeal hearing.

As I have already said, and I think the CMA accepts, it bears the burden of proving with cogent evidence that Flynn's prices were excessive and unfair, and it has chosen to do so by its 10% ROCE benchmark and its 6% ROS cross-check, and the Tribunal's task, with respect, is

to decide whether the CMA has thereby met its burden or not.

For all of the hundreds of pages of analysis in the Decision and in the pleadings, the CMA's approach to identifying Flynn's reasonable rate of return comes down to really a very simple hypothesis, we say, that a company's return on capital should equal its cost of capital. In other words, a company should earn enough to cover its costs. Mr Harman, the Tribunal may have seen, refers to these as its economic costs.

Now, one only has to say that out loud to realise it cannot tell you whether a price is abusively high. Of course the company must cover its costs. The fact that it earns more than is needed to cover its costs says almost nothing about whether its prices are excessive to such an extent that they call for quasi-criminal censure.

To put concrete figures on this, just for a moment, if Pfizer charged a price set at what the CMA says is its reasonable rate of return and Flynn charged its reasonable rate of return on top of that, Flynn would be earning £66,000 per year, the purpose of which would be to service its cost of capital.

I do not think we need to go to it, but that figure is in Dr De Coninck's statement, his seventh report, at

paragraph 28, and I am sure that will be explored in due course.

Now, that £66,000, as, sir, you have just been pointing out, is of course split across four separate products for which four separate infringements have been found, so the true allowance, and this is fairly back of the envelope stuff, but again, I do not think it is controversial, the true allowance is around £10,000 for the 25mg capsule, £19,000 for the 50mg, £20,000 for the 100mg and £16,600 for the 30mg.

Now, we can provide the maths behind the figures if that would be helpful for the Tribunal, but --

THE PRESIDENT: I think it would be, if you have used an example, then we will want to make sure we deploy it, if we do deploy, it accurately rather than inaccurately.

MS STRATFORD: I am grateful, but just to say it uses the CMA's assumptions and on things like cost allocation and so on it really -- it is nothing more than splitting up my £66,000 into the four products.

Now, of course, the CMA and Mr Harman's answer is that they are not saying that a return above the company's costs automatically means that a price is excessive. They say, and I can hear lots of whispering on this coming from my right, that there is a judgment call to be made about how far above that benchmark the

price lies, and one sees that clearly, for example, from Mr Harman's report, and I think it might be helpful to turn that up at this point. Bundle {XE1/15/11}. This is his third report which is the report that has been prepared for this remittal appeal, and I want to look briefly at paragraphs 2.2.3 to 2.2.4.

So at paragraph 2.2.3, Mr Harman explains that the CMA's cost plus methodology is designed to enable the recovery of capital employed and a recovery on capital which he refers to collectively as the company's economic costs. That is where that phrase comes from.

Then in the next paragraph, 2.2.4, he describes this cost plus methodology as "a filtering mechanism" on the basis that it might provide an early indication that prices are unlikely to be abusive or alternatively might, and I emphasise "might", indicate that prices are excessive.

Now, Mr Harman's logic is reflected in that paragraph of the Decision that I just showed you. I do not think we need to go back to it unless the Tribunal wants to. It is 5.417 of the Decision, finding that Flynn's excesses in the table that you will recall are material and sufficiently large to be considered excessive, and one cannot over-emphasise how much of the CMA's decision is loaded into that fairly short

paragraph.

The CMA is saying that Flynn's prices across all four strengths were 47% above its economic costs, and that is a sufficiently large gap to constitute an excess, and really that is the basis of the whole decision against Flynn on excessiveness, so the first limb of *United Brands*.

We say that is quite transparently what I am going to call a "sniff test". There is no real analysis behind it at all beyond Mr Harman's hypothesis that a company's returns on capital should equal its cost of capital.

THE PRESIDENT: Do those costs not have to take into account the riskiness of the commitment of the capital to the venture? I mean, if, for instance, I choose to lend money to a borrower who is a safe bet, who will absolutely repay, then the rate of return will be correspondingly low. If, on the other hand, I choose to invest in something which is a high risk strategy, a venture that might easily fail, then my rate of return ought to be adjusted differently.

MS STRATFORD: Yes, and that would, I think in this -- if we keep it very simple, at least for my brain, if we imagine a loan from a bank, that might be reflected in the interest rate, so that would be reflected in the

cost of capital. But the point that I am trying to emphasise at the moment is that the CMA's reasonable rate of return, they have taken the cost of capital, said that that constitutes -- should constitute a company's return on capital, and that is the end of it, that is your reasonable rate of return, and then anything above that is the wonderful world for the CMA of a regulator's discretion.

THE PRESIDENT: Well, indeed, but my concern is that you have got to, in carrying out those computations, ascertain the riskiness of the venture itself. In other words, Dr Fakes for example in his statement articulates certain issues about Flynn's business, he is identifying certain risks. For instance, the risks to continuity of supply, side effects, all these things are matters which, if they go right, are fine, if they go wrong then you are not going to make any money, you are going to lose your capital. All I am saying is, is that not something that one needs to take into account when one is saying: well, yes, X capital has been committed to producing this particular product, let us say it is £100. If that commitment is a safe bet, then you might say: well, the return should be equated to that of a loan to someone who is well able to repay, you are just looking at the time value of money.

If, on the other hand, to take a non-Flynn example, the venture is hugely speculative, the return you would expect to get on your £100 will be rather more than 4%; it will be, you know, 30%, 40%, 50%, if the risks of failure are that substantial. It may be more than that.

It does seem to me that a uniform rate is one that disregards that question of riskiness altogether, and I am just wanting to explore how far that is a problem with the CMA's approach, if it is, in your submissions.

MS STRATFORD: Well, I am certainly not suggesting there should be a uniform rate, and indeed, I do not think we disagree in principle with any of -- with respect with what you have been putting to me, sir. I think we would say that is where our empirical evidence comes in, because that is where you have, we say comparable companies in the pharmaceutical industry which I think one might say by definition is never going to be risk -- certainly nothing in life is risk-free, but pharmaceuticals in particular are always going to have a built-in level of risk, but we do say that is one of the reasons why you need to look at empirical evidence here.

Now, of course, you do need to be realistic about finding perfect comparators, and I am going to come back to that, but it is one of the reasons why we do stress,

as you know, that empirical is much better than theoretical here.

THE PRESIDENT: Yes. Just to put it crudely, if you are able to produce figures of pharmaceutical distributors who are marking up by similar amounts to the case under investigation, then you say: well, unless there is something very odd going on in a number of markets, in other words, assuming there is competition, then this ought to be a guide as to what a reasonable rate of return is. It goes to more than that.

MS STRATFORD: Absolutely, and that is an important part of Flynn's case.

THE PRESIDENT: Yes, I see.

MS STRATFORD: Just for clarity, in case anything I have said could be misunderstood. We certainly do disagree with Mr Harman's approach insofar as it attributes a universal rate of return to the whole industry. So we are certainly not suggesting that, but we do say that the CMA has adopted this cost of capital equals -- should equal return on capital. There you are, you have got your reasonable rate of return, Bob's your uncle and all we do at that point is that is our benchmark and we see where we go from there in terms of exercising our discretion.

THE PRESIDENT: I mean, let us take one of Mr Johnston's

examples. We had yesterday that very helpful table of alternative treatments for epilepsy, and Mr Johnston made the very interesting point that some products are so recent on the market that one cannot actually ascertain, because insufficient time has elapsed, what the chronic risks are in the long run. You simply do not know.

Now, that is a risk factor which exists in these newer drugs which does not exist in sodium phenytoin in that you have got -- I mean, I am hypothesising here, you may want to push back on the facts, please do, but let us say that the 100 plus years history of sodium phenytoin gives you a better understanding of the risks of treatment.

Now, those risks could generate a litigation risk. It is probably higher in the newer drug because you know less than in the older drug. Is that something that one ought to be bearing in mind when ascertaining the rate of return in respect of that particular product: the liability risk of the unknown side effects in the long run, to take it as an example?

MS STRATFORD: The CMA certainly have a sort of fairly extreme proposition that if you are an R&D product, you are a research and development product, you are a new product, then that is a completely different case. If

you are a generic, in their world, you should be pricing rock bottom, commodity pricing.

We do not accept that that is the only way that generic companies can lawfully price. To be quite plain about that, we do not accept that pricing above a commodity level is somehow always going to be abusive or liable to be found abusive.

In terms of risks, there is going to be evidence on that, so I do not want to anticipate that, but I would push back just very slightly on the idea that an old drug is necessarily thereby not risky. I accept the risks may be different, they may be more known, but regrettably in the area of medicines, unexpected risks do emerge sometimes after very many years, and we can all think of examples of that and indeed, I think there are some examples in the evidence.

THE PRESIDENT: Ms Stratford, I do not want to get hung up because I am really the last person to be articulating any point of fact to you, so the point I am making is I do not want to get drawn into where the risks are higher or lower, what I am putting to you so that I can understand how this all works is if in any given case the risks are higher -- let us say, it is a very well-established drug where the risks are, for whatever reason, higher -- is that something which needs to feed

into a rate of return and therefore is an indicator that a universal rate of return, unless the risks are universal, cannot be right?

MS STRATFORD: Is not going to work. Yes, well, in principle I see the force of that.

THE PRESIDENT: We will obviously come to the facts and I certainly do not want to anticipate those.

MS STRATFORD: I am grateful.

So coming back to my slightly pejoratively, but I think it is helpfully named sniff test, we say this is making matters worse. It is actually a sniff test based on an extremely low benchmark which we say bears no resemblance to reality, and, as we have just been discussing, reflects nothing more than Flynn's costs or their economic costs as Mr Harman would put it, and that is why I say so much of the CMA's Decision is loaded into its discretionary judgment that Flynn's returns were so far above the benchmark that they are deemed to be excessive.

Now, it might be said? What is wrong with the sniff test? The immediate answer we give is that excessive pricing is a quasi-criminal offence and the Tribunal in *Hydrocortisone* rightly recognised the stigma that attaches to it.

A company's compliance with rules of this kind

cannot, we say, be reduced to the discretionary judgment of a regulator. The other side of the coin is that companies need to be able to take advice on how to price lawfully. If I am approached by a company that wants to know if a proposed price is excessive, my advice cannot be: do not price too significantly higher than your costs. I do not think anyone would want to pay me for that. It is far too vague and offers no meaningful guidance at all, and --

THE PRESIDENT: Is there any evidence in the record to show, generally speaking, the correlation between price and unit cost, by which I mean variable costs attributable to the unit and an attribution of fixed costs generally, not just in the pharmaceutical industry, but generally speaking, how far prices in the real world track costs in that way?

MS STRATFORD: No, we have got our -- we have evidence from other pharmaceutical companies, and indeed, we have striven -- if that is a word -- over the months and years to make our margin comparators more and more focused on the type of company that Flynn is because we faced repeated criticisms from the CMA that the margins of these other companies were not -- their businesses were not sufficiently close to ours, but, no, in terms of a roving enquiry into other companies, the CMA would

have to gather that evidence and a company like Flynn would not have the powers, and certainly should not bear the burden, of having to gather that evidence.

We do have evidence obviously of Flynn's other products and that will come out in the evidence.

THE PRESIDENT: I am thinking rather more at the level of economic theory, and it may be that we ought to put this on the radar of the economists who are coming to assist us. Zoning purely in on the costs of producing a given product, to what extent is it right that in the real world generally prices track cost? If I go into a corner shop and buy a tin of soup and I spend £2 on my tin of soup, is the cost to the corner shop going to be measured in a 10% difference to price?

Now, intuitively one feels that that is probably not right because there are going to be all kinds of other products being sold by the corner shop which may have different margins, and so one may have a whole variety of different gaps between unit cost and unit price which are referable not just to the existence of unallocated common costs.

So really what I am interested in is the extent to which the real world does not track the world of perfect competition, where as of course we all know prices do trend to cost plus a rate of return to the seller of the

goods, but that is because you have got very peculiar assumptions in perfect competition which impel that outcome.

So of course I am sure one could produce reams of evidence on this but I am not encouraging that, I am encouraging a sense of how far an economist versed in practicality would say: well, cost does not inevitably result in a tracked price, and of course, we see all kinds of pricing structures which are not based on that. I mean, cost plus is one way, but we have dynamic pricing, we have pricing by reference to competitors, irrespective of cost. All of these things are forms of prices which are not intrinsically anti-competitive but which are not defined by reference to a given mark-up on cost.

Of course I accept that is one way of doing it, but the point I am really putting to you is, is it the only way of doing it?

MS STRATFORD: That is all very helpful, and I am sure we will all consider and the experts will consider for the purposes of the hot-tub whether there is something that can usefully be explored on that.

I come back to the fact that we are meeting the case that we are facing, and that is a case that has been constructed by the CMA in this quite specific narrow

way, but I do endorse the focus on the real world, and that is going to be a theme of our submissions, and we do submit that we can answer the questions, going back to my how do I advise my client problem, we can give a sensible answer to the question of whether a proposed price is excessive if we swap the finance theory of Mr Harman for some empirical evidence: what is a normal rate of return in the industry. We have focused on the pharmaceutical industry, and, as I indicated, even more narrowly within the pharmaceutical industry on types of companies that are, we say, remarkably similar to Flynn, but, sir, you are putting a broader proposition of looking more generally at other industries.

THE PRESIDENT: Well, take a concrete example. Ought it to be the case that whoever is advising Uber that they really should not be surge pricing in cases of higher demand because it is the demand that drives the surge, not the cost. Now, that is something which happens in many, many areas. Is it the case that that sort of pricing dynamic is the moment one is in a dominant position a questionable course of conduct given the jurisdiction to control abusive prices?

Of course you have the dominance filter to restrict the jurisdiction of the court, but is it the case that forms of pricing which are not directly informed by

cost, in other words, anything that is not cost plus, are those intrinsically questionable? That seems to me to be the wider implication of what the CMA are saying.

Now, you of course can say: look, empirically speaking, other players in the industry are generating forms of return which are different, and we do not need to go into how they price, it is just it is more than what the CMA has allowed, and of course that is evidence which goes to the same point from a different direction and we understand that.

MS STRATFORD: And it is the evidence, with respect, that a company in the position of Flynn can get hold of --

THE PRESIDENT: Can adduce, yes.

MS STRATFORD: -- and understand. I mean, it should not be the case that all of these companies are having to go off and understand deep points of economic theory.

THE PRESIDENT: Well, no, I would agree with that, but we do have not quite wall-to-wall economists, but coming close to that, so we probably ought to ask them the question even if they say: we cannot answer it because empirical research needs to be undertaken and we have not done that, I mean, that would be a perfectly acceptable response, but we do think the question ought to be asked at least, given that we have the resource.

MS STRATFORD: I am grateful.

Coming back to -- yes, I am reminded, I do not know whether the transcriber is needing a break?

Yes, please, she says.

THE PRESIDENT: I entirely understand. Is that a convenient moment, Ms Stratford?

MS STRATFORD: Yes, absolutely.

THE PRESIDENT: Very good. Well, we will resume at 11.15. We will rise for ten minutes.

(11.06 am)

(A short break)

(11.20 am)

THE PRESIDENT: Ms Stratford, before you start, just so that you can time yourself, I think it would be helpful if you could end or end part-way through your submissions just before 12.55, because I am haring off -- by way of full disclosure -- to Clifford Chance to give a lecture on something that has nothing to do with this case, but I will need to leave 12.55 sharp and we can then of course work out when we resume, if we need to resume, in the afternoon.

MS STRATFORD: I am very grateful. We all had in the timetable 12.30.

THE PRESIDENT: Oh, did you? Right.

MS STRATFORD: But if 12.55 is not going to put too much pressure on you and the Jubilee line, then that would be

great.

THE PRESIDENT: That is helpful. Well, let us not treat 12.55 as the absolute point, but quarter-to, ten-to, that sort of time is fine.

MS STRATFORD: Shall I see when I get to a natural pause.

THE PRESIDENT: See when you get to a natural pause. That is very helpful.

MS STRATFORD: We will see where I am at that point, but I am certainly feeling a strong inclination from this side of the bench if possible for us not all to come back at 3.00, instead for me to start tomorrow as planned. If -- I hope it will not be necessary, but it may then be necessary for me to go slightly over lunch, but Mr Holmes has indicated that would not be a problem because we have got quite a lot of slack in this week's timetable.

MR HOLMES: Sir, that is only subject to the Tribunal's ability to sit on Thursday -- slightly into Thursday afternoon if necessary, because at the moment I think we are due to finish at Thursday lunchtime, so that would be an alternative way of ensuring that we do not run into difficulties.

MS STRATFORD: We have got a free Thursday afternoon at the moment.

THE PRESIDENT: I see. We will double-check that, but

I cannot see that as being a problem.

MS STRATFORD: I am grateful.

So I was going through what we say are the problems with the sniff test or putting it more neutrally, a discretionary approach, and the final point I wanted to make on this is we say it gets the test the wrong way around, and you can see that, for example, from the CMA's skeleton at paragraph 129. It may be worth just very quickly getting that up at {XL/3/57}. The sentences -- in particular the sentences in the middle of that paragraph starting "rather". Sorry, starting:

"It argues that this is the wrong test for excessiveness. Flynn's argument is a straw man. The CMA has never suggested that the WACC is to be regarded as the test for excessive pricing. Rather, as explained in the Defence [paragraph] 2.19, the WACC is simply part of the Excessive Limb analysis as it measures the cost of the capital employed by the undertaking in supplying the product in question."

So there "cost of capital":

"The Court of Appeal approved the use of a benchmark set by reference to a reasonable rate of return on capital in *Phenytoin* [Court of Appeal]. Once Cost Plus is calculated the next step is to assess the extent of the surplus accruing to the undertaking after the

recovery of all costs (including...)..."

Oh, has it gone on the screen, I am sorry.

THE PRESIDENT: It seems to have gone.

PROFESSOR WATERSON: It has come back now.

MS STRATFORD: I am sorry.

I think I can probably make my point anyway, which is that the CMA's reasonable rate of return which should be the driver of assessing excessiveness is doing very little work beyond identifying Flynn's cost base and the real work is being done by the CMA's discretionary judgment, but the discretionary buffer, as we will see later from, for example, the *Aspen* decision of the Commission, exists to give a seller protection against pricing excessively because it just tips over a normal margin in the industry, a normal rate of return.

It exists, this buffer, for the benefit of the seller. It is not, we say, a get-out-of-jail-free card for the authority to rely on a bad benchmark which bears no resemblance to reality and then rescue itself by using discretionary judgment, and if I may, I think this is a helpful moment for me to come to the judgments in *Liothyronine* and *Hydrocortisone* for the first time, without needing to turn them up, I just want to make some points, if I may.

We acknowledge, of course, both judgments as

important ones in the excessive pricing field, but neither of them raised the critical question for Flynn of how one should go about calculating a company's reasonable rate of return, ie its plus, and the reason that is so is clear from the chart in Dr De Coninck's position paper which is at {XE6/4/5}.

This is a chart that Dr De Coninck produced in his position paper where one of the tasks, sir, you will recall the experts were asked to engage with, was considering the judgments, the implications of the judgments in *Liothyronine*, *Hydrocortisone* for this case and the left-hand bar in each case shows the CMA's calculation of the cost plus price for the product. The middle bar shows the actual price for the product, and the final bar shows the differential between the two.

In a case like *Liothyronine* or *Hydrocortisone* where the delta between the CMA's cost plus figure and the actual price lies in the many hundreds or even thousands of percentage points, one can see that the seller is not going to devote its resources to arguments about the size of the plus. They are just never going to alight on a rate of return which justifies their margins, they would be, if you like, tilting at windmills.

Our case is different. Flynn's excess has been found to be on average, using the ROCE basis, to be 47%

which means that its reasonable rate of return needs to be looked at under a closer microscope and cannot be approached as a sniff test.

There is a further overarching point here. The reason the CMA has had to resort to this approach is because it shies away from real world evidence, and the Tribunal, in particular, Professor Waterson, will recall that the thrust of the original Tribunal judgment is that the CMA needed to go away and get some empirical data about normal rates of return in the industry.

The CMA has studiously avoided doing that. The reason is that as soon as one looks at the real world, the obvious becomes clear. Pharmaceutical companies like Flynn routinely earn more than what Mr Harman has described as their economic costs, meaning that his ROCE benchmark says nothing of value about whether a price is excessive or not.

One can see what the CMA has and has not done in this respect if we go back to the Decision, if I may briefly, and this is at {XA1/1/24}. I want to look at paragraphs 1.94 onwards. This is a section containing a description of the CMA's remittal investigation, and across these next few pages the CMA's activities are grouped under three heads.

First, this is section I, it did some engagement

with Flynn and Pfizer as one would expect, looking particularly at paragraph 1.97 onwards on page {XA1/1/24}.

Then moving on to page {XA1/1/25}, second, this is section II, it gathered some additional evidence in relation to tablets. That is 1.100 onwards.

Third, and moving on to page {XA1/1/27} of this document, paragraphs 1.109 and following, it did something that the CMA terms "Other Remittal evidence gathering", and that involved, we can see, obtaining some new medical input about phenytoin, that is 1.109, holding some calls with clinical commissioning groups, 1.110, and looking at publicly available data on other AEDs, 1.111, and what is immediately apparent is that the CMA did no additional evidence gathering on the point that was central to Flynn's previous appeal and is central to the current appeal, what is a normal rate of return for Flynn.

We suggest that is because as soon as you do that, or if the CMA had done that, it would have become clear that its ROCE benchmark had no basis in reality, yet as I will come on to, the absence of an empirical analysis, was found to be a key flaw of the CMA's Decision under limb 1 excessiveness in the original CAT judgment.

We submit that the absence of this empirical

analysis is frankly disrespectful of the original judgment. It also means that by closing its eyes to real world evidence, the CMA is punishing Flynn for making returns in excess of a benchmark that is very significantly lower than what its competitors make.

The final point I wanted to deal with by way of introduction, and before I come to the facts, is about the vertical relationship between Pfizer and Flynn, and we have already dealt with this to some extent in our earlier exchanges, but it is important. You have seen what we have said about this at paragraph 10 of our skeleton, and in our submission, it is important to keep clearly in mind what has and has not been put against us. The CMA has not run a case that Flynn is to be treated as a single undertaking with Pfizer, or that our costs can somehow be combined with theirs. It has pursued separate infringement findings against each entity. Nor has the CMA run a case that Pfizer and Flynn's supply agreement is unlawful in any respect. Tellingly, as I have already mentioned, it opened an investigation into that issue and then closed it.

So there is no allegation that the supply agreement with Pfizer was collusive or an anti-competitive arrangement, or, therefore, that it can be ignored by eliding Pfizer and Flynn into a single undertaking.

The case we are facing, rather, is an allegation of excessive pricing based on cost plus methodology which uses each of the parties' own cost stacks against them, and that is perhaps unsurprising because without a finding that the supply arrangements are unlawful and can therefore be ignored, the CMA must carry out a cost plus analysis based on Flynn's actual costs.

The CMA's skeleton, I do not think there is any need to turn it up, but at paragraph 9 and it is a fairly colourful paragraph so the Tribunal may recollect that we are accused of salami-slicing costs between Pfizer and Flynn. It is not us that has done the salami-slicing, it is the CMA. We have responded to the CMA's case that Flynn's prices were excessive compared to its cost plus a reasonable rate of return and on the CMA's own case, those costs include the price paid to Pfizer for the drug.

Nor is it the case -- and I am going to come on to this -- that Flynn's costs for phenytoin including its supply costs paid to Pfizer were exceptionally high. There are other drugs, even in Flynn's portfolio, with higher costs.

The short point is that the Tribunal must decide whether the case put against Flynn in the Decision is sustainable or not. The case the CMA has chosen to

pursue and to which we have responded is that our prices were excessive based on our costs, including the prices paid to Pfizer plus a reasonable rate of return, and that is either a good case or it is not, but it is not, respectfully, open to the CMA to fashion another case against us in the course of trial, and certainly not one which would involve finding that Flynn's supply arrangements with Pfizer were in some way to be disregarded.

So with that I turn to the facts, and I am of course mindful that the Tribunal has already heard Mr Brealey and also has the benefit of the original Tribunal judgment. I am not going to tread old ground, but there are certain points I would like to highlight where Flynn brings a particular perspective to bear.

The overall story is that Flynn is a marketing authorisation holder, and like any company in the middle of a supply chain, it buys phenytoin from its supplier, here Pfizer, adds a margin and sells it on to the next person in the supply chain, in this case, wholesalers who in turn do the same thing, but it is not, I stress, for that reason, a mere post-box. As the MA holder for the medicinal product, Flynn holds a host of responsibilities and risks that nobody else in the supply chain does.

The Tribunal, I am sure, already has in mind from Mr Brealey's submissions that phenytoin was until 2012 sold, of course, by Pfizer under the brand name Epanutin, that the price had been depressed by what has been termed the waterbed effect of the PPRS, and then it was therefore a loss-making or only marginally profitable product.

Pfizer contacted Flynn with a view to taking over the marketing authorisation for the product, and just for your note that is at {XH/4/10}, and it was an important feature of negotiations that while capsules were making losses, the Department of Health was prepared to pay £30 per pack for the tablet formulation of the same drug, and maybe we could just very briefly look at one slide from a presentation that Flynn gave to Pfizer. It is at {XG/70/2}. This is Flynn's 1 July 2010 presentation to Pfizer, and you can see from that in particular the second bullet I draw attention to:

"Competitor products (tablets) are sold at [around] 30 [times] the price."

So it was front and central of the proposition from this product from the outset.

Once Flynn acquired the marketing authorisation for phenytoin, it proactively engaged with the Department

for Health. It did not, unlike in some of the other excessive pricing cases, try to slip its price under the radar, and if we could please get up {XG/155/1}, what happened was that Flynn requested a meeting with the Department which was held on 18 July 2012. This a note of the meeting. I am pretty sure this is the Department for Health's note, and at paragraph 5 in particular of that note it is recorded there that Flynn told the Department that it would not be economically viable for Flynn to continue selling Epanutin capsules as a brand without an uplift in prices, and that was because, as I have explained, the price had been depressed under the PPRS.

Then at paragraph 8 we see Flynn telling the Department quite transparently that it had two options on pricing: either it could genericise the drug, taking it outside the PPRS, in which case it would be priced, it was suggesting, at around 10% to 20% discount to the drug tariff price for tablets, or it could remain as a branded product with a one-off price increase within the PPRS, in which case it would be priced around 25% to 30% below the DT price for tablets.

One can see from this note that the Department did not say at that point: hang on, we are not happy with this, we do not consider the tablet price to be

a suitable benchmark or anything of that sort. Rather the Department suggested, you see that at paragraph 7, that Flynn submit an application for a one-off price increase under the PPRS.

PROFESSOR WATERSON: Can I just ask you, it would be priced at 10% to 20% lower than the drug tariff if sold as a branded product, 25% to 30% below the drug tariff price; what was the drug tariff at this stage?

MS STRATFORD: This is the drug tariff for the tablet which was £30. It had been since --

PROFESSOR WATERSON: It does not say the tablet there does it mean the tablet price? Oh, I see, using the tablet as --

MS STRATFORD: Paragraph 8, yes.

PROFESSOR WATERSON: Right, okay.

MS STRATFORD: I am very grateful, it is an important point.

PROFESSOR WATERSON: So it was not the drug tariff price of the capsule?

MS STRATFORD: No.

PROFESSOR WATERSON: Okay.

MS STRATFORD: That is why I took you to that slide earlier, from the very beginning of these discussions -- and as you know Pfizer had been in discussion with another company, Tor, even previously, but decided they were not going to manage the project appropriately -- right from

the beginning, the fact of the £30 tablet price was front and centre in the minds of where the pricing for this product would be, what would be an appropriate benchmark for it.

MR HOLMES: Just in case it assists the Tribunal, the drug tariff prices in respect of capsules are in table 2.7 on page 109 of the Decision. They are around £2.83 for the 100mg.

MS STRATFORD: That was the Pfizer price, but as I have just shown, that is not what was being referred to. This is a Department for Health note of the meeting. That was the earlier Pfizer depressed price. I am grateful.

So Flynn took up the Department's suggestion that it should submit an application to the PPRS. If we could get up {XG/160/1}, we see that the Department's pricing committee found on 26 July 2012 that there was no -- "PC decision", you see at the bottom:

"... there was no provision for this type of price increase under the terms of the PPRS."

So this was, if you like, a vires problem rather than any comment on whether Flynn was correct to use tablets as the benchmark for its own price.

Flynn therefore proceeded with its alternative option of genericising the product. So it de-branded the product and launched the drug as a generic medicine

under the name "phenytoin sodium Flynn hard capsules" and that was on 24 September 2012, as I am sure you have in mind.

Flynn's launch price was, therefore, benchmarked to the DT price of phenytoin tablets as Flynn had told the Department of Health that it would be. So Flynn's list price for a pack of 84 100mg capsules was £67.50.

Just for your reference, if it is helpful, that is in the Decision at figure 2.6. That is {XA1/1/107} just for your note. That equated, and Mr Brealey has already touched on this, to a 25% discount to the drug tariff price of phenytoin tablets, if you take the equivalent number and strength.

This is also explained again for your note, in case it is helpful, in Mr Williams' sixth report at paragraph 21, {XE2/6/6}.

Now, just to be clear about this, the list price is the price which Flynn submits to the NHS Business Services Authority and which the Department of Health uses to set the DT price for products like phenytoin capsules which are not readily available as a generic and are in what is called Category C.

Flynn's actual selling prices to wholesalers were lower than its list price. Again, I do not think any of these figures are in dispute, and at launch they

represented about a 12.5% discount in addition to the 25% discount from the drug tariff price of tablets. For your note, if it is helpful for reference, you can see this at table 2.5 in the Decision at {XA1/1/104}.

It may be worth just clarifying one factual point at this stage. I may be told this is so obvious that it goes without saying, but sometimes those can end up being some of the more important points. The drug tariff price is and was the only publicly available price for tablets and was therefore the only viable benchmark for Flynn and Pfizer.

Other companies' average selling prices, ASPs, so in other words, what happens below the drug tariff price, are not publicly available, and, indeed, would be confidential information which could not properly be provided to another seller.

So in short, ASPs are a black box and can never be used as a benchmark per se, and I think it is salutary for us to all -- and I include myself in this -- to remember that we only have information about other tablet suppliers' ASPs now because the CMA has gathered it for the purpose of this investigation.

THE PRESIDENT: So if I am a dispensing pharmacy, how do I work out where to buy from? I approach wholesalers and say: give me your price?

MS STRATFORD: Well, yes, Mr Williams may be the only expert who can assist us with these sort of practical real world -- I do not know whether his undoubtedly great expertise extends to what pharmacies do in the real world, but I venture to suggest that a pharmacist would be approached by different wholesalers with different prices.

We saw a little bit of that not at wholesaler level but maybe some at wholesaler level from some of the documents that Mr Brealey was showing the Tribunal yesterday. But the important point is that a company in the position of Flynn, for my purposes, a company in the position of Flynn certainly does not and could not have access to this pricing information.

Following the launch of Flynn's -- going back to my chronology, following the launch of phenytoin capsules, Flynn requested a further meeting with the Department of Health, and I do stress this was again Flynn's request for a meeting, and it was Flynn, not the Department, that sought to engage in transparent and constructive discussions about the pricing of phenytoin capsules.

By this time, Flynn had launched its capsule as a generic, as I said, on 24 September, just as it had told the Department it was going to do, and it had done it at a discount to the tablet price, again, as it had

told the Department it was going to do.

The second meeting was held on 6 November 2012, and there are two different sets of minutes for this meeting, but I do not think it matters for present purposes, so I am going to go to the Department's note at {XG/224/1} which are minutes of the meeting.

At paragraph 6, first of all, we can see the Department saying it was unsighted on how Flynn had arrived at its launch price. Now, that was not correct. I have just shown you Flynn had been transparent with the Department in how it had arrived at its launch price by reference to the tablet price.

The Department, looking a little higher up at paragraph 5, the Department said it had never confirmed that it was content with Flynn benchmarking by reference to the drug tariff price of tablets, but that it could not comment further on whether or not it was content with the tablet price.

Now, this, what I suggest is a fairly oblique comment, was the first time that the Department had given any indication that it might not be content with Flynn benchmarking by reference to the drug tariff price of tablets, and of course it was too late because Flynn had already launched at a discount to the tablet price, just as it had said in July that it would do.

We then, going on in the note to paragraph 8 {XG/224/2}, the Department asked Flynn for further information relating to its costs so it could understand the justification for the price, and Flynn, we can see, gave an initial answer to that question noting its costs of improving its supply chain to ensure a stable supply of the product and investing in a secondary source of manufacturer, and Flynn also agreed to provide that information by way of follow-up letter.

If we could just go to the follow-up letter which is at {XG/237/3}, and looking first at the final paragraph on that page, we can see Flynn explained that:

"... Pfizer and Flynn entered discussions to explore the basis on which Flynn might acquire the product and continue its supply on a generic basis, the only basis on which commercially viable prices could be achieved."

Flynn explained it had been totally transparent with the Department of Health about its pricing intentions, that was true, and then going over to the next page {XG/237/4} under "Cost of Goods" you can see Flynn explained that it had requested Pfizer provide more detail about its cost of goods but Pfizer had refused this request, and Flynn then quoted Pfizer's response in its letter, and I pause there just to note that if the Department did not consider Pfizer's response to be

satisfactory, it could have taken issue with it.

Flynn again reiterated that whereas Epanutin had been supplied by Pfizer at a price of around 3 pence per capsule, the drug tariff price for tablets had been at £1.07 for the last four years.

Now, Flynn, we say, could not have given a clearer indication of the basis upon which it considered its prices to be justified. Then further down, Flynn signed off the letter by saying it recognised the Department's concerns and:

"... would welcome further discussions with the Department on these matters."

Sorry, that is on page {XG/237/6}. I am so sorry. I think it is worth looking at that because it links to the next document I want to take you to.

So Flynn is saying:

"We welcome further discussions with the Department on these matters."

Then if we could go to {XD2/2/8}, this is the Department's response, and it is the only response, it is a holding reply, just saying -- Mr Pascoe is rightly saying I should point out that this attached the letter that I have just been showing you, and then we see the holding reply:

"Thank you for your time last week and following up

with this letter. We have obviously not had time to digest this in detail today. We will get back to you in due course."

But the Department never followed up, and the correspondence trail simply went cold. So that is the story behind Flynn's price for phenytoin. It is a long way from the facts of a case such as *Liothyronine* where the sellers attempted to increase their prices month by month under the radar.

Flynn proactively contacted the Department both before and after the launch of phenytoin and could not have been clearer it was going to benchmark its price to the tablet price, and, as Mr Williams, Flynn's industry expert, will explain in due course, I anticipate, that is the standard method of pricing in the industry.

Now, the CMA has now in its skeleton at paragraph 35 accepted clearly that there was benchmarking against the DT tablet price in this case, and Mr Brealey took you through that aspect of the story which sets this case apart from the other excessive pricing appeals for pharmaceutical products quite thoroughly, so I am not going to spend more time on it, but the fact is that Flynn was and has continued to be transparent about its pricing since then.

When the CMA opened its investigation, Flynn asked

the CMA at an early stage for guidance on what the CMA considered would be a fair price for the product. The reference is, again, I do not think we need to turn them up unless you want to, it is {XB/5/126}, that is in our notice of appeal at paragraph 322 which collects together the relevant references. The CMA declined to answer and has spent the next ten years making up its mind on that very question.

Another part of the story that is perhaps easy to gloss over because it has not been the focus of these remittal appeals is that Flynn faced competition from two other sources of supply: as the Tribunal knows, a company called NRIM and parallel imports.

This can be seen most clearly, in my submission, from the letter that my solicitors sent to the Tribunal recently on 20 October. It is at {XJ/46/1}, and that letter, as you may recollect, reproduces certain market share figures from the original Tribunal judgment. This is part of the response to what we have been calling "Tribunal question 2".

THE PRESIDENT: Yes.

MS STRATFORD: We also at the Tribunal's request, I should say, sent a monthly version of this data, but I think for present purposes we can just look at these figures.

Page {XJ/46/2} of that document contains a graph

showing the volume sold by Flynn and its competitor NRIM, and you can see there that Flynn's share of the market, so that is the blue line, falls quite significantly after NRIM enters the market. NRIM is the red line.

On page {XJ/46/4} we have those volumes expressed as a market share, and that table also produces an implied market share for parallel imports, and it is implied -- I think the Tribunal appreciates -- it is necessarily implied because we do not have parallel importers' sales data. It is fair to say that although the Tribunal found there was some competitive constraint on Flynn, it was not enough to exclude a finding of dominance, and of course I accept that, that is paragraph 251 of the original judgment, but --

THE PRESIDENT: Just so that we understand how these parallel imports occurred: we are talking about the sale by Pfizer to a non-UK distributer who then exports or imports into the UK off its own bat?

MS STRATFORD: That is my understanding. My understanding is I think I recollect that at least a significant part of them are thought to have come from Spain in this case, but that is neither here nor there in a way.

THE PRESIDENT: No.

MS STRATFORD: Lexon -- apparently a particular wholesaler

called Lexon.

THE PRESIDENT: There is no legal barrier to doing that; it is simply the costs of moving them across different markets that create a differences between a parallel importer and local importer.

MS STRATFORD: Yes, I do not want to start giving evidence but parallel imports occur when costs make that favourable. There have been, I believe, exceptional periods when the UK has actually been a parallel exporter, but generally we are a parallel importer. I am reminded -- thank you -- that you do need a parallel import licence, so it is not a complete free-for-all.

PROFESSOR WATERSON: So this product would be a Pfizer-branded product which could come in?

MS STRATFORD: Yes.

PROFESSOR WATERSON: Right. But NRIM, just to check, NRIM had a different source than Pfizer for its product?

MS STRATFORD: Yes.

MR DORAN: So the continuity of supply question only bites on NRIM?

MS STRATFORD: Yes, I think that is right.

THE PRESIDENT: Just so that we have the regulatory regime clear --

MS STRATFORD: I am sorry, I am getting -- you are the most

important, so --

THE PRESIDENT: I am very happy for you to get information from those behind you.

MS STRATFORD: I may have said something wrong, so maybe I should.

THE PRESIDENT: Well, let us correct it.

MS STRATFORD: I was being told to listen to you. Always a good tip.

THE PRESIDENT: Always a good tip. The question was simply this: you mentioned a parallel import licence.

MS STRATFORD: Yes.

THE PRESIDENT: Presumably, at least within the EU, as we then were, the marketing authorisation question would be dealt with at the other member state level, so it would be a question of Spain, or would there have to be a marketing authorisation issued within the UK for the parallel import?

MS STRATFORD: Yes, I think that is right. I should know. I do actually do a lot of regulatory pharmaceutical work so I should know the answer, but I am just going to check with Mr Cameron. (Pause)

These things are never totally straightforward especially in the pharmaceutical regulatory world, but the wholesaler needs to apply for a parallel import licence. That allows the wholesaler to place the

product on the market in the United Kingdom. We are talking now about pre-Brexit times at least. There are all sorts of other regulations about repackaging which may come into it as well, and there may be also complicated intellectual property questions about the circumstances in which a product can be repackaged and placed on the market here.

THE PRESIDENT: We have no desire to get into unnecessary controversy, but equally, it is possible that we will have to address parallel imports in the judgment if only to say they occurred and we do not have any figures, but I think it would be helpful if we had just a framework which ideally could be agreed so that we do not misstate the position in any judgment.

MR HOLMES: Sir, if it assists, we do not disagree or take issue with any of the situation as Ms Stratford has just described it, but we will liaise and see whether we can agree a position in relation to parallel imports.

THE PRESIDENT: Mr Holmes, that would be very helpful. It is simply to avoid us misspeaking in any judgment if we describe this.

MS STRATFORD: Mr Brealey has helpfully pointed out that there is quite a lot in the original Decision on this, so that may be -- rather than the parties trying to agree a note, that may be an easier way through.

THE PRESIDENT: That would be very helpful.

MS STRATFORD: However uncontroversial things seem to be, agreeing a note is not something that any of us --

MR O'DONOGHUE: To kill off the hare before it runs, 248 and 249 of the original CAT judgment, there is a finding that parallel imports were ultimately not a substantial factor in this case.

THE PRESIDENT: I am sure that is right, but I would rather have an understanding of how it works and then say it does not matter rather than say it does not matter without knowing how it works.

So if there is a description in the judgment I have, I am afraid, forgotten it, but a reminder would be very helpful.

MS STRATFORD: Yes, we will try and get you those references.

Just to deal with a point that the Tribunal raised yesterday about which parts of the Tribunal's original judgment are up for grabs or not up for grabs, if I can put it like that, we certainly are not inviting the Tribunal to redecide the question of market definition or dominance, but plainly the Tribunal is entitled to interrogate the facts, including the evidence relating to switching between Flynn and NRIM and indeed parallel imports for other purposes. So the Tribunal in its

previous judgment did not reach any definitive factual conclusion on that issue; it simply held applying the legal test for market definition and dominance that there had been some switching, but not enough.

That does not mean, we say, that the Tribunal must close its eyes to the existence of switching for any other purpose, and it has already been flagged that the medical experts will be giving their testimony on that issue next week.

The NRIM story links to a point which Professor Waterson made yesterday when he posited that companies operating in this sector will presumably benchmark their initial prices to the public drug tariff price of a comparator product, but in anticipation of their selling prices eventually falling as new suppliers enter the market and compete, and that was to some extent borne out by NRIM's arrival which provoked a price reduction and a loss of volume for Flynn, but I do just want briefly to show the Tribunal two documents which demonstrate that around the time of its launch, Flynn anticipated generic entry precisely along the lines envisaged by Professor Waterson.

The first is at {XG/225/2}, and this is a note -- it is in a note of a meeting with the Department on 6 November 2012 which I have already shown you, but

I now want to go to the bottom of page {XG/225/2} where it is recorded that Flynn told the Department:

"In 6 months we can expect competition from the other capsule licence holders."

Just to clarify, at that point that was NRIM which already had its marketing authorisation and, therefore, was an obvious competitive threat.

The other document I wanted to look at very briefly on this is at {XG/213/1}. This is an email from Richard Hambrook of the Department of Health to some other Department officials. Now, it is mainly about the Department's attempt to obtain certain information from Pfizer, but just looking near the bottom, third line from the bottom, he says there:

"His [that is Martin Bain of Flynn] only other comment was that he expected other generics to enter the market which would drive down the price. I read from this that it would force Pfizer to lower the selling price to Flynn."

We say both of these documents are of a piece with what Professor Waterson posited would be in the mind of a pharmaceutical company setting its prices. So it benchmarks to the drug tariff price being the only publicly available benchmark, in anticipation that prices will fall as new entrants emerge.

Now, the reason that fewer new entrants in fact emerged in the capsules market than in the tablets market is perhaps obvious: the CMA began its investigation in May 2013 and at that point, as Mr Brealey said yesterday, the market became subject to uncertainty which made it unattractive to new entrants. I am also mindful that the Tribunal has expressed an interest in the pricing arrangements between Flynn and Pfizer.

Now, as Mr Brealey showed you yesterday, there was an annual price review clause in the supply agreement, and we saw that following the entry into the market of NRIM, Flynn had to go cap-in-hand to Pfizer to seek a price reduction so that it could compete because it was losing sales to NRIM. Mr Brealey took you through those documents yesterday, so I am not going to revisit them, but just to give you the references because they are important for Flynn's case, they are at {XG/322} and {XH/104/1}.

Very quickly, another document on this point which Mr Brealey did not go to is at {XH/29} which is an email exchange, and if we could go to page {XH/29/2} of that document, it is relating to -- just to put it in context, it is relating to the one-off concession price reduction that Pfizer granted to Flynn in light of stock

that had built up by the time of the renegotiation of the price, and you can see if you look at this email that Pfizer only wanted to agree to this price reduction -- sorry, to the one-off concession so long as it could have access to audit Flynn's stock, and we can see then from a message coming back from Flynn questioning do they push back, do we really have to do a physical stock count, but on page {XH/29/1} you can see Pfizer prevailed, insisted and said: yes, we really do need a proper stock count.

Now, you may say why am I showing you that? Well, it is just one example, but I thought it was helpful for you to see at least one example, of the sort of discussions that went on reflecting a normal arm's length relationship between Pfizer and Flynn, and that is what I wanted to say about Flynn's relationship with Pfizer just from a factual perspective.

Finally on the facts, Dr Fakes -- Dr David Fakes of Flynn, has given evidence about Flynn's role in the supply chain. He was previously Flynn's CEO and is now its executive chairman. His two statements, as the Tribunal has seen, supplement those of Mr Walters who is now semi-retired, who gave evidence in the first trial for Flynn. Dr Fakes is going to be cross-examined on his statement, so I am certainly not proposing to go

through his evidence.

At this stage, I should just highlight four points if I may. First, as Dr Fakes explains, one of Flynn's main roles as a small pharmaceuticals company is to ensure a continuous supply of drugs to what is usually a small and declining patient base. So, for example -- and there is no need to turn any of this up, I think, at this point, I will just give you the references -- bundle {XC1/1/7}, Dr Fakes refers at paragraph 17 of his first statement to one of Flynn's products, barbiturates, where it serves just 170 patients.

The second of my four points is that that pattern of serving a small and declining patient base is very much what has happened and what was expected to happen with phenytoin.

As the Tribunal knows, phenytoin has characteristics which mean that patients should generally be kept on the same manufacturer's version of the drug, the continuity of supply principle.

Dr Fakes rightly expresses pride in his statement in the fact that Flynn has achieved that. So Flynn has never experienced a stock-out of phenytoin. These things do not just happen, they are the result of considerable expertise in managing the supply chain, and Dr Fakes explains at paragraphs 22 to 29 of his

statement the types of steps that Flynn takes to ensure a secure supply chain.

Third point, it is striking that Flynn's main competitor for phenytoin, NRIM, has not achieved that. So on the contrary, NRIM unfortunately has experienced stock-outs, and Flynn has had to step in to supply its patient base, that is Fakes paragraphs 30 to 35.

Fourth and finally, Dr Fakes explains that being a marketing authorisation holder is a risky business. It comes with a suite of responsibilities, as any member of the Tribunal who has heard previous cases relating to marketing authorisations will know. The responsibilities include things like pharmacovigilance monitoring, ensuring ongoing compliance with the marketing authorisation, submitting safety-related updates to the MHRA and so on.

Now, we fully accept that the more pedestrian of these tasks are outsourced, and Dr Fakes explains that that is normal practice, but that does not detract from the important fact that the buck stops with Flynn, with the marketing authorisation holder, both financially and reputationally if something goes wrong.

PROFESSOR WATERSON: Does Pfizer not keep some of the risks to itself?

MS STRATFORD: Professor, thank you, I was just going to

acknowledge that the indemnity which Pfizer provided to Flynn was concerned with manufacturing errors resulting in the capsules failing to meet the agreed specification, that is what the indemnity is about. There is a lot from the CMA about the breadth of the indemnity, but it is about manufacturing errors resulting in the capsules then failing to meet the agreed specification. But it would not extend to any other adverse medical events which regrettably do sometimes occur, and sometimes occur after many years, so there is a long tail of this responsibility and risk, and we say that all does provide -- and this brings me neatly back to the point which I was discussing, sir, with you this morning -- provides important context for the CMA's finding which I am going to unpack in due course, that Flynn's reasonable rate of return for phenytoin across all four strengths was, we say, a mere -- no doubt the CMA would say it is a lot -- a mere £66,000 a year.

So that is what I want to say on the facts.

Pressing on, I want to come to my third section and to look at the original CAT and the Court of Appeal judgments, and that is not so much for a statement of the law, which is largely common ground, but rather to see why the Tribunal rejected the CMA's assessment of

excessiveness last time around and what the CMA has or has not done to fix the position. This is a point that the CMA has ignored in its skeleton argument despite it being front and centre of ours.

Now, you might perhaps ask why should we look backwards: the question of abuse was remitted, and the CMA has conducted its investigation afresh. The original Tribunal judgment is, it might be said, in that sense water under the bridge.

With respect, we say that would not be the right approach. First, the CMA has not investigated afresh, its remittal decision is based largely upon the same body of evidence as the original decision, but more fundamentally, this appeal is not the CMA's opportunity to have another go at putting the same arguments which were rejected the first time around to a differently constituted tribunal.

Now, of course, in this case, Professor Waterson has sat on both appeals, so it is not an entirely different tribunal, but the point is the same: where the CMA has lost on an issue already fully argued before this Tribunal, then subject to any appeals, it should not get another bite of the cherry, and it would also, with the greatest of respect, be odd, I put it no higher than that, but odd if this Tribunal reached conclusions,

particularly on economic issues, which differed to the views which Professor Waterson expressed in his joint judgment last time around. So at least as a starting point, one would expect consistency between the two judgments.

On any view, it should not be controversial to say that subject to the Court of Appeal's findings, which I will come to, the conclusions in the original Tribunal judgment, which of course were reached after a hearing lasting about a month, including detailed evidence, that should be accorded significant weight and respect.

Just to turn to the judgment for that very specific purpose, if I may, it is at {XN1/2/82}, and I want to look at paragraph 256, and this sets out the structure of the CMA's original decision. It says that the CMA performed a cost plus analysis which involved calculating Pfizer and Flynn's costs, and then adding a reasonable rate of return. So, so far, so familiar.

Then moving on to 258, the tribunal notes that the CMA considered three different metrics for each company's reasonable rate of return: ROS, ROCE and gross margin.

259 {XN1/2/83} through to 261 all concern Pfizer's rate of return, so for now I can skip those, but 262, so on page {XN1/2/84} records that the CMA also found that

ROS was the appropriate measure for determining a reasonable rate of return.

Then moving on to 263 to 264, the CMA alighted on a ROS benchmark of 6% which, we will see later on, had been taken from the PPRS.

Then at the foot of -- if we can go on to 266 -- {XN1/2/85} I appreciate I am taking this quite rapidly but I know the tribunal will already be very familiar with these paragraphs -- at the foot of 266, the tribunal records Flynn's excesses based on that benchmark {XN1/2/86}.

Then at 267, it records the CMA's conclusion that those excesses were -- and I quote -- "sufficiently large to be deemed excessive", so sufficiently large to satisfy the first limb of *United Brands*.

Over the page {XN1/2/87} at 269, the Tribunal noted, this is five lines down, that:

"... the approach of the CMA was to determine whether there was any non-cost related factors which would increase the economic value of the capsule product behind Pfizer's and Flynn's Cost Plus. The CMA concluded that there were no such factors."

Again, this is rather familiar because the CMA is taking the same approach now.

Then the remaining paragraphs of this section I do

not need to go through specifically, but they record the CMA's conclusion that Pfizer and Flynn's prices were unfair in themselves and, therefore, the second limb of *United Brands* was satisfied.

For present purposes what I am interested in taking from this judgment is what the Tribunal found in relation to the CMA's and Mr Harman's analysis of the size of Flynn's plus, because that is the area where things have not moved on since the previous appeal.

If we could skip forward to page {XN1/2/105}, and really here I am focusing on {XN1/2/105-107} paragraphs 318 to 324 which is where the Tribunal considered the CMA's approach to calculating Pfizer and Flynn's reasonable rates of return, so their pluses, and I do not know if it would be convenient if I could just maybe ask the Tribunal to read or remind -- refresh its memory of those paragraphs and then I will just make some short submissions on them. So it is 318 to 324.

THE PRESIDENT: Yes, of course. I will read those now.

(Pause)

MS STRATFORD: I am grateful. These passages, as you will have seen, contain some very clear findings about the CMA and Mr Harman's analysis of excessiveness.

The first, at paragraph 318, is that:

"... the CMA's approach owes more to a theoretical

concept of idealised or near perfect competition, than to the real world..."

And there are two related ideas being expressed here: that the CMA's approach was theoretical and that its chosen theory was based on idealised rather than normal competition.

The second finding is perhaps the corollary of the first, that the CMA has, to use the Tribunal's words, on the whole avoided making comparisons with other products or companies. So in other words there was not any empirical analysis.

The third point I want to make is that Mr Harman was constrained by the terms of his instructions, this is paragraph 319, he was constrained to reviewing the CMA's existing work on excessiveness rather than starting with the blank sheet of paper.

The fourth point which comes out most clearly at paragraph 321 is that Mr Harman's theory that a competitive market should drive prices down to the minimum possible level of return, to quote {XN1/2/106}:

"... proceeded on the basis of theoretical or idealised competition ... rather [than] ... conditions of normal and sufficiently effective competition."

Then moving on to paragraph 323, the Tribunal rejected Mr Harman's ROCE analysis which of course at

that stage was being put forward as a cross-check for Flynn, but has now been elevated to the main benchmark for Flynn. That was rejected by the Tribunal as again being based on idealised rather than normal competition.

I should say for completeness, although we do not need to turn it up because I am going to deal with it later, if I may, that the Tribunal went on to reject the CMA's 6% ROS benchmark on its own terms, that is paragraphs 333 to 335 in particular, and that was because the PPRS was not a particularly reliable guide for a normal rate of return in this industry.

That is, of course, now become the CMA's cross-check for Flynn, while its rejected ROCE analysis has become its primary benchmark for Flynn.

The reason I have laboured this and taken you through these paragraphs is to show the Tribunal that nothing of substance has changed since these criticisms. All that the CMA has done is to reverse the order of priority between its ROS benchmark and its ROCE benchmark, but it has, in our submission, rather disrespectfully done nothing to address the root and branch criticisms made by the tribunal in this judgment. In particular, as we have seen, it has not taken these criticisms away and carried out an empirical analysis of the market which is what the tribunal was inviting it to

do.

I should say, it has tweaked the ROCE figures, but I think that is all going to be dealt with in the hot-tub and I do not really want to take time on that now.

Now, none of this analysis was disapproved by the Court of Appeal which, as we have said in our skeleton, upheld the tribunal's overall findings including in relation to excessiveness. The only finding of the Court of Appeal which is even arguably relevant to these passages is its conclusion that the tribunal erred insofar as it held that the CMA ought to have calculated a hypothetical benchmark price.

Now, this is not a point that the CMA has pressed in its skeleton, so I am going to take it quickly, but I think it might be helpful for the Tribunal if I have just covered it off now.

The short answer is we did not mind about the Court of Appeal's conclusion on that at the time, and we do not mind about it now. We have set out the relevant transcript references in our pleadings. For your note, it is at paragraphs 24 to 28 of our reply at {XB/11/14-16}, but I think the easiest way to approach the point is to look at the Court of Appeal judgment which is at {XN1/5/38}, and I want to go to

paragraph 122 of the judgment.

That records that Lord Justice Green agreed:

"... with the submissions of Ms Bacon [as she then was] 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."

Now, why were we happy to agree this point? Because it has never been part of our case that the CMA must calculate a hypothetical benchmark price so long as it identifies a suitable benchmark, whether that be ROS or ROCE and so on -- we will come on to debate what the right metric is -- and so long, and I stress this, as that benchmark is based on normal competition.

For present purposes, the point I want to stress is that this debate about the type of benchmark required, so whether it is price or margin, does not affect the core of the Tribunal's criticisms which were that the CMA and Mr Harman's approach was theoretical rather than empirical and was based on a model of idealised competition.

Those criticisms apply equally to a hypothetical competitive price and a hypothetical competitive margin,

and of course what the Tribunal was talking about in the key passages of its judgment were margins, so the 6% ROS margin and the 9 to 12% ROCE margin.

Sir, I was going to then move on to my next fourth section. I am in your hands depending on how much pressure you are under, but I could usefully make a start on that because it is, as I said, going to be my longest section, and then come back to it -- I am making pretty decent progress -- I think come back to it tomorrow morning as we intended.

THE PRESIDENT: Why do you not make a start and we will go on for five or so minutes.

MS STRATFORD: I am grateful.

So it is against that background that we ask what is Flynn's reasonable rate of return for phenytoin, what is its plus or, to put it more accurately, is the CMA's benchmark rate of return a reasonable one? If it is not, the Decision must fall for the reasons I have already outlined.

I am going in this section, just to give you a bit of a route map, I am going to cover the proper approach, so that is theoretical versus empirical, the debates about the metric, and, thirdly, what the empirical evidence will tell us about Flynn's reasonable rate of return, and that is where we come to the margin

comparators, and then very shortly at the end, and obviously all of this is going to be tomorrow morning now, I will say something about cross-checks.

So just to start with some common ground. It is always a nice place to start. We do not understand it to be controversial that: one, cost plus must include a reasonable rate of return; two, that is a hypothetical or counterfactual figure; and, three, the reasonable rate of return should be based on normal and sufficiently effective competition rather than on some other form of competition.

So rather, sir, as you succinctly put it yesterday, a price comparator is generally supposed to be a proxy for a competitive price, well, we say so too a margin comparator.

The question the Tribunal must decide is is the CMA's benchmark of a 10% rate of return on capital, which equals Flynn's alleged cost of capital, a rate of return which would obtain under normal and sufficiently effective competition, and a repeated theme of my submissions will be that the CMA simply does not know because it has not deigned to test its benchmark against real world evidence.

By contrast, we have put forward evidence from the real world and none of it bears any resemblance to what

the CMA puts forward as a normal competitive rate of return.

Now, as we have said in our skeleton, this is just paragraph 28 of Flynn's skeleton, but again, I do not think there is any need to turn it up, there are three issues for the Tribunal to decide.

First, what is the right approach to identifying a reasonable rate of return? The Tribunal here is faced with a straight dispute between, on the one hand, a theoretical approach, a purely theoretical approach, we say, and on the other, empirical evidence. We have seen that the previous tribunal unequivocally preferred empirical evidence.

Second, the second issue is what is the correct metric for measuring Flynn's returns? We say ROS and the CMA says ROCE, although it previously said ROS.

Third, what is the size of Flynn's reasonable rate of return? We say, unsurprisingly, that is to be answered by reference to real life evidence and, therefore, what has loosely been called comparators which I will come to tomorrow.

I am going to introduce, if I may, each of those three issues in turn. Maybe that is a convenient point to pause. I am very grateful.

THE PRESIDENT: No, thank you, Ms Stratford. We will resume

obviously tomorrow and to be clear, the Thursday is available in total, so you can use the afternoon.

Just to plan for tomorrow, I have a meeting out of this building at 4.45. I think if you budget for 4.00 that would be helpful. We could do an earlier start if that assists, but we are in your hands there. I see Mr Holmes shaking his head about the need for an earlier start.

MR HOLMES: I think we are in reasonable shape and subject to Ms Stratford's views, a 10.30 start should be fine for both tomorrow and Thursday in view of your very helpful indication.

I should say my hope is that I will not need much, if any, of the afternoon, but it is helpful to know that we have that as a buffer in case, for example, Ms Stratford's submissions run over slightly.

MS STRATFORD: I am grateful.

THE PRESIDENT: I am very grateful to you both. In that case, we will say 10.30 tomorrow morning. Thank you very much.

(12.45 pm)

(The hearing adjourned until 10.30 am on Wednesday, 8 November 2023)