**IN THE COMPETITION APPEAL TRIBUNAL**

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

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Wednesday 20th September 2023

Before:

The Honourable Mr Justice Marcus Smith
Eamonn Doran
Professor Michael Waterson

(Sitting as a Tribunal in England and Wales)

BETWEEN:

**Applicants**

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

**v**

**Respondent**

# Competition & Markets Authority

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## A P P E A R AN C E S

Mark Brealey 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, Conor McCarthy & Jennifer MacLeod on behalf of the Competition and Markets Authority

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**Wednesday, 20 September 2023**

**(10.30 am)**

**MR JUSTICE MARCUS SMITH:** Mr Brealey, good morning, and good morning everyone else.

Before we begin, just a few words from us. The agenda has many items, but most seem to be relatively uncontroversial. Before I invite one of you to take me through those items, I want to flag one point that goes to hot-tubbing, and add two other items to the agenda which will warrant brief discussion.

Starting with hot-tubbing, which is obviously closely related to expert evidence, and I think is also related to the anterior decisions that this Tribunal has handed down in Liothyronine and Hydrocortisone.

Now, we all understand that Hydrocortisone 1 has got some relevance to this case and the same is probably true of Liothyronine. The reason I stress Hydrocortisone is because we've delayed the position papers in this case to enable it to be taken into account. There's obviously a nexus there, but I think what I'm saying about Hydrocortisone is also true of Liothyronine; it's just it's come out earlier, so we haven't seen the nexus as overtly.

But it's important, I think, that we be clear as to the Liothyronine and Hydrocortisone matter, so that we can appreciate the extent to which those decisions may or may not have a bearing on these proceedings.

Obviously both decisions make certain findings in relation to the law, but those seem to me to be the minor aspects of those decisions, and whilst you can expect a high degree of consistency in respect of legal questions, I'm not sure that that's why these two decisions matter.

Much more to the point, both decisions make a number of findings in relation to what

I'm going to call economic fact, and in some cases quite general economic fact, and that I think is probably quite true of Hydrocortisone 1.

I think, therefore, it's quite important that we state, and state on the record, how we see these general questions. I want to be very clear that we do regard these matters as factual and therefore, at best, persuasive, and the extent to which they are even persuasive is going to depend on the evidence in this case and not on the evidence in the anterior cases, Hydrocortisone and Liothyronine.

Arising out of that, it therefore seems to us important that the experts -- and I'm mainly thinking about the economic experts, but it may be more widely read than that -- that the experts have an opportunity to push back on what has been said in Liothyronine and Hydrocortisone, to the extent they wish to do so. And it seems to us that this is best done in-chief by the experts, either through structured questions from the advocates calling that witness, or through a mini lecture. Frankly, we're indifferent as to how it's done, and we'll leave it to the parties to decide with their experts how it is achieved.

What we really want is to give the experts an opportunity to say their piece on their own terms, without having to sort of shoehorn it into answers in cross-examination. Cross-examination, of course, is designed to test the case, and I'm sure it would arise in cross-examination, but it won't arise on the experts' own terms, and I think it is very important that that message be sent loud and clear to the experts. If they want to say that they violently disagree, or violently agree with anything in these anterior decisions, then we would like that to be articulated in this sort of way.

However it's done, whether by structured questions or mini lectures, the experts can expect Tribunal questions -- I'm sure they would arise -- and that would need to be factored into the timetable as well.

The message is, we obviously all know that these decisions have been published, but

if the evidence in this case does not bear out what was found in Liothyronine and Hydrocortisone, then we'll follow the evidence in this case, not what has been said in the other cases, no matter how they have been put.

It does seem to us, even without these anterior decisions, there is something to be said, notwithstanding the expert reports that have been filed and the position papers that are to come, that there is a great deal of merit in an introductory, in-chief exposition from the experts, enabling them to both find their feet and to locate what they've said in the context of the case and orally, because we do perceive things differently when we read things and we hear things orally. That's part of the importance of our oral tradition. I anticipate that we will be encouraging this sort of more extended in-chief exposition in cases apart from this.

The reason I say that now is because it does seem to me to lead into the question of the teach-ins, which the parties have mentioned in their written submissions, and we are in the hands of the parties there. We just want to indicate that we do regard a teach-in as helpful, quite possibly in the area of QALYs, which seems to be quite a recondite area that we might need educating on.

I would only say two things in this regard: first of all, there may be, almost certainly will be, considerable areas of common ground between the experts, and that common ground will be buried in some joint report which we will, of course, read. But the experts should not assume, merely because something is common ground, that that has been embedded in the Tribunal's thinking. One of the virtues of the teach-ins are that, although the experts may think something is blindingly obvious to them, it is nevertheless worth articulating because it may not be blindingly obvious or hard-wired into the thinking of the Tribunal, and perhaps it ought to be. So that is one, I think, aspect of a teach-in which assists, in that it unpacks matters which are important but uncontroversial.

We don't have a problem with the teach-ins going into controversial matters, but we would expect the experts in that case to make clear that what they are saying is controversial and in dispute rather than something which is blindingly obvious but important.

We don't think it would be appropriate to have a separate section of teach-ins -- I think the timetable is going to be complex enough as it is -- but we would encourage the parties to think about how far a teach-in ought to be incorporated into an extended examination-in-chief of the experts when they're called, and we would trust the parties to get that balance right. If there's a dispute, then obviously we'll deal with it. But we are in favour of teach-ins, and I hope that is useful guidance.

That leads me onto the question of hot-tubbing, and there's obviously a nexus between unpacking the experts' reactions to prior decisions, having a teach-in, and hot-tubbing. Now, where the parties are disagreed, as they are here, as to the virtues of hot-tubbing, it seems to us that the course of hot-tubbing needs to be justified by the party advocating it, in this case the CMA, and there are a number of factors which have a bearing on this question. First, of course, our normal modus operandi is to allow each party to present its case and to test each others' case by way of cross-examination. That is the default, and hot-tubbing needs to be shown to be clearly better than this normal approach.

Secondly, hot-tubbing does involve a burden on the Tribunal, and I think it is right to disclose that the Tribunal has a rather busy term ahead of it, and that follows on after a rather busy last term. So the extent to which we have been able to do the pre-reading that the parties rightly expect is somewhat behind what it normally would be. So that is a second factor, which inclines us against hot-tubbing.

That being said, Professor Waterson has obviously been through this process once before, having sat on Flynn-Pfizer 1, and his view is that there are two areas where

the different approaches of the parties might appropriately be tested in a hot-tub environment, and that is the question of cost-plus and the question of comparators. As a provisional indication arising out of the economic expertise vesting in this panel, we would like the parties to consider whether there are areas where hot-tubbing might be appropriate. Obviously, there will be cross-examination following the hot-tubbing. And equally obviously the hot-tubbing would succeed the teach-in and articulation of disagreement with earlier matters.

It's going to be quite a complicated timetable, and that's, I suppose, a fourth reason why I'm a little bit wary about hot-tubbing, simply because it's going to involve an awful lot of jigsaw puzzle arranging in order to make sure that everyone is in the right place at the right time and that we are hearing the evidence that isn't heard in a hot-tub.

Just to anticipate one question which always arises in hot-tubbing, which is the purdah question. We're dealing with experts; we consider that we are lucky in having experts of an enormously capable and professional approach. Provisionally, I think we would release witnesses from purdah because they're not going to be influenced in their views by what their parties say, but the parties calling them are going to want to call on their expertise to understand points that they put. And so, unless there's a significant pushback, we will be minded to say that experts go into purdah when they're giving a segment of evidence, so they can't be told what a terrible job they're doing in the lunchtime adjournment.

Apart from that, we would be minded to abrogate the purdah rule when they have given that segment of evidence, and then they would be sworn again when they resumed whatever the next stage of evidence would be. So that's by way of indication in terms of making the mechanics work better, but the parties obviously should feel free to push back on anything that I've said there.

That was a rather extended discourse on hot-tubbing and expert evidence. That

brings me to the two additional agenda items, one of which is simply the significance, or otherwise, of the earlier Flynn-Pfizer decision and evidence. Now, we've got all this in the trial bundles. Our view, but, again, we would want you to push back if appropriate, is that this material is obviously admissible, but the extent to which it has weight is a matter that we will consider in the round. We don't really want to say any more than that, but if any party wants to say it's wholly irrelevant, then we would want to hear. But, equally, if any party is going to say you are bound by certain things, for instance the findings of the earlier Tribunal about the nature of certain facts, or credibility of certain witnesses, well, we will read it and attach what weight we see fit. If you want us to go further than that, then I think we need to have an argument about that. So that was the first new agenda item.

The second new agenda item I'm going to have to be quite cautious about. It concerns the second Hydrocortisone judgment, and I anticipate that Mr Brealey, certainly, Mr Holmes possibly, but Ms Stratford not at all, will know what I mean when I say problems arising out of the second Hydrocortisone judgment.

What I want to do is to ensure that all of the parties are on an equal playing field as regards Hydrocortisone 2. That is going to involve us sitting in private. I'm going to invite as limited a number of persons to remain in court whilst we discuss this.

As regards, Mr Brealey, your team, and Mr Holmes, your team, I imagine those will self-select fairly easily. Ms Stratford, you should remain in court with your counsel team, and if I can prevail upon you to have just one senior solicitor in addition.

**MS STRATFORD:** It may not be quite so complicated because Mr Firth --

**MR JUSTICE MARCUS SMITH:** Has read it. My concern is simply for this private session to keep the circle of knowledge as tight as possible. I'm not going to invite any kind of submissions. Obviously it would be inappropriate. The point of this session is to ensure, Ms Stratford, that you catch up, and that Mr Brealey's team and

Mr Holmes' team have the availability to take instructions in respect of Hydrocortisone 2 in relation to this case, rather than the Hydrocortisone case, in respect of which obviously they know, can take instructions, and are dealing with that part of the decision properly.

So I'm going to say no more about that at this stage, and we'll do everything else, and then deal with this question in private session in due course.

I would only say that I've considered who should, on the Tribunal's part, be present in court, and my colleagues have not seen Hydrocortisone 2, and I think it is better, at least at this stage, that they continue not to know about the content of that decision. So I will deal with the private session myself. If that needs to be revisited, obviously it can be later on, but I would rather, even as far as the Tribunal is concerned, keep the knowledge of what the second Hydrocortisone decision says as tightly confined as possible. So that's how we'll proceed. Whether we continue to proceed in that way, well, we'll see, but that's how we'll proceed this morning.

That's been a rather long introduction. Mr Brealey, I'll invite you to push back on anything that I have said, and any of the other parties obviously should chip in, and then we can go through the other items on the agenda, I hope a little bit more quickly.

**Submissions by MR BREALEY**

**MR BREALEY:** Thank you, sir. Taking them in reverse order -- I won't do the cautious one first -- but on the weight, in principle we've got no problem with weight, but you will have seen from our notice of appeal that we do put some emphasis on the previous evidence. Now, whether that is binding or not, one can debate.

In my submission, we should not have that debate now. We can put that in our skeleton because ultimately whether it is binding or how much weight should you put on it, it can sometimes be semantics.

But clearly to flag the issue, we put Mr Poulton up before, and he can't give evidence

now, and it is a remittal, and so we feel slightly prejudiced by the fact that there is a remittal when there is certain factual evidence that is at large.

So, to cut to the chase, I don't have a problem with the proposition, although in my submission I think the parties do need to address how much weight should be attached to the previous evidence. Indeed, the CMA relies on Poulton and some of the cross-examination of Poulton.

But it is probably a question of weight, because this is a separate trial, but the big thing is that we should not really be prejudiced by having to call -- we haven't called Mr Poulton again, because this has been going on for 12 years, and things change. He is no longer with the company, for example.

**MR JUSTICE MARCUS SMITH:** Well, Mr Brealey, that accords very closely with how we see things. What I wanted to do was to close out, as it were, the extremes, absolutely binding, wholly irrelevant, because those seem to us not to be the way in which one should see this evidence. But I must say, I entirely take your point that questions of weight, can only really be assessed when we've heard the totality of the evidence, and speaking from a position of being conscious that I have a somewhat large reading mountain to climb and I'm not very far up it, I don't feel very qualified to say more about weight than that. But it does seem to me that you're right that we ought to have an argument in closings about whether something is so weighty, for whatever reasons, whether you couldn't call the evidence again or whether you could, or whether it was particularly compelling, or whether it wasn't, we should have that debate in closings rather than set it out in advance, because that's something, frankly, which I'm not in a position to do, and it would be pretty wrong to do it.

**MR BREALEY:** Thank you, then, sir, on that. That's our position on that, and I don't necessarily believe that people are necessarily going to disagree with that.

On the question of the experts and the hot-tub, can I just give you our position and

then how we react to the suggestion. As you have probably seen, Pfizer is quite against hot-tubbing in this case.

**MR JUSTICE MARCUS SMITH:** Yes.

**MR BREALEY:** And I'll come back to this in a moment. But this is for three reasons, essentially: one is, one sees from the timetable -- and I don't know whether the Tribunal has -- it's the trial timetable.

**MR JUSTICE MARCUS SMITH:** Yes.

**MR BREALEY:** It's 7.18. I don't have an electronic bundle, but it's 7.18. Tab B4 apparently in the electronic bundle. You will probably see it anyway. But 7.18, agreed timetable.

I say there are three reasons. The first reason is when one looks at this timetable, you see there is much to do and there is limited time. And as the Tribunal is very, very well aware, we are meeting serious allegations here. Proceedings have been going on for a considerable period of time, and it's absolutely critical that Pfizer and Flynn can put their case to the experts, as you say, sir, in the normal way, and the last thing that we want to do is to be short of time in cross-examination because we will be given a certain amount of time, for example, to cross-examine Ms Webster, who is the economist.

So that is the first reason. We have a very restricted timetable.

The second reason is, of course, in the normal course of events, the Tribunal can put questions to the experts. That's what normally happens, and obviously that is a clear benefit. And we don't see the need for a hot-tub in circumstances where we're restricted on time and we need to cross-examine, but the Tribunal still has the opportunity of putting its own questions to the experts in the normal way.

The third reason is that we, in paragraph 4 of our skeleton, did suggest this teach-in. We thought it would be a good idea. Whether it is -- I would imagine it's going to be

a mix of questions in-chief and a teach-in, so that if they forget to say anything I might say: well, what about this. So just to let the experts spout on without any focus is probably a bad idea. But that is essentially, in my submission, if we have -- whether it is 30 minutes per expert or whatever, or even an hour, or 45 minutes for the teach-in, that is where, if necessary, Professor Waterson can ask the questions which the Tribunal can ask of each individual expert as it comes along.

But I am very concerned that if we -- , for example -- we've got a day between me and Ms Stratford to cross-examine the economist on the other side who is going to talk about ASPs, and ASPs is absolutely fundamental to this case, it is one thing the Tribunal will have picked up, because Pfizer benchmarked the price of the capsule by reference to the tablet. We need sufficient time to cross-examine the key expert who is coming to this Tribunal to say: well, ASPs are not a good comparator. And we need the flexibility to put our case to that expert.

So we have restricted time. Clearly the Tribunal can put questions in the normal way as we go along, but a combination of the teach-in, plus the hot-tub, in my submission, is taking too much time away from my ability to put Pfizer's case to the Tribunal and to the witness.

So I do push back. I'm not so much concerned with cost-plus, as you would have seen from the notices of appeal. I am concerned with the second limb of unfairness and the comparators, the £30 drug tariff, the ASP, and we say the Pfizer price when one looks at the graph is within the range of a comparator. But I need to be able to put that case, and if we've got a teach-in, plus a hot-tub, two counsel that need to cross-examine the CMA's expert, we are going to run out of time. That is my main concern, particularly given this is a remittal hearing that's been going on for so long.

So I am strongly pushing back, sir, and with the greatest of respect to the rest of the panel, on a hot-tub on comparators. In my view, the Tribunal has ample opportunity

to ask relevant questions during the course of cross-examination and during the teach-in.

**MR JUSTICE MARCUS SMITH:** Well, that's helpful. Can I give an initial response to that, and then I'm going to invite Professor Waterson to articulate why he is keen on hot-tubbing in addition to the bells and whistles of a teach-in and a pushback on anterior decisions.

Cards on table, I am more of a hot-tub sceptic than some of my colleagues, so my initial reaction when there is a dispute about whether hot-tubbing is or is not useful, is to say: well, we will do it the usual way. That being said, one always pays a great deal of attention to what other parties say, and I do attach considerable weight to what the economist expert on the panel has said in advance of this hearing.

I am keen to ensure that we have everything available to us to achieve a proper outcome. But the point that you have made about timing is, it seems to me, really rather a critical one. This is your appeal, and, as you say, these are serious matters, and I do not want anyone, particularly the appellants, leaving the courtroom thinking that they have been short-changed in terms of an ability to put their case.

So there are two things I think we can do to ameliorate that. First of all, we can place extremely tight time constraints on the hot-tub. We'll want to discuss that amongst ourselves, and with the parties.

Secondly, we are open to extending the court day if that is needed and it may be that we want to talk about that now. We can quite easily accommodate 10 o'clock starts. We can quite easily indicate that we will be sitting beyond 4.30pm. So we can, without particularly breaking into a sweat, obtain an hour on the court day each day, so as to ensure that we have enough time.

Now that, I hope, will go some way to assuaging concerns about being squeezed. I know all the advocates will be efficient in terms of their use of time, but it's precisely

because I know you will be that I place considerable weight on your submission that you are worried about time.

I wonder if those two elements remove some of the problems, but before you tell me that they don't -- if they don't -- I think, Professor Waterson, it would be helpful to have on the record your take on the two areas of potential hot-tubbing that we've identified.

**PROFESSOR WATERSON:** Thank you, yes.

I think the main issue that I think is worth exploring in a hot-tub, in my view, but I'm willing to be persuaded against, but my main thinking is that, of course, there is a linkage between Pfizer and Flynn, in the sense that Pfizer sells directly to Flynn, and so it's possible -- I don't say it's necessary -- but it's possible that Pfizer may put a position which is, to some extent, incompatible with a position that Flynn might put, because you have different interests in the outcome.

**MR BREALEY:** Yes.

**PROFESSOR WATERSON:** So that strikes me as potentially difficult to pick up in cross-examination. So that's my main concern: that the ability to pick up potential -- I don't say necessarily, but potential contradictions between the Pfizer position and the Flynn position.

**MR BREALEY:** So would that be the -- when one talks about comparators, I mean just kind of in a dialogue here, if I can, is that the main concern? We're not talking about whether the ASPs are subject to workable competition, or ... that would be the discrete point for the comparator hot-tub?

**PROFESSOR WATERSON:** I think that would be the main point. Yes, I don't want to tie things down.

**MR BREALEY:** No. But if we are gaining an hour, so that's -- we're down for five days. So that's five hours. We've got a reserve day. I'm sure that that can be accommodated, because you have, sir, highlighted an issue in the case. There are

two separate abuses, and there may be some -- well, I won't call it conflict of interest, but there are differences of view.

**PROFESSOR WATERSON:** Yes.

**MR BREALEY:** And if you wanted to explore that with the experts, I can see the sense in that.

I would also respectfully request that any questions be put in advance, so that the expert has at least -- I mean, whether it's two or three days, whatever, so that it's not just on the hoof, and so that can be an informed dialogue between yourself and the experts.

I would imagine that's not just on Flynn's perspective. It's not just their economist, really, it is also their industry expert, their accountancy expert. And it may actually also be Mr Harman.

So on that discrete issue, if we could have the questions at least with some notice, so everyone knows what they've got to address, and with a -- whether it is a two-hour -- I mean, I can't believe it would be more than two hours.

**PROFESSOR WATERSON:** I think that's right.

**MR BREALEY:** But with, say, a two-hour slot, then I can't realistically push back on that.

But I do believe that it will be possibly a hot-tub of five experts, because the CMA will want to have a view. I don't believe their economist will have a view, but Mr Harman, the accountant, might have a view. Our economist will have a view, and Flynn may have two people having a view.

But I haven't -- no one is kind of kicking me. I can't -- I see the sense in that.

**PROFESSOR WATERSON:** Thank you.

**MR JUSTICE MARCUS SMITH:** Well, that's very helpful. Ms Stratford, we'll come to you in a moment, and obviously Mr Holmes after that.

But just to get a sense of the sensitivities arising out of hot-tubs. There's the timing question, which we've addressed, very helpfully. There's the advance notice question, which seems to me a very sensible thing, and it will certainly improve the efficiency of the process if the questions can be articulated in advance.

Just so that I have it on the record, is there a, what I'll call a queering the pitch sensitivity to the hot-tub process? I mean, one always has a problem when one is cross-examining of wanting to have, as it were, untraversed territory when one is cross-examining things, and one can see on certain topics traversing the area in a hot-tub might actually fracture a cross-examination that has been carefully thought through, intending to approach matters from a certain angle.

Is that something which is underlying your concerns about the hot-tub process in respect of certain topics, notably ASP. Or is it really just that the hot-tub isn't an appropriate way of dealing with that particular topic by way of example?

**MR BREALEY:** My main concern -- hot-tubbing is very often what the Tribunal wants, and what the Tribunal wants, very often it gets.

But I see the sense in hot-tubbing. However, I am to a certain extent aligned with you, sir, which is that it cannot be at the expense of cross-examination.

Now, if we had all the time in the world, then in an ideal world we would have both. But I can't emphasise too much that we need the time properly to put forward a case just to kind of say: well, you've got one and a half hours each on such a big issue as ASPs is just -- it's not doing Pfizer justice. So it's the time aspect of it.

But I well see that if there is this discrete issue, it may well be that you get all the people together, and Professor, you can ask the questions.

**MR JUSTICE MARCUS SMITH:** Thank you, Mr Brealey, that's very helpful.

Ms Stratford.

**Submissions by MS STRATFORD**

**MS STRATFORD:** Thank you.

So just going back to the beginning, again, of Mr Brealey's remarks, so we don't lose sight of the helpful comments about admissibility and weight and so on, I don't think I need to -- I think we agree with what Mr Brealey has said on that.

The only marker I would put down is that there was talk about the extremes and that something could never be binding. I think it's important here to draw a distinction between evidence that may have been given at the first trial, and findings of the Tribunal. In our mind those are two different species of -- have a different quality. I wouldn't want anything I'm saying now to rule out that we may well be saying that there are certain findings by the Tribunal that weren't appealed that are binding.

But, subject to that, I fully agree it could be dealt with as points may or may not come up during the trial and dealt with in the skeleton in the normal way.

**MR JUSTICE MARCUS SMITH:** Well, that's helpful. Just to respond on that point, because it's an important one, we have, as Mr Brealey has said, a rather protracted history here, in that we have the Tribunal's first-instance decision. We have an appeal to the Court of Appeal which was not 100% approving of what the Tribunal found, and then we have a remittal resulting in a new decision.

So the extent to which there is something which is binding is sitting in somewhat troubled waters. So without saying there can't be a binding aspect, it does seem to me that it's going to be important that those parties who are asserting that there is something which is binding do so as early as possible, just so that we can get a feel for, as it were, the fixed points in terms of decision-making that we, on your case, or on some other party's case, would have to navigate around. I'm not saying that we would want to argue about those at the beginning, I think they would appropriately be argued at closing. But it would be helpful to know what they were, and I'm not going

to close out any later formulations of what is binding, because cases change over their hearing.

But to the extent there are bits where you could say now, or in opening, or at some early point: look, this is something which we say the Tribunal cannot circumnavigate, that is something I think which would be helpful to know, just so that it would draw the other party's fire and enable the Tribunal to think about the point.

**MR BREALEY:** Sorry, can I just give an example?

**MR JUSTICE MARCUS SMITH:** Of course.

**MR BREALEY:** For example, at the beginning of 2012, Pfizer said that it benchmarked the capsule by reference to the tablet. Now, there were issues about that. Mr Poulton gave evidence. Pfizer said it benchmarked the capsule by reference to the tablet. Essentially, the Tribunal accepted that evidence.

In the present proceedings, the CMA has not gainsaid that, it has not really disagreed with that. So whether one calls that binding or not, but it should be a finding of fact that should not be disturbed, and we should then proceed onwards in the light of that finding, so we don't have to reinvent the wheel again.

So that would be an example where we are quite keen, if there is no real disagreement, if the Tribunal has already found this as a fact, then really this Tribunal should not be saying: well, we don't believe that Pfizer did benchmark our reference to the tablet. It's that sort of issue.

**MR JUSTICE MARCUS SMITH:** Yes, and in a sense I suspect that most of the points that Ms Stratford might be saying are binding and you might be saying are binding would be sufficiently uncontroversial for it not to matter whether we're talking about weight or whether we're talking about bindingness, because we'll simply be incorporating it. It's those instances where there's a dispute that it's going to matter, because clearly there the party relying upon the finding will be wanting to give it as

much weight as possible, and you will be wanting to say: look, you can't avoid following this particular fact, and accepting it.

I suppose I should qualify what I said earlier about early notice, that I'm really interested not in those facts which are uncontroversial, you know, there I think the difference between weight and bindingness doesn't really much matter. But it's those bits where you are saying this is a fact, and Mr Holmes is going to be standing up saying: well, it is, but it's wrong. And at that point we get into a hard-edged debate between bindingness and weight, and it's those, as it were, aspects that would benefit from, I think, early formulation.

**MS STRATFORD:** Thank you. Well, I'm sure all parties have heard what you have said on that, and we'll take that away.

**MR JUSTICE MARCUS SMITH:** I'm grateful.

**MS STRATFORD:** Coming onto the format of expert evidence and hot-tubbing. As you know, our primary position is that we should have conventional cross-examination rather than hot-tubbing, and we've explained that in our skeleton. I'm not going to repeat any of that or traverse the ground Mr Brealey has already covered.

But engaging, trying to engage constructively with what's been said this morning, if, contrary to that, there is to be some form of hot-tubbing, and listening to the Tribunal's initial indication, I think it's important from Flynn's perspective just to step back for a moment because there has been mention of a cost-plus hot-tub and a comparator hot-tub, and that raises -- particularly piques our antennae, and I'm just going to explain why.

As the Tribunal may have seen already, or will see when reading in, a key part of Flynn's appeal is its reasonable rate of return; i.e., what is the size of the plus in the cost-plus. And that, we would also note in parentheses, is a very important differentiator from the Liothyronine and Hydrocortisone cases, and the Tribunal's ruling

in those cases where the size of the plus was so large that argument about how it was arrived at really weren't going to shift the dial.

We say that identifying a reasonable rate of return is an empirical exercise, and as you've probably seen, we've put forward a series of margin comparators to show what the normal rate of return in the medicines industry is, and there are various different species of comparator. But if I can call those, perhaps, margin comparators, and those are different from the pricing comparators, which is really what Mr Brealey has been focusing on when talking about the tablet ASP, and obviously Flynn also has grounds of appeal going to that.

But I hope it's helpful, I just wanted to draw that distinction because using the word "comparator", for both of those different species of comparator that arise in this case, can lead to unhelpful elision, and from our perspective, we would strongly resist any hot-tub structure which placed our margin comparator issues, lumped them in with an overall comparator hot-tub. They are, really, a central part of our case on cost-plus, and I think it is important to stress that.

If we are talking about a cost-plus hot-tub, we would see that as including all of Flynn -- and it is mainly Flynn rather than Pfizer here, I think -- all of Flynn's and the CMA's expert evidence on the size of the plus, but much of which, as I say, relates to Flynn's margin comparators.

Just to be more concrete, in practical terms that would be Dr De Coninck for Flynn, Mr Williams, the industry expert, Dr Majumdar for Pfizer, I believe -- Mr Brealey is nodding -- and then Mr Harman for the CMA.

Then potentially -- and I'm not sure whether this is also being envisaged -- there would be a separate hot-tub on what we would refer to as pricing comparators, which are tablets and other AEDs. Again, just being practical about it, that would be both Dr De Coninck again, Mr Williams for Flynn, Dr Majumdar and here it will be Ms Webster for

the CMA. I hope that is helpful. Obviously, I am not going to touch on there is also the expert evidence on medical issues and on QALYs, and those are not areas of expertise that Flynn has directly engaged with, so I don't need to say anything about those.

**PROFESSOR WATERSON:** If it's helpful, Ms Stratford, in a previous hot-tub there were some experts who were experts on one particular aspect, and other experts who were experts on another particular aspect. In my questioning, I distinguished and suggested that particular experts might not want to comment on a particular point, and others would be asked to comment. And I think that would accommodate your suggestion.

**MS STRATFORD:** Thank you. Yes. That's helpful. But it's also particularly that aspect of comparators, margin comparators, which, as I understand it, there could be a divergence between Pfizer and Flynn, is firmly part of any cost-plus hot-tub.

**PROFESSOR WATERSON:** Yes.

**MS STRATFORD:** I'm grateful. Maybe that's what I need to say for now, unless there are other points on which I could assist.

**MR JUSTICE MARCUS SMITH:** That's very helpful, Ms Stratford.

Before, Mr Holmes, you rise, can I just articulate how, I think, provisionally we ought to proceed, and then, Mr Holmes, you can tell me how far that doesn't align with what the CMA envisages itself.

It seems to me that on ordinary days -- and I appreciate there are a couple of days which are, for Tribunal reasons, different -- but on ordinary days, we should sit at 10.00am and run through until 5.00pm, and we should probably aim to sit for three-quarters of an hour rather than an hour for the short adjournment as well.

Now, that gets us essentially an hour and a quarter extra each ordinary day. Now, that places burdens on both the teams of lawyers and advocates who are appearing,

and if that's causing a problem then I would want to know. I don't think it will cause a problem for the witnesses, because there's no one in the box that long, but clearly, we would have to accommodate tiredness by way of breaks.

It will cause problems for the shorthand writers because they will have a long day. In other cases where this has happened, we have managed to arrange a different transcriber for the morning and for the afternoon sessions, so you get a short day, in fact, rather than a long day, and maybe that is something that the parties could think about in order to ensure that we are in advance building in as much time as is needed, even if we don't actually end up needing it.

Within that framework we will have to accommodate the teach-in elements and the pushback on prior decision elements that we've already discussed, and I don't read anyone in the room saying that is a bad idea, but, Mr Holmes, I appreciate I haven't heard from you yet.

The question of the hot-tubs, we are not going to direct that they take place. We are going to facilitate their taking place with a view to calling them off if they are not a good idea. I think we need to do a bit more work on how they are framed.

At the moment we have two hot-tubs in mind: comparators and cost-plus. I would want the parties -- I appreciate Ms Stratford has articulated who should be in each tub, but I think the parties should first of all identify and agree who should be in each tub, and then I think the CMA ought to identify those topics that they think are appropriate for hot-tub consideration. For that then to feed through to Professor Waterson, and for him then to work out what areas of questioning and what questions he would want to put in the course of that hot-tub process. We can then see, with a fair degree of granularity, how much time and how much disruption to the ordinary process this addition will generate. My hope and expectation is that it will be unintrusive, and certainly not prejudicial to the position of the appellants in this case.

If it is, then I think we will have to discuss that further down the line. At the moment I think we ought to proceed on the basis that we're exploring the hot-tub option. We are not, as I say, going to direct it, because we want to get the details sorted out a little more clearly. But we are, to be clear, not closing it out: we are kicking the tyres of the proposal with a view to ensuring that it works.

Before I hear Mr Holmes on that, Mr Brealey, Ms Stratford, is that a problem for you both?

**MS STRATFORD:** Well, I must say I had very much hoped to come away from today's hearing with a clear understanding of the basis on which we were preparing this trial, and I suspect the other advocates may feel the same. I'm getting a nod even from Mr Holmes. But at the same time, I can appreciate that developing a hot-tub may be a process from which the Tribunal would welcome the parties' input.

I think there was only reference to the CMA proposing topics. I would presume it would be a process between all the parties.

**MR JUSTICE MARCUS SMITH:** The reason I mentioned the CMA is because they're keen and you are not, and so I imagine the number of topics that you would say are suitable for hot-tubbing would be vanishingly small, whereas the number of topics that the CMA would identify would be larger.

The reason I suggested it was because I want to give Professor Waterson every assistance, and indeed the other members of the Tribunal every assistance in working out what are seen as appropriate topics for the hot-tub. Obviously I would expect those topics to be notified to the appellants and for the appellants to push back and say: look, you must be joking, this is not something that is remotely possible before it comes to us.

I do think it is important that we put a little bit of flesh on the bones of the notion of hot-tubbing. Of course we could say: fine, we will have a hot-tub, that is if you know

what is going to happen, but that actually isn't helpful to the applicants because it's what goes on in the hour or two hours, or however long it is, for the hot-tub, and what is asked that actually matters in terms of your preparation. That's something which I don't think we can nail down today.

The reason I'm being a little vague around the edges is because I think certainty, either saying no hot-tub, or saying definitely a hot-tub, provides a false sense of certainty rather than a true sense of certainty. But the point you've made about preparation is well made: we need to press the accelerator on framing the hot-tub question sooner rather than later. I'm not going to make any directions in terms of timing, but I do think we need to move quite fast on this so that all of the advocates know what areas are going to be traversed in what way at the trial which is a month and a half away.

**MS STRATFORD:** Well, you will appreciate I would strongly urge a very compressed time. At the last CMC the parties went away and had useful discussions, and I wonder whether that could be employed today on this question.

**MR BREALEY:** I'm sorry, I thought where we had landed was there is an issue about the Pfizer/Flynn relationship, whether that's one hours, two hours, three hours, is a question for the Professor. We've clearly agreed to that, but we have put a very strong marker down saying that the other disciplines need to be tested by cross-examination, and it is for the CMA, if it wants, in correspondence to seek to justify it. But our clear marker is that we should proceed on the basis of standard cross-examination plus the teach-ins. We've got the teach-ins, and I've already made this point, if you've got the teach-ins plus hot-tubs, then you've got your cross-examination, that cross-examination is going to be squeezed.

We are receptive to the Tribunal's suggestion on the Flynn and Pfizer relationship. That's going to take some time. The CMA can, in correspondence, put its case, but at least the Tribunal knows where we are. We have already thought about this and we

are against it.

**MR JUSTICE MARCUS SMITH:** Okay. Mr Holmes.

**Submissions by MR HOLMES**

**MR HOLMES:** Thank you, sir, if I could start just with the question raised as additional business concerning the status of the first Tribunal proceedings. I can be very brief on this. We agree with you, sir, that evidence arising from those proceedings is admissible, and it's a question of weight which will be determined in due course.

The only matters that aren't on the table here, as we understand it, are those of market definition and dominance, which were finally determined by the Tribunal last time around and weren't within the scope of the remittal. The entirety of abuse was remitted.

Insofar as there are findings of fact relating to abuse, I suspect that you are right, sir, from the first Tribunal judgment, that those will not be controversial, but it will be useful to understand from the appellants which particular facts they rely on at an early stage so that that can be clearly understood and worked out. But I don't think much further can be done about that today. I think the main proposition is that we agree with you, sir, that previous evidence is admissible, but weight to be determined following submission.

On the question of hot-tubbing, we wouldn't presume to tell this Tribunal what it will find most helpful in terms of hearing evidence. This is a very experienced Tribunal which has sat in many cases, it has its own experience of how evidence has been heard and what it has found helpful and useful.

We, as we set out in our skeleton argument, we do see in the particular circumstances of this case an argument for streamlined hot-tubbing on a particular part of the economic and the accountancy evidence, and that aligns closely with the suggestion of Professor Waterson, as we understand it, and the particular considerations which

favour that in this case is the one which Professor Waterson has identified, the fact that the evidence is somewhat tangential. The parties are not aligned, and a hot-tub provides a good way of teasing out those differences.

The second point is, there are a fair number of issues and a fair number of experts. As Flynn describes in its skeleton argument, it's a bit of a mosaic with different experts speaking to different topics, and that means that there will be quite a job of work for the Tribunal to pick over the cross-examination scripts which will need to jump around from topic to topic, according to each expert's coverage, in order to get an overview.

Now, of course this Tribunal, as I've already said, is well experienced and able to master complex cases, but I think there would be efficiencies, there would be convenience for the Tribunal in hearing certain key topics grouped together, so that it hears at one go what each of the parties' experts has to say about that topic, and what they each have to say about one another's evidence. Certainly my own experience as counsel in the Liothyronine case is that that was a very effective and advantageous feature of the hot-tubbing that was done there.

But we fully accept that this is a case-by-case assessment. There can be no presumption in favour of hot-tubbing. On the contrary, we understand that cross-examination is the usual way in our system of law in which evidence has traditionally been tested.

On the question of whether this cuts across the opportunity for parties to put their own case, we don't see the hot-tubbing as an alternative to cross-examination. There should be scope for cross-examination to follow, so that if parties don't feel particular points have been explored to their satisfaction, their counsel can consider them further, and time should be built into the timetable to allow for that.

As regards the concern about queering the pitch, I think one can't be too absolutist about that. No counsel can expect to have pristine snow, and that's partly because

where they come in the running order, there may already have been someone who has asked a whole series of questions. The evidence may have emerged in a particular way as a consequence. In this case, of course, the Tribunal, for good and sensible reasons, is proposing to have oral examination-in-chief, which will require counsel to do some quite agile acrobatics in the light of what's said.

We don't think that can be treated as an absolute prerogative of counsel. We think it's all a question of the individual circumstances of the case, and in this case we think that there are circumstances which commend a streamlined hot-tub with cross-examination on other topics not included within its scope to follow.

The number of experts we don't see as a problem. It's been done in that way before now and it has worked. This Tribunal isn't afraid to innovate and to try new things. Having five experts of mixed disciplines, economics and accounting, doesn't present insuperable difficulties.

Equally, the difficulty to which Ms Stratford was alluding, the fact that there are cross cutting points which don't perhaps neatly pigeonhole and not all experts cover all points. That can be dealt with simply by having -- going along the line and those experts who have evidence to give on points addressing that point.

We think that the hot-tub would necessarily be longer than, I think, the one to two hours that Mr Brealey suggested, but it can really readily be accommodated in the timetable. If we can just go back to the timetable to show you why that is the case. I think, Mr Brealey, I have it loose, I think it was at tab B4 of the bundle, 7.18 of the electronic bundle.

**MR JUSTICE MARCUS SMITH:** Yes.

**MR HOLMES:** You can see at present five days were set aside for the economist accountant and industry evidence. We were slightly surprised to hear Mr Brealey express concern about the time for cross-examination, as his client pressed in

correspondence for that to be reduced to four days. But, in any event, one sees immediately following those five days there is a reserve on 23 November, which would ordinarily be a sitting day, a day which has been left fallow.

At the start of the following week, on Monday, 27 November, which would also ordinarily be a sitting day, there is another reserve. Tuesday, 28 November is a non-sitting day because of Tribunal availability.

But you see at the end of the timetable there is another reserve day, Friday, 1 December. And, if necessary, the QALY evidence could be pushed back to allow yet a further day.

So really this timetable was rightly described by Flynn in its skeleton argument as a generous one. It's really quite slack. Now, we don't object to that. We can see advantages to it. But the suggestion that parties will be timed out from cross-examining seems to us quite fanciful in those circumstances.

The mechanics that you have suggested we understand. We appreciate that hot-tubs are burdensome on the Tribunal, and that equally perhaps the scope of the hot-tub hasn't crystallised because we've been focused really more on the threshold question of how the evidence should be given rather than the precise scope and coverage of the hot-tub.

We agree, as Ms Stratford said, even Mr Holmes accepts the need for this to be resolved quickly. We think that that can be done very soon after receipt of the position papers. I think they are due on 25 September, and we propose to write to the Tribunal and the parties in very short order as soon as we have digested those after that, with suggestions, having heard what Professor Waterson has to say.

If the Tribunal could give an indication soon after that about whether it's content to proceed with a streamlined hot-tub, then that would be extremely helpful. So, as Ms Stratford said, the parties could go about the business of preparing their oral

examination.

Two further points, if I may. The first concerns teach-ins. Now, I alluded to the fact that these, to some extent, present a challenge for counsel because you have a block of examination-in-chief or presentation and if that comes immediately before when counsel rises to their feet and starts putting questions, that can be quite challenging. It's precisely for that reason that oral examination-in-chief has been somewhat curtailed in modern civil procedure, as you're aware, sir. Obviously, it may not be that efficient, because you will have questions in your script, which may be duplicative or unnecessary, in view of what's said in the opening comments of the expert, and you may equally have new questions which you need to put, or questions need reframing. So doing that on your feet in real time is challenging.

Now, one way of addressing that concern would be to group this examination-in-chief session at the beginning of each of the blocks of evidence which the parties have agreed are a sensible way of grouping the material; that's to say the economic/accounting evidence, the medical evidence and the QALY evidence. So you could have each of the experts doing their examination-in-chief and then you could have a short pause and cross-examination to follow. That would address that concern, if the Tribunal were content with it.

It could also fit quite well, I should say, with a streamlined hot-tub. Because you could have at the start of the hot-tub for each of the experts that process of examination-in-chief with, perhaps, each expert in turn going into the box, and from the second-row counsel putting some short questions or the expert explaining their position. So that might be quite a convenient way of doing that if it were attractive to the Tribunal.

The final point concerns sitting times. We hear what you say, sir, and we're very grateful to the Tribunal for its willingness to accommodate longer days, and that may

be helpful -- may be helpful -- in relation to the economic expert evidence in particular, in light of the concerns that Mr Brealey has raised.

In general, however, given that the timetable is quite generous, we do wonder if it's necessary to extend sitting times in that way, and we do have a specific concern about parental issues which arise for certain members of our team. One member of our team, counsel team, in particular is returning from parental leave, having a young baby, and we're already finding ways to accommodate that in the way that we organise ourselves at trial. But I think a day which sits longer would undoubtedly present greater practical difficulties for people in that position.

So we would urge the Tribunal to confine that to the period where it is needed, and the collateral benefit of that, of course, is also that the Tribunal has more time to digest and consider the material outside court hours, and also the court day is less heavy on all concerned.

So, you know, we would, I think, propose that that be confined specifically to the economic and accounting evidence if needed.

Those, sir, subject to any questions from the Tribunal, are my submissions.

**MR JUSTICE MARCUS SMITH:** Thank you.

Just to deal with that last point first, the reason for raising timing early is because if you run into difficulties later on, you then have the burden of a last-minute change, which is all the worse for those who are most affected by it.

We hear what you say about the generosity of the timeframe. Is it sensible to say that we will, on those days when we are hearing the economists, accountants, industry experts, in other words the block under the heading on page 7.18 below Tuesday -- well, no, Wednesday, 15 November and following, it is those dates that are most critical in terms of potential squeeze on time, and that we should have the timings that I was floating on those days; that's to say the 15th onwards, but stopping when

the QALY analysis begins?

**MR HOLMES:** Yes.

**MR JUSTICE MARCUS SMITH:** Is that an appropriate compromise? Mr Brealey, is that dealing with your concern about timing, which I think was mainly on the economic evidence rather than the QALY evidence?

**MR BREALEY:** Yes. I think that if -- well, we start on 14 November with the clinicians. That should be -- we have said that one day should be sufficient there, so we probably don't need to start at 10 o'clock.

We did, just to meet Mr Holmes' point, we have said four days, and two days in reserve. So we always thought that six days would be for the block economists, accountants, industry expert evidence, and that's what we suggested in the correspondence, because we always know that people run over in cross-examination. That's why you've got the ...

So, yes, we can start at 10.00 am there, and I think when we get to the QALY, which we'll come onto a bit later on, maybe, we can revisit it, but we can start at 10.30, and if we've been pushed, we can start at 10.00 am on Wednesday, 29 November.

The short answer is, to give everybody fair due, we can have the 10.00 am start beginning on the 15th and ending on the 23rd.

**MR JUSTICE MARCUS SMITH:** Well, that's helpful, Mr Brealey. We'll do that, in that case.

**MR HOLMES:** I'm grateful.

**MR JUSTICE MARCUS SMITH:** It's just that there are, as regards this block of evidence, a number of additional concerns. There's the teach-in, there's the hot-tub. There's the push back on prior decisions. All of these are extra time.

On top of that, one has the fact that this is a Tribunal that does ask questions, and I don't want, when that happens -- and it will happen -- I don't want Mr Brealey sitting

there feeling as if he is having his teeth pulled by a particularly unsympathetic dentist when his time is being used by questions that he feels he could have better put himself than the Tribunal.

It's there that I am most concerned that we ensure that all of the parties, but the appellants in particular, feel that they have had every opportunity to develop their case. Since that is something that both appellants and the CMA are happy with, we'll extend the hours there. We will try not to do so elsewhere. But we will, obviously, keep the matter under review, try not to extend them, but we'll have to cut our cloth depending on how pressed we become.

So that's very helpful on timing.

Just, then, to nail the hot-tubbing question, to the extent we can today, we are, I think, deciding that there are going to be only two hot-tubs, maximally, comparators and cost-plus. We are, I think, keen to have locked down the membership of those tubs today or tomorrow if possible. I don't see any reason why that can't be done.

We would like, simply because it will assist Professor Waterson, we would like to have assistance on those topics that the parties think can be covered, and I think the prime mover there ought to be the CMA, not because they're automatically going to be included in -- that's not the case -- but because it would assist, I think, us, in working out those areas that we may not have thought of, because we are coming from behind the parties in terms of the learning curve. So we do want assistance there.

Equally, the fact that a topic has been identified post position papers as something that the CMA wants in the hot-tub, is by no means a guarantee that it will be in. We are simply looking to scope the nature of the problem, and I hope that is giving Ms Stratford and Mr Brealey enough certainty about how we're going to proceed, whilst ensuring that we get the process right.

That's what we will do in regard to hot-tubbing, and I hope that the position papers will

lend further certainty to what is going on, and obviously we will think further about those areas that we want to have dealt with.

But, Mr Brealey, Ms Stratford, you should both feel alive to an ability to push back if you feel that the hot-tub process is getting out of control and is prejudicing the important ability in your clients to put your case through cross-examination.

**MR BREALEY:** Well, we will just eat into the CMA's time!

**MR JUSTICE MARCUS SMITH:** Ms Stratford.

**MS STRATFORD:** I would just reiterate my point that since there is going to be -- obviously we've been having a debate about whether there should be hot-tubs at all, but since there are going to be, on Flynn, for Flynn's part, and I obviously can't speak for Pfizer, we would want to engage constructively with the CMA about topics for the hot-tub. I just think it's important to stress that, so that there's no misapprehension about that.

**MR HOLMES:** Just to say that we hear that and we fully understand the need to engage constructively with the parties, and we will endeavour to do so.

In order to accommodate the point that Ms Stratford rightly makes about the difficulty of a strict taxonomy between on the one hand the comparators material and on the other hand the cost-plus material, it may be useful to think of this as not two hot-tubs, but a single hot-tub which covers both topics with different experts contributing in response to different questions. But I just plant that seed now with the parties and with the Tribunal.

**MR JUSTICE MARCUS SMITH:** Well, we expect in every case -- and this case will be no exception -- the parties to take offline issues like this to make sure the mechanics work, and we invite the parties to do that in this case.

I suppose the only point I am making is that we are regarding the parties' work in this regard as a helpful set of suggestions which we will then take and parse as we see

helpful ourselves. Clearly, at the end of the day, it is the benefit that the Tribunal gets from the hot-tub process that matters as a second order question, the primary question being that the time for cross-examination not to be eroded.

We encourage the parties to discuss that. I know they would in any event, but I say it for the record. We will then look at the fruits of that process, and if it seems to us to work, well, the parties can take it we'll probably run with it. But we will apply an independent mind to the question and let the parties know, because I do think, Mr Brealey, you've got a very good point about questions and areas to be examined. We will endeavour to ensure that that is dealt with as early as possible, so that everyone knows what's coming down the track.

The final point on teach-in, taking your various points in reverse order, Mr Holmes. If it can be achieved, we can see a significant benefit in having the teach-in in block form, ahead of each type of evidence. That works for us.

We are only going to have to be conscious that this is going to be a slightly complex timetable, and it will be necessary to ensure that the experts know exactly what is coming down the road for them, and we don't, as it were, have the wrong people in court at the wrong time, because it's not the usual sequential one which is after another process. We have a lot of commonalities of different sorts, which we will need to work out.

The parties should, I fear, in addition to their other burdens, ensure that they update the agreed trial timetable, so that we all know where we're coming from on timings, and who is needed at what particular time.

Does that bring the hot-tubbing and the evidence question on this area to an end? If it does, is this a good time for a shorthand writer break? I don't want to cut you off, Mr Brealey, of course.

**MR BREALEY:** No, no, no. Is there a shorthand writer? Maybe there is. But we can

have a break.

**MR JUSTICE MARCUS SMITH:** I'm assuming there's one offline. I'm so used to it happening offline. But if we're not, then we can carry on.

**MR BREALEY:** No, we can have a 10-minute break.

**MR JUSTICE MARCUS SMITH:** I normally get some voice piping up out of the ether saying, "Please rise", but that hasn't happened.

We'll rise, and perhaps someone could tell me whether we are being transcribed or not when we've risen. So, we'll come back at 12.10.

**(11.59 am)**

**(A short break)**

**(12.12 pm)**

**MR JUSTICE MARCUS SMITH:** Mr Brealey.

**Submissions by MR BREALEY**

**MR BREALEY:** So if we look at the agreed list of issues, I think we've done number one.

**MR JUSTICE MARCUS SMITH:** Yes.

**MR BREALEY:** I think, I believe, that we are fairly agreed on the directions to and for trial. I think, subject to anybody -- I mean, subject to obviously you, sir, saying yes or no, we've agreed the length and the time limit.

**MR HOLMES:** Sorry, we haven't agreed length, to be clear. As I understood it, the Tribunal gave a very clear direction last time that it was not imposing strict limits. Our position is that we will be as brief as we can, and we trust the other parties will, too. But we don't consider there was any agreement as to length.

**MR BREALEY:** Approximately, then.

**MR JUSTICE MARCUS SMITH:** The parties will know that we will read shorter submissions twice over, longer submissions once, and it rather depends on what you

think the cost-benefit is. But the shorter the better.

**MR BREALEY:** We will be succinct.

**MR JUSTICE MARCUS SMITH:** But we're not going to put limits on it.

**MR BREALEY:** I think it's all pretty much uncontroversial, at the moment.

**MR JUSTICE MARCUS SMITH:** Indeed.

**MR BREALEY:** The trial timetable, as I said, we've looked at.

The fourth is the permission for reply evidence of the CMA.

**MR JUSTICE MARCUS SMITH:** Yes. This is the Hawkins issue.

**MR BREALEY:** Now, there are two issues here: the CMA actually needs permission --

**MR HOLMES:** Sir, I tend to agree with the point that was just made. It's surely my application to adduce this evidence, so I think I should probably open it, if that's to the Tribunal's ...

**Submissions by MR HOLMES**

**MR HOLMES:** So the Tribunal will have seen that this concerns a second witness statement from the CMA's witness, Mr James Hawkins and we seek permission to adduce it. It was served in draft form in the usual way on the parties on 8 September 2023. Mr Hawkins is a senior official at the National Institute for Health and Clinical Excellence, NICE, and he gives factual evidence arising from the evidence of Pfizer's health economist, Dr Skedgel, who has applied a particular NICE methodology, the QALY framework.

The second statement identifies what Mr Hawkins regards as certain factual inaccuracies in Dr Skedgel's reply report. It also concerns one point made in respect of Mr Hawkins' first witness statement by Pfizer's medical expert, Professor Walker, in his reply report. We say that this evidence is relevant to the issues arising in the case, and neither of the appellants, as we understand it from their skeleton arguments, have

taken issue with that. The Tribunal will obviously want, when assessing the expert evidence on economic value, to ensure that it is proceeding on a correct basis in fact. As a senior official at NICE, Mr Hawkins can authoritatively address the way in which the QALY framework operates, as well as how NICE has evaluated Phenytoin in its relevant guidance documents.

In recognition of the relevance of Mr Hawkins' evidence to the QALY expert evidence, the parties are agreed in proposing in the agreed timetable that Mr Hawkins' evidence should be heard alongside that expert evidence.

Second, we say that there is no unfairness or prejudice in admitting the evidence at this distance from trial. The appellants have identified none in their skeleton arguments. The draft witness statement was served two months prior to the trial. Dr Skedgel will have the opportunity to address it in his position paper and in his evidence at trial. Indeed, having Mr Hawkins' evidence on the points addressed in his second statement we say is in the interests of fairness and transparency. It means that the Tribunal and all parties are aware of his position on relevant matters before he gives oral evidence.

That prior notice is particularly important in circumstances where, as by agreement, and at Pfizer's request, Mr Hawkins will be giving evidence after Pfizer's medical expert, Professor Walker, and given that Pfizer's medical expert makes comments in respect of Mr Hawkins' evidence, which will need to be put in cross-examination, it's appropriate that Professor Walker sees now what Mr Hawkins intends to say about those comments.

We say that none of the objections raised holds water. First, the evidence is described as evidence in rejoinder. However, it's not unusual for factual matters to arise from the expert process which require some additional factual input. The important thing is that the Tribunal has before it the factual evidence it needs to assess the expert

opinion evidence.

Second, there is an objection to the length of the exhibit, however it only consists of eight lengthy documents which were exhibited in their entirety. It can easily be cut down to relevant extracts of under 20 pages, and indeed of the eight documents, one is already in the bundle and another is also referred to in Dr Skedgel's evidence.

Finally, Pfizer and Flynn complained at the time taken to bring the evidence forward. We've covered this in our skeleton argument. The CMA carefully considered Pfizer's reply, raised the points in Pfizer's reply with Mr Hawkins and served a draft of his evidence as soon as it was able to do so, bearing in mind the summer break.

The real question for the Tribunal is whether the evidence is relevant and whether there is any prejudice in admitting it. On neither of those points have the appellants identified any substantive objection in their skeleton arguments, so I apply to have the evidence adduced.

**MR JUSTICE MARCUS SMITH:** I'm grateful, Mr Holmes.

Mr Brealey.

**Submissions by MR BREALEY**

**MR BREALEY:** That all trips off the tongue quite easily, with the greatest of respect. I will park the question of what we do with it, but I think the Tribunal does need to know what has gone on and what this evidence goes to.

Just to take the last point first. Mr Holmes, I think, basically was picking up from paragraph 23 of his skeleton, where the CMA says:

"The appellants have asked for an explanation as to the timing of the statement."

It says:

"That is simple [this is 7.10], the CMA has carefully considered Pfizer's reply, raised the points in Pfizer's reply with Mr Hawkins, and served it as soon as it had been able to do so, bearing in mind the summer break."

So everything was done expeditiously.

But one has to just remind ourselves of what the timing is on this, and I'll give the Tribunal the dates.

On 12 October 2022, we have Walker 1 and OHE 1. That is in our notice of appeal.

On 17 December 2022, we have Hawkins 1, with the defence.

On 14 April 2023, so 14 April, we have Walker, the next Walker, and OHE 2. So that's where we put our reply in.

Just note, 14 April 2023. As Mr Holmes says, we didn't get Hawkins 2 in draft until 8 September 2023, so that is five months after the evidence we put in reply. The CMA serve Hawkins 2, it's a 17-page statement, with a 1000-page exhibit, which both Walker and Dr Skedgel have to look at. No explanation why it's taken five months. April, May, June, it could have been given to us before the summer.

You can't have one rule for one and another rule for another. One has to have some orderly case management here. Just to serve it in draft on 8 September, we say, is not appropriate, and is prejudicial, because it does affect how we address it in the position papers. And we've got to put a skeleton argument in on 16 October.

Just to say: well, they did it as quickly as possible, actually we don't understand that because, as they say, it was 14 April when they got the evidence in reply.

Reading this, and -- so that's the first point, and all I'm doing is submitting to the Tribunal that this has been served late and it does cause prejudice, because it is a 17-page statement with a 1000-page exhibit five months after the reply. To say that it doesn't cause any prejudice I think is wide of the mark.

The second point that I just want to pick up on, Mr Holmes says this is factual evidence, and we've been concerned for some time about factual evidence. Can we go to Hawkins 2. I've got a hard copy bundle, it's tab B5.

If one goes, for example, to page 12 of his witness statement, page 19, and read

paragraph 42. Now, remember, this is supposed to be a factual statement. He is responding to Dr Skedgel's expert report, and he says:

"Dr Skedgel found Phenytoin to be more cost effective (with a high degree of certainty) than all other ASMs [that's anti-seizure medicines] recommended by NICE in 2012 as third-line therapies apart from Pregabalin. I also consider this result to be inconsistent with the recommendations made in NICE's 2012 epilepsy guideline. From my experience of working with guideline committees if they had accepted the outcomes of Skedgel's analysis in their consideration of the cost effectiveness of ASMs, then Phenytoin (and Pregabalin) would have been recommended at a higher line of treatment than the other ASMs under consideration."

Now, when one comes to see whether this complies with the Practice Direction:

"I understand it's not my function to argue the case. I understand the purpose of this witness statement is to set out matters of fact of which I have personal knowledge."

It's very difficult to see how paragraph 42 is really a factual statement where he's saying that if somebody had done this, then Dr Skedgel would be wrong. One is straying into the realms of expert evidence here.

We get landed with this very late on, and it certainly has elements of opinion evidence, and outside -- I mean, the Tribunal has been quite strict with its Practice Direction saying it's only statements of fact of which you have personal knowledge. This man is actually taking his experience and applying his experience to an analysis. That is not a fact in the -- if anything, it's an industry expert.

So that is another way, another reason why we have been prejudiced, because this is not simply this witness of fact saying: this is how the NICE guidelines work. He is actually making some assessment.

What do we do with it? We will obviously object at trial to any opinion evidence that goes in. It may well be that the CMA want to reconsider Hawkins 2 and strip out any

"I consider that" and consider any opinion evidence, and I would invite the CMA to do that.

Clearly the QALY is very, very important to this case, and to economic value, and if I can just, in 20 seconds, explain what this is going to.

Essentially, this is going to whether Phenytoin is value for money to the NHS, because you take the cost of the medicine, so this is what the CMA complain -- the cost of the medicine is too high. But QALY then looks at the savings to the NHS of someone who has seizure freedom. So if one is seizure free, you no longer go into hospital and see a doctor in hospital. You no longer need to see someone as an outpatient. You then have personal social care, so someone doesn't actually visit you in your home. So there are certain costs which are saved to the NHS which this QALY analysis balances against the cost of the medicine, and it does it in a certain way, which we shall see.

Now, that is why it is, to a certain extent, a question of economic evidence, and paragraph 42 seems to be straying into the realms of opinion, assessment and economic evidence.

It's not just a question of: well, we did this as quickly as possible, because no, they didn't, because they had it on 14 April. It's not just a question of: this contains straight matters of fact because, no, there is elements of assessment here. And so I don't want to make a dog in the manger submission here, but the Tribunal does set out certain rules that the parties have to adopt. There is orderly case management, and there is a clear dividing line between witnesses of fact and experts.

If something comes late, and it is being -- and the factual witness is straying into some sort of expert assessment, we're entitled to bring that to the attention of the Tribunal. Clearly, because this is such an important point, we are not in the business of excluding factual evidence even though it has been served very late and seems to be straying into opinion evidence, we will deal with it.

It is right for me, on behalf of Pfizer, to draw this to the Tribunal's attention that this wasn't done as quickly as it should have been. It has caused certain consternation and prejudice to both Walker and Skedgel, and it is not just a simple question of it being a straight: this is how NICE guidelines work, Dr Skedgel has misread this. Where are the actual personal ... **(Pause)**

So that's why. Those are the problems. Clearly the Tribunal can deal with it. It can be admitted, but with the caveat that they should revisit it, if necessary, and strip out what is essentially expert opinion, which they should do, or we'll have to object to it when he gives evidence.

But, as I say, we're not in the business of excluding relevant evidence, because it is an important point. It does go to the value of Phenytoin, and clearly the Tribunal has to have all the evidence that the parties say that is relevant. But it is right that I draw your attention to the fact that it is being served very, very late. Five months gives us essentially five weeks to deal with it before the service and in our skeleton, and it is not just a question of factual evidence.

But, as I say, we invite the CMA to reconsider certain aspects of this which stray into opinion evidence, but we're not in the business of excluding it and our experts will have to deal with them.

**MR JUSTICE MARCUS SMITH:** Ms Stratford, do you have anything to add?

**MS STRATFORD:** My Lord, despite Mr Holmes' liberal use of the plural here, this isn't directly relevant to Flynn, and we have sat on the side lines. But we do think it is right, as Mr Brealey has said, that the lateness needs to be explained.

**MR JUSTICE MARCUS SMITH:** You support Mr Brealey's position that you don't really have anything to gain?

**MS STRATFORD:** Exactly.

**MR JUSTICE MARCUS SMITH:** I'm grateful. Thank you very much.

**Submissions in reply by MR HOLMES**

**MR HOLMES:** So, sir, the first point concerns why Hawkins was served when it was. Obviously, without waiving any privilege, Mr Hawkins is not being paid to give evidence and he is a busy professional who plays an important role within NICE, and he has many other demands on his time.

The question for the Tribunal, in my submission, is whether, from where we are now, two months ahead of trial, there is any real concern of unfairness or prejudice in the ability of Mr Brealey and the relevant experts to digest his evidence and to address it in their position papers, and in the skeleton argument. There's no suggestion -- no concrete suggestion -- that there is any such specific difficulty.

The second point was an objection that this is not factual evidence. This is the first time that this objection has been raised. It's not been raised in correspondence, and it's not been raised in Mr Brealey's skeleton argument. It picks on one paragraph where Mr Hawkins gives evidence based on his experience of sitting on guideline committees.

If you turn back to page 2, you will see the basis on which this experience is based. At paragraph 2, he explains that he works within NICE's centre for guidelines, and he has worked on the development of NICE guidelines for 10 years. So he has experience to bring to bear. And the paragraph 42, to which Mr Brealey objects, is perfectly permissible factual evidence. Indeed, factual witnesses frequently do express views based on their personal experience. To offer one example, Dr Fakes, one of the witnesses in these proceedings for the appellants, states:

"In my opinion and experience products supplied from low-cost countries are more likely to experience stockouts than products supplied by manufacturers in European countries."

It's perfectly standard to give evidence based on experience of a trade or a practice of

that kind.

The fourth point concerns the need for an orderly process, and we accept that. It is the standard practice where you have evidence after the usual process to serve it in draft form and to invite parties to make any objection they wish. That is what the CMA did as soon as the evidence was ready to be served in that form. So we don't accept that there was anything improper or out of the ordinary in the way in which the CMA has raised this and brought it before the Tribunal.

Unless I can assist you further, those are my submissions in reply.

**MR JUSTICE MARCUS SMITH:** No, I'm very grateful, Mr Holmes.

(12.36 pm)

**Ruling (pending approval)**

**(12.43 pm)**

**MR HOLMES:** Much obliged, sir.

**Submissions by MR BREALEY**

**MR BREALEY:** I think that is four. I think everyone is agreed on the protocol, that's issue five, unless Mr Holmes is going to tell me I'm wrong.

Position papers at six. The parties are moving forward on that, and the experts will have to deal with Hawkins 2 in the position papers.

Yes, seven, I would ask the Tribunal to assist the appellants on this. Updates on the current stages of the bundles, including the use of Opus 2 at the main hearing. At the moment, the bundle, as I understand it, the whole bundle is not quite there yet, and I think we're waiting on the CMA to finalise that.

I would, through the Tribunal, urge the CMA to get on with that, because the time is ticking now for us to put our skeleton in on 16 October and we really do need to get Opus fully up and running so that we can use it properly and put the citations in any

skeleton argument.

Until we get it updated, I'm not going to get any hard copies, and we're not going to have it fully on Opus, so I would urge the CMA to get a move on with assisting the appellants in getting Opus properly up and running. So that's what I would submit on point number seven.

**MR JUSTICE MARCUS SMITH:** I'm grateful. I know from my own experience how difficult it is to prepare without references, and I'm sure the CMA heard exactly what you have said, Mr Brealey, and I endorse it.

**MR HOLMES:** Indeed, sir. I should say that the pleadings, evidence and decision are all up on Opus already and have been referenced. It's only the contemporaneous document bundles which are taking a little more time because of the need to deal with the number of documents provided by the appellants for inclusion and which need to be checked for confidentiality. But I think we've indicated in correspondence that we are confident that that can be done by the end of September, so it should be done in good time prior to the --

**MR BREALEY:** End of September, that's --

**MR JUSTICE MARCUS SMITH:** The problem, Mr Holmes, is it's actually the contemporary documents that are the most important documents to reference. You know what paragraph in the pleading you're going to be referring to.

**MR HOLMES:** That's well understood, sir. The documents are all known to the parties, of course, because they're provided by them.

**MR JUSTICE MARCUS SMITH:** I mean, I noticed when I looked at the Opus files that there is, I think, a confidential set and a non-confidential set.

**MR HOLMES:** Yes.

**MR JUSTICE MARCUS SMITH:** Can we assist the CMA on the questions of confidentiality, or is it a problem of confidentiality in disclosing to the appellants?

**MR HOLMES:** I think probably not to the appellants, but can I take instruction on that to check?

**MR JUSTICE MARCUS SMITH:** Indeed. **(Pause)**

**MR HOLMES:** Sir, those behind me have heard what you say and will endeavour to get it done on a more rapid track. Even, perhaps -- I can't make any promises on my feet, but during the course of next week.

**MR JUSTICE MARCUS SMITH:** Well, that would be helpful. Let me say this. First of all, it's very important that we get the referencing sorted out. Secondly, and I'm sure the CMA know this having traversed this sort of area a number of times before, that I am very keen for the confidentiality tail not to wag the preparation dog. It does seem to me that, of course, the CMA is obliged to ensure that confidential material is protected.

On the other hand, this material is going into Opus subject to the express rule that this material cannot be used for collateral purposes. Of course the bundles are going to be confidential, at least in the first instance, because they're the only ones who can access it, confidential to the parties.

The real problem, as I see it, is that there might be a reference in the course of oral submissions or cross-examination to material that could be confidential, and it may be that the CMA could indicate to the parties the broad areas of concern that it might have in terms of what could be inadvertently said in open court, so that the appellants can respect that, and we can deal with matters elliptically or by invitation to read in the course of the hearing without having everything very carefully marked up in a way that obviously in the ideal world one would want it done, but which just takes an awful lot of time.

I suppose what I'm saying is that if the CMA were minded to speed the process up by cutting a few corners, then they can take what I've said now as an endorsement of that

approach, and that those corners ought to be cut, not because confidentiality isn't important -- it is -- but because it takes second place where it can appropriately be protected by other means to the appellant's ability to ensure -- at the end of the day it's for our benefit that we have references that we can actually trace through, produced in good time.

So I hope that gives the CMA some comfort. I don't want to suggest I'm making any criticism of the CMA, it's more an attempt to remove the burden of doing a job conscientiously, and what I'm saying is that in this case speed trumps a super conscientious job.

**MR HOLMES:** That's very helpful, sir, and we will proceed on the basis of that indication.

**MR BREALEY:** On the agreed list of issues, I think that is it, unless there's any other business.

Then we've got the third discrete point.

**MR JUSTICE MARCUS SMITH:** Indeed. Well, first of all, let's check whether there are any other non-Hydrocortisone 2 points arising. Ms Stratford shakes her head. Mr Holmes.

So we are done in that case.

What we'll do, I don't think we're going to be very long on the Hydrocortisone 2 point, because it is really -- the aim is to put all of the parties, and Ms Stratford's team in particular, on a level playing field as to what the point actually is.

**MR BREALEY:** Yes.

**MR JUSTICE MARCUS SMITH:** So should we try and rise now.

**MR BREALEY:** Can I just -- I beg your pardon. Obviously Hydrocortisone 2 is quite sensitive. I don't know whether it is, at first, those who know can find out from you, sir, what the issue is and whether that can be done in any other way than getting more

people into the confidentiality ring. I just, without giving anything away, I'm not sure -- although I know -- I'm not actually sure what the broader relevance of it is to Phenytoin, and I don't know whether you would welcome just five minutes' dialogue between those who do know and yourself as to whether it is necessary, or, of course, I respect if you have thought about it and you do think it's necessary, then so be it.

**MR JUSTICE MARCUS SMITH:** Well, frankly, I'm in agreement with you: I don't think it is necessary. But I think that everyone who is before the court is entitled to take their own view regarding the relevance of Hydrocortisone 2 to Phenytoin, and it's for that reason that I think it's important that we ensure both those who are in the know and, of course, to an extent you are, but you can't actually talk about it to your clients in this case, because the ring is not extended here. We have, of course, Ms Stratford's position that she actually doesn't know anything about this. Although one person, at least, in her team does. But, again, he can't talk to her.

I don't want to create a situation where I'm inviting work for no reason. On the other hand, I do want all of the parties to be able, if they are so inclined, to take the matter further, so it's that very limited question that I'm anxious to address.

I absolutely do not want the ring to be widened any further. So can I suggest this: that only those who are presently within the Hydrocortisone 2 confidentiality ring stay, plus Ms Stratford and her junior, and, as I understand, you have one solicitor who is already in the ring, and we can therefore keep matters pretty tight, and I can say what I need to say.

I'm not expecting, frankly, there to be any submissions from the parties today.

**MR BREALEY:** No.

**MR JUSTICE MARCUS SMITH:** Really all I'm trying to do is ensure that if, in the future, which I don't expect, but if in the future there are points to be made, everyone is on a level playing field with regard to their making them.

**MR BREALEY:** I understand.

**MS STRATFORD:** I'm in the fortunate position of having two juniors. I presume it's intended to include both?

**MR JUSTICE MARCUS SMITH:** Two juniors will be fine. We are all professional here and, Ms Stratford, you are coming rather late to this particular party.

I don't think it will take very long. Shall we rise for five minutes and see if we can knock this on the head before 1.15 and then we will have the afternoon free.

We will rise for five minutes, and then I will sit alone for the rest of the matter.

**(12.54 pm)**

**(The hearing in public concluded)**