IN THE COMPETITION APPEAL TRIBUNAL

Case No. 1251/1/12/16-1255/1/12/16

Victoria House,
Bloomsbury Place,
London WC1A 2EB

28 February 2017

Before:

THE HON. MR. JUSTICE ROTH
(President)
MR HODGE MALEK QC
DERMOT GLYNN

(Sitting as a Tribunal in England and Wales)

BETWEEN:

GENERICS (UK) LIMITED
GLAXOSMITHKLINE PLC
(1) XELLIA PHARMACEUTICALS ApS
(2)ALPHARMA LLC
ACTAVIS UK LIMITED
MERCK KGaA

Appellants

- and -

COMPETITION AND MARKETS AUTHORITY

Respondent

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HEARING

A P P E A R AN C E S

Stephen Kon and Christopher Humpe (instructed by MacFarlanes) appeared on behalf of the Appellant (Generics UK Limited).

James Flynn QC (Brick Court), David Scannell (Brick Court) and Charlotte Thomas (Brick Court) (instructed by Nabarro) appeared on behalf of the Appellant (Glaxosmothkline PLC).

Robert O'Donoghue QC (Brick Court), (instructed by Clifford Chance) appeared on behalf of the Appellant (Xellia Pharmaceuticals APS (1) Alpharma LLC (2)).

Sarah Ford QC (instructed by MacFarlanes) appeared on behalf of the Appellant (Actavis UK Limited).

Ronit Kreisberger (instructed by DLA Piper) appeared on behalf of the Appellant (Merck KGaA).

Jon Turner QC (Monckton), Marie Demetriou QC (Brick Court) David Bailey (Brick Court), Thomas Sebastian (Monckton), Ravi Mehta (Blackstone) and Elizabeth Kelsey (Monckton) appeared on behalf of the Respondent

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THE PRESIDENT: We are starting just after 10.00. We do have to finish at 4.15 pm today, so with the short breaks that is effectively about five hours.

If you can communicate that you have divided it equally between you so it is about an hour and a quarter each?

MR. TURNER: Yes.

THE PRESIDENT: Thank you. Yes Mr. Kon.

MR KON: I appear, sir, with Generics UK Limited with Mr Humpe, who I will refer to as GUK.

Given the relative shortage of time that we have, I am going to obviously refer to quite a lot of material and cases. I will not take you to each and every authority or piece of material, but insofar as I do not take you to anything and you would like me to, obviously I am more than happy to do so.

I would start by saying that unlike IVAX, about whom we heard a lot yesterday, GUK fought extremely hard to get onto the market with its own paroxetine product. However, as you know from yesterday, on 23rd October 2001 GUK was injuncted under the anhydrate patent because Mr Justice Jacob found there was a clear arguable case of infringement and GUK had failed to clear the way, as he put it. A landmark judgment which you have already heard something of.

As a result, GUK was restrained, injuncted, and to obviously break that injunction would have been a contempt of court, from disposing or offering to dispose of any pharmaceutical preparation containing paroxetine hydrochloride. So a very wide-ranging injunction in the usual terms in the Patent Court.

In addition, shortly thereafter, and this was the only case that this occurred that GSK brought such proceedings, GSK brought proceedings under the hemihydrate patent after the grant of the injunction, and that litigation was stayed pending the outcome of the anhydrate case.

You may ask why GSK did that. I suspect there were two reasons for that. Firstly because they had tested a product which they believe was substantially the same as our product in Australia and found traces of the hemihydrate in that product, and secondly because no doubt GSK saw the advantages of building up a litigation context over a period of time.

We say that those two factors, (a) the fact that we were injuncted, and (b) the fact that we had a double jeopardy in relation to the hemihydrate patent, are highly relevant to assessing the position of GUK. I would emphasise, of course, that I am only here to address the position of GUK.

THE PRESIDENT: Yes.

MR. KON: Now, how does the CMA deal with that in their decision? They say five months after the grant of that injunction on 13th March 2002, quoting from the decision, again materials you have seen:

"GUK was induced by value transfer" to settle and delay entry into the market.

That is the decision in paragraph 6.3 at page 240. I do not intend to take you there, I do not think it is in dispute.

Our submission in that regard is GUK was not induced as a result of a value transfer to re-enter the market. The evidence, we believe, is very clear, that it was not a value transfer that induced GUK to do so, it was a loss in any confidence on the part of GUK that it was going to be successful in the substantive patent proceedings that were due to come on, as you know, in the middle of March.

The key decision-maker in that regard for GUK was Mike Urwin, who has given evidence, was called by the OFT, as it then was, to provide further evidence on contemporaneous materials that are cited in our notice of appeal, paragraphs 3.22 - 3.23 of our notice of appeal.

What I thought would be helpful would be to take you to that contemporaneous evidence.

THE PRESIDENT: To the contemporary documents? Yes.

MR. KON: Absolutely. I will then go on and demonstrate how Mr. Urwin explained that contemporaneous evidence before the OFT, and he was so surprised by characterisation in the statement of objections of that evidence, as he gave it to the OFT, that he in fact made a further witness statement to clarify what he meant.

I obviously am alive to the questions you have raised concerning the probative value of different forms of evidence. I believe the evidence here is consistent and strong, that GUK settled because it was going to lose the proceedings.

THE PRESIDENT: But you are not calling him here?

MR. KON: No, we have not. But equally, we believe that there is nothing in the CMA's decision to throw doubt on the credibility --

THE PRESIDENT: Is there any reason you could not have?

MR. KON: One of the reasons is that Mr. Urwin obviously has not been available to GUK for many years. He has not worked for GUK for ten years. He obviously was tracked down, literally tracked down because he is a South African national, and in the end we decided that the evidence which he gave to the OFT speaks for itself and it is not adequately contradicted other than on the basis of inference by the CMA in its decision.

May I take you, first of all, to an email from Mr. Urwin of 12th March 2002. The full reference is bundle {A2/15F/1}. As you will see, this is an email exchange. If you go over the page {A2/15F/2}, there is some correspondence between Eddie Hart, who was one of the managers of GUK, and Mike Urwin.

One of the questions that arose was, it was at the time when the settlement negotiations were taking place before the settlement agreement was concluded, but at a late stage in the final negotiations with GUK, and one of the questions that arose is, well, we are committed to Sumika, whom you referred to yesterday, sir, and how do we deal with Sumika if we are going to settle with GUK?

I will not take you throughout the email, it speaks for itself, but if I may refer you to the email which is on the other side, which is the email to Richard Saynor, and you will see it starts with the word "Sumika". If you go down seven or eight lines, it starts:

"Bear in mind ..."

This is what Mike Urwin is saying at the time to a senior individual, Richard Saynor, who was actually the managing director of GUK.

THE PRESIDENT: This is a reply, is it?

MR. KON: This is to Richard Saynor and it is following on from the Eddie Hart exchanges, but it is essentially a new email to Richard Saynor. But it is in the same trail, if you like. It is in the same email exchanges that the Eddie Hart email forms part of.

You can see various people have been forwarded on various email chains.

THE PRESIDENT: Give me a moment to follow it.

MR. KON: Sure.

THE PRESIDENT: It starts with the Steve Self to Eddie Hart, does it, early in the morning?

MR. KON: There is an email to Eddie Hart on the next page which was sent to Mike Urwin.

THE PRESIDENT: One second --

MR. KON: He raises the issue of Sumika.

THE PRESIDENT: "... an expectation of ongoing business ... we have to keep them in the loop ...

"... what are we going to do about Novartis ..."

MR. KON: Which is a completely unrelated issue. I must admit I do not know what that is related to.

THE PRESIDENT: It is not related to --

MR. KON: I do not think it is other than, as you know, the CMA puts a heavy emphasis on the fact that this email was simply pretextual and it was simply a way of determining not that it

was felt by Mike Urwin that he had very little choice but to settle, but rather it is in the context of discussions with Sumika, and so that was included in the email exchange.

THE PRESIDENT: He says:

"I would like to be better informed on what you are doing with GSK."

MR. KON: Yes. I mean, Eddie Hart is saying what is going on.

THE PRESIDENT: Because Steve Self is --

MR. KON: Is in the R&D team of GUK.

THE PRESIDENT: Then the next one is following on from that.

MR. KON: To Richard Saynor, to whom all of these people report.

THE PRESIDENT: He is the managing director, is he?

MR. KON: Yes. From Mike Urwin, and I think it is worth saying, and it is an important question, Mike Urwin is the decision-maker in the Merck Group. He is the person who takes the decisions. He is the person to whom the R&D team are reporting, the commercial team are reporting, the lawyers are reporting and the internal patent officials within GUK are reporting.

The paragraph obviously that I want to take you to is the paragraph starting "bear in mind". He talks about Sumika, he talks about the fact that they will need to compensate Sumika because they have been committed to Sumika in the event that they were able to market the Sumika product, and he says -- may I go there, sir?

THE PRESIDENT: Yes.

MR KON: "Bear in mind that the only reason we are contemplating a distribution agreement with GSK is because there is a real chance we may not prevail in the courts ... and Sumika need to understand this very clearly."

In other words, what he is saying to his MD and the rest of his team to whom this is copied is: we have little choice but to settle with GSK and it is important that Sumika understand that. He is not in any sense resiling from the fact that some form of compensation needs to be paid to Sumika, but it is not an excuse for Sumika, it is an explanation of why GUK is settling.

We shall see in a moment what the CMA makes of that, but we believe this contemporaneous email speaks for itself in terms of the reason why, at this late stage, Eddie Hart is being told, together with Richard Saynor and others, look, we have no choice --

THE PRESIDENT: He is not saying we have no choice, is he?

MR KON: He is saying we are contemplating this because there is a real chance we may not prevail in the courts --

THE PRESIDENT: But I do not think it shows we have to. Any litigant, as you know well, they never get advice: you are bound to win. There is always a real chance you may not succeed, whether it is this appeal you are conducting now or anything. There is always a chance.

MR. KON: There is a chance, there is a real chance. May I take you to the rest of the email correspondence?

THE PRESIDENT: Yes.

MR. KON: This is the head of a company who has been litigating for nine months for GSK, who has, to some extent, put his reputation on the line in taking them on. First of all, he has been injuncted back in October. Now he is clearly of the view that there is a real chance that he is not going to succeed in the litigation.

Let me move on.

THE PRESIDENT: I can't imagine he ever thought there was not a real chance unless you were pointing to advice that told them you are bound to win.

MR. KON: Let me take you to the top of that email.

THE PRESIDENT: Which is --

MR. KON: This is an email sent to John Montgomery from Eddie Hart as well. Sorry, from Mike Urwin as well. This email is an email which has gone to John Montgomery, because John Montgomery is, within the Merck group, in Australia, the supplier, as I've mentioned to you, who are going to supply the active ingredient, the raw material, to GUK.

He says:

> "In case nobody else has been keeping you informed, discussions with GSK have restarted re the above. We have a real concern that we may not prevail in the patent case ..."

I emphasise that Mr. Mike Urwin is not a lawyer:

> "... so a settlement ... [seems] to be the best way to go - provided the numbers are right."

Much is made of those words and I will talk to you about those words in a moment. He is reiterating the fact that in his view there is a real prospect of not succeeding in the litigation.

If I may take you to a further email which is actually post the settlement, but very shortly post the settlement. It is an email to Cecil Taitz, dated 12th April 2002. It is to be found in bundle {A2/15H/2}.

If I may take you to --:

> "Re your proposal [Alpha cut of paroxetine] ..."

He is giving all the reasons again why we need to think, ie GUK need to think, how to deal with Sumika.

He said:

> "I think they are making some form of proposal," this arises out of the compensation, "so we cannot react until we see that."

This is after the settlement:

> "Meanwhile, the following to consider with them ..."

Going to (c), I think the rest is not relevant:

> "We were injuncted - and may never have prevailed ie there was a risk that we might never have launched in the UK [hence the settlement]."

Of course you can say it is equally arguable that they may have prevailed, but what was Mr. Urwin as the decision-maker thinking both immediately before and after the settlement? Clearly he is of the view, based on the advice he received from all those I have already referred to, that they are not going to prevail in the litigation. Whether one discounts that evidence on the basis that he may have won, but to argue that there was not a real possibility of GUK having invested for nine months in this litigation, we say this paints a very coherent picture. One particular aspect of this that I would refer you to, this same email, point (e), he says very clearly as the commercial person in charge of this:

> "We would not have launched at risk - which means a launch probably December 2003 earliest."

Do you see that, sir?

THE PRESIDENT: Yes. I do not understand that, because I thought that if you had not been injuncted you would have launched.

MR. KON: No. We would have launched at risk at the time immediately prior to the injunction. What this evidence shows, we submit, and it is clear --

THE PRESIDENT: But that would have been a launch at risk.

MR. KON: That would have been a launch at risk, but this is written nine months after the grant of injunction.

THE PRESIDENT: Just pause there. So at the time before the injunction was granted, that is the basis --

MR. KON: We do not resile --

THE PRESIDENT: -- you were preparing to launch?

MR. KON: We were preparing to launch and we would have launched at risk, and the injunction itself --

THE PRESIDENT: Obviously the injunction stopped you launching, that is clear. But what is the significance of the injunction in the settlement? I do not understand.

MR. KON: Perhaps jumping ahead to what I was going to say --

THE PRESIDENT: Sorry, I do not want to take you out of order.

MR. KON: I am perfectly happy to do that. The injunction suggests the following, and we say the evidence is quite compelling in that regard.

Firstly, it is quite clear that the injunction, even if, quod non, we would have been successful in the litigation in March 2002, it is almost certain, and we say ex post the evidence is clear, that that injunction would have continued in place for a considerable period of time pending the exhaustion of the appeals process. Firstly.

Secondly, we say that in the event that we were to be successful in the litigation, it became very clear to Mr. Urwin that GSK would have continued the fight and GUK would of course have been liable for a very substantial sum in damages in the event, as indeed occurred, again with the benefit of ex post knowledge, if in the event that the anhydrate patent had been upheld in whole or in part, because of course we would have been infringing the patent at that particular point.

THE PRESIDENT: Sorry, you were saying if GUK had been successful in the litigation.

MR. KON: Yes.

THE PRESIDENT: In other words, you were found not to infringe.

MR. KON: Correct.

THE PRESIDENT: Then GSK would have continued the fight.

MR. KON: Would have continued the fight, and as you will see if you look throughout the litigation, even when GSK have been wholly or partly unsuccessful in the litigation, it retained the right, and indeed in some cases Mr Justice Pumfrey granted the injunction, the injunction was extended pending the appeal.

THE PRESIDENT: I am sorry, I thought that is your first point. The injunction would have continued in place to the exhaustion of the appeal? It is the second point I did not understand, where you say if GUK had been successful --

MR. KON: But ultimately GSK were to overturn that successful judgment on appeal. In other words, if the patent, for example, had been, as occurred with the BASF, invalidated in part but validated in part, in other words part of the patent -- and then subsequently that was upheld and it was found that GUK had infringed the valid part of the patent, it would have been liable for a very significant sum in damages to GSK because it would have been infringing throughout the period that it had been marketing the product.

THE PRESIDENT: These are alternatives, you mean?
MR. KON: These are all alternatives, absolutely, but the combination of those two factors --
THE PRESIDENT: But it is the same --
MR. KON: It is not the same, sir, with respect.
THE PRESIDENT: If litigation had gone on, one assumes the result on validity would have been the same as it was. There was a judgment, the trial went ahead, your client did not take part, but it is hard to think that GSK would have done better at the trial if it had faced the opposition of your client as well as BASF.
MR. KON: I suppose that depends on the skill of our advocacy.
THE PRESIDENT: I say it is hard to assume the result would have been worse for GUK, better for --
MR. KON: One would hope that were the case, but it is speculative.
THE PRESIDENT: If you face two opponents, or your advocate was Richard Arnold --
MR. KON: Having said that, sir, we did not have the same product and so it was possible.
THE PRESIDENT: The validity of the patent did not depend on your product.
MR. KON: Agreed.
THE PRESIDENT: So the result could have been the same on validity.
MR. KON: Correct.
THE PRESIDENT: Yes, that is what is I am saying. So it is the process claim. We do not know what the result would have been on infringement because it was not argued, and that (inaudible) product. There would then have been, irrespective of the result, an appeal. We know when the judgment came, because there was a judgment, there was a trial --
MR. KON: Mr Justice Pumfrey's judgment or the --
THE PRESIDENT: Yes. If there had been, you say the injunction might have continued, probably would have in this --
MR. KON: Almost certainly.
THE PRESIDENT: That seems to me reasonable. Again, nothing is certain, as you say, but highly likely an expedited appeal. This was a speedy trial because there was a generic waiting to enter, fairly standard, expedited appeal.
MR. KON: Still a number of months, quite a few months.
THE PRESIDENT: So it probably would have been about another five or six months.
MR. KON: At least.
THE PRESIDENT: Well, that is looking --
MR. KON: That is more or less --

THE PRESIDENT: What expedited patent appeals were at that time.

MR. KON: Yes.

THE PRESIDENT: So that was the situation then. That is what they faced.

That would have taken it to some time in early 2003.

MR. KON: Well --

THE PRESIDENT: So that is the effect of the injunction. Of course it meant you could not launch at risk in 2002. Equally, it meant that when you might launch you would not be at huge risk. You would know what the position was, which has great commercial benefits.

MR KON: I mean, insofar as you are saying, you saw Mr. Urwin's assessment, December 2003?

THE PRESIDENT: This is what he says --

MR. KON: In April --

THE PRESIDENT: -- what to say to Sumika, is it not? The following to consider --

MR. KON: Well --

THE PRESIDENT: How we should present our position to Sumika.

MR. KON: "Meanwhile the following to consider with them ..."

THE PRESIDENT: Yes. Your client has to go back to Sumika who were expecting a big order and explain why it is they are not going to get it and what the position is, and he is suggesting this is how we can do it.

MR. KON: There is nothing to suggest this is pretextual on the part of Mr. Urwin at all. There is nothing to suggest that Mr. Urwin is doing anything more -- and this is where his evidence to both the OFT and his subsequent witness statement I think is relevant.

THE PRESIDENT: I just do not understand on what basis he says "December 2003 earliest".

MR. KON: On the basis of the advice that he has received, because as I said, Mr. Urwin is neither a lawyer nor a patent expert.

THE PRESIDENT: But we are not seeing that advice. You are not disclosing it to us, are you?

MR. KON: It has not been disclosed.

THE PRESIDENT: You are free to disclose it if you want to.

MR. KON: But there you have it.

THE PRESIDENT: Yes.

MR. KON: Perhaps I could take you, albeit that it is obviously an explanation after the event, but I think it is worthwhile going now to Mr. Urwin's witness evidence to the OFT when he was asked by the OFT to explain this.

Again, there is no reason to believe that Mr. Urwin is in any sense not being entirely candid and honest with the OFT in relation to what these emails mean.

THE PRESIDENT: Yes, we make some observations about that.

MR. KON: Helpfully, I have just been passed the details of the anhydrate appeal date. The actual date was 25th June 2003.

THE PRESIDENT: Of course because it was not expedited because there was no injunction. It was not an expedited appeal, Mr. Kon, because there was no injunction. At that point you were --

MR. KON: But it does not --

THE PRESIDENT: You do not get an expedited court appeal save when there are strong reasons for it.

MR. KON: But does that not assume the outcome of the litigation, sir?

THE PRESIDENT: No, not in the least.

MR. KON: Because --

THE PRESIDENT: No. They got an interim injunction against you on classic American *Cyanamid* principles on the basis that, yes, we will grant an injunction on balance of convenience and we will have a speedy trial, so the injunction will not last too long, six months.

MR. KON: Yes.

THE PRESIDENT: In fact, the trial did not take place, as far as you were concerned, because you then settled. If you had won the trial, you say -- and I understand -- GSK would have said, well, we want to continue the injunction because we are going to appeal.

MR. KON: Yes.

THE PRESIDENT: And there is a fair chance on the same basis they would have got it. But, again, on the basis then that the Court of Appeal would have said yes, because an injunction is in place, this will be an expedited appeal with an early hearing date. But that was not the basis of the BASF appeal, because the BASF was a pure validity claim; there was no infringement, there was no injunction. It was not an expedited appeal.

MR. KON: I am not best able to speculate how long the appeal would have taken to come on. The one thing I would remind you, sir, is that we were still being sued under the hemihydrate patent, and that had remained stayed pending the outcome. So no sooner would GUK have been liberated by a Court of Appeal judgment in the scenario that you are painting to me, that GSK would have then returned under the hemihydrate patent -- we are the only party to have been sued under the hemihydrate patent -- and it would have all started off again.

The evidence shows quite clearly that there was a very serious concern on the part of GUK that it also infringed the hemihydrate patent, and that is corroborated by Vivien West in the evidence given on the part of GSK.

THE PRESIDENT: Can you show us the GUK evidence on the hemihydrate? You say there was serious concern.

MR. KON: Yes, I will take you to {A2/15D/1}.

This is Mr. Rosenberg who was involved in the patent litigation, and he says --

THE PRESIDENT: He was your head of patents; is that correct?

MR. KON: Correct. He was the in-house patent lawyer. Actually not a lawyer. In-house patent agent, forgive me.

THE PRESIDENT: Yes.

MR. KON: This is an email which says:

> "Whilst I am confident of winning in the long run ... that is the operative word ... long. GSK will delay, if they can, when it suits them and alternatively push for deadlines to give us pressure. Obviously we will have to cope with all of this ... and ultimately we will win ..."

Without giving evidence myself, I know Mr. Rosenberg well enough to know he believes all patent challenges will ultimately win.

Now he goes on to say:

> "... the anhydrate patent is invalid, we can prove that now."

He was partly right and partly wrong on that:

> "... the tablet patent is invalid or could be restricted to hemihydrate only.
>
> "... the hemihydrate patent is more difficult to knock out, but possible. If GSK argue that there are traces of hemihydrate in our product ..."

Ms. West has already given evidence on this, as we have said, in her witness statement, making it clear. Paragraph 61 of Ms. West, if I remember correctly. She makes it clear that they had found traces of hemihydrate in the Australian equivalent product:

> "... whilst again I think we can win it could take a long time going through appeals etc to get the landmark ruling that something less than 1% is irrelevant," that is the issue in the hemihydrate, what is the percentage of hemihydrate in the patent, "in each country."

What he is saying there is clearly we go out of the frying pan into the fire here, because even if whenever one speculates the appeal would have been heard, we then go straight into the hemihydrate litigation and that is precisely why I believe, although I risk giving

evidence myself here, but that is precisely why the December 2003 date is perfectly possible. Because if GSK at that point, let us say in December 2003, crank up the hemihydrate litigation, which we have seen evidence from them to say they would, there is no doubt that they would be able to protract the litigation for a very considerable period of time.

It is worth bearing in mind that we are, so far as I recall, the only party to have been sued on the hemihydrate patent, and that is because --

THE PRESIDENT: I think Alpharma --

MR. KON: Was Alpharma? They were, forgive me. Alpharma was also --

THE PRESIDENT: And then GSK dropped it.

MR. KON: Well, ultimately because pursuant to the settlement.

THE PRESIDENT: No, they amended their claim.

MR. KON: I am sorry, you are talking in relation to Alpharma.

THE PRESIDENT: Alpharma.

MR. KON: I am sorry, I thought you said GUK.

May I take you, if it were helpful, to the evidence given to the OFT by Mr. Urwin. It is at {A4/62/33}.

This is where Mr. Urwin is being pressed in the same way that you have been pressing me.

THE PRESIDENT: I am sorry, the date of the document is?

MR. KON: The date of the document is -- it is an interview that took place on 17th December 2012.

THE PRESIDENT: Yes, thank you.

MR. KON: Dan Moore of the OFT is pressing Mr. Urwin in relation to some of the contemporaneous emails that we have been looking at.

He says:

> "... did somebody come to you ..."

This is Mr. Moore seven or eight lines down:

> "And I am just trying to understand sort of, did somebody come to you with a percentage chance of winning for example?"

If you will forgive me, I will not read the rest of it because I am conscious time is marching on. I want to take you to Mr. Urwin's response to that:

> "I mean there's always a chance that you are not going to prevail, that is true, but not one that is specifically identified to a weakness in the product formulation. I mean you can lose because the jury or the judge or somebody else is persuaded that your

argument's bad and the brand's good or vice versa. But when something's identified, from my position of scepticism and conservatism that was bad."

So Mr. Urwin is acknowledging that he was sceptical and conservative in relation to the chances of actually winning, in particular in the light of what had occurred in the interlocutory proceedings.

THE PRESIDENT: This is what I do not understand. What is the relevance of what occurred in the interlocutory proceedings?

MR. KON: The relevance is there was a legal prohibition on GUK marketing the product. Secondly, GSK had --

THE PRESIDENT: Sorry to interrupt you. The fact that there was legal prohibition is just stating there was an injunction.

MR. KON: Correct.

THE PRESIDENT: But it does not affect the chances of outcome of the trial.

MR. KON: But in the meantime, again, as the evidence of Vivien West makes clear, the GUK product had been fully tested and the risk assessment had changed.

THE PRESIDENT: That is nothing to do with injunction.

MR. KON: It is to do with the reasons why we settled, sir.

THE PRESIDENT: Yes, I understand all that. It is just you keep referring to what happened in the interlocutory hearing. But that seems to me irrelevant. Things happened since, that is something else.

MR. KON: The evidence is clear that the injunction that was granted was a complete surprise to everyone. For eight years there had not been an interim injunction granted in a patent infringement action such as this. The judgment of Mr Justice Jacob, where he provided that you had to clear the way, clear the undergrowth, there was no precedent for that particular --

THE PRESIDENT: But that does not affect the merits of the trial, does it? It is simply an approach to the grant of interim relief.

MR. KON: Mr. Urwin is a commercial individual who is trying to form a judgment on the merits of, on the one hand, the offer being made by GSK to him to settle, and on the other hand, the risks involved in the litigation.

The injunction took away a significant amount of confidence because he believed, and all the evidence points to that if it is read fully, that he was going to win the injunction. He lost the injunction. In the meantime, GSK tested the GUK product and it was clear that there

may well have been an infringement of the patent, and in addition traces of hemihydrate were clearly there in the product.

THE PRESIDENT: I think I made it clear I understand the second two points. I do not understand the fact that Mr Justice Jacob came up with the idea that you ought to clear the way first if you want to avoid an interim injunction, has any bearing at all on the advice that your client would have had from its very experienced lawyers -- to whom, as you say, Mr. Urwin was not a lawyer so presumably he got legal advice, I am sure -- of the chances of winning at trial. Because the reasoning of Mr Justice Jacob was absolutely nothing to do with the merits of the case at trial.

MR. KON: Mr Justice Jacob, of course, could have found that the case was not arguable and therefore did not grant the injunction.

THE PRESIDENT: Mr. Kon, come on, with a serious allegation of infringement and validity, you cannot decide that on --

MR KON: I think --

THE PRESIDENT: The whole point of *Cyanamid* was that you cannot get into that sort of mini trial.

MR. KON: I agree, sir, but for Mr. Urwin a combination of these factors, including a hemihydrate exposure --

THE PRESIDENT: As I say, I understand the hemihydrate point but I do not see what the injunction has to do with it.

MR. KON: There we have it. I cannot put it in any other ways to you, other than to say that Mr. Urwin was looking at this from the point of view of risk exposure and risk assessment, and the risk assessment changed, and that is a very significant factor, we say.

THE PRESIDENT: Yes.

MR. KON: One can discount it, one can question it, but Mr. Urwin is very, very clear.

Let me take you, actually, to another paragraph. Let me take you to page 21 of the same document. It may explain further exactly what Mr. Urwin was thinking as regards the relevance of the injunction.

He says {A4/62/21}, internal 20, at the very bottom of the page:

> "I mean yeah, so just to elaborate one step further, my thinking probably at that point was, that if a judge believed that an injunction was appropriate, that he would have leant towards the GSK case rather than to ours. Therefore, my sort of ... my summation would have been, our case is weaker than I first thought. That is probably how I interpreted the injunction."

THE PRESIDENT: Sorry, I am not sure I have quite --

MR. KON: It is at the very bottom --

THE PRESIDENT: Bottom of page 20, yes.

MR. KON: It goes over to 21.

THE PRESIDENT: Yes, sorry. Give me a moment.

MR. KON: Sorry, it is not altogether easy to follow in these documents when they go over.

(Pause)

Perhaps I could take you also to the preceding paragraph on page 21, starting "when we got the injunction".

{A4/62/21}:

> "- when we got the injunction. The whole litigation ... is a fragile process. This would have been ... although this was not directly involved in that, it was part of the whole ... so an injunction definitely would have had a negative consequence and ... made me more risk averse."

So it is really consistent with what I was saying to you earlier, but it changed his risk assessment. None of this at all is referred to by --

MR. MALEK: Shall we look at the passage on the next page {A4/62/22}, which we looked at earlier. The top of the page has the word "summation".

MR. KON: Yes.

MR. MALEK: "... my thinking at that point would have been, I think, I think my thinking would have been, that to achieve an injunction, the company seeking the injunction would need to put up a case which suggested that they had a strong patent position."

That may have been his reasoning.

MR. KON: Yes. So we have an individual here who is taking the decisions, who says by his own admission that he is conservative, he is risk averse and his confidence has been knocked significantly by the grant of the injunction, who, in addition, is being sued under the further patent which would extend the litigation, by his own contemporaneous evidence, until December 2003 at the earliest. Indeed, that date is not fanciful when one looks ex post at actually when things started to change, both settlement agreements.

Therefore, he took the view that to be off the market from March 2002 with, of course, bearing in mind the Norton IVAX was on the market and was making significant headway in the generic market, was too much of a risk given the potential for him ultimately not being able to come on to the market in December 2003.

That is the way, I would submit to you, that commercial people take commercial decisions to settle litigation. As we are going to submit to you, that is also a very significant factor in viewing this evidence and the Sumika point, sir, that you raised. If I may go to that.

Mr. Urwin read in the statement of objections -- I will not take you to it unless you wish me to -- the OFT's understanding of the email exchanges that we looked at earlier in relation to Sumika, and he was outraged, frankly, by the characterisation that was put on it.

As a result, he felt compelled, in order to correct the record and correct the interpretation, which is the same interpretation that you have put to me and that the CMA put in the decision, that this was really all he was trying to do, was to overstate the litigation risk to Sumika in order to serve a commercial purpose for himself.

I mean, as I say, he was disappointed that without any suggestion in his own evidence that that was the case, that the OFT should have put it to him. This is what he said in his witness statement in relation to that.

If I could take you to {A2/6B/4}, please.

At the bottom of the page, paragraph 12 --

THE PRESIDENT: The date of this is?

MR. KON: The date of this is 25th July 2013. So it was after the statement of objections had been issued, after he had given his own witness evidence to the OFT, and obviously ten years or so after the events concerned.

He says:

> "I am advised that the OFT believes that in my email to Cecil Taitz I would have wanted to overemphasise the risk that GUK would not have won in order to present to Sumika a position that best benefited GUK for the purpose of upcoming negotiations regarding how much GUK should pay Sumika to compensate it for no longer requiring API from it."

That is the active ingredient:

> "I do not understand how the OFT would have reached such a conclusion. I do not recall having suggested at the time that we needed to overemphasise the risk position to Sumika. Rather insofar as we were going to have any negotiations with Sumika, I would simply have wanted to make sure that they understood the position we were in and why we had decided to settle."

Now, this evidence is not addressed at all in the CMA's decision. The CMA make no endeavour at all to rebut that evidence, to call Mr. Urwin back themselves, to question it. I

submit to you that this is good evidence and it is evidence upon which we are entitled to rely before you, sir, going back to your question as to why we have not called Mr. Urwin. Then, equally, in relation to the same witness evidence, Mr. Urwin again gives evidence in his witness statement, the same witness statement, but if I could take you now to page {A2/6B/4} of that witness statement in the same document, but going back to page 4 in that document.

He goes on to say, if I can take you to paragraph 9, about halfway down:

> " I am advised that the OFT ..."

This is the John Montgomery email which, again, he believes was mischaracterised in the SO:

> "... as showing that my confidence was such that I would only contemplate settling if GSK offered 'a sufficiently high value transfer' ..."

That goes to my first point:

> "The OFT's understanding is incorrect."

This, again, that explains fully what Mr. Urwin's thinking was albeit after the contemporaneous evidence, but nonetheless not challenged by the CMA in its decision:

> "I had a real concern that GUK would not prevail. As I explained during the interview, the risks of losing the litigation with GSK were too significant to play around with probabilities."

Perhaps that is something we are doing in looking at the litigation counterfactual, which I will come on to hopefully, although I see the clock is ticking.

> "I also noted that the litigation process could have gone on for years and that if there was any hemihydrate in our product we would have found it difficult to have prevailed. Therefore at that point my objective would have been to settle on the best possible terms with GSK. This is effectively what I said in my email to John Montgomery."

I am not going to repeat that, sir, because I have already been there.

This evidence, as I say, has not been rejected specifically. Indeed, in the case of the first piece of email I referred to of Sumika, it has not been addressed at all in the decision.

So we say, ultimately, one other point I would make is a point that the CMA makes in its defence, I can refer you to the paragraph of the defence but I do not think it is in dispute, that GUK turned down a number of settlement offers and therefore it was confident in its position.

Anyone who makes that sort of submission clearly is not used to commercially negotiating. The way one commercially negotiates is to try and push back and never, of course, as we are about to find out of course in our Brexit negotiations, come up with your best offer first. That is exactly what Mr. Urwin says he was doing. There was a window of opportunity. He became increasingly risk averse and he pushed it to the wire, in fact to the door of the court. That is a perfectly reasonable way for a commercial person to behave, and the suggestion that all he was doing was hanging out for a better value transfer and that, therefore, explains the rationale for the settlement is misplaced.

Of course he was looking for the best possible deal, but that does not mean the sole inducement for him entering into these arrangements was the value transfer, and we submit to you that the CMA is placing an interpretation on Mr. Urwin's evidence that does not bear scrutiny. He was seeking an agreement on the best possible terms. The CMA also make the point, as you know, as a counterfactual that perhaps there was a better settlement counterfactual. In other words, we could have held out for a better settlement whether it be a different form of early entry or some other better terms.

But something, sir, that I would submit to you strongly on behalf of GUK is that what we know now is that GUK could not have improved on those terms, because we know that IVAX had extracted from GSK a term that GSK would not grant any better terms to any other subdistributor than it itself had been granted.

Again, I can refer you to that. It is essentially the IVAX GSK agreement at clause 2.2. I do not think that is in dispute and I do not think Mr. Flynn would take objection to me raising that at this point. From a GUK point of view, what they did not know is that there was a limit to how far lawfully GSK could push those negotiations.

So what we say is there was no better terms counterfactual, and the consequence of saying that the terms which GUK obtained were not good enough is that the only way they were not good enough is if GSK had been forced, or was required, or is required as a matter of law to continue with litigation.

We say it is impossible to see how either of those options could have produced a better outcome.

THE PRESIDENT: There was not much time for better terms because the trial was about to start.

MR. KON: That may well have been right, but that is not the case being put against us by the CMA.

The CMA is saying it is the mere fact that Mr. Urwin actually was pushing and pushing and trying to get better terms in itself is evidence that all he was interested in was the value

transfer. You know our deal was the same volumes, the same price, exactly the same, more or less, terms as IVAX. We did not know that at the time, but that was the inevitable consequence of where the negotiations went because that is all that GSK could lawfully offer.

Sir, I am very conscious that I am going to run out time sooner rather than later, so if I may continue. There are a number of other submissions I would like to make. I suspect I am not going to get to make some of them so I am going to go through them.

What I would like to say is that the CMA's case has shifted remarkably during the course of these proceedings. We know that the burden of proof on the CMA is it has to show strong and compelling evidence, taking account of the seriousness of what is alleged and that we are entitled to a presumption of innocence. I do not think that is in dispute. That is *Napp* .

THE PRESIDENT: Yes.

MR. KON: I will not take you there, sir, unless you wish me to.

THE PRESIDENT: No.

MR. KON: Equally, in *Argos* it is clear that the CMA should not elaborate, embroider or adapt their case. They should not produce better evidence. That should not be the object of these proceedings. But the key, I think, is in *JJB*, where this Tribunal made clear that really what is key is that the evidence that is produced to these tribunals should at least be within the broad framework of the original decision.

What we say, sir, is that that is not the case here. The reverse payment, as we have already seen, is at the very -- is the fulcrum upon which the whole of the CMA's analysis is based, and that is the basis upon which a restriction by object is derived.

A restriction by object emerges clearly on the basis not least of all of Professor Shapiro's evidence, which is now before this Tribunal. We understand that Professor Shapiro was advising the CMA, but he is not referred to in the CMA's decision.

But really we now see a shift in that position in the first joint experts' report, where, as I believe Mr. Flynn mentioned, Professor Shapiro acknowledges that a value transfer in excess of avoiding litigation costs, which involves a supply agreement, requires further analysis before it can be seen to damage consumers.

Now, that is a fundamentally different position to the position adopted in the proceedings. Also, Professor Shapiro concedes in his first expert report, he says looking at the impact on direct customers is the most reliable, most straightforward and reliable way to assess competitive effects. That is not what the CMA say in their decision. In fact, they say the complete opposite. They say there is not much value in looking at competitive effects in

this because it is an objects infringement and, as was submitted to you yesterday by Mr. Flynn, essentially their effects case is nothing more than a recycling of their objects case.

As regards prices to pharmacies, something I think you raised yesterday with regard to what is the value of all this evidence on pricing to pharmacies, I think the important thing to recognise is that at paragraph 3.387 of the decision, what the actual decision says is there was no apparent price change following the entry of the generic companies. I am happy to take you there, sir, but given timing constraints --

THE PRESIDENT: 3.387?

MR. KON: 3.387. There was no apparent price change following the entry of the generic companies, and yet this is a position that even the CMA's own expert now resiles from in the second joint statement where Ms. Webster agrees that there was a decline of somewhere between 2.7 and 3.4% on prices to pharmacies.

But I am not focusing, as you suggested it would be an error to do so, on exactly what the quantum of the decrease was. But I am focusing on the fact that the CMA make it very, very clear that there was no price change, and therefore what we submit to you is that the CMA's decision and the evidence put forward to this Tribunal in particular in relation to objects infringement, because we say there is no significant effects analysis, in any event is fundamentally changed and we think that is a relevant factor based on the authorities I have referred you to.

I would now like to take you briefly to the position of GUK under the VAEO, what we call the error under the VAEO.

We believe, for all the reasons that Mr. Flynn submitted, and I am not going to repeat what he submitted, that the position on the VAEO is unsustainable. There is absolutely no basis for the CMA to have treated the GUK agreement differently to the way the Norton IVAX agreement was treated, and we are working on the basis that the Norton IVAX assessment is the correct assessment.

Both agreements were settlements. They were based on vertical supply arrangements. As Mr. Flynn submitted to you, GUK was actually one removed, was a subdistributor, not even a primary distributor.

The evidence shows that GUK and IVAX both told GSK that they had a product to distribute. In terms of potential competitors which was discussed yesterday, there is no difference. We both have marketing authorisations. Ours was in the UK and theirs in Ireland. While they may have had a different prognosis, a different assessment of the exposure under the patent originally -- as you put to me a short while ago, GUK was

initially perhaps more bullish than Norton IVAX. Nonetheless their position was substantially identical.

One of the points I would like to make to you is that the decision itself acknowledges that it was not envisaged that IVAX would bring in independent generic supply to coexist with this agreement.

If I could take you to one paragraph of the decision, or at least refer you to it, I think it is an important paragraph.

THE PRESIDENT: Yes.

MR. KON: The reference is {V/1/539}, which is the decision bundle and the decision itself.

I will try and avoid, sir, taking you through -- if you look at paragraph B.111 at the very bottom of that page, this is the decision:

> "Although the IVAX-GSK agreement did not contain any contractual commitment on IVAX's part not to launch an independent generic paroxetine, it is clear from the terms of the IVAX-GSK agreement that *[IVAX-GSK]* was not designed to coexist with independent generic entry by IVAX ..."

What we say is that, again, on that score alone, the CMA distinguish our position from Norton IVAX, yet it is clear on the basis of the CMA's own decision -- we are not now in the days of the Restrictive Trade Practices Act. We are in the days when one is looking around these particular agreements to see what in fact was the reality of the position, rather than the technical drafting of an exemption. Indeed, the fact that there is a horizontal element involved in the decision is no different to the block exemptions of the EU where a non-compete is very often block exempted.

So the mere fact there was a non-compete in the GUK agreement, which is primarily the reason why the CMA seek to distinguish our position from IVAX, it simply does not bear scrutiny. We say it was an accident of timing that GUK came second. We say instead of fighting very hard, as GUK did, if instead of that we had gone first and gone before IVAX and we had settled on the same terms that we had substantially settled on, we would have been in the position that IVAX was in, which was being exempt under the VAEO, and not actually being told that we are in a substantially different position, notwithstanding the fact in all material respects these agreements were the same.

We consider that is a compelling point and that this decision falls at that very first hurdle, and therefore in itself is legally unsustainable.

Sir, in the time I have got available there are three other submissions I want to make to you. I feel I may not make them, so forgive me if I speed up a little.

On the objects analysis, this is being addressed by counsel for Merck. I will not say very much about it, but what I do want to say is quite simply that the CMA no longer denies that some competition was introduced into the market as a result of this agreement.

That in itself makes it extremely difficult for them to sustain an objects analysis. Now, we accept the point that you made to Mr. Flynn yesterday, that of course it is open to the CMA to believe there were or are counterfactuals in which greater competition would have unfolded, but this cannot form the basis of an objects case. That is an effects analysis, as you yourself made clear yesterday.

If the CMA believes in a counterfactual of more competition then it must undertake a full counterfactual effects analysis. But that is exactly what they failed to do in this case. You only need to look at the position of wholesalers, which Dr. Majumdar is going to be giving evidence on in a few days' time, where it is absolutely clear that their own witnesses accept that there was significant competition at the wholesale level.

We say there is nothing in the nature and terms of the GUK agreement from which you can derive an objects analysis. I am going to leave it to counsel for Merck to actually address that.

THE PRESIDENT: I do not quite follow why the fact that some competition is introduced precludes an objects analysis, and if the object is you could have an agreement which wants to introduce only limited competition to avoid more extensive competition and that could have the object of restricting it, it does not have to be to exclude all competition, just conceptually.

Leaving aside the facts of this case, but just as a general proposition, the fact that an agreement introduces some competition does not preclude it having the object of restricting competition because you have the object of preventing any more competition.

MR. KON: I accept that, sir. I think what we say are two things.

Firstly, one does need to form the view as to whether the agreement by its very nature is restrictive of competition, and therefore that begs the question: is the competition purely trivial? Which is, of course, the way that the CMA put it in their skeleton argument.

We say on any basis this competition is not trivial. You heard from Mr. Flynn in terms of the effect on volume. We say in terms of prices. Dr. Majumdar finds, for example, in his evidence that there is a 14% reduction in the price of paroxetine to wholesalers.

The CMA's own witness, Professor Shapiro, makes it absolutely clear that once you find upstream that an element of price competition is introduced, you need to look at it downstream. But all of these are effects analysis, they are not objects analysis.

So what we say, the tension for the CMA at this particular point is its own evidence undermines its own objects case as well as our own evidence, such as the evidence of Dr. Stillman and Dr. Majumdar, which we believe is compelling.

I think I would summarise, given the passage of time, what we say in relation to this on objects is that we say, quite clearly, that an objects infringement does mean an irreversible presumption of anti-competitive activity.

It may be that within the anti-competitive activity no material increase in competition is one way one can look at it, but it does have to create an irreversible or irrebuttable presumption.

What we say emerges out of this case is a rebuttal presumption is the case that is being put forward by the CMA. Indeed, those are the words used by Professor Shapiro in the joint statement at page 13.6.

THE PRESIDENT: We have seen it.

MR. KON: I will leave it to you.

We say there is a fundamental difference in the case put forward now and the case that they put forward, and indeed, we think the decision was flawed without that evidence for the same reason. But on this basis, we say it is untenable.

In the few minutes I have available, and I think I have another perhaps 10 minutes or so --

THE PRESIDENT: Take another 10 minutes.

MR. KON: Until I am attacked by my fellow counsel.

THE PRESIDENT: Take another 10 minutes.

MR. KON: Many thanks.

If I may talk in terms of potential competition and our position as a potential competitor, we have one fundamental submission on that.

Firstly, we say the injunction of course foreclosed us from competition. We accept we were potentially competitive before the injunction, but as long as we were injuncted we say we were not any longer a potential competitor because it was legally impermissible for us to enter the market. We think the authority, which we cite in detail in all of our papers before you, the E.ON Ruhrgas case, is very clear.

THE PRESIDENT: So if you were potentially competitive before, suppose you write to GSK saying, "We have a product, we are intending to enter in three weeks' time", they then say, "Well, if you do that we will issue proceedings for an immediate injunction". You then reach a settlement so that those proceedings are never issued. At that point you are a potential competitor. If you do not reach an agreement, the injunction is sought and issued,

three weeks later you reach a settlement, then you are not a potential competitor. Is that the point you are making?

MR. KON: If I understand the proposition you are putting to me, I do not think there is anything in that fact set you have just put to me that makes it illegal for me to market my own product.

It makes it contractually impermissible, but it does not make it unlawful for me to market the product, if I have understood the factual.

Here, as in the E.ON case --

THE PRESIDENT: Never mind the E.ON case --

MR. KON: It is switching from one to the other.

THE PRESIDENT: Are you saying that is your submission, that if you settled in the two weeks before the case was heard, then you say --

MR. KON: Before the injunction is granted.

THE PRESIDENT: Before it is heard, therefore even granted. Before it ever gets to court. At that point you are a potential competitor, but if you settle two weeks later when it would be unlawful for you to enter, then you are not a potential competitor; is that the distinction?

MR. KON: My answer I think is that if the settlement is not contained in an order of the court such that it would make it a contempt of court for me to market my own product, I would agree with the proposition you are putting to me.

But when it is contained in an order of a court such that I could potentially be imprisoned for marketing my product, then I believe it is a fundamentally different proposition. I believe E.ON is consistent with that, because you will recall in that case there was a market sharing agreement where it was impermissible to enter each other's market in France and Germany respectively. That was found by the court not to be a potential competition scenario for the simple reason that it was illegal for them to enter into each other's market until the directive concerned became directly effective. When it did become directly effective then they were potential competitors, and that was what the court had said.

I want to say very little more about potential competition given the passage of time, other than, firstly, the temporary nature of the injunction.

We do not think that that goes any further in terms of making us not a potential competitor or making us in the CMA's eyes a potential competitor, because what it is doing is prejudging the outcome of the litigation. To say it is not a temporary injunction assumes it is not going to be made into a permanent injunction. Since the injunction, if it were to become permanent, would continue, and indeed if you look at the BASF litigation, the

scenarios we have been looking at, we know it would have continued for some period of time as well as the hemihydrate situation I have submitted to you.

I believe it is clear that the characterisation or the mantra that this was temporary does not actually advance the CMA's case at all, and we say to you very strongly that the injunction itself prevented us being potential competitors certainly for as long as it was in place.

I would accept that when the injunction was lifted the situation would change, but there was no certainty that that was going to occur.

On *Lundbeck* sir, I am going to leave it to Mr. O'Donoghue because he is talking on *Lundbeck*. I think he will be distinguishing -- a spurious distinction is drawn by the CMA trying to draw a comparison between a marketing authorisation and the injunction. I am sure that that is something that will be addressed by Mr. O'Donoghue.

Finally, on effects -- and I am conscious that I am now in the last chance saloon as far as timing is concerned -- I would like to just follow up on where Mr. Flynn was yesterday.

There is one fundamental point to emphasise. That is the clear statement in the decision -- and I quote from paragraph 7.2 of the decision:

> "Neither the controlled entry by GUK nor the controlled entry by Alpharma had a discernible impact on market prices for paroxetine."

Let us be clear what the position is of the CMA on this.

It is, as somebody I know who used to appear very often in cases such as this says, the position of the CMA is essentially you cannot be a little bit pregnant. It says there was no discernible impact on market prices for paroxetine. An unequivocal position. Therefore, it is now obviously, as I have said, accepting that there is a discernible impact on competition, and we would like to make two points and I think I will limit it to that given the passage of time.

Firstly, the CMA mischaracterises the evidence given by Dr. Majumdar in relation to potential competition, and I refer in this context to paragraph 46(c) of the CMA's skeleton argument.

Dr. Majumdar has never claimed, and I do not think any party has claimed as such, that making supply agreements with generics in and of themselves necessarily improves the process of competition. Nobody has submitted that to you, the mere fact that you conclude those agreements. What Dr. Majumdar says, and this is where I am afraid the skeleton argument of the CMA is in error, consistently, and I believe this is consistent with the evidence given by Dr. Stillman and all other witnesses on the economic side of the case for the appellants, is that because the settlements and the agreements in general caused an

increment in competition relative to a no entry scenario, relative to a no entry scenario, the CMA was required to weigh up the immediate gains from entry against the possibility of gains at a later date.

Those gains could only arise if GUK won the litigation and would not arise obviously if GUK lost the litigation. This would have required the CMA to form a view on the length and the outcome of the litigation, the basis upon which GUK would have been able to enter the market in the event that it had won the litigation.

Dr. Majumdar also explains that none of this important analysis is something that has been undertaken in the decision, and in fact we would go as far as to say -- I refer you to paragraphs 42 to 48 of Dr. Majumdar's initial witness statement -- that this is a material omission which is fatal to the CMA's analysis because it just does not engage with the question.

We say, for reasons I have already submitted to you, that the object case fails and we say that the effects case does not get to first base. Therefore, in our submission, the effects case does not equally bear scrutiny.

Ms. Webster and others on behalf of the CMA come up with all sorts of explanations outside the decision to try to justify why this obvious movement in pricing both at the wholesale end and at the pharmacy level and at the NHS level, why they are not relevant, and in each case she departs from the decision.

She departs from the decision, she acknowledges that there was a decline in the average price at 20mg being paid by the pharmacists in her joint experts' report. She tries to argue that this was because wholesalers had faced different costs in having to deal with paroxetine products of different origin. No evidence to that effect. She deviates from what the CMA says in relation to parallel imports. She says the parallel import price is overstated in the decision.

So it is a rather strange situation that two of the experts put forward by the appellants are actually supporting the price put forward for parallel imports in the decision. Yet the CMA's own witness is saying it is wrong, and that is because she is trying desperately to explain how these price movements that I have referred to are to be explained.

She then comes up with two other arguments, saying it is a result of the overall decline in the market for paroxetine and, again, that is not the correct test. The correct way of assessing whether there is an overall decline in the market for paroxetine, if that is a relevant factor, is looking at what that decline would have meant with and without the settlement agreements.

But Ms. Webster does not do that. She just makes a point that there was an overall decline in the market for paroxetine, and therefore this must have had some impact on overall pricing.

Finally, she draws a distinction between open and closed prescriptions, which again is new evidence, and actually we do not see where it actually gets her.

So to summarise on effects, it is apparent from all I have said and others are going to say, I suspect, that the CMA has failed to establish that the settlement was unlikely to cause, and did not in fact lead to, a reduction of prices, that they have simply failed to show that. In fact, their own witnesses say otherwise.

This also means that the CMA has no basis to contend, which is essentially how it puts its case, that any counterfactual would undoubtedly have resulted in more competition. We say, and I think this is entirely consistent with what you said to us yesterday, the only way for the CMA to establish anti-competitive effects in such circumstances was to articulate a valid and realistic counterfactual, and in that counterfactual it would have to show that more competition was likely to have emerged.

I think that is almost word for word what you said yesterday, notwithstanding that it was drafted before you said it.

This is what we say the CMA has fundamentally failed to do in the decision. Because it has proceeded on the premise that it was not necessary in this case to have undertaken anything more than what I would refer to as a perfunctory counterfactual analysis. For that reason, in addition to all the other reasons I have submitted to you, this appeal should be upheld.

THE PRESIDENT: Thank you very much for keeping to pretty much time, given that I interrupted you several times.

We will now take a short break.

(11.20 am) (A short break)

(11.30 am) Opening submissions by MS. FORD

THE PRESIDENT: Yes, Ms. Ford.

MS. FORD: Sir, I am dealing with the facts from Alpharma's perspective, and I am also proposing to look across at the account of the facts that is given in the CMA's decision, because in our submission there are aspects where the CMA has fallen short of setting out a full and impartial account of the factual circumstances. We say that that omission then feeds across into the way the CMA assesses the legality of the Alpharma-GSK agreement.

Alpharma started taking steps to enter the paroxetine market in 2000 and 2001, and it sourced its paroxetine product from an Icelandic company called Delta. The active ingredient of the product came from BASF. It also obtained --

THE PRESIDENT: Sorry to interrupt you. Because I was just puzzling over that. The paroxetine hydrochloride API came from BASF; is that right?

MS. FORD: Yes, that is right.

THE PRESIDENT: Then it went to Delta in Iceland; is that right?

MS. FORD: Yes.

THE PRESIDENT: They produced the salt that went into -- and produced the tablets; is that right?

MS. FORD: I think I am right in saying the salt is what came from BASF, that is the active, and it is Delta that then form it into tablet form.

THE PRESIDENT: But they do not just do the tableting, they do a bit more than that: they do part of the process, do they not? Because what I was trying to understand is the inspection that was ordered in the proceedings was at Delta's plant in Iceland, it was not at BASF's plant.

MS. FORD: I think it was initially contemplated that it would be at BASF's plant and then at some point it was felt that actually the focus shifted to the Delta plant. The question was whether at any point in the process they had used a displacement step in order to displace the solvent.

THE PRESIDENT: But that would not be just making tablets obviously, that would be producing the material that was then tableted, I would have thought.

MS. FORD: I think at one point it was felt that the solvent might be displaced at the tableting stage, but really the enquiry was somewhere in the process had there been this displacement step which then caused the infringement of the process claim.

THE PRESIDENT: Yes, thank you. Sorry to interrupt you, but I was a bit confused by it.

MS. FORD: Sir, I was setting out the steps which we took to enter, and in our submission those steps were taken on a very specific basis and that was Alpharma's anticipation that BASF would succeed in invalidating the anhydrate patent and then they would clear the way for Alpharma then to enter.

Alpharma did not intend to enter at risk. Its strategy was always that it would only launch its paroxetine product after the anhydrate patent had been invalidated. We can see that from three places on the contemporaneous documents.

The first one is bundle {A9/184/5}. This is the witness statement of Tomas Norling of Alpharma ApS, which was made in the context of the GSK infringement proceedings against Alpharma.

If you turn on to page {A9/184/7}, at paragraph 8 you can see he explains:

> "BASF have also brought an action in the UK for revocation of ..."

That is the anhydrate patent:

> " ... and I understand that judgment in that case is expected very soon."

He then goes on to say:

> "On the assumption that validity would have been determined by now, Alpharma made preparations to market its version of the drug."

Then right at the end of this paragraph:

> "If the validity of the Form A patent is upheld at first instance the present policy of Alpharma is that it will not market its paroxetine hydrochloride product in its present form while that patent remains in force."

THE PRESIDENT: I am sorry, the date of this statement is?

MS. FORD: This is at the beginning of the Alpharma proceedings, 21st June 2002.

THE PRESIDENT: Thank you.

MS. FORD: If we turn on to page {A9/184/15} in this same tab, you see a draft statement from Andrew Collier. It is, in our submission, symptomatic of the delay in bringing these proceedings that we are working on an incomplete documentary record. So there are occasions when we are obliged to rely on drafts. You can see it is provisionally headed July 2002 in terms of the date.

If you turn in this witness statement to page {A9/184/17} to paragraph 7, he says:

> "Once we had obtained [it says produce but it should presumably be product] licence from the Medicines Control Agency it was Alpharma's intention to launch a paroxetine product as soon as the BASF decision (which I understand was the decision challenging the main patent covering paroxetine) was known."

He is again saying we are awaiting the outcome of the BASF litigation before launching.

The most candid statement to the same effect is in instructions to counsel, bundle {A4/63/1}.

Sir, these are instructions on behalf of Alpharma to counsel. If you turn to page {A4/63/3} in this tab, second paragraph from the bottom, you can see that counsel is told:

> "Alpharma are in a position to launch almost immediately following judgment in favour of BASF."

If you turn over then to page {A4/63/5}, the second full paragraph after the bullet point, you can see a clear statement:

"The reality of it is that Alpharma will not sell the product if the Form A patent is valid (they would not be allowed to) ..."

In my submission --

THE PRESIDENT: These were instructions to? What is the date of the instructions?

MS. FORD: It is in the Alpharma litigation. 13th June 2002. So we are talking just before the dates of the witness statements we have just looked at.

THE PRESIDENT: 13th June. So it was before the hearing, that is the first hearing, which led to the order for delivery of samples?

MS. FORD: That is right, yes.

THE PRESIDENT: Yes.

MS. FORD: Sir, in my submission, it is clear from those three documents that Alpharma was only prepared to enter the market once the anhydrate patent had been declared invalid.

The Tribunal has had the opportunity to read the CMA's decision covering this period. You see, for example, bundle {V/1/134}, an account of Alpharma's commercial position in relation to paroxetine. You see an account at paragraph 3.323 of the fact that Alpharma obtained a marketing authorisation, and at 3.324 you see the account of Alpharma's development of its paroxetine product {V/1/136}.

But in my submission, what you do not see in these paragraphs is any proper recognition of the very specific basis on which Alpharma was planning to enter the market, which was that it would wait until the anhydrate patent had been invalidated.

On 11th June 2002, GSK commenced its infringement proceedings against Alpharma, and as the Tribunal will be aware it alleged that Alpharma infringed at least claims 1 and 3 of the anhydrate patent, and also, at that stage, claim 1 of the hemihydrate patent.

As you referred, sir, there was an order made on 24th June 2002 of which we have a draft at {A9/184/10}.

THE PRESIDENT: Sorry, this is the draft?

MS. FORD: This is the draft. We do not have a final copy, but I do not think it has been suggested that it is not representative of what was ordered.

THE PRESIDENT: Can you give me the reference again?

MS. FORD: It is {A9/184/10}.

THE PRESIDENT: Yes. Thank you.

MS. FORD: You can see fourth paragraph down:

"And upon the Claimants agreeing to comply with any order this court may make if the court later find that the undertaking recorded in the following paragraph has caused loss to the Defendant and decides that the Defendant should be compensated for that loss."

This is the first point at which we see there is a cross-undertaking made by GSK.

The undertaking in the following paragraph, to which the cross-undertaking refers, turning the page to page 11, says:

"And upon the Defendant contractually undertaking to the Claimants not to sell or supply any crystalline paroxetine hydrochloride pharmaceutical preparation in the UK until the expiry of 7 days following the handing down of judgment in ... [the BASF litigation]."

The undertaking that has been offered is entirely consistent with Alpharma's strategy throughout. It is saying we are undertaking not to enter until after the outcome of the BASF litigation.

THE PRESIDENT: Yes.

MS. FORD: Sir, that is the first point at which Alpharma is a beneficiary of a cross-undertaking in its favour.

If you look at the relevant passages in the decision which govern this period of time, there is no mention of the cross-undertaking in damages.

That is, in my submission, a surprising omission. As the Tribunal is aware, one of the key issues in these appeals is whether the payments that GSK made to the Generics had any legitimate explanation. As the CMA is aware, Alpharma's case is that they were referable to GSK's contingent liability under the cross-undertaking. Given that, it is quite surprising to see that there is no mention whatsoever of the cross-undertaking in the decision at this point.

Sir, on 12th July 2002, Mr Justice Pumfrey handed down his judgment in the BASF litigation. That was a challenge to the validity of the anhydrate patent. As the Tribunal is aware, he found that the product claims, including claims 1 and 3 which were the subject of the infringement claims against Alpharma, he found those to be invalid, but he also found that the process claims, claims 10(1) and 11, were valid and those were the ones that were concerned with the displacement step to displace the solvent.

If you look at decision bundle {V/1/140}, paragraph 3.332, this is the paragraph in the decision where the CMA is setting out the outcome of the BASF litigation. You see quite strikingly that although they set out the fact that the original claims 1 and 3 had been

declared invalid, they make no mention of the fact that the process claims were declared valid.

The first mention you see of that is if you look forward to paragraph 3.334 {V/1/141}. This is a paragraph which is explaining an internal update made by Jakob Poulsen, and you see at the end of that paragraph in passing the mention that claims 10a and 11 remained in place after BASF litigation.

What happens then is that on 1st August 2002 GSK amends its claim against Alpharma and pleads against its infringement of claim 11, a process claim using a displacement step.

It is important to understand what a significant development that was from Alpharma's perspective because its strategy to date had been to sit back and let BASF do the work in terms of showing that the anhydrate patent was invalid, to clear the way. That strategy had essentially failed because BASF had only been partially successful.

Now Alpharma finds that the spotlight is on it for the first time to show whether its product actually infringes the patent, and it is dependent on BASF to help it show that its product is not infringing. What Alpharma finds is that actually BASF is not particularly enthusiastic about helping Alpharma show what it needs to show.

We can see that from bundle A9 --

THE PRESIDENT: Before you go on to that, you refer to the amendment.

MS. FORD: Yes.

THE PRESIDENT: Am I right that that amendment also dropped an allegation of infringement of the hemihydrate patent?

MS. FORD: It did, sir, yes.

THE PRESIDENT: Because obviously that would have been another worry, because the BASF litigation did not concern the hemihydrate patent at all, as I understand it.

MS. FORD: It did not, no, that is right.

THE PRESIDENT: So you had always faced that risk, irrespective of BASF --

MS. FORD: That is true, and we will see from a subsequent document that as far as we were concerned, that risk remained in the background.

THE PRESIDENT: So there was sort of bad news, good news in a sense. The good news that -- I appreciate you need to get through, you need to succeed on both, but at least you knew that GSK no longer seemed to think it had a good case against you on the hemihydrate patent.

MS. FORD: Sir, that is absolutely fair --

THE PRESIDENT: That is the assumption from dropping the allegation.

MS. FORD: Indeed, and the point is made in the decision, there is a cross-reference to a particular document where we describe the hemihydrate patent as GSK's strongest weapon. But of course, you have to read that in the context of our plan that we would only ever have entered once the anhydrate patent was out of the way.

It is almost the strongest weapon, assuming that we enter on the basis of our strategy that the anhydrate patent is dealt with.

THE PRESIDENT: You, at least at that point, had not been very concerned about the hemihydrate because you were prepared to enter if the anhydrate had been declared invalid.

MS. FORD: I think there is what might be described as a latent concern, because the concern was with the stability of the product and it might absorb moisture from the environment. Although at launch we felt there would not have been a risk of infringement of the hemihydrate patent, the concern was at a later date, due to the stability of the product, there might subsequently be an infringement concern. We will see that from the documents --

THE PRESIDENT: I understand that, but from what you said if BASF had won one, and that was the witness statements you were taking us to, then your client would have launched?

MS. FORD: Yes.

THE PRESIDENT: Taking that risk.

MS. FORD: Yes, I think that is fair.

THE PRESIDENT: Yes, thank you.

MS. FORD: Sir, I was about to take you to {A9/184/18}. This is another internal status summary on paroxetine. It is recounting the fact that there has been the hearing in the UK involving BASF and GSK. It summarises the fact that the patent has been revoked except for the process claims.

They say:

> "Next Monday our representatives in the UK will attempt to get the standing injunction lifted. In order to improve our chances it would be preferrable to disclose to the judge which steps BASF uses instead of the displacement step. While BASF has told us by phone that their process is not infringing, they have still not decided if and in what form they will file an affidavit to this effect. BASF are hesitant to provide details of their process, as they fear this information may be used against them ... BASF will probably make a decision this week."

You then see the suggestion how they might try and put pressure on BASF to give them the information they need, and their conclusion is because their direct provider is Delta it seems difficult to achieve, especially given the timeframe.

Then you see the recognition at the bottom there:

"Worst case scenario: the injunction is lifted, we launch now, but after lapse of some years GSK win an appeal. In this case we might face exceedingly high damages."

In my submission, what you can get from that is that Alpharma wanted to be able to say to the judge: look, this is the process we use, we don't use the displacement step. But they were dependent on BASF for help to show what they needed to show, and BASF is being essentially unforthcoming about whether and in what form they are actually going on help. They do not feel they have any basis to exert pressure on BASF to help and they recognise that if they go ahead and launch at risk then they face exposure to exceedingly high damages.

If we look at what the decision gets out of this document, it is bundle {V/1/141}, paragraph 3.335. The CMA's perspective is that BASF have told Alpharma that the product does not infringe, albeit that they have not yet produced evidence to that effect.

In my submission, that really does not properly reflect the import of the situation that Alpharma finds itself in at this stage.

Also, on 1st August 2002 there was the hearing of GSK's application for an interim injunction, and the judge made it clear that he was minded to grant the injunction. So Alpharma found itself in the position that it did not have a choice but to give an undertaking not to launch the paroxetine product on the market until after trial.

The undertaking it is obliged to give now is a very different one than the one it gave at the outset of the proceedings. It had previously said: do not worry, we will not enter until after judgment in BASF, which was always its strategy anyway and so was really not a great concession. Now it finds that it is completely precluded from entering the market.

THE PRESIDENT: But from what you are telling me, I thought it would not have wanted to enter anyway, given that the process claim had been found valid without the determination that it did not infringe. So it actually was not going to enter while that was hanging over it.

MS. FORD: Sir, that is absolutely right. The problem was, and we will see this reflected in the document, had there been a generic entry the following day, for example, Apotex subsequently succeeded in invalidating, Alpharma wanted to be in a position that it could take advantage and enter then. Now it has got this undertaking that even if that had happened, it has to wait until the end of the Alpharma proceedings.

THE PRESIDENT: It might have been able to apply if somebody else had entered under liberty to apply. I am not sure the undertaking was undertaking to do more than you say commercially it would not have done anyway.

MS. FORD: Sir, in my submission, there is a very real difference between undertaking not to enter until the outcome of the BASF litigation, which it always intended to anyway, and saying we will not enter until the conclusion of this litigation irrespective of the position on the market.

Alpharma wanted to be free to enter once there was generic competition on the market, once it was free to do so.

The consequence of this undertaking was that it was now injuncted until the conclusion of this litigation, and you can see the internal reaction --

THE PRESIDENT: All I am saying is if there had then been somebody else could take the risk. There were generic entrants who could have sought to gone back and applied to discharge the undertaking saying: circumstances have changed, there is now generic entry and the price is falling. That is all I am saying.

MS. FORD: Sir, I certainly see the point you are making. It certainly does not appear to be the perspective Alpharma were taking at the time.

If you look at {A9/184/48}, this is the email where they are reporting what happened at the hearing, and he says:

> "Unfortunately, I have disappointing news to report on paroxetine. The judge essentially granted the injunction. The good news is that he ordered a prompt full trial on October 23.
>
> "The judge was of the opinion that he did not reach the evidence presented him on this case because a simple plant inspection would end the matter on whether there was a displacement step in the process. Because he was inclined to grant the injunction, we simply represented that we would not market until the trial."

It goes on to say we did not have any choice. He says:

> "He also suggested that an independent expert simply inspect the plant to see the process and that this would resolve the matter.
>
> "Margaret is optimistic that as soon as the independent expert sees the process, and presumably agrees with us, we can strongly urge SKB to drop the case."

They are saying this is disappointing but we did not have any choice.

On the positive side, there is an order for a prompt trial, so the period of time that they are injuncted from entering onto the market at this stage is anticipated to be relatively short.

They are all thinking that this can be resolved fairly rapidly by means of an inspection at BASF's premises.

Even so, you can see the internal reaction at the top of this page to this news. It was not welcome news to Alpharma.

The corollary of the undertaking not to enter until trial was there was another cross-undertaking for damages. You can see that from the transcript of the hearing. It is the same tab {A9/184/42} of the bundle.

The first line where Mr Justice Jacob speaks on this page he says:

> "Of course there will be a cross-undertaking meanwhile."

Again, despite the fact that this really is a central plank of Alpharma's case, you do not see mention of this cross-undertaking in the CMA summary of the factual position.

There is then an internal update on 19th August 2002. It is at page 52 in this tab {A9/184/52}. You can see this is the document that I was referring to, sir, when you get the reference back to the hemihydrate patent.

They say:

> "[We were] originally accused ... of infringing ... the 'anhydrate ... and ... (the 'hemihydrate patent').
>
> "For [the hemihydrate patent] experiments conducted in connection with the present trial showed that no hemihydrate was found in the tablets. Stability studies conducted by Delta indicate the tablets are stable over time, but this may become an issue again. Presently, Alpharma is not accused of infringing the hemihydrate patent."

It is a concern in the background that the hemihydrate patent may become an issue again.

As for the anhydrate patent, they are pointing out that you have still got the residual claim 11 concerning the displacement step.

You see the summary of the perception at the time:

> "BASF claims not to use this step, and are willing to allow an inspection, given the right confidentiality assurance."

Alpharma has given the undertaking not to enter. An inspection is likely to resolve the matter at the beginning of September 2002.

THE PRESIDENT: They have got the agreement from BASF to the inspection which they were worried about.

MS. FORD: They seem to be saying they were willing to allow an inspection.

THE PRESIDENT: So they got them to agree.

MS. FORD: But they are pinning their hopes on the inspection resolving the matter, early trial, problem solved.

THE PRESIDENT: Yes.

MS. FORD: Those hopes were then dashed on 2nd September 2002, because what happened was that Alpharma got the news that their independent expert has not been able to find any solvent in Alpharma's product, which might imply that actually a displacement step had been used in order to get rid of the solvent.

You can see that {A9/184/62} at the bottom of this page is an email from Margaret Lewis, who is Alpharma's external lawyer. She is saying --

THE PRESIDENT: Is she from Stephenson Harwood?

MS. FORD: Yes.

She is saying:

"I have to report some not so good developments ...

"You will remember that the SKB experiments failed to identify the acetone in the tablets; confident in the knowledge that the API contained a considerable amount of acetone, we said that was because their experiments were flawed.

"Our expert has now reported that he cannot find acetone in the tablets either."

What she is saying is: we thought that the problem was with SKB's experiments, we were confident a displacement step had not been used, now our expert is saying, "I cannot find the acetone either".

You can see at the bottom of this email --

THE PRESIDENT: Can I just read it. (Pause)

So that was their expert. Have I got this right? Then there was going to be an independent expert, independent of both sides. Is that right?

MS. FORD: I had not thought that was the case. What is being reported is the problem about Alpharma's expert.

THE PRESIDENT: Yes, I am looking at the end of the email:

"I mentioned to Jakob that we are still waiting for nomination of an independent expert. I have prepared ... I will send them to Simmons & Simmons ..."

Who I think were solicitors to GSK:

"... as soon as we have the nomination."

MS. FORD: Sir, I am told that we do not know the answer to that. It may be there was an independent expert.

THE PRESIDENT: It says so.

MS. FORD: The BASF inspection never actually took place. We are simply unable to assist in relation to that.

THE PRESIDENT: I mean, Simmons were acting for GSK, were they not?

MR. FLYNN: Yes.

THE PRESIDENT: They were preparing instructions to counsel. They will not send them to the solicitors to the other side unless it is on a joint basis, presumably. That would be quite normal.

MS. FORD: Certainly that would make sense.

THE PRESIDENT: It is a question of whether the process is in that form or that form, yes. So that is where they were on 2nd September.

MS. FORD: That is where they were. There is a particular recognition in the last line of that email that:

> "... in the light of the Delta development the inspection may not be as productive as we had all hoped."

That is reflecting the fact that they all thought it would be resolved rapidly and easily by means of an inspection, and actually that may not be the case at all.

THE PRESIDENT: Yes. Thank you.

MS. FORD: There is then a further blow for Alpharma on 4th September 2002 because it is told that its product also apparently infringed the dry tableting patent. That is at {A9/184/66}. If you look at the heading "Other relevant EP patents and applications":

> "... (the 'dry tablet process patent') has claims directed to a process for formulating tablets containing Paroxetine in the absence of water. Delta has confirmed their process falls within the terms of the issued claims. Therefore, if the patent is upheld in its present form, it may impede the activities of Alpharma for the designated states ..."

Including GB.

THE PRESIDENT: Yes. You might have to go in the UK, I see.

MS. FORD: They have been told by Delta that their process infringes the tableting, the dry tablet process patent.

THE PRESIDENT: They may have to take proceedings to invalidate the tableting patent in the UK.

MS. FORD: Yes.

THE PRESIDENT: For a further 50 to 100,000 ... and another six months. Yes.

MS. FORD: So the position by September 2002 has become quite substantially clearer than it was when Alpharma first started taking steps to enter. It looks like it might well infringe the anhydrate patent because nobody can find the acetone, and so it is suggested that a displacement step might well have been used. It has been told by Delta that it does infringe

the dry tableting patent and it is also concerned that it might infringe the hemihydrate patent as well.

So it is in that context that you then start to see internal consideration at Alpharma of whether or not it might be possible to halt production of all the process that it had put in train.

I have various examples of that. The first one is at {A9/184/70}. This is an email with the subject:

> "Paroxetine - production to continue?"

It says:

> "Further to the note below the WIP at Delta represents in excess of 6 months stock ... I do not know if it is too late to put the brakes on production now - a decision would need to be made today at the latest I should think."

Turning on to page {A9/184/77} in this tab, in the middle of the page you have an email here to Godfrey Tucker from Torben Laursen, which concludes:

> "With all the current litigation problems I suggest we cancel all orders we can cancel as of now. This thing will draw on for a very long time ..."

Page {A9/184/79} in this bundle.

THE PRESIDENT: Sorry, that one is dated?

MS. FORD: That one is dated 3rd October, I think.

THE PRESIDENT: Yes.

MS. FORD: What we are seeing is emails going through the period September to October.

THE PRESIDENT: Yes, thank you.

MS. FORD: Page 79 in this bundle {A9/184/79}. This is 4th October, an email from Torben to Godfrey Tucker:

> "It is unlikely that we can launch Paroxetine in the UK in the near future. I will ask you to investigate whether some of the UK stock held in Iceland can be repacked to meet demand in other markets who will launch before the UK. Otherwise I am concerned that we will end up with some serious scrapping during 2003."

Then {A9/184/112} in this tab. This is an email again from Torben Laursen to Annette Turner. He finishes this email by saying:

> "Currently we must not place further orders until we have an overview of patent situation and the possibilities of reusing UK stock elsewhere, and we must try to cancel orders which are not produced yet!"

So over these two months there is a general theme of anxious internal consideration being given to whether or not we can halt paroxetine orders that are already in train.

If you look at decision page 147 {V/1/147}, paragraph 3.349, the CMA's take on these documents over this period is:

> "Various Alpharma internal documents produced in September 2002 and October 2002 indicated that Alpharma was still considering the possibility of launching paroxetine in the UK in the coming months."

In my submission, that does not properly reflect what is going on in those documents.

Sir, it is in this context that Alpharma approaches GSK and initiates settlement discussions.

In my submission, that is an important detail because the CMA's story is that Alpharma was still set on entering independently, and GSK somehow induced it to abandon its plans and paid it not to do so.

But we see that it is Alpharma that approaches GSK and proposes settlement. That is at tab {A9/184/75}.

This is an email from Robert Wrobel of Alpharma to Carl-Aake Carlsson:

> "My general thoughts on an approach to Paroxetine is that we should make a proposal to Glaxo along the following lines."

THE PRESIDENT: The date is slightly cut off by the hole punch.

MS. FORD: It is. The date is 24th September 2002. So it is shortly after the various revelations about the weakness of the patent position, and it is contemporaneous with the discussions that we have seen about the need to reconsider the paroxetine orders.

The date is actually quite important because you see the CMA saying, well, the findings of your experts, Alpharma, that you might not be able to prove there was not a displacement step, those findings did not prevent you from continuing to litigate. But what we see is that almost immediately after those findings, you see Alpharma internally saying, "I think we need to make an approach to GSK".

You will also note point (1) from what they are looking for is:

> "We would agree to delay a launch of the product until a date which is later than the October trial date but sooner than October of 2003 (the assumed date of an appellate decision on Paroxetine)."

Two points on that.

First, this is Alpharma's perspective as to how long it might take for them to get a final decision in the paroxetine litigation. They are currently working on an October trial date. We will see that that actually gets deferred again. Even with an October trial date they

think that it is going to take a year to get through judgment and through an appeal out the other side.

So they are thinking a period of 12 months to get a full answer, and what they are proposing to GSK is that they agree that Alpharma could actually enter earlier than that. So they are hoping to negotiate early entry.

You then see if you turn the page {A9/184/76}, Alpharma's report of what happened when they met with GSK. This is Torben Laursen reporting on a meeting with Mark Reilly on 1st October 2002.

He has a section which says:

> "The highlights of the talks."

And he summarises what has been discussed.

You can see right at the bottom of that section:

> "He [ie GSK] understood the value of an early entry by us compared to any other competitor ..."

This is what Alpharma was asking for:

> "Consequently this must be factored into a contract. GSK wants to supply product to us if we enter. They want to attack all non-GSK product entering the market, and he stated that he would struggle to get a contract approved by the legal department in which we can launch a Delta product at a later stage. I asked him to think this over again - an issue for further discussion."

So what in my submission you are seeing here is that Alpharma went in wanting to try to negotiate early entry and GSK were essentially saying, no, we are not willing to agree to that. That is particularly relevant given the CMA's counterfactual, which is that the parties might have settled on better terms because here you see Alpharma going in and pushing for better terms and getting rebuffed.

THE PRESIDENT: Well, that is their opening response.

MS. FORD: It is indeed, and it remained their response.

THE PRESIDENT: Alpharma are saying, well, think about it.

MS. FORD: Indeed, we are saying let us keep it on the table. But of course we know ultimately the settlement that was reached did not permit Alpharma early entry.

Turning on to page {A9/184/81}. This is another report of a meeting with GSK which took place on 11th October 2002. Here we see Alpharma setting out the compensation that it is hoping to get from GSK for the fact that it has stayed out of the market from early July. They are saying:

"The loss we have suffered since early July. We said the value was £2.5 million a month as our gross margin foregone. That situation was likely to continue well into January if we win in the December trial date."

So by this time what was originally envisaged to be an October trial has been pushed off until December, and they are calculating what has been their loss respectively by being kept out of the market for that time.

They are also saying:

"Inventory we have in Iceland.

"Attorney fees.

"Image loss ..."

These are the heads of loss that they are looking to GSK to compensate.

An agreement in principle was reached on 21st October 2002. The parties then started exchanging drafts of the agreement.

THE PRESIDENT: Sorry, I know you are under time pressure. Can I just look down the rest of that email, which is reporting on the settlement discussions.

MS. FORD: Yes.

THE PRESIDENT: You have taken us to the beginning of it. (Pause)

Thank you.

MS. FORD: There is a draft which was exchanged starting at page {A9/184/99}. This is a draft which was sent by Alpharma. It is Alpharma's mark-up of GSK's draft.

You can see that, for example, in point (3) in the draft Alpharma has marked it up to say that the £3 million is:

"... in respect of the cross-undertaking in the litigation."

That is a relevant mark-up given the CMA's case that actually none of these payments are in any way referable to the cross-undertaking in the litigation.

THE PRESIDENT: The date for it?

MS. FORD: A date for this? The cover email is at page {A9/184/104} in this tab. So it is 7th November 2002.

THE PRESIDENT: It is the day before the agreement was signed, I think -- sorry, 7th November. Sorry.

MS. FORD: Yes. The agreement was on the 12th.

THE PRESIDENT: Yes.

MS. FORD: Just going back to page {A9/184/100}, the other amendment that is notable in this draft is that you can see Alpharma specifying:

"Alpharma shall be at liberty to sell the product that is involved in the Litigation and GSK agrees that it shall not accuse such product of infringing any GSK intellectual property."

At this stage Alpharma is trying to get GSK to agree that this will be an end to it, and that once the agreement expires we are free to sell without being accused of infringement.

The next draft you see is a draft dated 11th November 2002. This is at {A9/184/105}. The cover email, for reference, is at page {A9/184/110}.

Just going back to page 105, the actual mark-up itself, if you look then at what is now clause (3), you can see that the reference to the cross-undertaking has now been taken out.

You can see, turning the page {A9/184/106}, clause 9:

"This Agreement is in full and final settlement for all claims that have or could have been brought by GSK and the GSK Group against Alpharma in respect of Alpharma's dealings in the product that is the subject of the Litigation prior to the date of this Agreement."

Then you see the reservation of respective rights. Again, this is another example of Alpharma trying to negotiate what would have been a more favourable deal and essentially getting rebuffed by GSK.

THE PRESIDENT: This draft has come from GSK or?

MS. FORD: No, I think this is a further draft coming from Alpharma. If you look at the email in {A9/184/110} --

THE PRESIDENT: If you just tell me.

MS. FORD: This is another draft coming back from Alpharma. Somewhere in between all the proposals that Alpharma has made have been taken out, essentially.

THE PRESIDENT: Yes.

MS. FORD: We say that really is very relevant when you are asking is there a realistic counterfactual that Alpharma could have got a better deal.

The agreement itself was then concluded on 12th November 2002. It is in {L/11/1}. I do not propose to address the Tribunal in detail on the terms of it. The only point that I planned to flag up is clause 1 of the agreement which envisages that the parties will then consent to an order in the form of the draft order attached to the agreement.

If you then turn on to page {L/11/4}, you can see the draft minute of the order, and you can see that the defendant:

"... be discharged from its undertaking not to sell or supply any crystalline paroxetine hydrochloride pharmaceutical preparation in the UK as set out in the order of Mr Justice Jacob."

So from Alpharma's perspective, it has now managed to get rid of the permanent injunction which had prevented it from coming in during the period of the litigation.

We will see when we go to the IVAX agreement that instead it has gone back to the point that it can enter when the anhydrate patent is invalidated.

You have also then got the claimants being discharged from any liability on its undertaking, given in the order or in the order of Mr Justice Jacob, dated 24th June 2002. So the two cross-undertakings are now discharged.

Again, that is relevant in the light of the CMA's position that notwithstanding that, the payments that were made under this agreement are not referable to the contingent liability in the cross-undertaking.

The Alpharma IVAX agreement was concluded on 20th November 2002 and it is in {L/13/1}. Looking to page {L/13/17}, you can see clause 65.2. This is the number of packs: 500,000 packs. Clause 5.2.

Clause 6.1 on that page at the bottom, you can see the supplied price, £8.45. Clause 11.1, which is on page {L/13/11}, you can see a provisional term for the agreement of one year.

Then turning over the page, clause 11.3, you can see that Alpharma has the right to terminate this agreement on one month's notice. {L/13/12}

THE PRESIDENT: Yes.

MS. FORD: One of the things that really does not come through from the terms of the decision is what a good deal this was for Alpharma. Notwithstanding that it did do its best to negotiate an even better deal, this is still a very good deal for it.

First of all, it has now gone back to the position, because it can terminate on one month's notice, that if the way is cleared for any reason, then it can terminate immediately and it can go into the market. That was always its strategy throughout, and it has gone back to the position that it can now do that when it feels that the way is cleared.

In the meantime, it can now enter earlier than it otherwise would have done with an authorised generic from IVAX. Mr. Collier's evidence when interviewed by the OFT was that this was an attractive offer. That is at bundle {A2/15O/101}. This is Mr. Collier's interview with the OFT.

If you then turn on to page {A2/15O/127}, you see the first thing that Mr. Collier is saying on this page:

"... looking at the ... allocation supply, quote of half a million packs, 15% market share would have been more than adequate to serve all our existing accounts less the ones identified in, in clause 3, allowing for the fact that IVAX were already supplying the market as well as Generics UK."

Interpolating there, clause 3 is Boots, Lloyd and Moss business.

He is saying leaving that aside, what we were being offered here was enough to serve all our existing accounts.

He then goes on on the following page {A2/15O/128} to talk about the margins that they were being offered.

THE PRESIDENT: Clause 3 is a reference to?

MS. FORD: I think he is referring to an email where they summarise the key points of the proposed settlements.

THE PRESIDENT: Sorry, who summarises?

MS. FORD: He has been taken to a contemporaneous document which sets out the terms of the settlement, and I am just looking for the reference.

If you look back at page 277, Mr. Moore is saying:

"It is useful to go into page 52. This is a further email from Mr. Laursen."

We are now at 11th October 2002 and it relates to the UK settlement negotiations for paroxetine.

THE PRESIDENT: Sorry, this email of 11th October on the settlement negotiations?

MS. FORD: I think it is one of the ones I have taken you to, sir.

THE PRESIDENT: 11th October? (Pause)

Perhaps you can let us know later. I think it might be useful.

MS. FORD: Yes.

THE PRESIDENT: I do not think it is because you say clause 3 identifies certain --

MS. FORD: I will confirm where it is.

THE PRESIDENT: Perhaps at some point that would be helpful.

MS. FORD: What we can see from page 279 is that what he is talking about is the supply amount that has been offered to Alpharma and he is saying that is more than adequate to serve all our existing accounts, less the ones identified in clause 3.

You then see over the page, 280, Mr. Moore is putting to him:

"Just so I understand sort of the margins, so effectively is the margin calculation that we are talking about here your supply price is 8.45 under this arrangement, your average selling price would be 10.50, so effectively £2.05 would be your margin?"

That is what is put to him, and he says "indeed".

He goes on to say:

> "Which would compare with the usual 5p a pack or whatever on all the other products that were made, so in itself it was still an attractive offer."

Margin of £2.05 compared with an average margin of 5p that you have been used to. Clearly, it is a good deal for Alpharma.

In those circumstances I pose the rhetorical question: what else was Alpharma supposed to do when being offered this sort of settlement? It is faced with a fundamental change in the merits of the entry that it anticipated when it first set all this in train and it has got a very attractive offer on the table. Is it obliged to carry on defending the litigation to the bitter end in order to avoid it being said against it that it somehow stifled a loss of a chance that it might have won the Alpharma litigation?

Well, as we understand the CMA's case, the CMA says, no, in principle you are perfectly entitled to settle. No objection is taken to settlement in principle. So is Alpharma instead obliged to settle by capitulating completely and just throwing in the towel in order to avoid the suggestion that any sums it receives from GSK are received essentially in consideration for agreeing not to enter the market?

Again, as we understand it, the CMA position is, no, it is legitimate for you to settle on terms that entail value transfers to the generic entrants. So we are left with it is okay to settle and it is okay to accept payment under a settlement agreement, provided only that it is not that payment which induces Alpharma to accept restrictions on entry into the market which it would not otherwise have accepted.

In my submission, that inducement cannot be made out on the facts of Alpharma's case because it comes through very clearly that the settlement properly reflected Alpharma's changed perception of the merits of independent entry.

THE PRESIDENT: I mean, while these discussions were going on, of course in parallel, preparations, until the agreement were going on for trial which you said it would have been put back, I think you said, until December, and we heard there were instructions for another independent expert. Do you know if that had happened by then?

MS. FORD: The BASF inspection never happened. I will check what the position is with the Delta inspection. (Pause)

Sir, the BASF inspection did not happen. We do not know whether the Delta inspection happened.

THE PRESIDENT: I think it did. I think we do know because Ms. West tells us about it.

MS. FORD: In that case Ms. West may know better.

THE PRESIDENT: I do not know, I am just reading the evidence. I do not know any more than what is in the evidence. They gives GSK's perspective on it, but I just wondered if you had anything on Alpharma's. It happened before 14th October because 14th to 16th October GSK are analysing the results. So I do not know -- presumably Alpharma were doing the same -- what the results were.

MS. FORD: I do not think we have anything which reflects Alpharma's perspective on that, and I will check and confirm if we discover anything. But it is the oddity of the position that Actavis finds itself in, that it is trying to recreate what happened from the CMA's file.

MR. MALEK: Can we just go back to the early email of 24th September, which is at {A9/184/75}.

MS. FORD: Yes.

MR. MALEK: What do we take from the passage just after the third bullet point:

> "We would receive an immediate payment from Glaxo in consideration of our agreement in (1) and (3) above. I would suggest that the amount of payment we propose should be based upon the profits which will be made by Glaxo by a further six months of exclusivity rather than our launch profit model"?

What do we take from that?

MS. FORD: Sir, to a degree I am speculating for the reasons that I have explained to the President, which is that we are reconstructing the documentary record, but Alpharma is in the position that it is trying to maximise the payment that it gets in settlement from GSK, given that GSK has a contingent liability. It is saying we could take two possible measures of loss: the amount that we have lost or the amount that Glaxo has lost by virtue of the six months of exclusivity while we were precluded.

THE PRESIDENT: The amount that Glaxo has lost? I thought it was the amount that Glaxo will achieve.

MS. FORD: The amount that Glaxo would have achieved.

MR. MALEK: That is the point I am putting to you. What do you say about that?

MS. FORD: I say it is perfectly legitimate for Alpharma in a negotiation context to be saying how can we maximise the value of the settlement that we get from GSK? Given that GSK has a contingent liability to us under the cross-undertaking, how do we in our negotiation position put to them the amount that we say we should be receiving?

THE PRESIDENT: But this does not relate to liability under the cross-undertaking. It relates to the benefit GSK is going to get if we keep out.

MS. FORD: That is the measure that they are thinking of putting to GSK, but the basis on which they are entitled to try to ask GSK for payment is that GSK is on the hook for a cross-undertaking if Alpharma were to succeed in the litigation.

THE PRESIDENT: That is one basis. The other basis is we can come in and you will lose that profit. I mean, that is the other negotiating stance. We will win at trial, trial is imminent, you have not established there is infringement on the experiment because this is dated -- it is September. It has not taken place yet. Well, you are going to make a lot of money if we do not come in.

MS. FORD: Sir, in my submission, there is nothing to preclude Alpharma from taking the strongest position it can in these negotiations. That is exactly what it is doing.

The question for the CMA and for the Tribunal is whether actually it was the receipt of the payments which induced Alpharma not to enter, and in my submission, you cannot reach that conclusion on the totality of the documentary evidence.

Mr. O'Donoghue has made the point to me that of course in the end we did not put those terms to them, we put the terms that were at page {A9/184/81}, that I have taken you to, which is the loss we have suffered since early July.

You can see that is what Alpharma is then asking for, and they estimate that to be 2.5 million a month as our gross margin foregone.

Sir, I was going to take you on to the fact that the agreement was then extended on 14th November 2003. You can see that in bundle {L/12/1}. Sir, it is extended for a period of a further 12 months. There is an increase in supply, supply for 620,000 packs, and you can see that the marketing allowance continues.

Then on 5th December 2003, so shortly into the extension period of the agreement, you then get Mr Justice Pumfrey declaring that the anhydrate patent was invalid in the Apotex litigation. That is the judgment at {D/6}, but we do not need to turn it up.

This is exactly the circumstance that Alpharma always envisaged that it would be able to enter the market. The anhydrate patent has been taken out, the way is clear for Alpharma to enter, and nothing in the terms of this agreement precluded it from doing exactly as it always intended to do. So it serves one month's notice under the extended agreement, that is at bundle {L/14/1}, on 13th January 2004.

THE PRESIDENT: Sorry, that is L14?

MS. FORD: Yes. In my submission, Alpharma did in fact enter at the earliest possible opportunity. It would not have entered any earlier at risk. We have seen what its strategy

always was and it did exactly what it always intended to do. It did not enter any later by virtue of this agreement.

THE PRESIDENT: You do enter?

MS. FORD: We do enter.

THE PRESIDENT: There is no claim for infringement of tableting patent or hemihydrate patent against you?

MS. FORD: No.

THE PRESIDENT: Which were not invalidated by Mr Justice Pumfrey?

MS. FORD: No.

THE PRESIDENT: So it looks as though the anhydrate patent is the critical one, does it not? It rather looks that way.

MS. FORD: Sir, we launched essentially when Apotex launched, and I think two other Generics launched. So the position is the market is open now. Other people are in. There is a limit to the extent to which it would have been, from GSK's perspective, a useful exercise to try to injunct once the horse has bolted, so to speak.

THE PRESIDENT: No, you would not be injuncted, but it is damages risk, is it not?

MS. FORD: Our understanding was that they did not enforce against anybody.

Sir, the final point that I intended to make was to put these events into context for the purposes of Actavis' ground of appeal on excessive delay to point out where they fit into the chronology.

THE PRESIDENT: Yes.

MS. FORD: We have an agreement which was concluded on 12th November 2002. The IVAX supply agreement was 20th November 2002. They were terminated on 12th February 2004.

THE PRESIDENT: Sorry, 12th?

MS. FORD: 12th February 2004, so it is one month from when we gave our notice on 13th January 2004.

THE PRESIDENT: Yes.

MS. FORD: The OFT only commenced its investigation on 11th August 2011. Already at that point over seven years has passed since the cessation of the alleged infringing conduct. You then get the publication of the statement of objections in April 2013. So that is over nine years after these events. Then the decision itself on 12th February 2016, another three years later. So we are now 12 years after the relevant events.

We do submit that that does constitute excessive delay. We have set out in our notice of appeal and our skeleton what we say are the consequences of that. We have found

ourselves in the position that we are advancing an appeal without the assistance of factual witnesses and, as the Tribunal has seen, we are relying on an incomplete factual record, including drafts of documents because we do not have the final versions.

THE PRESIDENT: Yes.

MR. MALEK: Are you saying that the authors of the emails that we saw earlier, are they just unavailable or you do not know where they are? Have you traced any of them?

MS. FORD: The position is as set out in our skeleton which is that all the key persons are no longer employed by Actavis.

MR. MALEK: That is not the case, obviously. It does not mean people are not going to co-operate if they are no longer employed.

MS. FORD: Certainly we have not had access to any of the key people that were involved in the negotiation of the Alpharma-GSK agreement. The only person left is Helen Toogood and she did not have any direct role in the negotiation.

MR. MALEK: Was any attempt made to try to trace any of these people?

MS. FORD: I will take instructions on that. (Pause)

I am told that we did make attempts to speak to Mr. Andrew Collier who, it transpires, was speaking to the CMA. So we were unable to speak to Mr. Collier. We did not then go across to the US --

THE PRESIDENT: Why does that make you unable to speak to him if he has spoken to the CMA?

MS. FORD: He was not prepared to speak to us, sir.

THE PRESIDENT: Right. Mr. Poulsen was the other one who seems to feature quite a lot.

MS. FORD: Mr. O'Donoghue points out that he has said in his witness statement that he was:

> "... not involved in the discussions relating to the settlement agreement between Alpharma and GSK, and I am therefore unable to offer any explanation for the rationale behind the framing of the individual terms of the agreement."

So query to what extent we would have been assisted by that.

THE PRESIDENT: He was in charge of the patent side, was he not, for you, on your assessment of --

MS. FORD: No, I do not think he was. He says quite clearly he was not involved. This is in the CMA's --

THE PRESIDENT: He was not involved in the settlement discussions, but he was involved in your internal considerations of the strength of the risk you faced on the patent claim because he writes those reports, does he not?

MS. FORD: He was the director of sales and marketing at Alpharma Limited.
THE PRESIDENT: Poulsen?
MS. FORD: No, sorry, we are at cross-purposes. I was talking about Mr. Collier.
THE PRESIDENT: I am talking about Mr. Poulsen.
MS. FORD: He was the patent attorney.
THE PRESIDENT: He writes those reports; you took us to some.
MS. FORD: Those people that were actively involved in the negotiation were then employed by the former parent companies of Alpharma, which were then essentially separated from Alpharma and were based in the US. We did not go over to the US to --
THE PRESIDENT: Why not?
MS. FORD: I think the position is that those companies are then here in their own right. The CMA brought them in as --
THE PRESIDENT: If you are making a point to us that you have had difficulties because of delay because the factual record is incomplete, the obvious thing to do is to go to the people involved and ask them to fill out the picture.

The fact that they are not employed by you, unless you say "We sacked them all under such difficult terms that they will not talk to us", or there is some good explanation or somebody has died, or whatever, then that is the normal thing one does. That is the point of Mr. Malek's question.

I think we are slightly struggling to understand, if you are making the point of being in difficulties through an incomplete record, why you did not.
MS. FORD: Sir, I am not able to assist you any further on that point.
THE PRESIDENT: Thank you very much.

Would it be sensible to rise early and come back early? Would you be happy with that?
MS KREISBERGER: I would, sir. I was going to suggest that. Thank you.
THE PRESIDENT: We will come back, can we say at 1.45 pm. 5 minutes can be valuable.

(12.50 pm) (The short adjournment)

(1.45 pm)
THE PRESIDENT: Yes, Ms. Ford.
MS. FORD: Sir, you asked me to come back to you on two points.
THE PRESIDENT: Yes.
MS. FORD: The first was the location of the email which Mr. Collier was talking about in his email of 14th October 2002. That is {A2/15O/61}. The second was you asked about what was going on with the Delta inspection process while the settlement negotiations were

going on, and you were correct, sir, that Ms. West referred to it in her witness statement at paragraphs 93 to 94 at {E/1/25}. There are also some contemporaneous documents at {A9/184/89} to 92 and 98.

THE PRESIDENT: Thank you very much.

Yes, Ms. Kreisberger.

Opening submissions by MS. KREISBERGER

MS. KREISBERGER: Thank you, sir.

I appear on behalf of Merck. I am appellant number 4 in the line-up, so I will do my best to speak without repetition, hesitation and deviation.

To that end we focus on what we say are the key analytical flaws in the CMA approach. I intend to take this at a brisk pace and I hope in the course of the submissions to pick up some of the Tribunal's questions of yesterday particularly.

If I could just set out what I was proposing to cover. First of all, just very briefly to touch on the theory of harm, just set it out in brief terms. I will then come on to identify my criticisms of the theory of harm.

I will then briefly summarise the relevant legal framework. You have already heard from Mr. Flynn on that. Then I will come on to develop the four key criticisms that I will identify, and then I would like to say a few words on what we say is a failure of analysis in relation to effects in relation in particular to the effects counterfactuals. So if I am going to be timed out I will make sure I spend a few moments on that.

Turning first to the CMA theory of harm. The theory we know is a simplistic one. The theory is that where you observe in a patent settlement what the CMA now terms a sizeable payment and some form of limitation on entry, you can then presume that the payment induced settlement and that the settlement is therefore anti-competitive and unlawful without any reference to or testing of its effects.

So that is the theory, and obviously it has the great advantage from the CMA's perspective of being an easy presumptive approach without being troubled by the facts. The CMA's intention here is clearly to add a new category of agreements to the object box, which are presumptively bad.

In my submission, the theory is wrong because it does not establish that settlements of this sort reveal a sufficient degree of harm, and that the CMA is therefore entitled to jettison the effects analysis for the following four reasons, which I will then come on to develop for you, if I may.

The first is, here, the facts do not fit the theory, or rather CMA has picked the wrong case to test its presumptive theory out and that is because, as you have heard already at length, these are early entry agreements.

The CMA's approach is: I observe a payment, therefore the agreement is presumptively anti-competitive. We say, no, first you need to test the effects of early entry. It is a very simple proposition. All the expert economists are agreed on this so we are immediately not in the object box for that reason. I will come back to that.

My second key criticism is that the theory of harm is conceptually flawed because it ignores the objective fact which is common ground, which is settlement may not have occasioned any restriction of competition, of lawful competition at all, let alone to a sufficient degree. So, again, the facts do not fit the theory here because GSK could have won.

I would like to show that the CMA has really misunderstood at a basic level the case law on which it relies to build its case, and I have in mind there *Actavis* in the States and *Lundbeck*. I realise *Actavis* is not binding but it is of interest.

I hope there to pick up the President's specific question of yesterday, which is: what about cases where generic entry was unlikely?

Turning to my third criticism, the CMA instead of looking at the counterfactual adopts a subjective notion of inducement, and we see phrases like "the means matter". We say that is misconceived and really the reason for this is the fourth point, which is that the economic underpinnings do not support an object approach in this case. That is the pay for delay inference.

We say for the above reasons the CMA's approach falls foul of the strictures of the Cartes *Bancaires* test on restrictions by object.

If I could turn to that test and just say a few words about the legal framework. We have set out the points in Merck's skeleton at paragraphs 8 to 35. We say there that *Cartes Bancaires* is the authoritative restatement of relevant legal principles.

It is striking that the CMA skeleton is actually silent on that test. Of course it would prefer a world without *Cartes Bancaires*. Instead, the CMA adopts a different tack, which is this is now all settled law in the light of *Lundbeck*. The CMA makes a startling submission at paragraph 84 of its skeleton, that the *Lundbeck* appeals are irrelevant and that the Tribunal should only make a reference if a point of law is unclear, and they say it is not unclear here. Now, Mr. O'Donoghue is addressing you on *Lundbeck*, and of course if that case is factually distinct the argument falls away. I do not propose to address you on this. But I would like to make this observation -- and I realise that we may need to deal with *Lundbeck* at a later

stage if the Tribunal is not with us on our principal ground in relation to *Lundbeck* -- that is this: that the CMA skeleton has got the test wrong. The test under Article 267(2) of the Treaty is whether a reference is necessary to enable the Tribunal to give judgment. That is a matter which is wholly in the Tribunal's discretion.

There is well established authority on this. I am not proposing to take the Tribunal to that at this stage, but essentially a reference is necessary where it is required to do justice or where the point is substantially determinative of a case.

Now, of course, the appellants all disagree that *Lundbeck* is dispositive in the CMA's favour. I obviously make that very clear. But if in what we hope is the unlikely outcome that the Tribunal is not with us on that, the reliance which the CMA now places on Lundbeck in its skeleton means that that case cannot be relied on as against the appellants, which would mean a reference is necessary.

It would be fundamentally unjust to decide this case on the basis of findings which may soon be overturned by the Court of Justice. So the CMA have pinned their colours to the *Lundbeck* mast. Well, this case cannot be decided on that basis now.

THE PRESIDENT: When you say it cannot be relied on, what you mean is it cannot be relied on as a final judgment here. It can be relied on on the basis that we would be bound so to decide by *Lundbeck* on that hypothesis, but *Lundbeck* is under appeal. Therefore, we should refer the question of are there distinguishing points from *Lundbeck* or, indeed, is *Lundbeck* right.

MS. KREISBERGER: That is precisely the submission, because we know the appeal is soon to be heard.

Turning, then, to *Cartes Bancaires*, I was not going to take you to that authority and it is obviously a critical authority. We have covered it extensively in written submissions so I think I can be brief since Mr. Flynn has already addressed on you this. What I would like to do is summarise the framework.

THE PRESIDENT: Can you give us the reference.

MS. KREISBERGER: I will. I have all the bundle references, and if convenient it can be flashed up on the screen. I will not delay --

THE PRESIDENT: You have a short time, but at least let me know where to find it.

MS. KREISBERGER: I am grateful, sir.

As we set out in the skeleton, what we really say is *Cartes Bancaires* sets out what we might call the five golden rules of identifying a sufficient degree of harm, which could be treated as something of a route map, and these are the five rules.

THE PRESIDENT: Sorry to interrupt you again. Have you put them as five rules in your skeletons?

MS. KREISBERGER: They are headings, but if I take you through them now, sir, it will be absolutely clear to you. If you need the reference to the skeleton, it is paragraphs 8 to 35 and that is {S/5/3}.

THE PRESIDENT: Sorry, 8?

MS. KREISBERGER: Paragraphs 8 to 35 of Merck's skeleton, {S/5/3}.

THE PRESIDENT: You have not put them out as five golden rules --

MS. KREISBERGER: No, I have not. That is the gloss for today.

I would say they work as a good route map. The first is the restrictive interpretation of the concept. That is at judgment paragraph 58. That is at I/51/13. That is your starting point.

THE PRESIDENT: Sorry, what is I/51 --

MS. KREISBERGER: Sorry, 19I/51/13 is the bundle reference, authorities bundle.

THE PRESIDENT: Is that tab 51 of bundle 19?

MS. KREISBERGER: I think bundle 19 is the hard copy bundle. But for the electronic bundle I think it is -- I have it here, it is {Auth-I/51/13}.

That is the reference to the concept being restrictively construed. I think what that means --

THE PRESIDENT: You have referred in your skeleton also to the Advocate General, have you not?

MS. KREISBERGER: I have, yes, and I will come to the specific --

THE PRESIDENT: What is the reference to that?

MS. KREISBERGER: The reference to the Advocate General is {Auth-H/6/8}. If you are looking at the physical bundle that is the same one.

THE PRESIDENT: No, it is not.

MS. KREISBERGER: It is the one before, sorry {Auth-H/6/7}.

THE PRESIDENT: They are not together. It is slightly confusing having two different --

MS. KREISBERGER: Sorry, I was relying on --

THE PRESIDENT: I do not know how that has come about that we have different electronic references to physical ones.

MS. KREISBERGER: So 16 in the hard copy bundles.

MR. MALEK: That is the tab number?

MS. KREISBERGER: Then it is tab 6. So it is 16, H6.

THE PRESIDENT: Yes.

MS. KREISBERGER: So the significance of the restrictive interpretation, paragraph 58, is that the category itself must be narrowly construed. So this is a significant aspect of the test. As a general proposition, in my submission, that means really if in doubt, test effects. Testing effects is the standard approach. Reliance on a presumption is reserved for obviously malign cases, and this brings the concept back into line with its underlying justifications, which is it gives the benefit of procedural economy but not at the expense of legal certainty. It would not be right to have the benefits of a shortcut where legal certainty is threatened.

I say that is the starting point, to be restrictively interpreted.

MR. GLYNN: Could I just ask, if the object were to exclude potential competitors from a market, talking in the abstract not in the case now, would you accept that that was an object?

MS. KREISBERGER: It depends what you mean, sir, by the object was to exclude potential competitors, because that is rather assuming the answer. The question is: how do you get there?

MR. GLYNN: No, I understand, of course it is very difficult to establish it. But conceptually, if it was clear that the purpose of an agreement was to exclude competitors, then that would, in your mind, be a satisfactory basis for calling it an object.

MS. KREISBERGER: I think that is uncontroversial, but subject to that proviso: that it must be clear.

MR. GLYNN: Absolutely, I understand.

MS. KREISBERGER: So the second what I call golden rule is that for written agreements it is principally a textual analysis and that is paragraph 65 of the judgment. It is the wording that must reveal a sufficient degree of harm.

Then one goes to context, assuming that the wording does reveal a sufficient degree of harm. Context has two limbs. The first limb of context is: do you have regard to all aspects of context? That is absolutely uncontroversial. It is in all the case law, paragraph 78 of *Cartes Bancaires* on page 16.

Second limb: but do not assess potential which is used in the sense of possible, possible effects under the guise of taking account of context, which was precisely the mistake that the General Court made in *Cartes Bancaires*. That is paragraph 82.

Just an additional word on each of those limbs. You must not ignore an exculpatory contextual feature and I rely here on Advocate General Wahl who says that the context must either reinforce or neutralise the view reached based on the wording of the agreement.

I would give the example here of the case of BAGS v AMRAC, which the President will be very familiar with. In that case there was a collective negotiation between racecourses to sell their media rights and the claimants, the bookmakers, said that is naked price fixing and an object restriction.

The judge found that it was not price fixing, it was not a restriction by object, because of a contextual feature. He found that the fact that the racecourses were confronted by a monopsony purchaser of their rights, that was the feature which meant it was not a restriction by object.

It was a contextual finding. That is the right way to approach context. Obviously we make submissions here that there are very clear features which are exculpatory.

Then coming back to the second limb, if you do need --

THE PRESIDENT: Sorry, you said that emerges from the Advocate General? Must not ignore exculpatory features, and the reference?

MS. KREISBERGER: It is paragraph 44, and the bundle --

THE PRESIDENT: We have the bundle.

MS. KREISBERGER: It is page 8. BAGS v AMRAC is in the bundle at 7C6 and pages 100 to 101 make that point.

So returning to the second limb on context, if you need to conduct a fact-based analysis to work out what the possible effects of a provision might be, that is your very clear signpost, do not pass go, go straight to an effects analysis.

I think this answers the President's question of earlier. The question was: what if you have an agreement that introduces a little bit of competition in place of a counterfactual that would be very competitive, more competitive? If you need to look at the effects to work out how the scales stack up, and I am going to come on to that in effects, if you need test effects at all you are in the effects box.

THE PRESIDENT: But you might not need to look at anything. Say there is a patent which is a complete monopoly, this agreement allows small volume and only one source and does not allow free entry, you do not need to look at anything else.

MS. KREISBERGER: Sure, in the abstract. But here, if you are trying to work out whether this is genuinely continuation of a monopoly or there are pro-competitive elements, and I will come on to talk about this, what I am really saying is if you have to look at effects to do that, you cannot then later come back to the object box. Presumptive approach is, at that point, off the table.

If you have to test effects because it is not clear, then you have got to test effects.

THE PRESIDENT: It is a one-way traffic --

MS. KREISBERGER: Exactly.

THE PRESIDENT: Once you are out of your object box you cannot go back.

MS. KREISBERGER: Then we come back to restrictive interpretation. That leads me to my fourth point. If, having considered wording and context on that basis, the finding is that effects are unclear, then it is not an object restriction. It's a really simple proposition.

References to the *Cartes Bancaires* judgment are 55 to 56, which refers to capacity to effect competition not being enough.

Paragraph 69 and paragraph 82. Paragraph 69 talks about the formulae, the pricing formulae in *Cartes Bancaires* being capable of restricting competition. That was an insufficient premise for a finding of restriction by object.

The short point is the object category is not there to capture these types of agreements. The benefits of procedural economy do not apply. You have to test effects. That is the standard approach. That is what we saw in *Cartes Bancaires*: how do the pricing formulae affect the new entrants in that case?

Similarly, *Maxima Latvija*, which I think is a very significant case. There, giving the supermarket a right of veto in the lease to keep competing smart chains out obviously has the potential to exclude competition. But the Court of Justice said that is not enough. Merely giving the supermarket the right to veto, all that shows is a potential to affect competition. That shows how high the threshold is.

THE PRESIDENT: Sorry, again?

MS. KREISBERGER: That is Maxima Latvija. I do not have the reference. I see it is in my skeleton. Perhaps someone could give me that reference.

THE PRESIDENT: My copy does not have references to the authorities bundle.

MS. KREISBERGER: Sorry, you are quite right, sir. It is a reference to Maxima Latvija. Someone will give me that in a moment.

The fifth of the golden rules I would like to flag now and then come back to, if I may, because I think it is something of interest, which is the need to look for experience. Sir, you have posed some quite searching questions about that which I had hoped to answer.

If I could just raise the issue now. Both the Court of Justice at paragraph 51 and Advocate General Wahl at paragraph 5, which is {H/6/9}, paragraph 59, referred to experience.

The Advocate General refers to experience based on economic analysis. He says that is when you can rely on object. When a restriction is constantly prohibited, it is reasonable to penalise it directly. That is paragraph 55. It is the last sentence "in my view".

Just to give you the reference, sir, on Maxima Latvija, it is {Auth-I/56/1}. In hard copy it is volume 19.

THE PRESIDENT: Thank you.

MR. MALEK: I do not know whether this is practical, but for my part it would be very helpful if sometimes someone could look at the skeletons on the S bundle and then add in the references to the authorities, and then I can follow that when I go through your skeletons.

MS. KREISBERGER: We would be very happy to do that, yes. Absolutely.

MR. MALEK: Thank you very much.

MS. KREISBERGER: So the headline point, the overall remark in relation to experience is that sometimes, not often enough, competition law is easy: if I agree to fix prices with you, it is obvious that prices will be insulated from competitive forces. That is the easy case.

It is not my submission that experience is always necessary for the easy case. Sir, that is the question you posed, really, about object to exclude a potential competitor. That is not my submission.

But my submission is that when competition law is difficult because the impact of a particular arrangement on the market is not clear cut, then experience becomes relevant because one looks for an emerging consensus. So what one is saying is it may be that over time one moves from a detailed analysis to a presumptive rule. That might be appropriate.

It is a procedural shortcut which is earned over time based on empirical evidence or economic analysis.

The reason for this is if one does not have a clear consensus of that sort, the undertaking is entitled to the benefit of the doubt.

Where there is uncertainty, controversy or debate, the undertaking is entitled to a full effects analysis. I am going to pick up this theme again when I turn to the settlements. But we are not suggesting there is a complete straitjacket because of experience.

I was going to leave the legal principles there simply with a view to time and then turn to the finding in this case of restriction by object.

In my submission, the CMA approach contravenes each one of those five golden rules. The wording of the --

THE PRESIDENT: Just pausing a moment. There is, of course, procedural economy in the object approach, but it is not in the legislation a procedural rule. Quite different from per se rule of reason in US anti-trust law. That is a gloss put on by the courts for effectively procedural economy on a broad statutory way.

The treaty is object or effect, not effect but sometimes procedural economy. So you can get effect through object. There are alternatives. So if one can establish it is an objective test using object in a different sense, that an agreement has the purpose of excluding or restricting competition, procedural economy is not really relevant. It is in the statute.

MS. KREISBERGER: So I would answer the question by reference to -- I am simply referring to the construction given by various advocate generals, including Advocate General Wahl in --

THE PRESIDENT: He does say --

MS. KREISBERGER: He does say that, and Advocate General Kokott has said that as well. It seems to me that he is right as a matter of principle. You are quite right the distinction is there, no one questions that, but one has to ask in construing it what is its purpose? It is a strong thing to do, to say to an undertaking: I will assume that this arrangement is anti-competitive even though there is some serious doubt as to the effect it has on the market. I am not going to test its effects, we are going to place it in the object category. What is its purpose if not procedural economy? Why would one simply not test effects in every case? Well, it would be absurd to expect competition authorities to prove effects in cartels because we are confident they are bad for consumer welfare.

THE PRESIDENT: Well, they are not bad if they have no effect or a minimal effect. They are bad because they usually do have an effect.

MS. KREISBERGER: If put into practice they will always have an effect.

THE PRESIDENT: If they work, yes.

MS. KREISBERGER: Because it insulates the players from competitive forces. It seems to me if one is not talking about procedural economy, why do we reserve this category? I agree it is in the Treaty, but it must be right, and it is now established law as a result of *Cartes Bancaires*, that we should construe it restrictively because its benefits are -- it is not just procedural economy, it is legal certainty and deterrence. But that is a great cost, which is the cost of testing effects, and that is not to give the undertaking the benefit of the doubt. So it is not the standard course. It is an ambitious course in this case, of course.

Turning to the settlements. In my submission, the wordings -- and of course my submissions are directed to the GUK settlement. The wording of the settlement having proper regard to context does not reveal a sufficient degree of harm because it does not reveal any direct or obviously malign impact on competition. That is because the wording shows that GUK was able to get on to the market immediately, and that the agreement not to deploy GUK's product, its own product, was in settlement of litigation.

So its product was a potentially infringing one, and one gets all that from the wording of the settlement.

We say that the settlement, based on its wording, was pro-competitive having proper regard to context.

THE PRESIDENT: You say the fact that its product was potentially non-infringing, which is the other way of saying the same thing, and the potentially non-infringing product was excluded does not reveal a sufficient degree of harm?

MS. KREISBERGER: That is my submission. I am going to come on to that. We certainly do not shy away from that aspect, and I would like to deal with it in a moment head on.

We say that you cannot shoehorn this into the object box. Taking early entry first, the CMA says at 47 of their skeleton -- I am not suggesting we turn it up -- paragraph 47, that the appellants are wrong to suggest that the CMA should have considered the effects of early entry where you have what they are effectively saying is an inducing payment. They say it is wrong to say you should have considered effects where you have the payment.

In my submission that is fundamentally illogical. That is the tail wagging the dog. Where you have early entry, as here, on the face of the agreement, you have to test effects to ascertain the impact on competition. You cannot discount the possibility of pro-competitive effects on these facts as part of the object analysis. The CMA does not get the benefit of the procedural shortcut.

It is striking -- and I am not the first person to refer to this so, again, there is no need to turn this up -- that all the economists agree that further analysis is required to ascertain the effects of the distribution agreement. For your note, Professor Shapiro's first report at paragraph 63 covers that, but that has already been brought to your attention.

So we say, as I said, that means you are in the effects box. Now, that is reinforced by the CMA's own case. The CMA's case that there were no pro-competitive benefits depends on an assessment of factors which are extraneous to the settlements and go beyond permissible contextual factors, because they are not exculpatory, it is not a BAGS v AMRAC case and they do involve a detailed analysis of effects, potential effects in particular as regards price.

I think Mr. Flynn has already drawn your attention to this, so just briefly for your note, Professor Shapiro in his report, which is at {H/1/21}, refers to three categories of evidence. At paragraph 84 he refers to volumes of parallel imports. At paragraph 91 the quote is:

> "The evidence strongly suggests that GSK would have faced inelastic demand."

At 93, he says:

"We can also learn about the likely effects ... on ... price ... by observing their actual effects."

This is precisely the same mistake as in *Cartes Bancaires.* This is addressed at paragraph 32 of Merck's skeleton.

The issue in *Cartes Bancaires*, which is at paragraph 82 {Auth-I/51/18}, the Court of Justice said the mistake the General Court made was to start assessing the actual difficulties faced by banks on entering the market, and so on. In other words, if you are observing effects, the presumptive approach is off the table.

So in present circumstances, payment does not permit circumvention of effects because of early entry. Frankly, it is vividly illustrated by the extent of economic evidence going to effect in this case. It is a clear signpost that this is an effects case.

Two further comments at this stage. First, Professor Shapiro acknowledges the need to test the pro-competitive effects of the entry agreement. But he says, but nonetheless he still adopts a presumptive approach. My submission is, no, that is not an issue that Professor Shapiro is qualified to comment on because that derives from the object effect distinction.

THE PRESIDENT: Why does the extent of economic evidence establish this as an effects case? There is an effects case --

MS. KREISBERGER: There is an effects case.

THE PRESIDENT: -- as well so there has to be evidence from effects.

MS. KREISBERGER: Because it is relevant to the allegation of an object restriction, because in my submission, you have to look at that first. You have to look at the extent of the pro-competitive effect as a result of early entry.

So the question of whether you can still adopt a presumptive approach, well, you cannot. Certainly, put it this way, the need to test effects takes you out of the object box. You cannot then fall back on object once you start looking at effect. Secondly, we dispute the submission that this would leave an enforcement gap.

All it means is that the CMA does not have the opportunity to circumvent an effects analysis. It means that the burden of proof is on the CMA. But we think these are matters which can be investigated and can be addressed.

As I set out in the written submissions, we certainly do not make a scope of the patent submission.

THE PRESIDENT: Sure.

MS. KREISBERGER: So that should be sufficient to dispense with the object restriction. But I then come on to deal with what I said was my second criticism, which is the fatal flaw in the theory of harm, which is the counterfactual problem, if we can call it that.

It is well trodden territory after the last day and a half that the appellants say it is a perfectly realistic outcome that GSK would have pursued its patent infringement claims against GUK in one, and we have talked about the survival of the process claim in the anhydrate patent, the hemihydrate patent claim, which has never been tested.

Now, the CMA has not in any part of the decision or in submissions inferred from the outcome in the Apotex litigation that the merits of this case were poor. That is not a finding in this decision. So they accept that a GSK win was a realistic outcome. They do not dispute that.

There is a second important point. Not only do they accept that -- and I am not sure it is a point that has yet been brought out -- if GSK won --

THE PRESIDENT: I think that is in the litigation.

MS. KREISBERGER: In the litigation.

THE PRESIDENT: Which was anhydrate only.

MS. KREISBERGER: Anhydrate only. Yes. Hemihydrate is completely uncertain. We do not know.

If GSK won, it is accepted that GUK's own generic product would have been barred from the market. It is no part of the CMA's case that the Generics could circumvent the patent, the anhydrate patent, if it stood up, nor the hemihydrate patent. So a GSK win means that GUK could not deploy its own generic version of the drug.

THE PRESIDENT: Yes. That is how we understand it.

MS. KREISBERGER: It is quite an important point, and --

THE PRESIDENT: We have that point.

MS. KREISBERGER: It is relevant to the counterfactual because there is no uncertainty at that stage.

THE PRESIDENT: I mean, a win could be in one of two ways. I mean, it would have on win on both validity and infringement. If GSK won, then there would be no generic entry.

MS. KREISBERGER: Exactly. That was not the case in *Lundbeck*. That was really the point I wanted to draw out. I may just come back to that in order, just very briefly.

It is perfectly possible that no lawful competition, let alone a sufficient degree of competition, was restricted by the agreement. That is a plausible outcome.

THE PRESIDENT: Yes.

MS. KREISBERGER: Now, in my submission that is sufficient to say that the wording does not reveal a sufficient degree of harm, and the context confirms that that is a plausible outcome. Effects are not clearly established.

I was going to say a word on the Irish beef case, but I think I can deal with that very briefly. It is dealt with at our skeleton at paragraphs 55 and 60, which is {S/5/17} and 19, but I do not want to dwell on it because, as I say, it is dealt with there.

The CMA rely very heavily on Irish beef, and we say that is just misleading. That is to shoehorn the facts of this case into that Procrustean bed. In *BIDS* there was a clear counterfactual. It was withdraw a lawful competitor versus no withdrawal in the counterfactual. It was reducing the number of lawful players.

The CMA talks about this situation as if it were comparable, as if this was simply a payment to a competitor not to enter apropos of nothing, as if the settlement did not exist. We say that is fundamentally a bad distinction because of the counterfactual issue here.

Can I also address the distinction between actual and potential competition here. In my submission, in the Irish beef situation it would make no difference at all to the analysis whether the processors were actual or potential competitors in the market or about to enter the market. Similarly here. Whether or not the real concrete possibilities test is met, we say it is not, but whether or not it is met, the objective fact is the generic drug may have been infringing and therefore not lawful.

THE PRESIDENT: That is at the heart of this case, it seems to me, of whether one can say a restriction of -- this is not the potential competitive point, it is a different point -- of one possible outcome, namely full generic competition, is sufficient.

MS. KREISBERGER: We of course say it is not.

THE PRESIDENT: You say it is not because that is what it is all about. As you say, and as the CMA accepts, it is possible that GSK would have won. That strikes at the heart of the whole case.

MS. KREISBERGER: We agree. That is very much central to our submissions in the case we have run here, and I am going to talk a little bit about the different types of case one might have which I hope might be of assistance in getting to the problem here, and also the loss of a chance of a court ruling point.

So if I might start just briefly by altering the facts, giving a hypothetical example with altered facts. Lets assume we did not have the Apotex litigation opening the gate to generic entry and let us assume GUK did settle with GSK, as they did in March 2002. Then let us

assume that Alpharma was unable to settle with GSK and so GSK went on to pursue its patent claim against Alpharma and won on the process claim.

Again, making the assumption that GUK and Alpharma's products were made in similar ways, we might then know, in that world, that GUK's product was infringing, and as I said, if GUK's product was infringing that is a complete barrier to entry.

In that case we would know that no lawful competition has been restricted by the settlement. But if one adopts the CMA's test and applies it to that set of facts, it does not allow for that settlement not to be anti-competitive presumptively, a restriction by object.

The test is simply sizeable payment plus entry restriction. That is an anti-competitive restriction even though subsequent events, at the time that it was entered into, the CMA would say that is presumptively anti-competitive, even though we would subsequently find out that is not the case, and in fact there is no restriction of competition at all.

It seems to me that is a good litmus test, in my submission. That is why the approach is conceptually wrong and it really does bring with it the risk of type one errors of the sort of just posited.

THE PRESIDENT: If one can reach a view as to the potential outcome of the litigation, not obviously certain because it did not take place, or of what the parties thought -- not the potential outcome -- was the likely outcome of the litigation and that one can infer the parties thought that GSK would probably lose, does that change the analysis?

MS. KREISBERGER: Precisely, sir. You are one step ahead of me. That was the next point I was going to come on to.

There is, of course, the evidential difficulty of how would one go about proving it. If there were contemporaneous evidence that no one thought this patent was going to stand up, then one would be in a different world.

If I could just develop that point, because that is precisely the point I wanted to come on to. In my submission, we say that the CMA has basically misunderstood some of the case law here. If I could ask you at this stage to turn up two Actavis judgments which is -- I am going to refer to the hard copy -- in authorities 19. It is J/5/43.

THE PRESIDENT: Are these the US judgments?

MS. KREISBERGER: These are the US judgments. I am simply referring to it to make the point, sir, that you have in mind, how might this be different, then of course, in my submission, draw a distinction between what I say is an easy case because it is no part of the CMA's case that the merits were poor that GUK was likely to enter in the absence of settlement.

In my submission, that is a fundamental feature of this case. If one turns up *FTC v Watson* at tab 5. This is the judgment of the --

THE PRESIDENT: Just give us a moment. Hard copy it is 19, and then it is --

MS. KREISBERGER: Then it is {Auth-J/5/43}.

This is the judgment. It is at page 43. It is the Court of Appeals for the Eleventh Circuit judgment. (Pause)

This is the judgment that went up to the Supreme Court in Actavis. If you turn then to page {Auth-J/5/45}, there is a summary of the FTC's complaint.

The fourth line up from the bottom, the judge summarised that:

> "The key allegation in the FTC's complaint is that the patent holder was 'not likely to prevail' in the infringement actions that it brought against the generic manufacturers and then settled. According to the FTC, the reverse payment settlements unlawfully protected or preserved a monopoly that likely was invalid and that should not be shielded from anti-trust attack."

Then if I could just briefly take you to other references on a similar theme.

Page {Auth-J/5/56}, second paragraph:

> "The lynchpin of the FTC's complaint is its allegation that Solvay probably would have lost the underlying patent infringement action - that is, Watson and Par/Paddock had a strong case that the 894 patent did not bar their entry into the generic AndroGel market."

Next page, {Auth-J/5/57}57, last line:

> "The FTC then filed this appeal, contending that it had sufficiently pleaded an anti-trust claim by alleging that the parties had entered into the settlement agreements even though Solvay was 'not likely to prevail' in the infringement actions ..."

Then perhaps if I just leave for your note page {Auth-J/5/71}, second paragraph, it is the same point again:

> "The FTC argues that its 'not likely to prevail' allegation sufficiently states an anti-trust claim ..."

So that is the basis upon which the FTC's case that led to the Supreme Court judgment in Actavis was mounted.

So what you see here is that the FTC was not afraid to express a view about underlying merits. That is why it makes sense that the Supreme Court treated the payment in that case as a workable surrogate for a weak patent. They said the payment is a proxy for the party's serious doubts about the patent's survival.

If I could just give you the reference for that, it is {Auth-J/6/12}.

Here, we say the CMA is not entitled to do that because it is no part of their case that the patent was weak or that the parties thought the patent was weak.

Sir, that picks up your point. One might have a case where there is very strong evidence that the parties thought this was a great ruse because everyone knows what the outcome would be if it went to court. But the CMA did not draw any substantive inference from the Apotex litigation, that is not in the decision, and they do not engage with the hemihydrate patent at all.

THE PRESIDENT: Do they draw any inference from the size of the payments?

MS. KREISBERGER: In Actavis?

THE PRESIDENT: No, in this case.

MS. KREISBERGER: They refer to it being a sizeable payment and being above litigation costs.

THE PRESIDENT: They draw an inference that is an indication that the parties thought the patent was weak?

MS. KREISBERGER: But not in this case, because the CMA says in terms we are not making that finding, and that finding is an unnecessary finding for us to make. So they cannot have it both ways. They cannot say we accept genuine uncertainty, but by the way the payment is enough.

I hope I will have enough time to come on to the economic evidence which Merck have adduced, which says you cannot rely on a payment always in every case indicating a weak patent. It is no part of the CMA's case; they cannot make that point now.

So what one finds in Actavis is despite those very strong facts, very clear factual findings, that the patent was unlikely to stand up, the Supreme Court still rejected any presumption of anti-competitive harm. That is despite the fact, I would draw your attention to the fact that a presumptive approach was being urged on the Supreme Court by an amicus curiae brief signed by a number of signatories, which included Professor Shapiro.

The Supreme Court said no to per se and no to the US middle ground of quick look. Now, just pausing there, if I could take you to paragraph 10 of Actavis, so that is {Auth-J/6/12}, paragraph 10. The court here refers to quick look, at times in parenthesis, in that paragraph.

> "('Quick-look analysis in effect' shifts to 'a defendant the burden to show empirical evidence of pro-competitive effects'.)"

That is really what the CMA is trying to do here.

The CMA is saying any countervailing benefits must be dealt with under 101.3. That is a good parallel for the approach that the Supreme Court rejected in Actavis, which was a

weak patent case. I think it is important to understand Actavis as a case which rejects the scope of the patent test. The FTC v Watson judgment that I took you to applied scope of the patent. So they said you cannot have any exclusionary effects in patent restrictions. What they found in Actavis, if one goes back to paragraph 1, which is on page 5, the key finding is that payments can sometimes violate the anti-trust laws.

Just above I:

"Payment settlements can sometimes violate the anti-trust laws."

We do not dispute that here.

What they found is that settlements with payments are neither presumptively unlawful or presumptively lawful. They must be evaluated under their longstanding rule of reason framework. So it is genuinely surprising to see the CMA place so much emphasis on Actavis in the first few paragraphs of their skeleton, because it directly contradicts the objects case. But I think they have misunderstood the factual premise of that judgment and its conceptual underpinnings.

I would like to come back to the point that I have already flagged for you, which is experience. Now, Mr. Flynn said that the US law is still at an early stage. We would make a rather different point because the FTC have been looking at these for some years. But the point we would emphasise is the one I made earlier, which is that there is no emerging consensus in US law if you look at the last ten years.

This is really what Advocate General Wahl was getting at. If you could just turn up very briefly now -- I do not rely on the correctness of this judgment, I only rely on it for the point about no consensus, which is the *Valley Drug* US judgment. It is the same bundle {Auth-J/8/12}.

That is one of the early cases. This was back in 2003, so not long after the settlements.

If one turns to paragraph 38, which is on page 12 --

THE PRESIDENT: This is long before Actavis.

MS. KREISBERGER: It is. The only point I am making here is that the court applied the scope of the patent test. So when you ask: what does experience bring to the table here? What experience brings to the table is when something as complex as this, where you have different authoritative views -- one view in *Valley Drug* is that these are presumptively lawful when they are within the scope of the patent. It is not appropriate to put a settlement of that nature in the object box. There is a very respectable heritage of these sorts of settlements being outside the scope of anti-trust altogether.

THE PRESIDENT: Did that change after Actavis?

MS. KREISBERGER: Then Actavis said neither presumptively lawful or unlawful. We were at the beginning of this road in this jurisdiction, but the point here is that there are no facts in this case which suggest that the absence of experience in this jurisdiction should not be a bar to putting it in the object box, because what we have is not a clear cut case. We have a difficult case which involves early entry and we have no experience of it.

One also bears in mind legal certainty. Back in 2003, one might have thought these forms of settlements are entirely benign, can never be within the scope of anti-trust. That is really the only point I make here. We do say experience is relevant, given the difficulty of the facts, given the different views one sees, given the lack of any emerging consensus.

Just a very brief word on *Lundbeck*, which I know Mr. O'Donoghue was dealing with. In that case, not only did the General Court express doubt about patent strength, likelihood of litigation and so on, but critically for the point I was making earlier -- I will just give you the reference and not call it up -- two references. The General Court found that the crystallisation patent in that case did not allow the exclusion of all competition in relation to citalopram. That is paragraph 435. {Auth-W/1/93}

THE PRESIDENT: That is a different *Lundbeck*, that is *Lundbeck* itself?

MS. KREISBERGER: That's the Lundbeck Lundbeck, yes.

That links back to paragraph 97. It is not expressly linked, but it brings back the point at paragraph 97 where the General Court held that there were other routes to market which were available circumventing the patent. So that is why I stress in this case it is no part of the CMA's case that if GSK had won, GUK could still get onto the market. Whereas in Lundbeck they said the Generics could. Merck disagreed with that as a matter of fact, but that is a factual finding.

Keeping an eye on the time, I think I will turn to the economic arguments. In the time left to me I would like to cover the argument that the means matter that the CMA makes, that the payment induced the restrictions, and the economic arguments in support, the pay for delay inference. Then just a couple of minutes on effects.

So the inducement argument, we say, first of all, it is really a tendentious formulation to say that this was inducement for not entering the market. It is the point I made earlier. It treats this agreement as if it were apropos of nothing to exclude a drug. It was not. It was in the context of a potentially infringing drug.

But substantively, that is a comment on language really. Substantively, the means do not establish a sufficient degree of harm. We say it is conceptually wrong because it depends on the counterfactual. Even if payment facilitated settlement it may have been a

subjectively necessary component to bridge the gap, and where the competition was restricted depends on the counterfactual, and payment, in Merck's submission, based on the evidence which Dr. Jenkins has presented, it can be consistent with a pro-competitive outcome.

This, by the way, brings one back to Actavis. Payments can sometimes restrict competition. Sometimes they do not. There is no presumption here.

If I may deal with the pay for delay inference. This is set out in Merck's skeleton at paragraphs 88 to 100 {S/5/27}. To deal with this briefly, I am going make five points on the pay for delay inference and why the CMA is wrong to say the means matter. All we need to do is look at the payment. We say that is not enough.

First, the inference does not assist you as a matter of technical approach. If you need to tests effects, as I said, that puts you in the effects category. Professor Shapiro acknowledges that further analysis is warranted here.

Second point, the inference suffers from the counterfactual problem that we have been discussing, and all the experts agree that this is the conventional starting point of the analysis. That is at bundle {I/1/18}. The statement is at paragraph 1(ii)(b)(9) and Professor Shapiro acknowledges that the inference is clearest where the patent is weak for all the reasons we have just discussed, because it affects one's analysis of counterfactual.

That is at paragraph 53 of his first report, {H/1/14}. That's really the central problem here.

Third point, the inference did not persuade the Supreme Court to adopt a presumptive approach urged on it, including by Professor Shapiro himself. Fourth point, the inference does not establish a sufficient degree of harm. It is really no more than a signpost that the settlement may have an anti-competitive effect.

It does not help you on object, and then one goes to test effects, which I will speak about in a minute. But really what one sees in Professor Shapiro's evidence is that his concern is about an enforcement gap. It is really a regulatory or policy-driven approach. We say there is no enforcement gap, you just have to test effects.

The FTC were not scared of testing effects. The CMA does not want to get into this. There is no good reason for this. You have to grapple with the underlying issue of how likely is generic entry.

My fifth and last point on the inference is that it is effectively a theoretical construct which relies on a specific set of assumptions. It relies on theoretical notions of symmetric information, risk neutrality and perfectly efficient bargaining. But the real world does not necessarily work like that. So if there is asymmetry in the parties' perceptions of market

strength and patent size, which Mr. Flynn referred to in his submissions yesterday, if there are inefficiencies in bargaining or if the brand exhibits some risk aversion which means it is willing to give something -- here it was willing to give early entry to preserve the position -- well, then Dr. Jenkins' evidence shows that the payment could be necessary to achieve the benefits of agreement. That is common ground.

One sees that most clearly in Dr. Jenkins' second report, section 3. That is at {G/5/7}. 7 is where it starts. Then if one goes to page {G/5/16}, that diagram is really the nub of the economic evidence, which is that where you have these features, particularly information asymmetry which is not unusual, it just means that the parties think different things about patent strength, then it is possible to have a pro-competitive settlement with payment.

All that really means is payment was necessary to facilitate entry. Professor Shapiro agrees with this. This is not in dispute. So then one knows, again, one is not in the object box. You have to come on to test effects. So I have still got to deal with that bit of the analysis. But to talk about the payment inducing no entry is simply not true. Here it may have induced early entry compared to a counterfactual of no entry.

I am going to turn to effects now. That really sums up all the points we want to make on restriction by object. I think I am actually ahead of time.

Really, the point I wanted to make is on the CMA's counterfactuals. They make this point that the pursuance of litigation is always more competitive because there is the mere possibility of a successful outcome. This is the loss of a chance point.

They say we cannot be expected to form any view about the underlying merits, and they say we should not be told otherwise because that would place practical hurdles in our way and our job should not be made more difficult. To use Professor Shapiro's phrase, we would say that is an abdication of investigative responsibility.

The President highlighted yesterday, if one turns to the continued litigation counterfactual, the conceptual issue about how to go about the balancing exercise. We would put it like this: on one side of the scales you have the pro-competitive benefits associated with early authorised entry, which is price for the period of time while the injunction is in force, so that there can be no independent entry, and there are other benefits as well. I will just give you the reference for your note.

That is Dr. Jenkins' comment in the joint statement at point 1(ii)(b)(11), which is at {I/1/19}. She says there are other benefits of GUK being in the market even if the price drops. They have not been observed, and that is benefits associated with allowing the manufacturer to be faster to market once patent protection is removed.

It is a really extreme contention to say that some entry leads to no benefits at all and is effectively a sham and a continuation of monopoly. We say there are some benefits and as long as they are non-trivial they sit on this side of the balance.

Then how do you ascribe a value to what goes on the other side the scales? We will have to hear from Mr. Turner as to how he ascribes a value of competitive harm to the notion of uncertainty. But we would say this: the mere loss of a chance of litigation cannot be the relevant competitive harm because any patent settlement involving some form of entry restriction, with or without payment, would fall foul of that.

So conceptually, that position is indefensible. Certainly out of line with Actavis.

Sometimes you can have a restriction, but it has to be something more than there could have been litigation.

THE PRESIDENT: Chance is not litigation. Litigation is the certain counterfactual that the chance is the chance of GSK losing. That is the chance.

MS. KREISBERGER: Agreed. I am sorry if that is not clear. The point is it is the loss of a chance of a court ruling. That is what it comes to, because --

THE PRESIDENT: Loss of a chance --

MS. KREISBERGER: Exactly --

THE PRESIDENT: It has to be a positive --

MS. KREISBERGER: Of course, loss of a chance of a ruling incorporates one way or the other.

THE PRESIDENT: It may not because, on the strength of the patent, if one gets into that, it is a weak patent, the loss of the chance --

MS. KREISBERGER: This is precisely my point, that is not part of the case. All the CMA says is it is uncertainty, it is the loss of a chance of a ruling. They do not anywhere in this decision say "We think it is more likely than not that generic entry would have taken place had there been no settlement" and that is a critical aspect of this.

THE PRESIDENT: Yes. We have that point. But when you say on the other side there is that loss of a chance of GSK that they would fail at judgment.

MS. KREISBERGER: What we say is you have got actual benefits on one side and you can say that payment facilitated early entry with actual benefits. That is on this side of the scale. Without payment one might not have had early entry. So that is on this side of the scale. On this side of the scale you have, well, it might have been a win or a loss, but it is certainly no part of the case that it would have been a win.

If the CMA could have said "This would have been a generic win, they would have come onto the market", then your scales might go like that, but that is not the case so we are back to this. Mere uncertainty cannot get you there.

If the CMA wants to take on these cases, they have got to go for cases where they can show generic entry was unlikely. They cannot simply say "We do not know, that is too difficult, we should not have these problems of enforcement".

THE PRESIDENT: Well, it is very difficult to show what the outcome would be unless you can draw inferences either from the size of the payment or what the parties were saying internally at the time.

MS. KREISBERGER: Absolutely.

THE PRESIDENT: You cannot do it any other way.

MS. KREISBERGER: Let's look at Actavis. One has an example there of a case where the FTC said: we can tell you that the patent would not have stood up and the parties --

THE PRESIDENT: But I do not know on what basis they said that.

MS. KREISBERGER: I do not know what the factual underpinnings were, but they did not feel unable to reach a view. They clearly got to a view.

Or one has Lundbeck, one aspect of the case is these patents were not a market barrier because the Generics could have tweaked their formulation or dealt with someone else.

THE PRESIDENT: Were there not some internal documents in *Lundbeck* expressing their view of the likelihood of success?

MS. KREISBERGER: There were. They talked about a 60% chance of success and so on, but I am emphasising a different aspect, which is even if Lundbeck had won, even if Lundbeck had sued, that does not matter because the Generics could have got to market a different way. That is my point.

THE PRESIDENT: That is a much easier case.

MS. KREISBERGER: Exactly.

THE PRESIDENT: But --

MS. KREISBERGER: The fact that the CMA has picked a case where they say they cannot say anything, they have not been able to rely on any contemporaneous evidence which shows the parties did not believe in the patent because that does not exist here, that does not mean that one should resolve these matters against -- not giving the appellants the benefit of the doubt.

There is a clear burden of proof for an effects infringement. They have to show strong and compelling evidence that anti-competitive effects were not likely. If they cannot do that the

effects case fails. It is as simple as that. They have to show evidence that but for this settlement generic entry was, at the very least, likely.

THE PRESIDENT: We have that point.

MS. KREISBERGER: Sir, unless there is anything else I can assist on.

MR. GLYNN: If I might, presumably the Generics firms would have entered without the payment. There would be access to the market in itself, which was part of the agreements that they reached, would have had some value to them?

MS. KREISBERGER: Sorry, if they had authorised entry?

MR. GLYNN: If the agreements had not included any payment, but had simply been: we will let you into the market under whatever controls were there in the different cases. They would have entered, would they not?

MS. KREISBERGER: We do not know. That is what our economics evidence goes to, that the payment would have been a necessary means to bridge the gap to achieve a settlement involving early entry. So the payment --

MR. GLYNN: You think the payment was necessary to achieve --

MS. KREISBERGER: Early entry, exactly. That is what Dr. Jenkins' evidence goes to. That is the diagram I took to you, that those are the pro-competitive settlements where payments achieves early entry effectively.

THE PRESIDENT: Yes. Although the indication from Alpharma was that they were not prepared to enter at risk. That is what we were told and shown evidence to the effect. So anything they could get was of benefit, but for them the payment was not necessary for them to get early entry, they just were not prepared to go ahead. That is my understanding of the case, and then they get this large payment on top.

MS. KREISBERGER: I understand that.

THE PRESIDENT: Yes. There is nothing in the judgment of the Eleventh Circuit that I have not read, other than the bits you have just taken us to in what became known as the Actavis case, I think -- although at that point it was called Watson -- that explains on what basis the FTC --

MS. KREISBERGER: The FTC reached those views, no.

THE PRESIDENT: Because they did not do a sort of alternative patent trial, did they?

MS. KREISBERGER: No, that is not going to be feasible. Perhaps that is something we can come back to the Tribunal on.

THE PRESIDENT: Yes. If there is something in the judgment that would be interesting.

MS. KREISBERGER: We will check the surrounding evidence as well.

THE PRESIDENT: Yes. Thank you very much. You kept precisely to time.

Shall we take our short break now.

(3.10 pm) (A short break)

(3.15 pm)

Opening submissions by MR. O'DONOGHUE

THE PRESIDENT: Yes, Mr. O'Donoghue.

MR. O'DONOGHUE: Sir, we are nearly on the home straight.

I see, sir, that with the exuberance of my colleagues I have been somewhat squeezed.

THE PRESIDENT: Not in the patent litigation sense, but we can go to 4.25 pm.

MR. O'DONOGHUE: Sir, that will have to do me.

Sir, on *Lundbeck*, three preliminary points, if I may. First of all, obviously it is only an object case and therefore does not bear on the effect case at all. The second point, of course, is that my client and a number of other people in this room and other people not in this room are appealing the judgments, and therefore, insofar as I take findings in the Commission decision and judgment, it is not me getting a machine gun out to my own foot. In the context of an appeal, the findings are what they are.

The third point is I operate on a slightly analogue basis, which is that I will go to the hard copies. The only thing I need are the Commission decision and the judgments. The *Lundbeck* judgments are in W, hard copy; the Commission decision is in volume 10 of the authorities. I do not think I will need anything else, and rather than a life shortening experience of having to give two sets of references at each and every point, if we could work from the hard copy that would be great.

MR. GLYNN: You would not also be able to work from the other one, would you? You prefer not to?

MR. O'DONOGHUE: Beyond my current capabilities.

THE PRESIDENT: I think if it is just a reference to the electronic copy, which I think for the Commission's decision is it {Auth-F/16/1}? Are you referring to several of the *Lundbeck* judgments or --

MR. O'DONOGHUE: Sir, yes, there are a number. I think just the *Lundbeck* judgment itself.

THE PRESIDENT: Just the first one. So that is in {Auth-W/1/1}. I think that will be the same in the electronic bundle. That is the same one in the electronic copy. We are sort of there, I think.

MR. O'DONOGHUE: Crisis averted.

What I hope to do in the time is canter through the Commission decision and the *Lundbeck* judgment reasonably quickly, and then at the end I am going to make five or six submissions as to where the decision in the judgment leaves us for the purposes of this case. Starting with the Commission's decision, if I may. Just to fill in the patent position, which is crucial.

THE PRESIDENT: So that is F/16/1.

MR. O'DONOGHUE: Yes, forgive me. I want to start at paragraph 123, if I may. {Auth-F/16/53}

THE PRESIDENT: Which is page 53.

MR. O'DONOGHUE: Sir, yes. The starting point is that the patent for the compound had expired by January 2002 in *Lundbeck*. You will see underneath that at 124:

> "As early as 1997, therefore, Lundbeck started planning for possible generic ..." gaining up to 70% of the market within five years, ie by 2002.

A few pages on, if I may, at {Auth-F/16/61}, 147.

THE PRESIDENT: Page 61.

MR. O'DONOGHUE: Sir, yes, thank you. The compound patent having expired, plan B was a whole series of process patent. So from July 2000 to 2002, the 18 months before the expiration of the compound and basic process patents *Lundbeck* applied for 14 new process and related patents of which it withdrew or allowed to lapse eight before December 2006. Now, of the process patents the critical one was the so-called crystallisation patent, and we see that dealt with in detail over the page at {Auth-F/16/62}, paragraph 149:

> "According to Lundbeck, Lundbeck's 'enemies' labelled the crystallisation patent 'high school chemistry' and considered that it was not novel ... This process patent became Lundbeck's main legal weapon to fight generic market entry in the EEA with infringement litigation."

And so on.

THE PRESIDENT: So far, similar.

MR. O'DONOGHUE: Sir, yes. But we are coming to the critical difference.

Then at 150, this is the point referred to by Ms. Kreisberger:

> "... in the proceedings before the Commission, Lundbeck had stated ...
>
> "They [the Generics] could have entered the market using the Cyanation or Alkylation method ... [which] the Generics could invent (eg the Matrix ... or Sumika process)."

Then there is a complaint of them choosing one particular method.

Then continuing in the same section at 153, which is on page {Auth-F/16/65}, so at the top of that page. So there was actually an inspection of the matrix facilities by Lundbeck in November 2002. Then across the page in 154 {Auth-F/16/67}:

> "Following the inspection, Lundbeck withdrew its application for an interim injunction, a hearing ... scheduled in December."

Then, sir, at 157, a point which has been mentioned, just to give you the reference, at page {Auth-F/16/68}:

> "In an internal assessment ... Lundbeck estimated the chance that the UK judge would hold the crystallisation patent invalid at 60%."

Then we see in a sense the upshot of that assessment at paragraph 160 page {Auth-F/16/69}:

> "An internal Lundbeck document probably dated shortly after the settlement ..."

Then it lists the findings. Then it looks at the alternatives. So the alternative to settlement.

> "The UK judge would have ruled:
>
> "No infringement.
>
> "Patent invalid.
>
> "Vindicated matrix and completely dismissed any doubt of fabrication.
>
> "Lundbeck pay all costs.
>
> "Condemned Lundbeck."
>
> "... Avoiding a humiliating defeat" further down at 160.

Then, sir, a few pages on at {Auth-F/16/77}, 184, and {Auth-F/16/79}. At 184 the process patent was called the last line of defence against imminent generic entry. Then at a couple pages on, at 187, page {Auth-F/16/79}, this is Lundbeck describing its so-called policy of deal making. They describe it as follows, they say:

> "It is like a poker game.
>
> "We have been dealt a mediocre hand-no aces, a couple of queens and some small uneven cards.
>
> "But we have a large pile of $$$ at our side.
>
> "We call it the art of playing a losing hand slowly."

Pausing there. One of the things the CMA skeleton says, which is extraordinary, is they say that this point about a large pile of dollars, well, that is the same as paroxetine because GSK paid the Generics.

In my submission, one cannot possibly, having read this note, say that that fact of payment bears any reasonable relation to the facts of this case.

No one has suggested for a second that GSK had a mediocre hand and, in fact, the contemporaneous evidence is extremely clear. The Generics perceived high risks of losing and Ms. West's evidence, which has not been contested in any shape or form, is that GSK had strong confidence in its patents.

Then at 188 just to complete the internal thinking:

> "Do we want a deal? I guess a deal would be $10-$20 million or even more. My opinion is that it will be difficult - anti-trust wise, costs and value for money..."

So that is the patent position. In my submission, what one gets from the *Lundbeck* point, clearly, is that the last line of defence, as they called it, was extremely weak. There was contemporaneous assessment of high chances of invalidation. There was a description of a mediocre hand and there was the game or the art of playing a losing hand slowly with a large pile of dollars at their side, while recognising anti-trust risk.

Now, I will get to my submissions at the end, but pausing there. In my submission, what is critical to understand about *Lundbeck* is that the weakness of the patent position, as acknowledged contemporaneously by *Lundbeck*, drives the entirety of the situation in this case.

It certainly drives the question of potential competition. It touches on the separate question of whether outside of the patents the generics had other opportunities. The answer is they did. This critical fact pattern in **Lundbeck** cannot be disentangled from the analysis in the judgment and in the decision itself and if there is a central criticism of the CMA in this case, is what they do is they take stray phrases here and there from the judgments and say, "Aha, there is a general principle". That is not a correct approach. The patent position is front and centre of *Lundbeck* and it was extremely weak indeed.

Now, if I can go on through the Commission's decision on the critical issue of potential competition, starting, if I may, at 621.

THE PRESIDENT: Sorry you are in the --

MR. O'DONOGHUE: Still in the Commission's decision, at page 209.

THE PRESIDENT: I think you need to give the page numbers always because that is how they --

MR. O'DONOGHUE: Forgive me. It is {Auth-F/16/209}, internal paragraph 621. So the heading is "Potential competition in the case at hand."

The Commission says:

> "As the facts in chapter 7 have shown, at the time Lundbeck and the generic undertakings concluded the agreements ... Lundbeck's basic patent on the ... compound ... had lapsed by January 2002 in most EEA [countries]... This meant that

citalopram markets in those contracting parties of the EEA were open to generic competition, as generic citalopram medicine could henceforth be sold provided it met with regulatory requirements as to quality, safety and efficacy as confirmed by a marketing authorisation."

In my submission it is crystal clear from *Lundbeck* itself that the patent position or rather the lack of a credible patent position drives the potential competition analysis, that is exactly what 621 in my submission says.

We see more of the same over the page, {Auth-F/16/210} recital 622:

" ... Lundbeck considered at the time that generic competition is foreseen on markets where the product patent has expired, that is to say in most EEA contracting parties at the latest as of January 2002."

That, of course, is at or even before the dates of the settlement in that case. At the bottom of that page, 623, the last line:

"In December 1999 Lundbeck wrote: 'By 2002 [again the date of the settlements], however, generics are expected to have captured a substantial share of Cipramil sales'."

Over the page at {Auth-F/16/211} third of the way down:

'the UK is the market which Lundbeck expects to be hit most severely by generic competition. Immediately following patent expiry in January 2002, generic sales are expected to take 60% of the citalopram business.' Given this assessment of the immediate and strong impact of generic competition on Lundbeck's market share (previously at 100%), there can be no doubt that potential generic competition exerted competitive pressure on Lundbeck well in advance of the expiry of the compound patent in January 2002 in most EEA countries."

A couple of pages on, if I may, {Auth-F/16/213} paragraph 628. Sir, at the start of that paragraph the Commission cites from AstraZeneca, which is that a patent is normally assumed to be valid. That is the presumption of validity.

They then go on to explain what that means in the context of Lundbeck and they say:

"This does not, however, in the view of the Commission, mean that the possibility of challenging the validity of a patent should be disregarded for the purpose of assessing the potential for competition, all the more so when the compound patent has expired and the medicine in question can in principle be sold."

Then at the bottom of that page the Commission points out that:

"In this case, it has, with respect to the likelihood of invalidity or of infringement of Lundbeck's patents, relied on assessments by the parties themselves, in particular as found in contemporaneous documents."

I have shown you some of those and in my submission it is crystal clear what the contemporaneous assessments were.

Now, a couple of pages on again, if I may. In a sense, were there a point of any doubt this brings it home. 634, page {Auth-F/16/216}. The provision says:

"Even if the argument were accepted that potential competition could be absent if it were - objectively considered - impossible to enter the market because of Lundbeck's process patents, the fact is that Lundbeck itself confirmed to the Commission that its process patents were not capable of blocking all possible routes to the market."

Then we see over the page {Auth-F/16/217} five different processes said to be non-infringing, which are listed. Again this is Lundbeck itself. This is not the Commission on a solo run.

This leads to, in my submission, a devastating conclusion at 642, page {Auth-F/16/220} where the Commission says:

"However, such restrictions are all the more likely to be illegal when the restrictions agreed do go beyond the substantive scope of the patent, in the sense that the same restrictions could not have been obtained by the patentee's right to oppose possible infringement before the court."

At the bottom of the page it says:

"With the expiry of exclusivity on the compound patent, the market for a citalopram was in principle open. Any commitment from a generic undertaking not to sell citalopram (here with reference to the compound, whether API or medicine) for a certain period cannot be justified by patent law simply because a process patent does not give the patent holder rights outside the patent's scope, which for process patents is limited to the particular process covered by that patent and products directly obtained by the patented process. Any such clauses (also referred to as out of scope obligations) indicate, like the payment itself from the originator undertaking, that the object of the agreement was to commit the generic undertaking to stay out of the generic citalopram market entirely for the duration of the agreements, irrespective of whether or not the generic products with the generic undertaking might have come to sell would have infringed any process patents."

Now, a point which has not been made by anyone on this side of the room is, well, just because the patent settlement is within the temporal, geographic and product scope of the patent, that means we win and we haven't made that argument and that is the argument which has been criticised by the CMA.

What the Commission in my view, at 642, and in the other paragraphs I referred to, comes very, very close to saying, without perhaps actually saying is that it wasn't even convinced that the settlements in Lundbeck were within the scope of the patents.

Now, that is one of the grounds of appeal being pursued by my clients and other entities before the Court of Justice. But these findings are there in the decision and at least in the facts of *Lundbeck* they do come rather close to suggesting that the settlement was not within the scope of patent. The same cannot possibly be said in our case.

When GSK says in its skeleton the settlements were narrowly tailored, that is what it means.

If you could turn to how the General Court looked at this. I can take this a bit more quickly. I am now back to the W bundle, tab 1. Starting, if I may, at paragraph 127 which is internal page 30. {W/1/30}.

> "... it must be observed then that, in the present, case Lundbeck's original patents had already expired when the agreements at issue were concluded, and that the crystallisation patent had not yet been definitively granted in the UK ..."

That was one of the points I should have mentioned. At least in the context of the UK settlements, the crystallisation patent of the UK had not actually been granted by the time of the settlement agreement. That was a further point.

The court says:

> "The grant of interim measures in favour of Lundbeck in the UK against Merck (GUK) and Arrow would therefore have been, if not impossible, at the very least unlikely in the event that those undertakings entered the UK market before that patent was granted. Consequently, it is unlikely that Lundbeck could have obtained injunctions against all of the generic undertakings ..."

Then at 128 the General Court picks up on the point we have just seen in the Commission decision:

> "It must therefore be found, as the Commission did ... that in general the generic undertakings had several routes constituting real concrete possibilities to enter the market at the time the agreements at issue were concluded ... Those possible routes including ... launching the generic product at risk, with the possibility of having to face proceedings brought by Lundbeck."

Then, at 129, and this is a critical phrase in my submission:

> "That possibility represents the expression of potential competition, in a situation such as that in the present case where Lundbeck's original patents, concerning both the citalopram API and the cyanation and alkylation processes had expired and where there were other processes allowing the production of generic citalopram that had not been found to infringe other Lundbeck patents, which the applicants themselves acknowledged in their reply to the statement of objections."

Now, pausing there, what Lundbeck is not saying in either the form of the Commission or the General Court is that merely being a defendant in patent litigation and having made certain preparatory steps towards entry does not make you a potential competitor.

It was dealing with a fundamentally different situation where it seems there was no effective patent position, outside of the patents there were other non-*Lundbeck* routes to market and it is that possibility that represents the expression of potential competition.

In case you were in any doubt, the court goes on to say:

> "In addition there were investments."

Essentially the only point made by the CMA against the Generics is, well, you had made some investments, you had a sort of sniff of the market.

Now the first point is that at 129, the General Court says, in addition there were investments. So there were anterior findings, but the real point is that a couple of pages on, at 159 {W/1/36}, it deals with the point of investments:

> "As regards, first, the investments made by the generic undertakings in order to prepare their entry to the market, it suffices to note that the Commission never considered that such investments sufficed by themselves to demonstrate the existence of potential competition ... The Commission, on the contrary, relied on a set of relevant factors ..."

So the point is that the investments are neither necessary nor sufficient, and insofar as they were indicators that went to potential competition, it was a series of composite points that were not related, at least exclusively, to investments.

Two or three final points, if I may, on this particular issue. First, paragraph 141 {W/1/33}. So court found that:

> "The Commission therefore did not err in relying on objective documents reflecting the perception that the parties to the agreements at issue had of the strength of *Lundbeck's* process patents at the time those agreements were concluded ... in order to evaluate the competitive situation between those parties ..."

I have taken you to at least some of those documents.

191, internal page {W/1/43}. This is the point we have seen in the Commission decision:

> "... Lundbeck itself confirmed that its new process patents were not capable of blocking all possibilities of entering the market, even though the crystallisation-based process seemed to be the most effective."

So there were non-*Lundbeck* routes to market; we have seen five of those listed.

One final point on this. At 131, page {W/1/31}, you will see this was not a case merely of potential competition. In the case of Sweden for five months, and in the case of the UK for a short period in August, which led to sales of £3.3 million in products, there was actual entry and Lundbeck even at that stage did not bring any infringement actions.

I accept this is a point that is confined to Merck and not to the other *Lundbeck* appellants, but *Lundbeck* was a case where at least for two periods there was actual entry.

Sir, one of the points that the CMA makes is, well, the absence of injunctions in *Lundbeck* was really neither here nor there, so the presence of injunctions in paroxetine does not get you anywhere.

Let us look at that issue, if we may. Sir, we can pick this up in the judgment starting at paragraph 121, internal page {W/1/28}.

So the ground of appeal which *Lundbeck* was putting in this context was patents are presumed to be valid, and therefore someone who is generic who is attempting to enter may be infringing, and therefore cannot be assumed to be a potential competitor.

Now, it is correct to say that as a matter of fact in *Lundbeck* there were no injunctions at the stage of the settlement agreements. In a sense, having seen the patent position, perhaps that is not terribly surprising. That is a relevant factual difference.

But the court nonetheless -- and I accept this is probably obiter, but in my submission it is highly relevant -- it does pick up on the point of injunctions. You will see repeated again at 122 the point about the 60% chance of losing. We have seen this already in 127 {W/1/30}, that because of the weakness of the patent position and because in the case of the UK the crystallisation patent had not even be granted:

> "The grant of interim measures in favour of Lundbeck in the UK against Merck ... and Arrow would therefore have been, if not impossible, at the very least unlikely in the event that those undertakings entered the UK market before that patent was granted. Consequently, it is unlikely that Lundbeck could have obtained injunctions ..."

In the previous paragraph, 126 on the previous page at {W/1/29}, it was not even certain that the appellants would actually have initiated litigation in the event that generics entered

the market. So not only was it unlikely that there would have been injunction applications, but it was not even clear that there would have been litigation.

In *Lundbeck* itself, apart from one case, I think involving Alpharma, there was no litigation. In a sense part of Lundbeck's strategy was to threaten litigation but avoid carrying that through, because the weakness of its position would have been laid bare.

A point picked up in GSK's skeleton is that the paroxetine interim injunction did actually feature in Lundbeck. We can pick this up in paragraph 263, which is internal page {58}. Starting at paragraph 263, sir, the argument being made by Lundbeck in this context was, well, the paroxetine interim injunction in the UK changed everything and after that stage an originator was much more likely to get an injunction, and therefore a generic was far more likely to be injuncted. This was essentially a game changer.

So in that context the General Court says, if their, Lundbeck's:

> "... interpretation of the Paroxetine judgment ... and their belief that they would be able to block the entry of generics by enforcing their patents, were correct, interim measures would surely have been granted against Arrow in the UK if Arrow attempted to enter that market with its generic medicinal products, thus allowing them to block that entry pending a favourable judgment on the substance."

The court makes the obvious point of, hang on a minute, if paroxetine was a game changer for originators, surely that made it more likely for you as an originator to apply for and obtain an injunction, not less likely.

But the point I want to emphasise for our purposes is an injunction in this context was equated with the existence of a blocking position. In a sense, there is nothing new or surprising. I mentioned this in my skeleton. The Commission guidelines, at least until they had rendered the *Lundbeck* decision, did say that to assess for a potential competition, you should assess the evidence of a blocking position, and it said it needed to be good evidence -- - that was the phrase -- of a blocking position. One aspect of good evidence was said to be the existence of an injunction.

So none of this, in my submission, is terribly surprising or novel.

The next point I want to deal with, if I may, is the question of supply agreements. In our case, the common feature of both settlements is that they included a supply agreement which allowed it for subdistribution of own branded paroxetine by the Generics in circumstances where they were injuncted. You have heard the figures mentioned, that this counted for about 75% of the total value of the settlement.

Now, in *Lundbeck* by contrast, save in two cases, there were no supply agreements. In the case of Ranbaxy and GUK there were, exceptionally, two supply routes. What the CMA tries to argue from that is to say, well, in *Lundbeck* there were also supply agreements and that got those appellants or Lundbeck nowhere. So in so far as supply agreements are said to be a distinguishing factor, (a) that is not true, and (b) it got them nowhere.

Let us look at that. That does mean going back to the Commission decision briefly. It is {Auth-F/16/281}, recital 799. Before I read that out, let me make one or two important preliminary points.

First of all, of course, the generics in this case, unlike Lundbeck, were injuncted. At the time of settlement, they could not enter. But the second point really is the critical one: in circumstances where, as I have outlined, there essentially was no good patent defence to generic entry because of the weakness in patents and the availability of non-*Lundbeck* routes to the market, then of course in that context it was obvious that turning around and saying, well, here is a supply agreement and that is pro-competitive was not going to get Lundbeck anywhere because the alternative in that context was that they were generics who, at that stage, could enter the market.

THE PRESIDENT: Well, it was not a hopeless patent. It was a 60% chance.

MR. O'DONOGHUE: Sir, yes, but they were non-*Lundbeck* routes, which were independent of patents. The Commission's phrase, which I have read out more than once, is the markets were open to generic competition.

One can perfectly see how in that context, which is not our case, offering a supply agreement may well not have been pro-competitive. That, in my submission, is a complete answer to the distinction the CMA tries to draw.

But it is also a bad distinction for other reasons, and this is where 799 comes in. The key point in *Lundbeck* was that they were resupplying a Lundbeck-branded product. In our case, the Generics had their own livery, essentially their own brand and get up, and they were independent, or as independent as they could be at the time, actors on the market who had a distinct identity from GSK.

Now, that had a number of consequences which are picked up here. In *Lundbeck*, 799:

> "... reimbursement levels in the UK were linked to generic entry into the market, not to any increase in the number of suppliers of the originator product. Thus, by turning Merck ... into an exclusive supplier of its own product, Lundbeck avoided any impact on the UK reimbursement level for citalopram, which Merck ... (and Arrow's) entry as a supplier of generic product would have had. This guaranteed Lundbeck continued

high profits on its sales of citalopram. Consumer interest rates were hurt, however, in that significant price decreases for citalopram that in all likelihood would have resulted from a generic entry were prevented for the duration of the agreement."

In our case it is common ground that the start of generic entry led to the drug tariff category shifting from C to A, and that because the category A reimbursement rate was based on Alpharma's pricing and some other market actors, there was an actual saving of £15.6 million under the drug tariff reimbursement rate for the National Health Service.

The settlement agreements in our case achieved the very thing that Lundbeck's sought to avoid and did avoid.

Then continuing at recital 800:

"... the agreement with Lundbeck also cannot be seen as a pro-competitive supply agreement that allowed Merck ... early market entry or substantially facilitated later market entry ... By distributing citalopram that was Lundbeck branded, Merck became dependent on Lundbeck and could not build-up any brand recognition as (generic) supplier of citalopram. Secondly, Merck ... was getting ready, at the time when it concluded the agreement with Lundbeck, to enter the UK market with its own generic product."

As we saw with Sweden and the UK in August, they did actually enter.

These are two critical differences, in my submission, and one is compelled to the conclusion that the supply agreements in this case were of a fundamentally different character and pro-competitive effect to the supply agreements in Lundbeck.

Sir, the next point I want to pick up on *Lundbeck* is also a very important point, also a critical difference with the present case. This is the question of profits.

If I can go back to the General Court judgment in *Lundbeck* in bundle {W/1/76}, paragraph 362, there the General Court notes:

"... the applicants do not dispute that the amounts which they paid to the general undertakings may have been calculated by taking into consideration the profit or turnover which those undertakings expected to make during the term of the agreements at issue if they had entered the market, which is a significant factor in that respect."

Now, the CMA skeleton argument I think goes as far as to say that the profit calculation was entirely irrelevant in *Lundbeck* and that is simply wrong, but the General Court describes it as a significant factor.

The point in my submission cuts a bit deeper than that because there were clear and uncontested findings in the Commission decision that in each and every case the payments made by Lundbeck under the settlement agreements exceeded, in some cases considerably exceeded, the profits the Generics expect to garner through independent entry.

Sir, if we can go back to the Commission decision on this point just to quickly give you the references. So the first reference in profitability for Merck is at {Auth-F/16/275}, 788.

THE PRESIDENT: Page 275.

MR. O'DONOGHUE: Thank you very much, sir:

> "... the totality of payments made by Lundbeck to Merck ... ensured Merck a profit of £7 million, roughly equal to what Merck had expected to make in the first year if it had entered the United Kingdom market with Natco product, but without any of the efforts and risks inherent in such market entry ..."

Just to give you the corresponding references for the others, in the case of Arrow it is recital 944 {Auth-F/16/332} in the case of Alpharma it is recital 1071 {Auth-F/16/372}.

Sir, if we can turn to the Ranbaxy reference, 1157, internal page {Auth-F/16/396}. In a sense this was an extreme case.

So the Commission says:

> "Lundbeck's transfer to Ranbaxy of the equivalent of 12.7 million euros in exchange for Ranbaxy not selling its citalopram to the EEA market considerably exceeded the profit Ranbaxy could have expected from selling the citalopram it had manufactured at the time of conclusion of the agreement."

So in each and every case there were clear and uncontested findings by the Commission that the payments in those cases exceeded the profits which would have been expected from generic independent entry.

THE PRESIDENT: I thought from that they say it is equal.

MR. O'DONOGHUE: Well, equal, yes.

THE PRESIDENT: Equal or --

MR. O'DONOGHUE: Equal or greater than. In our case, by contrast, we have the following.

First of all, there is no finding of the decision that the payments made by GSK matched or exceeded the amount of profits that the Generics could have garnered by entering independently. There is no such finding.

Now, secondly, this is not an accident of administrative decision-making because in annexes D and E to the statement of objections, the CMA attempted to do what the

Commission did in *Lundbeck*, and that was comprehensively demolished in response to the statement of objections. That is why in the decision there is nothing on this point.

Sir, that is not quite true. There are actually two footnotes which are interesting. If I can ask the Tribunal to turn up the decision, bundle {V/1/1}.

There are two identical footnotes. The Alpharma one is at 1037, which is internal page {V/1/315}. There is an identical footnote for GUK, which is footnote 935. What the CMA says there -- the corresponding paragraph, sir, starts at {V/1/314} at 6.178.

The CMA says:

> "It can be inferred that Alpharma considered the ... agreement provided it with expected returns that were higher than those associated with ... efforts to enter the market independently of GSK."

Then in the footnote, it says:

> "Alpharma's 'expected returns' would represent the average of the profits associated with the potential outcomes of its entry strategy (for example, the revenue and costs associated with each outcome relevant to its strategy (such as winning or losing any litigation, and the possible timing of its entry), and the probability of each outcome."

As I said, there is an identical footnote 935 for GUK. This arises in the context where instead of the footnote inference, the CMA attempted to prove this very thing and failed because that analysis in annexes D and E no longer formed part of the decision in any shape or form.

In my submission, this kind of inference, which really simply begs the question, isn't good enough and it certainly is not consistent with the findings made in *Lundbeck*

The third point, in a sense it gets even worse because what Dr. Stillman has done is essentially what the CMA should have done. He has in his annex 3, which he has elaborated on in his first consumer welfare report, he has analysed the comparison between the payments under the settlement with the payments that would have arisen on this probabilistic inference. His conclusion, which is entirely unchallenged by the CMA, is that, in fact, the payments under the settlements were far below the levels of payments and profits that would have materialised on this probabilistic assessment.

That evidence is unchallenged. In my submission, for the CMA to make good its case, it should, in the same way as the Commission did in *Lundbeck*, have reached a positive finding on this point instead of burying the issue in an inference in two footnotes.

It has not done this and the Tribunal is left in a very, very unsatisfactory position that there is no cardinal or metric by which you can understand why in this case the size of the

payment is relevant. It is simply asserted, well, this was a big payment and we infer that it was big enough to persuade you to settle and that is it.

Now, in my submission, that is not good enough. It falls a long way short of what was done in *Lundbeck*, and the fact that the CMA embarked on a course of trying to demonstrate superior profits and failed and has effectively withdrawn that analysis, and the fact that it does not challenge in any way Dr. Stillman's conclusion essentially on the same point, is fatal to its ability to rely or seek to make inferences from the size of the payment.

MR. MALEK: Where do I get the reference in the statement of objections?

MR. O'DONOGHUE: It is annex D for GUK and annex E for Alpharma.

MR. MALEK: The bundle reference.

THE PRESIDENT: Where are they?

MR. MALEK: You can give it to me first thing tomorrow morning, that is all right, if you do not have it straightaway.

MR. O'DONOGHUE: Sir, I do not.

Sir, I am conscious I have been doing a lot of reading by way of submission. In my submission, very, very briefly, there are five critical differences between *Lundbeck* and the present case. The first difference is the patent position. It is not in any sense comparable. The patents had either expired, had not yet been granted or were granted, were considered by Lundbeck to be very weak.

Second, both because of the patent position and because of non-*Lundbeck* routes to market, the Generics did and could launch a risk. Again, the Commission found the market was open to competition. That could not be said at the time of these settlements.

There were no injunctions at all in *Lundbeck* or, save for one case, even any litigation.

Fourth, the Generics in this case could supply their own branded products under supply agreements, and those agreements were bound to, and did, lead to pro-competitive benefits, including the reduction in the drug tariff by £15.6 million, wholesale price reduction and pharmacy price reduction, all of which is common ground.

Fifth, the finding in *Lundbeck* that payments under the settlements exceeded the profits from independent entry was critical to the objection to the settlements. The General Court described it as a significant factor. In each and every case there were findings that those payments matched or exceeded profits from an independent entry. Not only have we no such findings in this case, but past attempts to try to make them good have failed and have been withdrawn.

Sir, those are my submissions on *Lundbeck* unless I can assist you further.

THE PRESIDENT: Thank you very much. You have finished ahead of time, Mr. O'Donoghue. It has been very clear and helpful.

On the question of a hyperlink from the skeletons to the authorities, which we would find very helpful, you might need to speak to the Opus team about how that is done. I suspect you may have to refile skeletons with the links put in to the bundles. Is that something that could be done by Friday? It means we will not have it for when Mr. Turner makes his submissions, but I think it may be difficult for you to do it by tomorrow morning. If we say as soon as possible, if everyone can do that, that would be a great help.

I think they are hyperlinked to the documents, but not to the authorities. We have a lot of authorities bundles so it would greatly assist.

MR. FLYNN: Sir, I know that you are in a rush --

THE PRESIDENT: We have a few minutes.

MR. FLYNN: This won't take more than one. It is simply that yesterday you asked questions about evidence in relation to Tillomed and whether it had a viable source.

THE PRESIDENT: Yes.

MR. FLYNN: We have pulled out from the documents various materials in relation to that and have got a note, it is a one-page note, with few documents and references to the bundles which I will, if I may, hand up if you would find that helpful.

THE PRESIDENT: Yes, please.

MR. FLYNN: (Handed) I have copies for my learned friends. That is all I need to say at the moment. Thank you, sir.

THE PRESIDENT: We will look at that. Thank you.

MR. FLYNN: We have suggested that, insofar as there are documents that are not already in the bundle, they can be inserted in the overflow bundle, K. It may be you prefer to put the whole thing in in one lump simply as a note in the next tab in K. I leave that to how the Tribunal would like to organise its own documents. We will obviously make sure your bundles are updated very quickly.

THE PRESIDENT: Yes. I think probably all together. My bundle K is bursting, but ... (Pause) Maybe we will create a new, I hope, slim bundle just of notes handed up.

MR. FLYNN: Very well.

MR. O'DONOGHUE: Sir, I have located the two references that Mr. Malek asked for. The GUK annex is annex G,{A1/4/665}, and the Alpharma annex is annex C {A1/4/676}.

MR. MALEK: Thank you very much.

THE PRESIDENT: Sorry, the second reference is?

MR. O'DONOGHUE: {A1/4/676}.

THE PRESIDENT: Thank you. 10.30 am tomorrow.