IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

2 March 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

THE PRESIDENT: Just one moment. (Pause).

Mr. Turner, we have seen, of course, the CMA's letter to the Tribunal of yesterday and the note from GSK and your response. You are of course free to address us further but it might be helpful to indicate what our preliminary view is to that.

MR. TURNER: Yes.

THE PRESIDENT: We have looked at the Notice of Appeal. We think technically you are right that the early paragraphs should have identified more inferences of fact which are findings of fact than inference -- leads to a finding in the decision that are being challenged.

But, on the other hand, when you look at the body of the Notice of Appeal and what is said in it, both as regards the GUK litigation and the Alpharma litigation, we think it does there make clear that GSK is saying that they were confident in their patents and that the other product infringed.

Of course, with the Notice of Appeal were served the witness statements of Dr. Reilly and Vivien West which say that. So, as I indicated, we think the failure to follow the terms of the guide and the rules was clear upon receipt of the Notice of Appeal and could have been questioned then, you can see the evidence that was going to be called, and that we do not therefore think it is appropriate to require an amendment at this stage.

We do think, however, just for our own purposes, not for anything else, it would be helpful to have a note from GSK, as asked for by Mr. Malek, setting out clearly those particular points in the decision of fact that are not accepted. If it is an inference of fact, that is a factual finding, so we would like that note in any event.

MR. TURNER: Of course.

THE PRESIDENT: We see that there is no objection to you seeking to cross-examine Ms. West, even though GSK say it is not necessary but that is their view, but if you want to on Monday, as I understand it, she will be available.

MR. TURNER: Or another day.

THE PRESIDENT: At a convenient time for everyone. So that is our initial view on having read what we have seen -- obviously either you or Mr. Flynn can seek to argue the contrary -- on what effectively was your application that this point should not be accepted, unless the notice of -- an application is made to amend the Notice of Appeal we are not at the moment persuaded that that is right.

MR. TURNER: I do not know if Mr. Flynn wants to speak first but I do have some observations to make --

THE PRESIDENT: I think it is probably right for you to speak first because I think you are taking the objection.

MR. FLYNN: Sir, the only point I was going to make -- and I am not seeking to quarrel with what the Tribunal has said -- the only point I was going to make was, we say we are perfectly happy for Ms. West to be cross-examined. That is a decision for the CMA; whether that is consistent with their case is another point.

It is just it would be very helpful, given that she was not expecting it -- she has of course got plans, she has told us that she is prepared to drop everything now, she could be here on Monday, which would be within the timetable. Really we would like a decision today as to whether she is going to be called and of course we can discuss when that would be, but it can be fitted into the trial timetable.

THE PRESIDENT: I expect it would not be long, her evidence, in any event.

MR. FLYNN: I would not have thought so.

THE PRESIDENT: I think that is fair if you can inform -- it does not have to be during court hours, but by the end of today.

MR. TURNER: In that case, sir, because it will obviously impose a great deal further pressure on us at the weekend, we will wish to explore the relevance of that witness statement and if I may make certain submissions now directed to your remarks and see how we go.

THE PRESIDENT: Yes.

MR. TURNER: We have been proceeding on the basis that the Notice of Appeal contains GSK's case. The Notice of Appeal is what contains the pleas concerning errors of fact, both primary and secondary fact, which are relied on in support of the appeal.

If the electronic system is already up and running, if we go to {A/2/28}, you have paragraph 1.51 of their notice which I referred to before. This is where they say:

> "Whether any of the Generic Companies could have entered with a paroxetine product was the issue in the avoided litigation. That precise question is now moot and cannot be determined in this appeal, and certainly could never have been [decided] ...."

There they are saying that this Tribunal is not in a position to determine the patent law questions. The document entitled "Skeleton", which we received shortly before the trial, does not operate to amend the case in their Notice of Appeal. The Tribunal may recall that as soon as we received it, 15th February, we wrote to the Tribunal to point out that this should not be the occasion to raise new matters not in their Notice of Appeal. I do not know if you have copies of the letter but that is what we said.

THE PRESIDENT: Yes, I remember.

MR. TURNER: Then we, again in our skeleton, referred to the Tribunal Guide and the provision in paragraph 4.5 --

THE PRESIDENT: Before you go into all of that, you see I do not think that statement, that the Tribunal cannot determine what would have happened in the patent litigation and whether they could have entered -- I do not think that has been departed from. I do not see any attempt by anyone to get us to determine the outcome or the probability of outcome of hypothetical patent litigation, as you sometimes have to in a solicitor's negligence case where they miss a limitation period and the trial never takes because. But if you go on in the Notice of Appeal, the document you took me to, I am in a hard copy for that, at 2.51 --

MR. TURNER: I will come to it if I may at the moment. I take that point.

THE PRESIDENT: What they were saying there is not that the outcome of the patent litigation would have been in our favour; they are saying that GSK believed that its patents were strong and that these new products, which for GUK they had a sample, infringed and for Alpharma it is a bit less clear because, as Ms. West says, the experiment on the process claim, and it was only the process claim that was valid then, was inconclusive. But she says the patent was strong, validity -- that had been held at that point by Mr Justice Pumfrey. The question was -- infringement was unclear. So that was their belief.

That I can see is challenging an inference of fact in the decision but that challenge does emerge from the Notice of Appeal and the witness statements with it.

MR. TURNER: If I may I will turn to that specific in literally a minute. I first want to make a general point because the 230-odd pages of the document entitled "Skeleton" includes a very long discussion and we wish it to be clear -- and perhaps it is -- that no inferences of fact or primary facts are alleged to be errors by the CMA and material to the appeal which are not in the Notice of Appeal.

If that is clear, then we are rightly basing ourselves on the case against us in the Notice of Appeal. So, as a general point, because we are in trial, we wish it to be clear what case we are facing generally. Therefore, particularly because the note which has been received by GSK today seems to proceed on the basis that they are only concerned with errors of primary fact in their Notice of Appeal, which is wrong, we just want, as a general matter, first to be clear whether there are any inferences material to their appeal which are not in the Notice of Appeal but which they seek to rely upon as a general point.

Mr. Flynn may well stand up now -- and I would be grateful -- and say, "No, there are none".

THE PRESIDENT: But the particular ones that we are concerned with in how this arose, regarding Ms. West, is GSK's subjective belief of the strength of its patents.

MR. TURNER: Yes, I will turn to that right now but as a general matter --

THE PRESIDENT: So that is the specific one which is not identified in the paragraphs in the Notice of Appeal which say these are the factual matters we challenge, but which does emerge from later paragraphs in the Notice of Appeal.

MR. TURNER: For that one I will address that in a moment, but as a general matter, if there are other inferences --

THE PRESIDENT: Well we are asking for the names and we can deal with that and we will get it; that is the note that Mr. Malek asked for.

MR. TURNER: I am obliged. I will turn directly to the question of Ms. West.

It is said on their case, but not ours, this is relevant to the questions arising in these proceedings.

THE PRESIDENT: Yes.

MR. TURNER: I think it would be helpful then if we explained how we understand their Notice of Appeal. If you go to {A/2/149} you will have there paragraph 6.96 of their Notice of Appeal. Sir, it is expressed in a discursive style.

However, if you go halfway down that they say:

> "The CMA has no basis for taking from it a conclusion that GSK thought its patents were weak ..."

That GSK thought its patents were weak:

> " ... or that the generics were stopped from entering the market. On the contrary, as explained throughout the procedure, and confirmed in the evidence in this appeal of Dr. Reilly and Ms. West [two witnesses], the patents were strong, and GSK believed in them ..."

So there there seems to be a crystallisation of the point they are trying to say and they are saying they are relying on both Reilly and West.

THE PRESIDENT: Yes.

MR. TURNER: We have also reviewed the Notice of Appeal to see the reliance particularly placed on Ms. West. If I may, I think the first important reference is, in fact, at 2.40 at {A/2/43}. If you go -- this is just above the "IVAX patent dispute". You will see the last sentence there:

"These risks, combined with the litigation risk associated with complex and highly technical litigation, the expense of litigation and disruption to the business were all real concerns caused by the threats by the Generic Companies."

So that is their starting point. That does not refer to Ms. West directly. Then you go to {A/2/46}. This is the paragraph, sir, that you referred to.

THE PRESIDENT: Yes.

MR. TURNER: The last sentence with a footnote relies on Ms. West:

"GSK was nonetheless aware of the complexity of the patent issues and of the attendant litigation risk."

THE PRESIDENT: And the previous sentence, that is the important one I think:

"In particular, GSK was confident that its own [anhydrate patents] were sound and considered that GUK's product fell within the scope of those claims."

That is also Ms. West.

MR. TURNER: That is right.

THE PRESIDENT: That is the critical sentence, it seems to me.

MR. TURNER: Yes, I am obliged. Then:

"GSK was nonetheless aware of the complexity [and the] attendant litigation risk."

THE PRESIDENT: Yes.

MR. TURNER: Then you go to 2.59 at {A/2/48}. The penultimate sentence in particular, which comes from Ms. West -- you see it from the footnote. This is the now the Alpharma litigation:

"The inspection at Delta's premises had not conclusively resolved for either party the question whether the process claims in the Anhydrate Patent were used and this represented an added layer of complexity to the already complex issues to be resolved in the litigation."

They rely on Ms. West for that.

THE PRESIDENT: The first sentence effectively, I imagine, of that paragraph as well:

"At the time, GSK considered it was likely that Alpharma's product infringed the Anhydrate Patent process ..."

MR. TURNER: Yes. Finally footnote 393 at {A/2/134} for completeness. This relies on the evidence of Vivien West to the effect that there were actually other ways to get into the market. There were non-infringing routes open to alternative suppliers.

You have heard something about a distinction between this case and the Lundbeck one. That is a point that should not go on unremarked on.

THE PRESIDENT: Yes.

MR. TURNER: Finally, before I make a comment, if you turn to Ms. West's statement itself at {E/1/11}. Paragraphs 41 -- you will see under the heading halfway down:

"Litigation over paroxetine was particularly complex."

The heading (a):

"Unanswered legal question over the prior art."

I am saying this so you can appreciate also what the content of cross-examination -- how it might be necessary to explore it would go.

THE PRESIDENT: Yes.

MR. TURNER: In 41 she refers to that unanswered legal question in terms. If you turn over the page to 42, {E/1/12}, under the heading:

"Impossible to tell whether the ... process claims infringed ..."

This, sir, is a comment you made earlier in the hearing.

THE PRESIDENT: Yes.

MR. TURNER: She says we would not know that -- you cannot tell that by simply analysing the end product.

THE PRESIDENT: Yes.

MR. TURNER: Then 73 on page {E/1/21}

THE PRESIDENT: That is clearly right what she says there.

MR. TURNER: Yes. Absolutely. It refers therefore to that area of uncertainty about infringement. There she says -- as you will see at 73, she considers:

"... the Anhydrate Patent had valid claims and that ... product contained paroxetine hydrochloride anhydrate Form A which infringed ..."

This does bring together sir the Notice of Appeal:

"There were, however, litigation risks for GSK, particularly in relation to the issues described above ... and also in relation to difficult Points of Claim construction which had been raised ..."

So there she is identifying the risks that she perceived.

The final reference is at 98 on page {E/1/27}

THE PRESIDENT: Yes.

MR. TURNER: This is her evidence in relation to Alpharma:

"Neither side, it appears, was certain as to the true position following the inconclusive inspection in Iceland ... In the face of these uncertainties, the parties settled their dispute ..."

THE PRESIDENT: Yes.

MR. TURNER: Standing back, seeing the Notice of Appeal and the witness evidence in support, one asks oneself how is GSK saying on its case that this is relevant to the issues you have to decide? Are they saying that although you, the Tribunal, cannot directly assess the issues in the patent trial, Notice of Appeal 1.51, nonetheless you should deduce it, the patent strength, from Ms. West's evidence or, if not, how else is Ms. West's evidence relevant on their case because it will help us to understand -- and I hope the Tribunal -- why they are saying this is so important?

THE PRESIDENT: Shall I tell you at the moment how I see it is relevant; would that assist given that we have to decide the case?

There is a difference between the position at the time of the GUK settlement and the position at the time of the Alpharma settlement. A very significant difference. It arose because of the judgment at trial by Mr Justice Pumfrey, which, if I get this right, was delivered in July 2002, where -- I know it was on appeal but still it is a fully reasoned after a full trial. The Alpharma agreement came several months later after that judgment. At the time of the GUK agreement the litigation had not concluded. Therefore, there was an issue on validity and there was an issue on infringement, both unresolved.

What I understand Ms. West to be saying is that, at the time of the GUK settlement, GSK believed it was on strong grounds on validity and it was also, she says, firmly believed that the GUK product -- which presumably had been tested and analysed and there had been expert evidence, because this was a door-of-the-court settlement, so the trial was about to take place -- infringed.

But, she says, we certainly could not be sure of that and these are complex patents and there are all kinds of arguments, leaving aside the possibility of an erratic judgment, just the arguments in the case were difficult so there was a -- not a fanciful risk of losing them, there was a real risk of losing them, but we felt we had a good case against GUK. That is how I understand it. That was their subjective state of mind. She is not saying what would have happened in the trial. That is my understanding.

When you come to Alpharma, by contrast, all the claims in the patent have been invalidated except the process claims, so it came down to the process claim; that was the important one. She -- I am not even sure if the validity process claim was being challenged in the Alpharma trials. Certainly Mr Justice Jacob's interim observations at the hearing suggest it was all about infringement of the process claim because he thought an inspection of the

plant could resolve the case very easily. So that suggests that was just infringement. On that Ms. West says the position was uncertain.

I do not think she says, we were confident of the outcome. I think she says the opposite: we just did not know and neither side knew. That is my reading of the evidence. I do not know if my colleagues have read it differently. Just one moment. (Pause)

Particularly on the GUK, on the counterfactual there, I think GSK, as we understand it, are saying that, "We believe we had a strong case and we settled it with that state of mind", and therefore on the effects case they seem to be saying the likely counterfactual is "We would have won". I think. That I am not quite sure about.

MR. TURNER: May I make comment and then perhaps Mr. Flynn can clarify this.

THE PRESIDENT: Yes.

MR. TURNER: We understand in relation to both these companies, both Alpharma and GUK, there is perceived to by Ms. West, as she has described, to be elements of risk and there were different situations to address.

They fell along a spectrum and exploring that question with her in court at the moment might be a matter of some obscurity.

There has been no disclosure of legal advice by GSK as to what they were actually acting on, so this is a witness saying what she thought the precise level of risk was on a spectrum at a particular time many years ago.

That then takes me to my earlier question: how do they say it is relevant what Ms. West thought about the precise level of risk in either case?

THE PRESIDENT: I think you found in the decision that GSK -- and you quote from a lot of documents -- thought that the patents were very vulnerable and that that is the background in which -- and you analyse the internal documents and --

MR. TURNER: We proceed on the basis of uncertainty.

THE PRESIDENT: Yes.

MR. TURNER: We referred to the Rachel Parr notice, the contemporaneous --

THE PRESIDENT: Not just uncertainty of the element of litigation risk and complexity but actually the bit slightly deeper uncertainty of patent strength.

MR. TURNER: Which also Ms. West does accept. As you have seen, even in relation to GUK, she gives particular examples. So I ask again, I ask myself, how are they going to say -- and perhaps Mr. Flynn should clarify this now -- it is relevant what Ms. West thought precisely about the level of risk.

THE PRESIDENT: Thank you.

Mr. Flynn, I think what would be helpful to know is: is your case advanced on a basis that the position was uncertain and that is the basis on which the settlements were reached, or are you advancing on the basis that GSK believed it had a very strong case but there was always a small element of litigation risk? Those are two quite different situations.

MR. FLYNN: Sir, we have never put percentages on it and insofar as it is -- we have always said the outcome was uncertain. You were taken many times to the reply to the Statement of Objections yesterday and that is -- it is the point we make in our notes as well.

THE PRESIDENT: Is there any relevance then in Ms. West saying that she believed that the patents were strong and that GSK was confident that it would prevail against GSK?

MR. FLYNN: This whole discussion in a sense is going the wrong way round, sir, because I think if Mr. Turner wants to say there are inferences of fact drawn in the decision which GSK cannot challenge because they are not raised in its Notice of Appeal -- and the skeleton argument, as we accept, is not a pleading and does not amend it -- he can make that submission. But insofar as -- it was never clear to us -- and I think as the Tribunal has also indicated -- it is not clear whether in fact the CMA is saying GSK had weak patents, see Ms. Parr's note, that is the end of it, or whether it is just throwing that in, as we have said, for colour. We say there is no clear finding.

Mr. Turner has put his case, and said it again today, it is on the basis of uncertainty, you do not know what the outcome would be and then if it is settled then we can review that under Chapter I.

THE PRESIDENT: But uncertainty -- not just objective uncertainty but that GSK itself was uncertain?

MR. FLYNN: Well, GSK was uncertain. Ms. West's evidence is clear on that. GSK did not know what the outcome was but insofar as you want to know how they were actually feeling about it, she explains confidence levels and reasons for them. She also says what she now sees, having seen the other side's documents.

THE PRESIDENT: That is her comment on the other evidence. That is not really very relevant.

MR. FLYNN: She thinks it explains the settlement dynamics.

THE PRESIDENT: I know. That is her interpretation but we are interested in her evidence.

It is really that bit in her witness statement where she says that, in the paragraph that we have been looking at, 73. As far as the Alpharma one, I do not think she is advancing a state of confidence at all {E/1/21}. But as far as GUK, she is making a very positive statement in the first sentence.

MR. FLYNN: She is, sir. We say nobody should proceed in this case on the basis that GSK felt that its patent position was weak. Insofar as the case is sought to be aligned on the *Lundbeck* case, we say this is a very big difference. The strength of the patents is said to be a relevant issue and this evidence goes to that.

Mr. Turner may say actually we do not mind -- nobody can say what the actual strength of the patents was and nobody can say who would have won the litigation and all we are concerned with is settlement in a situation of uncertainty.

THE PRESIDENT: If CMA's case is that GSK did not think its patent was weak but did not think its patent was particularly strong but was uncertain, you are not seeking to challenge that; is that right?

MR. TURNER: You see how it is put, sir.

THE PRESIDENT: I see how it is put but it is the question of the relevance to the way you are putting your case, not what Ms. West says. Is that going to be a part of your argument that GSK considered its patents were strong?

MR. TURNER: Yes. GSK had confidence in its patents. It did consider that it had a strong case in these -- in this litigation.

THE PRESIDENT: That is part of your argument here?

MR. TURNER: Insofar as it is relevant to the issues, yes, that is our argument.

THE PRESIDENT: Mr. Malek is drawing attention to your skeleton argument at section 4, which is I think {S/2/90}, where you talk about the relevance of *Lundbeck*:

> "The relevance of the General Court's *Lundbeck* judgments."

And you summarise in 4.3 what you say are the various relevant points of *Lundbeck*. Then, on page {S/2/91}, subparagraph 5, you say:

> "Even within the scope of its patents, Lundbeck's patent position and its appraisal of its patent position, was weak according to the General Court's analysis."

You quote from the judgments. Then the last sentence:

> "By contrast, the patents relied upon by GSK were in force throughout ..."

That is the injunctions:

> " ... and GSK was confident in its patent position ..."

You are, it seems, seeking to draw a distinction based on GSK's subjective position that its patent position was strong.

MR. FLYNN: Yes, we do. We do say GSK had confidence in its patent position. It had -- was very conscious of the risks of litigation, as Ms. West painstakingly explains.

THE PRESIDENT: And there is a reference back to 2.50 in your skeleton on page {S/2/17}.

MR. FLYNN: It is a theme and it will be made in various places.

THE PRESIDENT: I see what you say there. I do not think it quite reflects what Ms. West says about the Alpharma litigation but still, that is the way you put it. So that is the case they are putting and they are relying on that, Mr. Turner, to distinguish *Lundbeck*. There is one point of distinction; is that right?

MR. FLYNN: It is important in terms of distinguishing *Lundbeck*, yes. If anyone is saying this is a weak patent claim, like the *Actavis* case Ms. Kreisberger was bringing to your attention the other day, this is not one where the originator's subjective intention was, we have a big problem with this patent. They have concerns about the uncertainty of litigation but they think they have good patents.

THE PRESIDENT: Yes. There are various other references and that is how it is relied on.

MR. FLYNN: I beg your pardon, sir. Just in terms of Alpharma, you might wish to remind yourself of paragraph 96 of Ms. West's witness statement {E/1/26}:

> "... we did not have enough information to be certain, the only method GSK was aware of ... was the displacement step covered by [the GSK process patent] ..."

THE PRESIDENT: Yes, I know that.

MR. TURNER: It is a significant thing to bottom out because Mr. Flynn says, insofar as this is relevant to the issues, before we take the decision to call a witness and work over the weekend to prepare for it, why are the precise confidence levels of Ms. West in winning litigation, because of the underlying merits of the dispute, in GUK or Alpharma, relevant to the issues, according to them, that you have to decide?

In paragraph 73 {E/1/21}, sir, she refers back to the earlier paragraphs I took you to, 41 and 42, making it quite clear that this is not merely litigation risk because of erratic judgments, but because of specific matters that were difficult in that case.

THE PRESIDENT: Yes.

MR. TURNER: Before one considers bringing a witness along to see what they now say, without us seeing the legal advice, was her precise confidence level, it is important to know why this is said on their case to be relevant to the issues that you have to decide. They are saying, perhaps, that in *Lundbeck* there was a difference and that they will seek to say that that is material, but it is not clear how.

THE PRESIDENT: I think they are saying that in *Lundbeck* the court took the view not based on hypothesising the outcome of patent litigation but on the basis of internal Lundbeck documents that Lundbeck considered it had what was described as a weak patent. They are saying that is, on their case, one of the bases of the reasoning in *Lundbeck*. You may

disagree with that but that is what they are saying and they distinguish this case because this is a case where internally they considered their patent was strong, although there were still some difficulties.

I do not think it is a difficult point to grasp, is it? That is where they say it is relevant and that if you say, on the basis of Rachel Parr's note or any other documents, that actually they thought their patent was weak, they challenge that through Ms. West's statement. They say that inference you draw or interpretation is not correct.

MR. MALEK: If I can just interject, if you look at what their case is, their case at paragraph 2.55 of their skeleton {S/2/20} is that their belief on the strength that this patent was strong and unwavering and there maybe a world of difference if you look at *Lundbeck* between someone with a patent right knowing they have a weak patent and buying off the opposition and somebody who believes they have a strong patent and they pay something to resolve litigation.

You may not agree with it but that seems to be their case and, at the end of the day, you have to make our own choice as to whether or not you want to cross-examine Ms. West. But it is quite clear to me, looking at paragraph 2.55, they rely on Ms. West very heavily and if you do not cross-examine, they are going to have a free kick. It is up to you to make up your own decision. I do not think it is going to take a long time to cross-examine her. You have some key points, you have the Ms. Parr email and various other things that go the other way, but this is their case and it is for you to make your own decision.

As regards the unfairness point that you are raising, I fully understand what your point is because if a party relies on their subjective intention and that subjective intention is going to be part informed by the legal advice, you may say it is unfair for them to say, "Well, I believe we have a strong patent", without you seeing whatever legal advice they are getting because these are big boys: they are not going to settle litigation of this size and pay this sort of money with a sophisticated company like that with extremely experienced counsel without going to them and saying "What are the odds? Where do we lie? Is this a 20% case? Is this an 80% case? Because if you are telling us it is a 20% case, we will pay whatever there is to keep these people off the market. If you are telling us it is a 90% case, then we can give them some small change, but we are not going to pay much money." You have your own choice to make but we cannot make it for you.

MR. TURNER: Of course. The assistance from this debate is that we have clarified -- I apologise for taking so long -- we have clarified precisely what the area of debate is and what they are saying.

MR. MALEK: Yes.

MR. TURNER: So far as our intentions are concerned, if I may, I would prefer to inform the Tribunal about whether we do wish to cross-examine Ms. West after the cross-examination which is the next up of Mr. Reilly.

MR. MALEK: That is perfectly fair because at the end of the day we do not want you to go over the same ground with more than one witness. If two witnesses are covering the same ground, it is not your obligation to put your case to every witness. So I think it is perfectly rational for you to say, let us make a decision once we have heard Reilly.

MR. TURNER: I am obliged.

THE PRESIDENT: That is from my point of view.

Of course it is open to you to submit at the end that it does not matter and this was not a material part of *Lundbeck*.

MR. TURNER: Of course.

THE PRESIDENT: But that is how the case is being put against you.

MR. TURNER: I am grateful.

THE PRESIDENT: Do you need any more from us at this stage?

MR. TURNER: I do not. I think I can now continue.

THE PRESIDENT: Mr. Flynn I think the position is clear and we do still want, please, that note setting out what are the inferences of fact in the decision that you challenge.

MR. FLYNN: We will look at that, sir.

THE PRESIDENT: If we have it by -- if we can have it by close of business on Friday that would be helpful.

MR. FLYNN: That is what we will aim for, sir. Opening submissions by MR. TURNER (continued)

MR. TURNER: Sir, before going to the facts and to pick up two things that were important from yesterday, Mr. Glynn asked me about reverse payments and I referred to the US authority and the brief statement there.

It is actually perhaps more helpful and relevant to show you how it has been used in the European setting. The *Lundbeck* judgment refers to it at {W/1/70}, paragraph 334.

This is talking about the Commission:

> " ... thus considered that although all patent settlements were not necessarily problematic from at competition law perspective, such agreements were problematic where they provided for the exclusion from the market of one of the parties which was, at the very least, a potential competitor of the other party for a certain period and

where they were accompanied by a transfer of value from the patent holder to the generic undertaking liable to infringe that patent ('reverse payments') [defined] (recitals 639 and 640 of the contested decision)."

If you go to authorities {Auth-F/16/21}. Here you have the key paragraphs in the Commission decision. If I may, I would like to the Tribunal to see those.

This also ties into a comment raised by the President the other day as well. 639:

"Nor is it necessarily the case that all patent settlements that contain payments of some kind would be problematic under Union competition law. Payments may, in specific legal and commercial circumstances, be instrumental to the finding of an acceptable and legitimate solution for both parties. This is the case in particular, but not exclusively, in cases where, for example, the generic undertaking had already entered the market and if each party in the course of litigation comes to consider that the likelihood of patent validity and infringement is high, a patent settlement may legitimately include not only a withdrawal from the market of the generic product, but also a payment from the generic undertaking to the originator undertaking to settle the damage suffered by the latter.

"Likewise, a patent settlement could include a payment from the originator undertaking to the generic undertaking, if originally, through legal threats or court action of the originator undertaking, the generic undertaking had refrained from entering the market and both parties come to consider later on, in the course of ongoing litigation, that there is in fact a high likelihood either that the patent is invalid or that it is not infringed.

"If in that case a patent settlement is concluded that allows for immediate market entry by a generic undertaking, such a settlement could legitimately include a payment by the originator compensating the damage suffered by the generic company. Another example of an unproblematic settlement including payment is the settlement of *Neolab* ..."

THE PRESIDENT: That is effectively under the cross-undertaking presumably?

MR. TURNER: Yes, essentially. That is when they say you would expect to see a payment from an originator. Turn the page please {Auth-F/16/220}:

"However when an agreement is concluded in which the generic accepts to exit or not to enter the market for a seniority period of time (in which case one would expect, if anything, a payment by the generic ... to compensate the originator undertaking for any damage it may have suffered) [a point I made yesterday] but instead the originator

pays a considerable sum money to the generic ... then such an agreement, whether referred to as patent settlement or not, merits the full scrutiny of competition law.

"The reason is that such a constellation would mean that the originator undertaking has paid the generic undertaking to accept to give up, at least for the term of the agreement, its independent efforts to enter the market. Because of the unexpected direction of the payment, such payments are referred to in literature as 'reverse' payments. In principle, the higher the originator undertaking estimates the chance of its patent being found invalid or infringed, and the higher the damage to the originator undertaking resulting from successful generic entry, the more money it will be willing to pay the generic undertaking to avoid that risk.

"The danger is that such payment, in the light of the specific circumstances of the case, may actually constitute 'exclusion' payments, that is to say payments by the originator undertaking to the generic undertaking in exchange for the latter's acceptance of commercial limitations which it would not, based purely its on the assessment of the likelihood which it would not, based purely on the assessment of the likelihood of infringing a patent and of invalidating any such patent, have the same incentives to accept in the absence of the payment."

That is a very helpful description of the underlying theory and why the reverse payment is considered to raise a competition concern in this way.

THE PRESIDENT: Yes.

MR. TURNER: The other area I would briefly mentioned, because it was again canvassed, was whether for an effects case, where you use a counterfactual, it is sufficient to rely on the agreement eliminating potential competition without an additional need to prove how that potential competition would actually have developed.

Sir, you said yesterday you were not immediately aware of case law where such an approach had been taken in an effects case. That is one where it is not being said the purpose or object of the agreement is to restrict competition.

THE PRESIDENT: Yes.

MR. TURNER: If I may go to our defence at {B/1/66}. At the bottom of the page, paragraph 225, we say:

"It is not possible to say with certainty exactly how that potential competition would have developed in the counterfactual, but the possibilities fall into only two categories."

That reflects my oral submissions yesterday. {B/1/67}:

"The continued litigation counterfactual was therefore appreciably more competitive than the Agreements. Similarly, while it is not possible to say whether the parties would have opted for a lawful, pro-competitive settlement instead of continuing with the litigation, if they had done so, it would by definition, have been appreciably more competitive than the Agreements. "

There we say there would have been a more competitive situation. That is our case.

THE PRESIDENT: Yes.

MR. TURNER: If you go on to {B/1/74}, at paragraph 249, we point out that:

"[The case against us] is that we must go further and show that GUK and Alpharma would have won the litigation and entered on an independent basis before they actually did."

We then refer to the horizontal agreements guidelines, referring to:

"... restrictive effects on competition which can be proved by reference to potential competition which would have existed in the absence of the agreement."

Therefore, we take from that the idea that in an effects case too the removal of potential competition can count.

THE PRESIDENT: That is clear; it is a question of how you interpret the idea of potential competition.

MR. TURNER: If we turn the page, please. We refer at 251 {B/1/75} to the *Visa Europe* case as providing an illustration. It was an effects case. We referred there -- perhaps I can take you directly to that case and to one or two extracts from it --

MR. GLYNN: I am terribly sorry there has been a technical problem on my machine, could somebody come and fix it.

MR. MALEK: Has your hyperlink version gone on the system yet?

MR. TURNER: It should have done.

MR. MALEK: Looking at that paragraph, you refer to that case but then --

THE PRESIDENT: It is not on here.

MR. MALEK: There is nothing to click on, is there?

MR. TURNER: Sorry, it is our skeleton which is hyperlinked; the defence is not. We will do that.

MR. MALEK: No great hurry but as long as we have that before closing.

THE PRESIDENT: At some convenient time; you have a lot to deal with. Yes, *Visa* which is?

MR. TURNER: In the hard copy volumes I am told it is tab 12. On the system it is at {Auth-G/24/43} of the judgment. Yes, this is within the judgment. Very briefly, because I can address it further as necessary --

THE PRESIDENT: The judgment, is it, you are going to?

MR. TURNER: This is the judgment itself.

THE PRESIDENT: That is not tab 12; that is the Commission.

MR. TURNER: Is it not? Sorry.

MS. KREISBERGER: I think it might be volume 15.

THE PRESIDENT: Thank you.

MR. TURNER: 15/24. {Auth-G/24/43}.

THE PRESIDENT: Thank you very much.

MR. TURNER: Sir, this was a case where in October 2007 the Commission had found Visa guilty of an infringement of competition rules and fined it for refusing to admit Morgan Stanley as a member of the Visa Europe system for over six years.

If you have on screen page 1782 of the report, {Auth-F/24/43} of the Magnum system, there is an appeal against the Commission's decision to the court, the third part of the plea in law, halfway down, you can see was:

> "Insufficient and erroneous analysis of the effects of ... nonadmission on competition."

Under that plea at 153:

> "The applicants claim that the Commission failed to meet its obligation to carry out a comparative examination of ... the competitive situation in the market in question in the absence of Morgan Stanley and, on the other hand, what it would have been if Morgan Stanley had been admitted as a Visa member ..."

So essentially the counterfactual analysis. Then, if you go forward to paragraph 162 {Auth-G/24/46}, the court under its findings refers to the first complaint and says that that is equivalent in essence to claiming the Commission had failed to establish Morgan Stanley was a potential competitor.

So it frames that effects problem in terms of whether they were a potential competitor.

Then, if you go to paragraph 166 {Auth-G/24/47} on the following page:

> "As regards the legal tests which should be applied ... the Commission was required to determine whether, if the Rule [the Visa rule] had not been applied to Morgan Stanley, there would have been real concrete possibilities for it to enter the UK acquiring market and to compete ..."

So it is a potential effects case and then at 186 {Auth-G/24/52}, on that basis they conclude that:

> "The possibility of Morgan Stanley entering the market in question was not purely theoretical, but, on the contrary, represented a plausible assumption. The Commission could therefore justifiably infer from Morgan Stanley's statements that it intended to enter the market in question."

Essentially they found that it was a potential competitor and on this basis they have said that the effects on competition had been sufficiently proven.

So, sir, in clarification yesterday -- and we can develop this in the closing submissions -- that is the way in which the effects case rests and this is a support for it which you have seen from the guidelines of that case.

Turning then to the facts -- and I return to the narrative and the responsive submissions to my friends'.

I begin with IVAX briefly. Mr. Flynn took you on Monday through a number of documents to suggest that IVAX, the first of the Generics to enter this supply agreement, to become the hub in the hub and spoke arrangement, was bluffing when it was suggested it was prepared to launch a rival paroxetine product and that GSK was, to quote its words "duped".

GSK now says in its skeleton that, with hindsight, it is clear that IVAX stood no chance at all had there been litigation between the parties. If you go to {S/2/29} at 2.85 you see there the proposition in the skeleton based on hindsight.

If you turn over the page please {S/2/30}, under the heading:

> "GSK believed that it would prevail in any future litigation."

Then curiously under that heading they refer to the documents which show IVAX's perspective and therefore this is relevant, IVAX's perspective, to the question of whether IVAX was bluffing and GSK was duped.

If you look at the first of those at 2.89 there is a quotation, as you will see from the bottom of the page, and you have to turn over.

At {S/2/31} you will see a quotation from IVAX -- this is an internal document which you had been taken to and it ends with them reporting to themselves:

> "GSK claim P2 doesn't work and if you attempt to use it you end up with hemihydrate therefore breaking P3 ..."

In fact, if you go to the document itself at {B4/178/1}, and look at the next sentence or the bullet immediately below you actually have IVAX's internal view:

"NHC claim 'there is sufficient information in P2 for a skilled man to reproduce' and therefore an anhydrous version can be made."

If you then return to the skeleton at {S/2/31} --

THE PRESIDENT: Sorry, one second.

MR. TURNER: Go back to that {B4/178/1}.

THE PRESIDENT: What are you drawing attention to, in that document?

MR. TURNER: Just above the word "active" towards the bottom, they are quoting the skeleton in connection with IVAX's perspective because they are saying with hindsight IVAX was bluffing and they were duped. They omitted -- this is an internal IVAX document --

THE PRESIDENT: Yes.

MR. TURNER: -- IVAX's perspective:

"The NHC or Norton Healthcare/IVAX claim."

THE PRESIDENT: Yes.

MR. TURNER: That was not included in their skeleton to reflect this point.

THE PRESIDENT: I see, yes.

MR. TURNER: The same approach to the document is clear from the following quotation at 2.90, in the skeleton at {S/2/31}. You will see there -- this is the bluffing company -- they are describing GSK's negotiating position in this way and they quote that:

"GSK's position included [in particular at the end] claim strong IP position and will sue generic entrants."

If you then turn to the document itself at {Z/313/10}, you will see that immediately under what they had quoted in the skeleton --

THE PRESIDENT: We are having a slight technical problem for some reason. (Pause) Thank you.

MR. FLYNN: I am sorry to interrupt, sir, but I think there may have been a misapprehension. The heading of the section in the skeleton which Mr. Turner is referring to is "GSK believed" and so on and these quotations support the belief of GSK. IVAX may have had other points but this is not what these documents are being quoted for.

MR. TURNER: Well, on the question of whether IVAX is bluffing, which is the proposition that I referred to, let me show you then the completion of these documents.

MR. MALEK: Just remind us, what is this document?

MR. TURNER: This document is an internal IVAX document which I believe is a presentation from the UK business to the IVAX US business.

THE PRESIDENT: This is the one that is referred to at paragraph 2.90 of the skeleton?

MR. TURNER: Yes.

To complete the picture and to show what the position was in relation to their proposition that IVAX was bluffing and that they were duped, you need to see also the completion of the slide, so if you look at the last three lines:

"IVAX position: developed a product that circumvents GSK patents product licence granted in Ireland in September 2001."

THE PRESIDENT: But these documents cannot actually show what GSK believed; they only show what GSK said to IVAX.

MR. TURNER: That is right.

THE PRESIDENT: What you say to your negotiating partner does not necessarily correspond in any negotiation to what your actual internal brief is, does it?

MR. MALEK: But what I think GSK are saying is that their internal belief was that IVAX had a stronger position or a stronger hand than IVAX in fact had and that may go to their subjective intention.

MR. TURNER: They say that --

THE PRESIDENT: Yes.

MR. TURNER: -- in relation to their perspective. They quote here IVAX internal documents which can only be relevant, therefore, because they are IVAX internal documents, to the question whether, as they say, IVAX was bluffing with the benefit of hindsight.

MR. MALEK: What this document shows -- it is just setting out both sides' positions: GSK are telling us, or they claim, they have a strong IP position and our position is the opposite here.

MR. TURNER: Yes. What it does not say is however we are playing --

MR. MALEK: No.

MR. TURNER: -- a hand of poker here; that is the point.

MR. MALEK: Yes.

MR. TURNER: In view of the time, perhaps I will spend five more minutes on IVAX and then stop, unless the Tribunal wish to stop now; I only have a small amount to go.

THE PRESIDENT: If you can do it in 5 minutes because we need to take our break, I think.

MR. TURNER: More particularly, they say that IVAX had no alternative option by the time it entered into the settlement deal. That is a crunch point. Skeleton {S/2/30} at 2.87(3). You will recall this point from Mr. Flynn's opening:

" ... IVAX did not consider other potential sources of supply (namely GUK and Tillomed) to be attractive and/or credible options for market entry ..."

So there is the proposition expressed in their skeleton. That was wrong. It is clear at the time of the IVAX agreement that they did have another strong option, that was taking supply from Tillomed, and, sir, as you rightly pointed out on Monday, IVAX signed heads of agreements with Tillomed on the day after signing the agreement with GSK.

If we call up briefly {K/51/10}. We went to it with Mr. Flynn. You have the IVAX witness, David Blanksby's statement, given to the OFT and you will recall there that he refers -- if you look at 5.7, for example, as well as 5.5 -- that they were not bluffing, that they did regard this as a serious and strong option as well.

MR. MALEK: Under those heads of agreement they had the same underlying price, did they not, 8.45?

MR. TURNER: That is right.

MR. MALEK: But without the further inducements that GSK were offering?

MR. TURNER: Yes that is right.

Finally, the last thing before the break, if we go to the side letter that we mentioned on Day 1 that formed part of the agreement. It is at {A/4/66}

THE PRESIDENT: Is this the side letter with IVAX?

MR. TURNER: Yes, it is.

THE PRESIDENT: We have it -- yes, I see. It is now in bundle L is it not, the agreements bundle? Is this the side letter of 3 October?

MR. TURNER: Excellent, yes. That is it. It is now on screen {A4/66/1}.

THE PRESIDENT: It is now in bundle L at tab 2.

MR. TURNER: We did look at this but at least on screen you had the first page. You did not have the second page. It is therefore not clear whether the point which the CMA has made about this is has therefore come out. That is on page 2 of this document {L/2/2}.

This was an intriguing arrangement. Paragraph 2:

> "In the event of SB [GSK] obtaining a judgment against GUK in the action, SB shall seek to recover damages from GUK as a consequence of its infringing acts. The amount of the damages so recovered ... up to an amount not exceeding 3.2 million, will be payable to IVAX within thirty days of receipt ..."

It is a contingent agreement there: if we go after them and we win, we will pay you that money. Then paragraph 3:

> "In the event of SB ceasing to prosecute, discontinuing or compromising the action, SB will pay to IVAX a sum equivalent to any consideration ... received either directly

or indirectly by SB ... from GUK ... as a consequence of the same, up to an amount not exceeding £3.2 million."

So what you see is that by the side letter there are further promises that they will, in relation to the separate proceedings between GSK and GUK, pay proceeds over to IVAX and that that formed part of the overall agreement and what was agreed to be paid.

Sir, if it is convenient, that concludes -- I am sorry I should -- I will make one final point about that, which is that this arrangement in the side letter is intention with the suggestion that GSK's arrangements with IVAX was in some way neutral about IVAX taking supplies from independent sources and indeed permitted IVAX to do that, which is a suggestion you will have seen in GSK's document entitled "Skeleton".

MR. MALEK: We have Mr. Reilly's evidence at paragraph 38 of his witness statement.

MR. TURNER: My point is that this arrangement, this supply agreement, could not sit commercially alongside IVAX taking supplies independently. It was an arrangement that was designed to remove IVAX's incentives to supply non-GSK paroxetine. I will just give you the reference for that without taking you to it now; it is in our decision at paragraph B112 and I will have to get you the Magnum reference.

Ms. Demetriou is covering the Chapter II abuse of dominance case and she will, as necessary, go through the structure of the IVAX agreement, which is not relevant to the agreement infringements later but it is also important finally to see what GSK expected would happen to prices after this agreement. If you finally go to our decision at {V/1/100} at paragraph 3.235, you have there an extract from Mr. Reilly's statement earlier that:

"[Their] expectation was that, as a consequence of the level of the supply price charged by GSK to IVAX, IVAX would be unlikely to be incentivised to charge prices that were significantly below those being offered by suppliers of parallel imported paroxetine and by. GSK itself, such that the financial impact on GSK would be minimised."

You see there the way in which Mr. Reilly at that stage describes the expectations.

Finally I have been given a reference which I think is {V/1/540}. This is an important part of the decision because it shows you -- and you will need to read this paragraph, although I do not propose to go through it now -- what the expectations were about how this agreement would have had effects on prices and incentives.

MR. MALEK: When you come back, could someone tell me where the Tillomed documents that Mr. Flynn produced are now housed on this system so I can find them?

MR. TURNER: The heads of terms?

MR. MALEK: Yes.
MR. TURNER: Yes.
THE PRESIDENT: We will come back at 11.50 am.
(11.45 am) (A short break)
(11.55 am)
MR. TURNER: Sir, the reference is {Z/231/1}, the heads of terms.
MR. MALEK: Can we have it up on the screens so I can see it? My screen is not showing that. It is just coming up now. (Pause)
It looks as though it was prepared on 2nd October, on the footer on the last page.
MR. TURNER: Yes.
MR. MALEK: I was just wondering why you signed an agreement on the 4th if you had already done the deal on the 3rd.
MR. TURNER: It is a mistake and you see it, I think, referred to by Mr. Blanksby, if we go back to {K/51/10}.
MR. MALEK: Do not change the screen.
MR. TURNER: It is misdated.
THE PRESIDENT: What, the agreement?
MR. TURNER: Yes, it should be two days earlier.
MR. MALEK: Which is as per the footer.
MR. TURNER: Yes.
MR. MALEK: Was GSK unaware of these heads of agreement when their own deal was signed?
MR. TURNER: I am not aware that there is evidence of that.
MR. MALEK: I was just wondering whether this was being used as a sort of lever.
MR. TURNER: I am not aware of specific evidence on that point but we will check.
MR. MALEK: Yes. That is helpful, thank you.
MR. TURNER: Sir, thank you.
That takes us onto GUK and its efforts to enter. We leave IVAX. We have just seen that GSK promised to pursue the patent infringement proceedings against GUK in the side letter. So the next step is to see what GUK was doing to break into the paroxetine market and simply for your note, the account in the decision of events concerning GUK begins at paragraph 3.249 of the decision. But what I would like to do now is to look at these steps by going to the witness statement of Mr. Saynor, the sales and marketing director of GUK, this being a witness statement that he produced for the interim injunction hearing. It is at

{A5/77/1}. You can see the date of this is 15 October 2001. If you go forward to page {A5/77/5} you have paragraph 14:

> "We first started to investigate paroxetine with a view to developing it for supply ... in February 1997."

They refer to having spent a great deal of "time, money and effort" developing the paroxetine product. At paragraph 16 on the same page you see that GUK was on the verge of launching its own paroxetine product. That is why GSK applies for the injunction.

At paragraph 17 you see that they had taken orders for 492,800 packs of paroxetine for customers in only two weeks in September 2001.

Over the page {A5/77/6}, above paragraph 18, this equates to about £5.5 million in sales for the month of October. Paragraph 19 on page 6, at the bottom of the page, is a conversation with Mr. Hart of GUK and Mr. Blanksby, who had become GSK's authorised sole distributor. He says that the selling price, if we turn the page please, for generic paroxetine to wholesalers would be in the same ballpark as the parallel import price for Seroxat, which was £11 a pack {A5/77/7}. That was their understanding.

At paragraph 37 on page {A5/77/11}, starting at the bottom, so we will be going over the page:

> "In my experience of the generics market, no pharmaceutical company has ever attempted to join forces with a generics company to supply a version of its product five years prior to the patent on the branded product expiring, yet that is precisely the position here, which begs the question: why is SB doing this? There are only two possible reasons that I can think of. The first and most likely is that it is a reflection of SB's views on the strength of its anhydrate patent, which was granted as recently as 1997. That is to say, the reason that SB is going to start selling generic paroxetine is that it can see that generic competitors will shortly be entering the market in any event, either because the anhydrate patent is invalid or because the competitors have a non-infringing product. The only other possible reason I can think of is the impending genericisation of Cipramil which is discussed below."

THE PRESIDENT: Cipramil is a competitive product, is it?

MR. TURNER: It is in the same class as SSRIs.

What is said there about the allocation of supplies to a generic and his understanding of what must have been the rationale applies also to the cash payments which were made. The fact of large cash payments itself reflects the concern of GSK about a defeat in defending its patent rights and the consequent loss of its market position. So we take what

this witness says there and says that that rationale applies also to what he was unaware of, the cash payments.

Then I turn to the GUK interim injunction. That was the 23rd October 2001. If you go to {D/1/1} you have there the judgment of Mr Justice Jacob.

GSK say that the CMA failed to grapple with the interim injunction because in their eyes -- perhaps if we go to their skeleton {S/2/106}, at paragraph 5.38 you will see this is the absolute opposite of a real and concrete possibility of entering.

Moreover it is said to be the crucial difference between this case and *Lundbeck*. If you go to paragraph 5.60 on page {S/2/112}:

> "The crucial difference on the facts between the present case and the *Lundbeck* cases is that at that relevant time GUK and Alpharma were unable to enter ..."

THE PRESIDENT: You are at?

MR. TURNER: I am now on page of 112 of the hard copy and 112 of the Magnum at 5.60.

THE PRESIDENT: 5.60, yes. A lot of the appellants say that, who rely on the fact there was an injunction.

MR. TURNER: That is right.

If we go back to the judgment at {D/1/5}, please. At the bottom of the page, page 4, and it runs over:

> "I have come to the clear conclusion that I am quite unable to decide the relative strengths of the parties' contentions."

There is no view on the merits. This is not saying that GSK are likely to win on the substance; this is an interim order.

The second point at page {D/1/8}, the judge considers the likely effect of IVAX entering the market as the distributor. He says from the top:

> "However, in my judgment, commercial considerations make it unlikely that they will do that."

Which is reduce the prices:

> "Consider the position of the Norton marketing manager. He buys from the patentee, who, incidentally, makes a turn at that moment. He then has to decide his selling price. There is no point in his being higher than the price of the parallel importers. He has to go equal to or below that price. Should he go equal to, or below, or much below? The answer, to my mind, is self-evident: he is to go close to/equal to. He has no other competitor to worry about, other than the patentee whose price is higher anyway. All he has to do is just to beat parallel importers who themselves cannot go

any lower because they cannot buy the product any cheaper on the continent. There is no incentive to take the price down and down."

THE PRESIDENT: Yes.

MR. TURNER: The third point at page {D/1/13}, this is about the likely impact if GUK did enter the market independently. The judge refers here to again the answer to what would then happen being self-evident. He refers to prices, if we go over the page {D/1/14}, I am sorry. (Pause)

I am sorry I will have to find the reference. He refers to prices being chased down in the price spiral. I have a false reference written in my note. If I may come back to that.

THE PRESIDENT: Is it at the bottom of page {D/1/8}?

MR. TURNER: It may be.

THE PRESIDENT: "What, then, if the defendants enter the market too"?

MR. TURNER: I am obliged:

"I think, again, it is self-evident. There will be price competition between the parallel importers who cannot go any lower, Norton who can go as low as they like, and the defendants. The price will be chased down. The effect of that chasing down may well be to force the patentees to lower their prices too. Mr. Arnold says the patentees do not say they definitely will lower their price, but it is evident that a collapse in prices may have that effect: they either lower their price or just simply lose their market. The potential effect of the entry into the market of the defendants will be to cause a price spiral."

[D/1/9]. That is the grant of the injunction.

THE PRESIDENT: That was, of course, GSK's evidence, that the judge was accepting.

MR. TURNER: He was accepting their evidence but it included their evidence that without GUK entering there was stability, which would be disturbed by GUK.

THE PRESIDENT: Yes.

MR. TURNER: Then if you go to GSK's skeleton at {S/2/45}, you have the perspective at paragraph 2.145(2) at the bottom of the page that:

" ... GUK's faith in its ability to prevail in the litigation ... was fatally undermined by ... interim injunction ..."

And a raft of litigation that might have occurred under the hemihydrate patent.

This then becomes an important contention on the other side because they say there is a fatal undermining at that stage. If you go to {B1/13/1}, you have the first of two documents which are cited. I will just give you the reference in our decision at 3.276 to 3.278 and the

bundle reference which I am not asking you to go to now is {V/1/113}. If you stay on this document you will see the statement from Eddie Hart of GUK to his team and you will see he says in the first paragraph, four lines up from the bottom:

> "We are confident that we do not infringe and will therefore be able to launch next year and claim substantial damages from GSK."

In the following paragraph:

> "Going forward you may also be aware that Norton have signed an agreement with GSK to launch the GSK 'generic' version of this product."

You have seen this before:

> "We are not fully informed as to the nature of this agreement but it is very likely that Norton will be heavily controlled ... in the amount of product they can sell and the price they can sell it at ..."

Then he refers to the managed nature of that arrangement. He says three paragraphs up from the bottom:

> "Additionally, it will be patently clear to our customers that Norton again are the generic spoilers in this regard ... by preventing true generic competition ..."

MR. MALEK: You say they are up for a fight there?

MR. TURNER: They are. In other words, the fatal undermining is not borne out by this subsequent document.

If we go to {B1/14/1}, we then have GUK writing to its customers. Turn the page please {B1/14/2}. At the top:

> "With regard to paroxetine, as you may be aware we are still fighting to bring this product to the market as quickly as possible. We are confident that we have a non-infringing product and will win our legal case. It is my greatest wish to be able to supply you and break GSK's dominance and manipulation of the product via other 3rd parties. I will keep you informed of our progress."

So they display, at least to their customers, a confident attitude. Then, if we go to {V/1/105} in the decision at 3.254, you have the reference that on 29th October they now receive their marketing authorisation. GUK then continue the litigation with GSK for another five months after the interim injunction was granted until the settlement on 3rd March 2002.

In GSK's skeleton, {S/2/42}, at paragraph 2.133, their submission is that:

> "GUK's braggadocio declined markedly ... after interim injunction ..."

And that leads us to examine the third point which is that GUK turned down offer after offer from GSK to settle.

You see that if you go to {V/1/119}

At {V/1/120} you will see from this -- and I am not going to read through it -- that there is a list of the various offers that are made to settle and the repeated rejections by GUK after the interim injunction.

If you go from that to {B3/97/1}. Here we are in November 2001 now, the end of November, the 27th. This an internal email, GUK, from Mr. Hart, and he is commenting on the latest offer from GSK at that point. You see the offer at the bottom -- you see at the top:

> "Good progress. They are obviously getting hungry for a deal. Their offer is now better than my minimum -- so they must be desperate? I am smelling blood."

THE PRESIDENT: What is "RM"? Do we know what that is?

MR. TURNER: We do not know what that is.

THE PRESIDENT: But he picks it up "some feedback on RM".

MR. MALEK: That is what you would expect: they want some legal input as to what is the strength of their position.

MR. TURNER: Yes.

The point that is being tested is the claim that on GUK's side at this point there had been a fatal undermining of confidence, no alternative options and only a motivation to enter into this supply deal with no other possibilities. But you will see, in fact, from this, the blow by blow development of their position.

Then, if you go to {B3/99/1}, which we saw yesterday, we have the internal GUK email dated 22nd December 2001, setting out the terms there of GSK's latest offer.

You see, as I mentioned before, halfway down that, GUK is making up its mind on the basis of the value being offered with an assumed level of, in relation to what they were going to be provided, gross sales, particular profit and net profit on very clear assumptions as to the levels at which this would happen.

MR. MALEK: We have the legal advice point again:

> "Having slept on this I am inclined to agree with your view that this is a poor return given the level of investment. That said I would like to be confident that we will win in March."

MR. TURNER: Yes. I am sure there is legal advice being referred to in these documents and, as one would expect, they are taking it as they go along. We do not see this legal advice.

However, this is not consistent with the legal advice being this is doomed to failure. On the

contrary, the only thing that is available to us to work with shows the commercial people working towards pressing ahead.

MR. MALEK: And that they were willing to take it to the court, were they not?

MR. TURNER: Yes, they did.

MR. MALEK: Clearly they would have got the legal advice. They say:

> "We need to let the legal team know to proceed by no later than the 2.1.02."

And they do proceed do they not?

MR. TURNER: They proceed all the way to the door of the court in March.

THE PRESIDENT: They did not want to incur the brief fees --

MR. MALEK: No, if it is a hopeless case.

THE PRESIDENT: -- when they are about to settle the case.

MR. TURNER: So if we go then to {B1/17/1}. We now have Mr. Urwin at the end of the year summarising, at that point, how they apprehended the offer to stand:

> "... their offers until the last minute before Christmas ..... but their final offer was still not acceptable. Richard and I will discuss early in the new year .... but, as long as you remain confident of winning (although there are no guarantees) .... we must push for the best deal we can .... and that means (under scenario 2 - which is the option under discussion) that we need the API covered -- plus a decent profit -- otherwise we should puch (sic) on with the case for ultimate launch."

Then, sir, as you say, they continue until the eve of trial.

On Tuesday, Mr. Kon went to an internal GUK email by Mr. Urwin the day before the settlement. If we could go to {A2/15F/1}. This, at the top, is the day before the settlement and includes on the third line:

> "The settlement and local distribution agreement seem to be the best way to go, provided the numbers are right."

Mr. Kon appeared to suggest that the phrase "provided the numbers are right" doesn't mean that the numbers affected the settlement. The natural and plain reading of this is that numbers mattered to the settlement.

Now, in addition to this, if you go to {S/2/45} and look at 2.145, at (2) you see, at the bottom, the lyrical reference to the "raft of litigation" and "being swept further downstream by the hemihydrate litigation". There are references from GSK to how the decision has taken no account of GUK's hemihydrate patent concerns.

If you go to {B3/109/1}, here you have an internal GUK email of 12th March from a Mr. Self, who is the head of research and development, to Mr. Urwin and to Mr. Hart and you will see that he says, just under "Dear both":

> "We have a court case on the anhydrate patent on March 26th ... let's say a decision is expected on this on 26th April ... roughly speaking ... we have a good case and will argue for non-infringement and invalidity."

Then he says:

> "We can then launch at risk ... they will try to injunction on the basis of the hemihydrate patent ... we think they will not succeed as we will argue that they should have gone for this action long before May: ie when they are likely to try for an injunction based upon losing the anhydrate case."

THE PRESIDENT: Just a minute. TT is another generic, is it?

MR. TURNER: Yes. TT is separate. That appears to be a separate matter.

THE PRESIDENT: I do not think it is a separate product; it is another generic to compete with Seroxat, I think. They tried to join in GUK case, they are saying when might they come in?

MR. KON: Sir, I think I can assist TT is Arrow Pharmaceuticals and TT is the individual concerned at Arrow pharmaceuticals.

THE PRESIDENT: Thank you very much.

MR. TURNER: Sir, what you get from this is, by 12th March, just before the trial, confidence including in relation to being able to launch at risk in relation to the hemihydrate patent.

MR. KON: Sorry could you just read the paragraph after the TT paragraph please?

THE PRESIDENT: "Even if they knock out the anhydrate and we do not they still face the hemihydrate issue just as well as we do ... the main point is though that we will know our position ... long before them so we can take a wait-and-see attitude, ie lets see how we get on and then decide where we are."

MR. TURNER: I am very happy that my friend has referred to that.

THE PRESIDENT: Yes. Steve Self is at Merck?

MR. TURNER: He is the head of R&D in the organisation. You will see also, in relation to TT and Arrow, the final line in that email, the bottom line:

> "... say politely but firmly no thanks, you play your cards, we will play the hand we have got."

What one does not see is the fatal undermining of confidence that apparently occurred in October 2001.

THE PRESIDENT: Yes.

MR. TURNER: If we now go to GSK's skeleton again at {S/2/53}.

MR. KON: I hesitate to interrupt, but could we just go back to the last document because I think there is a suggestion that this email concerns GSK and if one reads the first line of this email it says:

> "Just to confirm what I have discussed with both of you and to try to logically argue through the degree of threat from TT."

In other words, that is nothing to do with GSK itself; it is analysing the relative positions of Arrow Pharmaceuticals and GUK. Obviously it refers to the GSK litigation but it does not concern discussions with GSK.

THE PRESIDENT: I do not think it is suggested it concerns discussions with GSK; I think it is suggesting it concerns Steve Self's view of GUK's position in the court case with GSK, which was the case, he says, on March 26th; I think it actually was a few days earlier. It was starting the next day, was it not? I think. Or is there --

MR. KON: Arrow Pharmaceuticals sought to intervene in the proceedings between GSK and GUK and what this is referring to, sir, is exactly the position of Arrow Pharmaceuticals qua GUK and therefore, because they were refused permission to intervene in the case because it was too late and that is the background to this document. I only want to make that point clear.

MR. MALEK: I understand the background but the point that your opponent is relying on is really the second and third paragraphs, which is an expression that vis-a-vis GSK they feel they have a good case and they are going to argue for non-infringement invalidity and that is a trial that is about to come up.

MR. KON: That was the view of Mr. Self perhaps personally but not the view of Mike Urwin and there is other correspondence I referred you to --

THE PRESIDENT: That may be but that is why this document is being referred to.

MR. KON: I understand that.

MR. MALEK: To counterbalance what you said the other day.

MR. KON: I understand that but I wanted to make clear the context of this email and Mr. Self did in fact report to Mr. Urwin.

THE PRESIDENT: Yes.

MR. TURNER: If we go to GSK's skeleton at {S/2/53}. At paragraph 2.173, GSK refer to Mr. Self as GUK's "head of R&D", as expressing the pre-settlement internal view that:

> "... hemihydrate is a bit more tricky because we know that under certain circumstances our product can contain hemihydrate ..."

If you go from their quotation to the document itself at {A2/15G/1} here you have Mr. Self's email, 13th March 2002. He says that:

> "Hemihydrate is a bit more tricky because we know that under certain circumstances ... can contain hemihydrate ... think it is winnable but it is a bit more uncertain."

So the quote had not been completed. Therefore, the suggestion of a lack of confidence needs to be put in context.

At the end of GSK's skeleton concerning GUK, if you go to {S/2/57}, paragraph 2.179. GSK crystallises the essence of its case:

> "In short, as in the case of IVAX, the evidence relating to the GUK agreement simply does not sustain the CMA's contention that GSK either wished to or did buy off a good claim."

That is not the point made in the decision, that is not our case. We did not and do not need to find that GUK would definitely win the anhydrate litigation. Our case is that there was a transformation of the uncertainty into certainty by means of the large reverse payment.

Finally on GUK, if I turn to the settlement agreement itself very briefly, it is at {A2/9/1}

THE PRESIDENT: We have it in bundle L, I think.

MR. TURNER: I will leave that because Ms. Demetriou may go to a few of its provisions including in particular clause 8. Do you remember there was clause --

THE PRESIDENT: Leave it to her.

MR. TURNER: I will leave that to her. If you go to {Z/495/3}. This is an aspect of the GUK strategic plan. It is 21st June 2002 and it relates to the period 2002 to 2005. Here they refer to paroxetine under heading 2 towards the bottom of the page. You will see what they say about it:

> "[It is a] three-year deal and this has been built in for the period. This will generate £9 million in annualised sales and £2.8 million profit. There will also be £1.6 million in [something I am not sure what that means] and 12.5 million in raw material sales with an attendant cost of £5 million over the next three years."

So there you have --

MR. MALEK: What is the date again?

MR. TURNER: 21st June 2002. Therefore after the settlement what they are recording is a very clear and definite view of the value of the settlement and that the supply agreement as a component of that, therefore, can be factored in because you know not just your buy-in price but very clearly your expected selling price.

That is all I will say about GUK. If I move then to Alpharma.

Alpharma is covered in the decision at -- if you go to {V/1/136} you can see paragraphs 3.323 to 3.325 all on the development of the Alpharma product. Going forward, for your note, you will see that at 3.324 on that page Alpharma sign a contract with Medis to supply Delta's generic paroxetine. In fact, in the previous paragraph, 3.323, 29th April, Alpharma get their UK marketing authorisation and in 3.325 at the bottom of the page, Alpharma agree to pay £3.5 million for 360,000 packs of 20mg and -- if you turn the page -- 138,000 packs of 30mg of paroxetine. So those are the orders that have been made at that point.

If you now go to {Z/556/1}. You have not seen this document before. It is the new product team report of Alpharma. It is dated 28th May 2002, as you see from the top.

This merely shows you -- I am sorry the type is quite small -- the extent to which they had progressed in their plans. They had sent artwork for packaging to Delta and they were expecting significant deliveries of product, the 20mg and 30mg doses, and you can see the figures in the info column, second from the right: it is very small, but 20mg as well as 30mg.

So there you will see that they were therefore covering not just the 20mg dose, which is the sole product under the GSK supply agreement, but also the 30mg dose which accounts for, by value, about 30% of paroxetine supplies.

So that was what they were planning and arranging at that stage, May 2002.

If I turn to the topic of the BASF litigation. At {A/4/30} you have Actavis' Notice of Appeal. You will see at paragraph 90 their argument, now joined in by GSK in its skeleton, that Alpharma relied on BASF to clear the way and they say halfway down that that strategy failed.

Again, as with GUK, where the interim injunction is the fatal blow, here it is the BASF's failure entirely to clear the way. BASF's action is determined by Mr Justice Pumfrey on 12 July 2002. For your note, Ms. Ford made various criticisms of the decision and prominent in those was that, if you go to {V/1/140}, paragraph 3.332 of our decision did not mention that the process claims, 10 and 11, were upheld as valid and that had only been mentioned later.

THE PRESIDENT: Three paragraphs later?

MR. TURNER: Yes. That was not right. For your note if you go to {V/1/65} it had certainly been mentioned earlier at paragraph 3.131. There you see it.

THE PRESIDENT: Yes.

MR. TURNER: GSK's take Alpharma's response to the BASF action is no longer that Alpharma had concerns that its product might be found to infringe, which is what it said in its Notice of Appeal at {A/2/48}. That is the way they put the case in their Notice of Appeal.

THE PRESIDENT: Sorry, this is?

MR. TURNER: This is GSK's -- I am sorry 2.59.

THE PRESIDENT: This is?

MR. TURNER: GSK's Notice of Appeal.

THE PRESIDENT: This is GSK's Notice of Appeal?

MR. TURNER: Yes. GSK said halfway down -- because they have now joined in the point which they did not in their Notice of Appeal, they said halfway down:

> "Alpharma, for its part, still had concerns that its product would be found to infringe the anhydrate patent claims and/or the dry tableting ..."

But when you come to their skeleton things had developed.

THE PRESIDENT: But this in August 2002 it is referring to?

MR. TURNER: Yes. That is right. Sir, if you now go forward to their skeleton, {S/2/76} at 2.254(1) you see the way they now conclude things in the skeleton argument:

> "Alpharma's litigation had failed."

THE PRESIDENT: But this is later; this is in --

MR. MALEK: September.

THE PRESIDENT: This is after -- one is before Mr Justice Pumfrey's judgment, one is after.

MR. TURNER: This is September 2002?

THE PRESIDENT: The judgment was July I think, was it not?

MR. TURNER: The judgment was 12th July.

THE PRESIDENT: Is that not the difference?

MR. TURNER: I will go back to 2.59.

MR. FLYNN: Sir, if it might assist, while we are on the point, might I draw attention to page 98 of our Notice of Appeal? It is paragraph 5.3(d) which also refers to Alpharma.

MR. TURNER: If we can perhaps go back to 2.59 just to check that point at {A/2/48}

THE PRESIDENT: That is also after. Yes, I see.

MR. TURNER: It is also afterwards. So there is the development.

THE PRESIDENT: Yes, it is the process claims. I see.

MR. TURNER: Yes.

Then if you compare that with the reaction of Helen Toogood, Alpharma's marketing manager, which is three days after that judgment in BASF, at {B1/22/1}. She says, second paragraph:

> "In the light of last week's High Court ruling in favour of BASF and against GSK covering parts of GSK's patent covering paroxetine hydrochloride, it looks as if a big step has been made in the right direction as far as we are concerned regarding any future launch of this product."

Their perception internally does not appear to be that the litigation has failed.

If one turns to {B3/151/1}, we are now 16th July 2002. It is an internal Alpharma document, which was not in the appellants' opening. This is the in-house Alpharma patent attorney commenting on the proposed claims for the anhydrate patent. The point is he considered all the claims could be established to be invalid, despite Pumfrey J's judgment.

You see at the bottom of that page:

> "As a consequence claims 10 and 11 are not valid as they, according to the judgment referred to above, lack independent validity".

So there the patent attorney says, well, hold on --

THE PRESIDENT: Let me just read this. I think he is referring to the EPO proceedings. That is the way I read this. Because when he says:

> "In the light of the findings ... proposed claims should be refused ..."

Well, 1 and 3 and et cetera have been found invalid, so as far as the English proceedings, that is determined; it is only a question of any appeal. It seems to me that he is -- that is why he is relying on the board of appeal's case law, how they might analyse process claims.

MR. O'DONOGHUE: Sir, if I can assist, claim 11 in the Alpharma litigation in the UK was added by amendment subsequent to this.

THE PRESIDENT: That is right. Thank you. There had not been a claim for process against Alpharma until the amendment which was on -- well, it was served on 31st July, I think, but it looks to me as though, although he is referring to the British patent ... (Pause)

He may be referring to a proposal to amend. It is not very clear to me.

MR. TURNER: No. That seems likely if one goes to the decision {V/1/141} and 3.337 at the bottom. You are right, sir, it is subsequent to the litigation GSK does amend to include claim 11. So it may well be that that is right, that the application to amend is being referred to. Certainly the reference to the judge and to the lack of validity of claims 10 and 11 by the patent attorney are not compatible with the wind having been entirely taken out of the sails of Alpharma.

THE PRESIDENT: Yes.
MR. TURNER: That is the key point.
THE PRESIDENT: Anyway, he seems to be expressing the view that claim 11 will not succeed, that it will not be independently valid.
MR. TURNER: Yes. So what we know with Alpharma is that the patent fight continues for three months after giving the undertaking on the 1st August 2002 and a trial is then ordered to take place on 23rd October 2002.
THE PRESIDENT: Just one moment. Who was that note from?
MR. TURNER: Jakob Poulsen.
THE PRESIDENT: Who is he?
MR. TURNER: If you go back to {V1/1/141}.
THE PRESIDENT: You can just tell me.
MR. TURNER: He is Alpharma's APS's patent attorney.
THE PRESIDENT: Just one moment. (Pause)
Yes, thank you.
MR. TURNER: These are the documents -- as I say, GSK's case does appear to have stiffened somewhat in its skeleton. If you go to {S/2/78}, at paragraph 2.258 they say that Alpharma continue to fight, at the bottom of the paragraph:

> "Self-evidently all Alpharma could do was to struggle on with the pretence of its case, limit the damage by canceling orders and hope to sue for peace on terms that made its losses good. Inevitably that is exactly what Alpharma did."

If you go to {S/2/80} -- you have this at 2.266 in their skeleton:

> "Alpharma had decided to settle come what may ..."

That is five lines down. Perfectly clear that Alpharma had decided to settle, come what may.
Ms. Ford for Actavis read a report by the Alpharma patent attorney on 4th September 2002 and you will find that at {A6/128/1}. For anhydrate and hemihydrate, the reports are essentially the same as the report of 19th August --
THE PRESIDENT: This is the same Mr. Poulsen?
MR. TURNER: Yes. You now have the dry tableting patent referred to. This is a slightly enlarged version, so therefore in the final large paragraph, halfway down:

> "There is only a slim chance that the claims covering the anhydrate form will survive the opposition, but it might take years for EPO to reach a final decision after appeal. Margaret Lewis, Stephenson & Harwood has further made an estimate of cost ... and

for a time period of less than six months obtaining a swift decision for the UK, if Alpharma chooses to institute invalidation proceedings for this jurisdiction. The patent does not seem to have been used for infringement proceedings in any jurisdiction yet."

Sir, if we now go to Alpharma's reaction to GSK's Statement of Case in the patent claim on 4th November 2002. You find that at {A9/184/98}. So they have served their Statement of Case. This is heading into the patent trial. Jakob Poulsen writes to the team:

"Dear all, while GSK was expected to make a Statement of Case last Monday, 4th November ... this statement was very limited. Either they do not have a very strong case or they are going to surprise us all just before the trial.

"GSK is still claiming infringement of the claim (11) directed to use of a displacing agent. They have now measured a water content in the formulation after tableting of 2.9% w/w, corresponding to 8 molecules of water for each molecule of paroxetine. They therefore claim the water is a displacement agent leading to the low acetone content in the tablets. In short, there is no terribly disturbing news from the trial."

We can now compare that again if we go back to Glaxo and the skeleton argument {S/2/83} at 2.272. You will see again the lyrical way in which this is expressed at the end. It was -- the CMA invites the Tribunal to find it should have gone over the top into battle knowing that it would lose (battle).

That was not correct. It is also worth looking at one document relating to the renewal of the Alpharma agreement because that does shed light on Alpharma's position at the time a few months earlier. It is at {A6/145/1}.

This is an Alpharma presentation about Seroxat and the UK patent situation. You will not find a date on it but it was explored by the CMA and for your reference, footnote 563 gives the date.

We know from the discussion that the CMA had with the party that was about renewal that there was no precise date on it.

THE PRESIDENT: Sorry, could you just say again -- what is this?

MR. TURNER: This is an internal Alpharma presentation about paroxetine, the UK patent situation after they have made the agreement, and before any renewal of it.

MR. MALEK: Was this prepared by the lawyers? Because at the bottom it says on every page:

"Contains privileged/attorney-client communication".

MR. TURNER: It may have been. I cannot take it further than that. This was made available to us.

If we turn the page {A6/145/2}, slide 1, the dry tablet preparation invalidated by the EPO and no one sued on that patent:

"If patent is held valid on appeal, which seems unlikely, Delta likely infringes."

Then:

"Process patent (displacement step); patent revoked in its entirety pending appeal."

THE PRESIDENT: Do we know when the EPO invalidated the dry tablet patent?

MR. TURNER: No.

THE PRESIDENT: That must be a matter of public record.

MR. TURNER: We can certainly find that out. So far as the process patent and the displacement step are concerned:

"Patent revoked in its entirety pending appeal."

That probably helps us date this as after December 2003.

THE PRESIDENT: But is that the -- I do not know what that is. Is that Mr Justice Pumfrey's judgment in Apotex?

MR. TURNER: It appears to be yes. Because this is therefore after the supply agreement has been made with Alpharma.

THE PRESIDENT: That was in November 2002 --

MR. TURNER: Yes.

THE PRESIDENT: -- and Mr Justice Pumfrey's judgment was not until December 2003.

MR. TURNER: Yes.

THE PRESIDENT: So that puts this into 2004, which is before the extension.

MS. FORD: Sir, paragraph 3.119 of the decision tells us that the EPO invalidated the dry tableting patent on 15th May 2003.

THE PRESIDENT: Thank you very much. 15th May 2003 for tableting invalidated. The reference in the decision, Ms. Ford, was at?

MS. FORD: 3.119(c).

THE PRESIDENT: Thank you.

MR. TURNER: If we go to the footnote in the decision, sir, it is at {V/1/150}. Footnote 563 at the bottom refers to this document:

"This document was submitted by Actavis and was described as having been prepared in connection with the decision whether to terminate or extend the supply arrangements with GSK or to launch Alpharma's own product."

So the party described it as being concerned with that question.

THE PRESIDENT: It may be to do with the final termination, which was in January 2004.

MR. TURNER: Yes. It appears that it may well have been to do with that. So we can date it reasonably precisely.

THE PRESIDENT: Which fits because Mr Justice Pumfrey's judgment was early December 2003. Alpharma served its notice in 13th January 2004. This is probably in between the two.

MR. TURNER: Yes.

THE PRESIDENT: Does that make sense?

MR. TURNER: It does. That seems very likely. If we go back to it at {A6/145/2}. The reference simply at the end in relation to the process patent:

> "Tough argument for GSK to win, likely no infringement."

So they have settled in the previous year, but in reflecting on the strength of the patent from their perspective then, probably at the beginning of 2004 likely no infringement is the perspective that they record.

MR. MALEK: Then if you look at A6 or whatever, there is a summary chart which is quite helpful on 129/5. {A6/129/6}.

THE PRESIDENT: How is this document helpful?

MR. TURNER: It is helpful because it shows that at that date, probably the beginning of 2004, Alpharma is saying there is likely no infringement.

THE PRESIDENT: But that is in the light of Mr Justice Pumfrey's -- I do not know what he found about -- I have not read his judgment. He invalidated the claim. Whether he also took the view that if it were valid the Apotex product did not infringe, I cannot remember.

MR. TURNER: Sir, you may be right.

THE PRESIDENT: It may be informed by the judgment and all I am saying is the view that Alpharma had in January 2004, after there had been a judgment on the process claim may not be terribly informative as to what their view had been at the time they made the agreement.

MR. TURNER: It is a point well taken.

MR. MALEK: Their view here is that on appeal they thought that GSK was not going to prevail.

THE PRESIDENT: On appeal against Apotex?

MR. MALEK: Yes.

THE PRESIDENT: Yes, as indeed they did not in large part, effectively.

MR. FLYNN: Ms. West's statement at 102 says that Mr Justice Pumfrey found the process claims invalid and also not infringed.

THE PRESIDENT: And also not infringed?

MR. FLYNN: In the Apotex.
THE PRESIDENT: I see. That rather makes the point. Would that be a sensible --
MR. TURNER: That is a sensible moment.
THE PRESIDENT: Thank you.
(1.01 pm) (The short adjournment)
(2.00 pm)
MR. TURNER: Sir, before we start can I make a request which is that the sun is directly on us and as a result I cannot see the screens.
THE PRESIDENT: The blinds should come down. They have not come down. Is there someone here who knows how to do that? (Pause)
Just give us a moment.
MR. TURNER: Thank you.
Sir, I was concluding the CMA's response in relation to Alpharma and the question whether Alpharma had essentially given up the ghost prior to the date of concluding the settlement with GSK.
THE PRESIDENT: Yes.
MR. TURNER: A further insight into Alpharma's approach can be seen from a document which is relied on heavily in the decision at {V/1/152} paragraph 3.359. It is essentially quoted pretty well in full. I don't believe I am omitting anything material from it. It is from the Alpharma email of 14 October 2002.
The subject line of the email is:
"UK settlement negotiations for paroxetine: meeting October 11th 2002."
You will see from the footnote -- the first footnote on the page what the -- where we get that from. Then if you turn the page {V/1/153} you will see what is said there.
First of all recording what GSK said to them were the benefits to them of the deal:
"Keep patent defence intact. Maintaining stability and predictability (they are also in the middle of budget 2003)."
Then, if you go down to the middle of the page:
"GSK will offer a lump sum and/or monthly payment which can be turned into either a cross-undertaking as part of the settlement or a promotional fee. We clearly have to negotiate this further and decide the minimum we can accept."
A little bit below that you see, just over from "Key issue to evaluate", "Decide minimum lump sum".

What you gather from this is at this point they are still deciding what is the minimum to make the numbers right, to use the language of GUK.

Then, later on 23rd October --

THE PRESIDENT: They do say that they need to get the tableting patent invalidated, do they not? At the bottom of that page.

MR. TURNER: They do:

> "The earliest possible time we can have the tableting patent invalidated ... as long as that patent is in place ... it will be impossible to launch before well into 2003 due to that patent. Renegotiations with Delta is an issue we will have to bring forward."

We certainly do not say that there were not negative elements to consider as well, at least in relation to timing.

What we can see, however, is that it was a bargaining process in which they were asking and trying to decide what was the minimum sum that they could accept and they were regarding it as a package.

If they went go forward to paragraph 3.361, it is on that page. 23rd October 2002 and there has been another meeting between GSK and Alpharma. What you see is the genesis here of the value transfers and the labels which are given to them and you saw that yesterday.

So if you perhaps turn the page {V/1/155}, you see the reference -- I believe we have gone back to this before. You will see for example in 4 and 5 the reference to 3.5 million "other" and in paragraph 5:

> "Linked to this we will get £0.5 million which Brendan cleverly suggests to name 'promotional allowance' in the contract to make it hard money."

Just before moving on there is one further point raised by GSK and Actavis about what Alpharma was expected to do. You can see this most clearly from Ms. Ford's skeleton at {S/4/12} at paragraphs 40 to 41.

This is the rhetorical question that is framed in her skeleton argument and which she also made orally:

> "One might rhetorically ask, what is a generic company such as Alpharma to do in such circumstances? Must it, once it has taken steps towards market entry or found itself embroiled in infringement litigation, pursue that litigation at all costs for fear a settlement will be condemned as anti-competitive? The CMA complaints that the GSK-Alpharma agreement 'delayed ... Alpharma's contribution to the competitive process' which might (or might not) have led to the 'finding of a non-infringing product' an outcome which 'would have led to true generic competition'. Must

> Alpharma continue to fight the Alpharma litigation at all costs in order to avoid such a loss of a chance? Surely not. Indeed, the CMA appears to concede that an agreement between competitors to delay potential independent entry would be legitimate provided it arises from an assessment of the strength of the patent."

Then:

> "Alternatively, then, must Alpharma capitulate completely in order to avoid the suggestion that it has accepted payment in return for agreeing not to persist in its efforts to enter independently? Again, the CMA claims to accept that not all reverse payment settlement agreements are anti-competitive and that it all depends on whether the value transfers have a legitimate purpose."

So the claim is that essentially you are in an impossible situation, if this is the law because there is only a binary choice: you either fight to the bitter end or you capitulate completely because you must avoid the suggestion that you have accepted a payment in return for agreeing not to continue efforts to enter.

But the answer is not binary. Actavis is right to recognise the CMA does not say that either scenario is obligatory. There is a third way, namely that the parties can settle, they could settle without value transfers and from the originator, and Alpharma proposed precisely that sort of arrangement. If you go to the decision at 3.355.

If you go to {V/1/150}, you will see there that what was being proposed on 24th September 2002 at paragraph 1 involves a mixture of things:

> "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). For example, perhaps April of 2003."

There they are talking about independent product. So that was their proposal. At that time -- for completeness at paragraph (4) they said that they would want an immediate payment from Glaxo in consideration of that agreement in (1) and (3) above -- if we turn the page:

> "I suggest the 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."

There they were proposing something which we say was certainly legitimate but where it is essentially something bought by a large reverse payment, which seemed to be part of the proposal there; that part is not what we say is acceptable.

So far as the Alpharma/GSK agreement is concerned, I am not proposing to take you to it at this point but I will take you to one Alpharma email internally discussing the extension of the agreement.

That is at {A9/184/133}. So here you have an email dated 4th September 2003. It describes the settlement and in the second paragraph it refers to:

> "GSK: having guaranteed us a certain amount of money, £1.2 million a year and 500,000 packs of paroxetine ... (approx 25% market share). We have had several discussions with GSK regarding extending this agreement and have come to what we believe are favourable terms."

So it is the cash value crystallised. Then just above "Summary of terms" they say:

> "If we do not renew the agreement, we will be faced with launching the paroxetine product in the face of the GSK patent and, while we are comfortable we will win, we will incur legal fees, could face a injunction and of course substantial damages if we ultimately lose."

In terms of the merits of the litigation itself --

THE PRESIDENT: The date of this you said is?

MR. TURNER: 4th September 2003, therefore prior to the Pumfrey judgment. I am sorry -- this is on renewal.

THE PRESIDENT: 4 September 2003?

MR. TURNER: I am sorry, the *Apotex* judgment in December 2003.

THE PRESIDENT: Yes and they did extend, did they not?

MR. TURNER: Yes, it was terminated the following year. If it pleases the Tribunal, that is all I say in opening in relation to the facts.

What I will use the remainder of my time for is to turn to some of the key points of law arising from the *Lundbeck* judgments which have been ventilated so far in the hearing and I will attempt to avoid ground that has already been covered. Then Ms. Demetriou is going to very shortly deal with the vertical agreements' exclusion order point.

If I may then turn to the law. Those being the facts, the question is how to analyse those facts in the framework of Article 101 of the Treaty and section 2 of the Competition Act.

All the parties agree that the basic legal principles for assessing a restriction by object are contained in the Court of Justice Judgment in *Cartes Bancaires v the Commission*. We will not go to it for the moment, but that is {Auth-I/51/1}.

Prior to the General Court's decision in *Lundbeck*, the argument between the parties in the notices of appeal and in our defence centred around how those principles fell to be applied in this sort of context.

We now do have the *Lundbeck* judgments as of 8th September last year and the General Court has specifically provided, explicitly, the principles from *Cartes Bancaires* to a context which is the same as our case, reverse payments by originators in the pharmaceutical industry to induce settlements for patent litigation in fact situations which are very similar to our own case.

In *Lundbeck* you also had an originator which transferred substantial value to potential generic entrants to induce them not to launch their own independent products. The General Court upholds the Commission that the agreements had as their object the restriction of competition and they weren't eligible to be exempted. The court rejects arguments by the applicants in those cases which parallel arguments advanced by the appellants in these proceedings.

There is one overarching point to make before we look at the substance of it and that is that GSK accepts that the court's reasoning is entitled to respect but they say it is not safe to rely on the judgment as a final source of law.

The European General Court's interpretation of the treaty in this field is the European law that the Tribunal applies unless and until set aside by the Court of Justice, possibly in 18 months' time or longer.

But at the level of domestic law, section 60 of our Competition Act also says, in terms, that when the Tribunal applies the Chapter I prohibition, it must act with a view to securing consistency with any relevant decision of the European Court and that includes the General Court as applicable at that time.

THE PRESIDENT: If I can interrupt you, Ms. Kreisberger put it, it seemed to me, if I understood her correctly, slightly differently from Mr. Flynn.

Ms. Kreisberger said that if we think that *Lundbeck* is out of line or might be wrong -- I do not think she suggested we could decide the case contrary to the General Court. Mr. Flynn did make that submission. She said we are not bound to decide it in compliance with *Lundbeck*; we could and we should take into account the fact that *Lundbeck* was under appeal, we cannot ignore that, and that then if we had doubts we could refer.

MR. TURNER: Yes.

THE PRESIDENT: Do you agree with that?

MR. TURNER: Yes, I do agree.

THE PRESIDENT: In other words, we cannot decide definitively contrary to the General Court but we either, you say, have to decide it consistently with the General Court or we make reference?

That is how I understood it and she is nodding.

MR. TURNER: Yes. If you stay and make a reference then you will not be deciding it and therefore section --

THE PRESIDENT: That seemed to me to be correct; do you agree with that?

MR. TURNER: We do agree. It is correct subject to one significant qualification, which is this: that the mere fact that a judgment is under appeal to the higher court in itself does not mean that this Tribunal should stay its hand. It is whether the Tribunal considers that there are substantive good reasons for doubt.

THE PRESIDENT: That must be right. If we think -- we cannot just by -- because they have appealed, if we think the appeal is hopeless, we would not have to make reference, yes.

MR. TURNER: I turn then to *Lundbeck* itself so that the Tribunal can see what the case was about and what was argued by Lundbeck and decided by the General Court and why it was to assist the Tribunal as the case now progresses to the conclusion of the hearing.

As we go along, I will address the various ways in which the appellants are seeking to distinguish or criticise this judgment or these judgments. The main judgment is in the Magnum system at {W/1/1}, case T4723.

THE PRESIDENT: If I can also interrupt you, we have been looking mostly at the main judgment; if and when there is something in one of the other judgments -- because I think there was some five or six of them -- that one ought to look at, you will let us know.

MR. TURNER: I will certainly do that. There is something coming up almost immediately.

THE PRESIDENT: Because otherwise one will basically concentrate on the main judgment and not have to plough through all of them. There is a lot of overlap.

MR. MALEK: For my part it would be helpful if all the parties can prepare a schedule of what they say are the relevant paragraphs in all these decisions so when I go through it I am not going to miss any reference.

THE PRESIDENT: I think that would be very useful, yes.

MR. MALEK: No commentary; just list the paragraphs.

THE PRESIDENT: Just the paragraphs that we ought to look at. You have been reading some out, Mr. O'Donoghue referred to a lot, other parties referred to bits here and there, so it is really just pulling it all together.

MR. TURNER: Yes. Sir, would you like the paragraph and the relevant paragraph for which it stands?

MR. MALEK: No, just the paragraph numbers.

MR. TURNER: Yes, we will do that.

If you open the first judgment, the main judgment, you will see paragraphs 1 to 14 identify the parties. There is Lundbeck itself in paragraph 1 and there are four generics, some of them now familiar to this Tribunal: Merck, GUK, Alpharma and Axellia, Arrow, mentioned earlier, and Ranbaxy at paragraph 12. Alpharma and Axellia at paragraph 10.

At paragraph 15 is a reference to the relevant product, citalopram, and at paragraphs 16 to 21 is a description of the patent position on which you have already heard certain submissions.

Paragraphs 16 and 17 relate to the compound or molecule patent, the original patent applying to the active ingredient. That was patented at different times in different countries and expired in January 2002 in this country.

All the other patents owned or applied for by Lundbeck are process patents, paragraph 18.

I now make a point following on from Mr. O'Donoghue's submissions. He took the Tribunal to the crystallisation patent which is referred to in paragraph 20, one of the patents. That patent covers a passage of purifying crude citalopram to make pure citalopram and that was the patent that Lundbeck knew was not the strongest of all patents. {W/1/4}

That is the patent in relation to which Lundbeck had expressed its own doubts. Perhaps if we go to the Commission decision to remind ourselves of that, the reference is {Auth-F/16/68}.

At the top of the page, at paragraph (157), you will see here is the reference to the 60% and the weakness:

> "In an internal assessment of 29th September 2003, Lundbeck estimated the chance that the UK judge would hold the crystallisation patent invalid at 60%. At this time, Lundbeck was still optimistic about its chances that if the patent were held valid, it would also be found infringed."

I can give you the other references but the reference to the 60% and the appreciation of weakness comes in relation to this patent. This was one of several. If you go back to the main judgment, if you still have that open {W/1/4} you have at paragraph 19 reference to the amide and iodo patents, two others. Those were two different processes by which medical grade citalopram could be made. Those process patents and I stress were the only ones relevant to the case of *Ranbaxy*, an active ingredient supplier.

If we go to that judgment {W/2/3} paragraph 9. You will see there that that:

> "The EPO granted Lundbeck a patent protecting the process using amide ... on 19th September 2001 and a patent protecting the ... iodo patent later on 26th March 2003."

To concentrate on amide. If we go over the page to page {W/2/4} paragraph 14, second indent:

> "Lundbeck performed laboratory analyses of that citalopram and concluded that the processes used infringed the amide patent and the iodo patent, the latter not having yet been granted ... whereas Ranbaxy Laboratories disputed the existence of such infringements."

What you had was an infringement dispute in that case relating only to these other patents and not the one that Mr. O'Donoghue took you to.

Then if you go to page {W/2/26} at paragraph 144 you will see the court noting that:

> "The applicants themselves acknowledge that before concluding the agreement at issue they believed that it was possible they would succeed in litigation with Lundbeck..."

Possible, note, that they would succeed in litigation with Lundbeck:

> " ... in the context of an infringement action based on the amide and iodo patents. While it can be accepted that there were no certainties in that regard, it must nevertheless be borne in mind that during the meeting of April 2002 and in the preamble to the agreement at issue, they maintained that their processes did not infringe Lundbeck's patents. In particular, it must be noted that, as can be seen from inter alia the eighth and ninth recitals in the agreements at issue, the applicants have never admitted that the processes that they used, which corresponded to their patent applications in India, infringed Lundbeck's intellectual property rights; rather, they wished to avoid litigation, the outcome of which could not be foreseen with absolute certainty."

So those were, as the court recorded this, the relevant perspectives at the time and the legal analysis that it applied in this case was the same as the legal analysis that it applied in the main case.

I am reminded by Mr. Bailey, who is involved in the case, that Lundbeck had never expressed doubts about the validity of that patent, let alone 60% chance of it being found to be an invalid patent.

Beyond that there were patent disputes between Lundbeck and each of Merck, Arrow, Alpharma and Ranbaxy, which you can see from the sub-bullets of each of the paragraphs summarising the agreements, to give you the references, paragraph 26.

THE PRESIDENT: Sorry paragraph 26 of what?

MR. TURNER: I am now in the main judgment, I apologise, on page {W/1/5}. That is the agreement with Merck. Paragraph 35 {W/1/8} relates to Arrow. Paragraph 39 {W/1/9}, that is the Arrow Danish agreement. Paragraph 42 {W/1/10} is Alpharma. Paragraph 47 {W/1/12} is the agreement with Ranbaxy.

You will see the last bullet on that paragraph, page 13:

> "Lundbeck and Ranbaxy... arrived at an agreement to ... avoid costly and time-consuming patent litigation, the outcome of which could not be predicted with absolute certainty ..."

Lundbeck did actually bring proceedings against one of these Generics, Alpharma. If you go to paragraph 42 on page {W/1/111} and look at the fifth bullet:

> "The seventh recital recalls that, on 31 January 2002, Lundbeck filed a lawsuit with a United Kingdom court (the infringement action against Alpharma) seeking an injunction ... for infringing Lundbeck's intellectual property rights."

That related to infringement of the crystallisation patent. So there was a real patent dispute between Lundbeck and each of the Generics and the General Court's judgment -- I refer to a negative -- does not say anywhere or imply anywhere that the analysis turns on the absence of litigation being on foot. For example, if you go to paragraph 382 on page {W/1/81} there is a reference to the uncertain outcome of the potential patent litigation. That uncertainty being eliminated and being replaced by the certainty that they would not enter during the terms of the agreement.

So far as the agreements in Lundbeck are concerned, you see, if you go back to paragraph 23 on page {W/1/5} that they entered into a group six agreements with four generic companies and I will only look at one of those, which is the Lundbeck/Merck agreement. Paragraphs 24 to 29, on page {W/1/5}, summarise the provisions of this agreement covering the UK.

You will see from the first sentence of paragraph 25 that that agreement was for a year's duration. They do not in this summary refer to quite an important element of it, which I am afraid you do have to go forward to paragraph 217 for, on page {W/1/49}, which is that there was an entry restriction accepted:

"Following the conclusion of the ... agreement with Lundbeck ... Merck abstained from launching generic citalopram on the market until the end of the term of the agreement which was initially planned for July 2003."

Then, if you go back to paragraph 26, in the first indent there is recorded:

"... the risk that certain actions envisaged by GUK ... in marketing, distribution and sale of the products" might constitute the infringement of the intellectual property rights. So there was the patent dispute {W/1/6}.

The second and third indents refer to how, under those agreements, Lundbeck would pay £2~million for the delivery of the products, and in the third indent, delivering the products up for £1 million. So a combination of £3 million.

The fourth indent, Lundbeck agrees to pay the infringer of its intellectual property rights. That is therefore a reverse payment. The fifth indent, here is the reference to entering into an authorised supply agreement. This is the non-cash value transfer on top of the cash, whereby Lundbeck agrees to supply GUK with its own finished product.

Finally, in paragraph 26, the final indent related to a profit guarantee; guaranteed net profits. Lundbeck guarantees them net profits of £5 million for the sales of Cipramil.

Then, for the anti-competitive implications of all that, if you go forward to the *Merck* judgment, a different judgment, at {W/4/35} and 36. 175, at the bottom of the page 35, the court says:

"Secondly, it should be pointed out that for the sake of completeness that the Commission rightly found in its decision that due to the provisions of the UK agreement, taken in context, Merck no longer had any incentive to purchase citalopram in the form of API from a third party, or to sell citalopram in the form of finished products other than those of Lundbeck, even though it was in principle free to do so under the UK agreement."

"It must be borne in mind, first of all, that Merck undertook, under Article 3.2 of the UK agreement, to sell Lundbeck's Cipramil in the UK during the terms of the agreement and that, under Article 6.2 ... the payment of GBP 5 million, described as net profits, was conditional upon the sale of a certain volume of those medicinal products in the UK during the term of the agreement. It must also be noted that the sum in question was to be paid in several tranches which allowed Lundbeck to ensure satisfactory performance of the agreement:

"Accordingly, even though Merck could in theory have sold types of finished products other than those of Lundbeck, it had no incentive to do so, since it was able, without

taking any risks, to obtain GBP 5 million as guaranteed profits for the sale of Cipramil under Article 6.2 of the UK agreement."

Before going any further, I will just identify the principles applied and the decisions reached by the General Court which are relevant to your task. We have the consideration of potential competition and the consideration of restriction by object.

Under potential competition I am going to take it for the moment and for opening that I will not give you further assistance on that; it is the real concrete possibilities test that can be developed further as necessary in closing. But what I will do is turn to what the court said about the correct way to assess evidence relating to potential competition because that does bear on the task you are about to carry out.

Paragraph 138 of the main judgment at {W/1/32}. This is where the General Court confirms the Commission's approach in taking into account evidence which is prior to or contemporaneous with the date of the agreement.

You have seen paragraph 139 before. If you go to paragraph 142, please {W/1/33}. You will see the objective evidence relied on by the Commission and referred to by the General Court and the striking resemblance between that objective evidence and the material in this case. So objective evidence is referred to five lines down in that paragraph and it is such as: the investments already made, the steps taken in order to obtain a marketing authorisation, and the supply contracts concluded with, among other, their API suppliers.

"Those various pieces of evidence have also been expressly contested by the applicants, as regards each generic ... and will be examined in the sixth to ninth parts below."

Those were what were taken as relevant to potential competition. At paragraph 144, towards the bottom of that page, there are two points of real significance as to how the Tribunal should evaluate GSK's case.

First, in the first sentence:

" ... although other statements contemporaneous with the conclusion of the agreements ... might suggest that the generic[s] ... had doubts concerning the non-infringing nature of their products, or that Lundbeck was consequenced of the validity of its patents, those statements are not enough to call into question the conclusion that the generic undertakings were perceived as a potential threat for Lundbeck and were liable, by their very existence, to exert competitive pressure on Lundbeck and on the undertakings operating in the same market (see, to that effect ... *Visa*) the strongest

evidence in that respect is the very fact that Lundbeck concluded agreements with generic undertakings in order to delay their entry to the market."

See to that effect the *Toshiba* case. We say that the same approach should be taken by the Tribunal in this case.

The next point is the question whether challenging a valid patent in litigation can itself be evidence that there is a real concrete possibility of entering the market.

If you go to page 34 in {W/1/34} you have paragraphs 149 to 155. The heading under 148 is:

"The third part, alleging that challenging a valid patent does not constitute a real concrete possibility of entering the market."

If you go to paragraph 159 {W/1/36} you will see that at the bottom of that paragraph the Commission rightly submits that:

"In order to establish the existence of potential competition it is not necessary to demonstrate with certainty that the generic undertakings would have entered the market and that that entry would inevitably have been successful, but only that they had real concrete possibilities in that respect. To assert the contrary would amount to denying any distinction between actual and potential competition."

We say that we also do not need to show that because it would amount to showing with certainty that the Generics would have entered the market and any doubts remaining on that question are dispelled by the General Court. If you go to paragraph 165 {W/1/38} in the first sentence:

"Fourthly, the applicants wrongly argue that the Commission should have demonstrated that the generics ... would have brought legal proceedings and that they would have been successful before the competent National courts."

Then, it was not required to be demonstrated. Paragraph 163, if we go back a page please, deals with the timing of entry to count as potential competition {W/1/37}.

You will see there an important point made that, in order to establish:

"... the existence of potential competition, the case law requires only that the entry to the market take place within a reasonable period, without fixing a specific [time] limit in that respect."

(2.45 pm)

(Short break due to technical issues)

(2.55 pm)

THE PRESIDENT: Yes, I think we are all working again.

MR. TURNER: I am obliged. Just closing off this point about the absolute legal barrier in the form of not having marketing authorisation. On page {W/1/41}, paragraphs 179 and 180, there is there a reference to the fact that even when you are preparing, 179, to get a market authorisation, even if it is taking more time than was foreseen, nonetheless you have, halfway down, real concrete possibilities of obtaining those MAs within a sufficiently short period and entering, in that case, the citalopram market in several EA countries by using the mutual recognition procedure.

At the end, the court recalls that in the present case the Generics had begun making preparations to enter the market one to three years before the expiry of the original patents and they were engaged in an intense race to be the first to enter the market after the expiry of the patents.

In view of that, at 180, the Commission says that the -- the court says that the Commission did not err in finding, in recital 620 of the decision, that the absence of a MA did not mean that the generic medicinal products were not capable of entering the market in the near future, while the generic undertaking continued to take steps to obtain the necessary authorisations in that respect before concluding the agreements at issue with Lundbeck.

There is then just one further issue that needs to be addressed in this setting at this point, which is the reference to what the General Court called the paroxetine judgment, which was the interim judgment of Mr Justice Jacob, which we have looked at earlier today giving GSK permission or granting its application for an interim injunction against GUK pending a speedy trial.

GSK highlights this as a material point if we go to {S/2/113} at 5.61 of its skeleton argument. But in our submission -- and I will merely adumbrate this now -- it has no bearing to the issues that you have to decide.

The General Court discusses the paroxetine judgment of Mr. Justice Jacob at paragraphs 258 and following, beginning on page {W/1/57} of the main judgment.

You have to start in fact at page {W/1/54}, paragraph 240, where you will see that the applicants in *Lundbeck* invoked the judgment of the High Court of 23rd October 2001, the paroxetine judgment, from which it follows according to them that:

> "A generic ... cannot enter the market before it has proved that its product does not constitute an infringement, which Arrow was unable to do."

That submission was incorrect. It is not necessary for a generic to prove it does not infringe before it can enter; under English law the patentee sues for infringement and must show it.

At paragraph 258 {W/1/57} you have Lundbeck's argument based on the *Paroxetine* judgment, and the interpretation of national law and the European Court says that:

> "A question relating to the interpretation of national law of a member state is a question of fact, in respect of which the General Court is required, in principle, to carry out a comprehensive review."

At paragraph 259 the General Court briefly summarised the fact that the balance of interests favoured in the facts of the case for granting an interim injunction and notes there that the generic, GUK, had not cleared the way by informing the originator of its firm intention to launch its generic product.

At 260 the General Court does not rule on the interpretation and exact scope to be given to the *Paroxetine* judgment. It does not do that and does not consider its effect. It simply notes that there are differences between the *Lundbeck* case and the case which gave rise to that judgment.

At paragraphs 261 to 263 what you find are three differences noted by the court between the facts of *Lundbeck* and Merck and GUK which were sufficient for its purposes in that case. Those are, first, the fact that in Lundbeck there had been contact between Lundbeck and Arrow, this is 261, to discuss the issue of generic citalopram. It goes back to the clearing the way point.

Second, that GSK's anhydrate patent had existed throughout the period that GUK was preparing to enter the market, although Lundbeck had only applied for its crystallisation patent shortly before it settled with Arrow {W/1/58}.

The third point is that if Lundbeck's interpretation of *Paroxetine* was right, this is in the middle of 263, which the court did not decide, and on the basis of their belief that they had be able to block the entry of generics by enforcing their patents, if that was right, then interim measures would surely have been granted against Arrow if it had tried to enter, thus allowing them to block that entry, the final words, "pending a favourable judgment on the substance".

So there it is, as it were, put as a credibility point. The key points therefore --

THE PRESIDENT: Sorry, just one moment.

(Pause)

Yes.

MR. TURNER: In 263 what we are saying is if you are right about what that really means, if it is that strong, why are you paying money to them to get them out of the frame because you

would have been able to block the entry of the generic, interim measures would surely have been granted, but you did not even do that.

THE PRESIDENT: Yes.

MR. TURNER: It is an experienced undertaking advised by specialist lawyers: why did it prefer to conclude the costly agreement, such as the Arrow agreement, which merely allowed it to delay Arrow's entry into the UK market?

Therefore the key points which arise from this consideration of the General Court are these: the General Court is not finding that if you have an interim injunction in the UK there is not potential competition; it recognises that, even on Lundbeck's submission, entry is blocked until you get judgment in your favour on the substance; and that general principles which I have now read to you, because it is liberal throughout the text of the judgment, about when potential competition exists, those show that it is not necessary to prove that entry would definitely have happened, only that entry would take place within a reasonable time and not a fixed time.

The touchstone is the real concrete possibilities which subject the originator to competitive pressure and a strong indication of the competitive pressure is the very fact that the originator is willing to pay a large sum of money in order to avoid further steps being taken.

So that is potential competition. I will deal quickly with restriction of competition by object, which is --

THE PRESIDENT: I am not sure I fully understood it but are they not saying in paragraph 263 -- as you submitted, it is a credibility point. If you are really saying your position was so strong, then you would have got an interim injunction.

MR. TURNER: Yes.

THE PRESIDENT: So how does that translate to a case where the patentee has obtained an interim injunction?

MR. TURNER: It does not mean that you have got an interim injunction that they are saying that that is a definitive block; it is merely saying that on the facts of this case, although they say that this was a measure that would have been readily granted, on the facts of that case, they did not even bother to get it; they merely took steps advised by specialist lawyers to enter into this agreement designed to avoid it.

THE PRESIDENT: Yes.

MR. TURNER: So we come to restriction of competition by object in paragraph 331 {W/1/69}.

These are the second, third, fourth fifth and sixth pleas alleging infringement of Article

101(1). The Commission had erred in law in the assessment that these agreements have the object of restricting competition.

The applicable principles and case law -- they begin at page {W/1/71} for your note, paragraph 338. I will begin at 339 on page 71.

At 339, the essential legal criterion for identifying a restriction -- an agreement having the object of restricting competition is:

> "Whether an agreement reveals a sufficient degree of harm to competition."

That is the process of competition. So there is no need to examine the effects. That cites *Cartes Bancaires*. That is also the legal test applied by the CMA in its decision.

If you go forward to page {W/1/92} --

THE PRESIDENT: That is 340?

MR. TURNER: I am coming back to that, I do apologise.

Page 92, paragraph 434, just for your note, to see how they began that, which was to say that:

> "By the judgment in CB [*Cartes Bancaires*], the Court of Justice did not call into question the basic principles concerning the concept of a restriction by object set out in the previous case law."

We now go back to page 71. That case law arises from the fact that:

> "Certain forms of coordination between undertakings can be regarded, by their very nature, as being injurious to the proper function of normal competition ..."

Contrary to -- again, the reference, should you wish to go there, is {S/2/120}. It is GSK's skeleton again. At paragraph 6.17 you will see at the bottom of the page the way they frame the legal proposition. They say halfway down:

> "Bearing in mind the restrictive approach endorsed in *Cartes Bancaires*, either to point to past experience of effects analysis enabling it to develop a theory of harm establishing that agreements of the time at issue are so obviously harmful that it is not necessary to engage in effects analysis ..."

So you have to go through that process first:

> " ... or to show that it is obvious that an agreement has harmful effects."

It does not say that. The proposition concerns agreements which by their nature are injurious to the functioning of normal competition; it is not about showing particular effects from it.

Paragraph 341 is another paragraph that GSK are keen on. It refers to examples of object restrictions based on what experience shows. GSK says, among other things, that the CMA has no experience of its own to rely on.

But the level at which *Cartes Bancaires* expresses this proposition is -- second and third lines:

> "... consisting in the exclusion of some competitors from the market."

That sort of behaviour, market exclusion, is behaviour which is an object restriction and at the very beginning of my opening I took you to the approach taken on that by the Commission and endorsed by the court in the *Ranbaxy* judgment.

This is a species of market exclusion agreement. The General Court deals with a similar argument by *Lundbeck* to GSK's later on, page {W/1/93} paragraph 438:

> "... contrary to what is claimed by the applicants, it is not necessary that the same type of agreement have already been censured by the Commission in order for them to constitute a restriction of competition by object. The role of experience, mentioned by the Court of Justice in paragraph 51 of the judgment in *CB v Commission* does not concern the specific category of an agreement in a particular sector, but rather refers to the fact that it is established that certain forms of collusion are, in general and in view of the experience gained, so likely to have negative effects on competition that it is not necessary to demonstrate that they had such effects in the particular case at hand. The fact that the Commission has not, in the past considered that a certain type of agreement was, by its very object, restrictive of competition is therefore not, in itself, such as to prevent it from doing so in the future following an individual and detailed examination of the measures in question having regard to their content, purpose and context." {W/1/94}

Paragraph 343 on page {W/1/72}. That sets out the well-established criteria that need to be taken into account: you look at the content of the agreement, you look at its objectives, and you look at the economic and legal context of which it forms a part.

Sir, in relation to an issue that we debated yesterday at 344, although the parties' intention, subjective intention, is not a necessary factor in determining whether an agreement between undertakings is restrictive, there is nothing prohibiting the Competition Authority, the national courts or the courts of the Union from taking that factor into account which is what happened in this case.

The parties' assessment of the strength of the patents, largely covered partly in relation to the debate this morning, but GSK in its skeleton presses the argument, you will recall, that the contested agreements do reflect the parties' assessment of the strength of the patent.

If you go to page {W/1/73} and paragraphs 346 and 347, you will see there that *Lundbeck* was making arguments to similar effect and they refer at 347, you will see, further down, that there was no written evidence, four lines up, showing the parties' lack of confidence in the strength of the patents.

It is essential for you to see how the General Court then addressed that approach as a matter of law. At 349, having recorded the submission, they say:

> "It must be recalled that the Commission considered, in the contested decision, that the fact that the restrictions contained in the agreements at issue had been obtained through significant reverse payments was decisive for the legal assessment of those agreements ..."

Decisive. At 352 over the page {W/1/74} -- we went to that yesterday -- there, again, that is the encapsulation of the central proposition perhaps in the main judgment.

I am asked by Mr. O'Donoghue to refer to 354 {W/1/74}:

> "It must be noted, in that respect, that the Commission did not find, in the contested decision, that all patent settlement agreements containing reverse payments were contrary to Article 101(1) TFEU; it found only that the disproportionate nature of such payments, combined with several other factors — such as the fact that the amounts of those payments seemed to correspond at least to the profit anticipated by the generic undertakings if they had entered the market, the absence of provisions allowing the generic undertakings to launch their product on the market upon the expiry of the agreement without having to fear infringement actions brought by Lundbeck, or the presence, in those agreements, of restrictions going beyond the scope of Lundbeck's patents — led to the conclusion that the agreements at issue had as their object ..."

The point made on the appellants' side is that all of these issues which we say are the particular factors which arose in that case, but which are quite clear, were not necessary to the essential reasoning of the court and they say form part of the essential reasoning of the court. That is no doubt an argument that can be held in closing.

To pursue Mr. O'Donoghue's point, if you go over the page {W/1/76} to paragraph 360, you will see there that the court does say that the Commission took the view, three lines down:

" ... taking into account a series of factors in that respect ... that where such agreements contain significant reverse payments, which reduce or eliminate any incentive for the generic ... to enter the market ... without, however, resolving the underlying patent dispute, those agreements fall within the scope of Article 101 ... In such cases, the transfer of value replaces the autonomous assessment, by the parties, of the strength of the originator undertaking's patents and the assessment of their chances of succeeding in potential litigation based on those patents or concerning their validity."

Paragraph 361 puts the same point in colloquial terms that the payments, as you will see from the penultimate line:

"... thus served as a deal clincher and were decisive."

At 366 {W/1/77} there is a reference to a body of evidence which was relied on in the present case by the Commission to demonstrate that it was the size of the reverse payments which induced the undertakings to accept the limitations and not the existence of the process patents or even the desire to avoid the expenses of litigation.

Well, the body of evidence is set out in 354, the paragraph that Mr. O'Donoghue asked me to read. If we go back to that paragraph {W/1/75} and we take them in turn, the disproportionate nature of reverse payments, which we clearly do have in this case, for the amounts; those payments were combined with several factors.

Second, the fact that the amount of those payments seemed to correspond to the profits anticipated by the Generics if they had entered the market. That was a particular feature of this case. It is not necessary -- and it is clearly not necessary as you see from -- I will give you the other General Court judgment here, this is GUK {W/4/58}, paragraph 296. If you read the proposition there:

"Further, the Commission cannot be required to show that the reverse payments exceeded the profits expected by Merck if it marketed its generics in order to show the existence of a restriction by object. The mere existence of a reverse payment could therefore be taken into account by the Commission as a relevant contextual element in order to establish the existence of such a restriction in the present case. In the absence of any alternative explanation, that payment may be regarded as consideration for the restrictions imposed by the agreements at issue ... [this is important] since it is not certain that Merck would have accepted those restrictions in the absence of that payment and it can be seen from the evidence referred to in the ... decision that it accepted those restrictions provided that the numbers 'stacked up'."

Provided the numbers were right. So again we have a very clear statement in the General Court's reasoning that you do not have to reach that threshold; it was a particular feature of the main *Lundbeck* case and that the general reasoning of the court is exactly as we say.

THE PRESIDENT: So you say, is that right, that they refer to these several other factors as reinforcing the view taken by the Commission, which is upheld, but they were not either individually or cumulatively necessary factors?

MR. TURNER: That is so.

MR. O'DONOGHUE: Can I ask you to look at 362 please?

THE PRESIDENT: I think we already have.

MR. TURNER: We did.

THE PRESIDENT: A few minutes ago.

MR. TURNER: We will probably leave it until closing now because I have some way to go.

The third point is the absence of provisions allowing the Generics to launch their product on the market on the expiry of the agreement without having to fear infringement actions brought by Lundbeck. If we are back in 354 of the main judgment and the third particular factor. {W/1/75}

As I have shown the Tribunal, that was the same as the position in this case.

Finally, the presence in those agreements of restrictions going beyond the scope of Lundbeck's patents, the scope of the patents point. That does not arise in the present case but whether the limitations fall within the scope of the patents is very clearly not decisive.

If you go, for example, to paragraph 401 in the main judgment on page {W/1/85} you see that:

> "In any event, even if the restrictions contained in the agreements at issue potentially fell within the scope of Lundbeck's patents, in that they could also have been obtained through litigation, the contested decision rightly finds that this was merely a possibility at the time the agreements at issue were concluded, replacing that uncertainty in relation to whether or not the generic undertakings were infringing and to the validity of the applicants' patents with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue constitutes, as such, a restriction on competition by object in the present case, since that result was obtained through a reverse payment ..."

THE PRESIDENT: You say the scope of the patent is not decisive. You are saying it is not necessary. It might be decisive, but if it was beyond the scope --

MR. TURNER: I am sorry, it is not the necessary feature. Perhaps if we look at paragraph 490 on page {W/1/103}, for the scope of the patent.

There we are:

> "In the light of that case-law, and of the inherent objectives of Article 101 TFEU which require, inter alia, that each economic operator must determine independently the policy which it intends to adopt on the market ... in order to protect consumers from unjustified price increases resulting from collusion between competitors ... the Commission was entitled to refuse to apply the 'scope of the patent' test in the present case in order to evaluate the agreements at issue in the light of Article 101(1) TFEU."

At 499 {W/1/105}, second sentence, four lines down:

> "The Commission did not commit any error of law in rejecting the 'scope of the patent' test as the relevant test for the purpose of examining the agreements ... in the light of Article 101 ... As the Commission points out, the relevant test in the present case was the concept of restriction by object, as developed by the case law of the European Union courts ..."

The General Court's overall conclusion on object is very clear and emphatic. It is paragraph 436 on page {W/1/93}:

> "The Commission correctly applied the case law in its decision, which consists in determining whether an agreement may by its very nature be regarded as restricting competition in a sufficiently serious manner as to be classified as a restriction by object in the case at hand".

You will recall I think I took you at the top, paragraph 435:

> "It follows from the general scheme of the contested decision and from recitals 802 and 1338 in particular, that the agreements at issue were comparable to market exclusion agreements, which are among the most serious restrictions of competition."

The last matters I will take you to before concluding relate to certain matters raised in the economic evidence in this case, whether reverse payments fall to be justified on the basis that they see a symmetry of risks between the two parties or a need to bridge the gap by making a payment, which, if made, will mean that a pro-competitive deal benefiting customers will be arrived at.

Lundbeck put forward a number of arguments as to -- explanations, I should say, as to why these reverse payments were made and two of them are the same as the one put forward now by the appellants.

On page {W/1/79} you have paragraph 372. We must take it from 370 -- I shall not read the whole of that -- on page {W/1/78} -- perhaps if you read to yourselves 370 down to 371. You will see the arguments put by the applicants concerning the asymmetry of the risks between the two parties.

THE PRESIDENT: Just a moment if you want us to read it.

MR. TURNER: Yes. (Pause).

THE PRESIDENT: How far do you want us to read?

MR. TURNER: 372 {W/1/79}. I can read that aloud. It is:

> "... therefore, according to the applicants, that asymmetry of risks which the generic undertakings exploited by giving the misleading impression that they were about to sell their infringing products, and which gave them the necessary power to extract payments from Lundbeck. Both the economic literature and the contested decision, in particular in recital 640, also recognise that the greater the damage the originator undertaking estimates it will suffer as a result of market entry by generic undertakings, the more money it may be willing to pay those undertakings in order to avoid such a risk."

Which is common sense and matches a remark by Mr. Malek earlier. If we go forward to page {W/1/81} you have paragraph 381:

> "According to the applicants, the asymmetry of risks allowed the generic undertakings to bluff the applicants in order to obtain significant amounts of money by pretending that they were preparing to enter the market with non-infringing products."

382 {W/1/81}:

> "However, that merely confirms the Commission's theory that there was significant uncertainty, at the time the agreements at issue were concluded, as regards the outcome of the potential patent litigation, and that that uncertainty was eliminated and replaced by the certainty that the generic undertakings would not enter the market during the term of those agreements."

So it is actually a point that is taken in favour of the commission. At 383 we have this:

> "Furthermore, the fact that a reverse payment may constitute the only means of reaching an agreement ..."

It is the only way we will settle:

> " ... by 'bridging the gap' between the parties to that agreement does not mean that such a payment constitutes a legitimate means of reaching such an agreement or that that agreement is exempt from the application of competition law, in particular in

circumstances where: (i) the amount of that payment appears to be linked to the profits expected by those generic undertakings if they had entered the market; (ii) the agreement does not enable the resolution of the underlying patent dispute; and (iii) the agreement contains restrictions going beyond the scope of the originator undertaking's patents."

The three factors I have already considered.

MR. MALEK: Can you show me where the analysis is done on that first issue in this case, if it has been done?

MR. TURNER: The analysis of?

MR. MALEK: Item 1. Has someone -- it is probably in the decision somewhere -- you look at what the payments are going to be and how that relates to the profits they would have got had they entered the market independently.

MR. TURNER: Yes. I do not have that at my fingertips, if I may --

MR. MALEK: Give it to me tomorrow; as long as I have that reference there.

MR. TURNER: We will do that.

The --

MR. MALEK: I am talk looking for it in our case, not in this case; has that analysis been done?

MR. TURNER: No, that analysis -- one of the appellants pointed out that was done in the Statement of Objections. The position taken in the decision is that it is not necessary because you can infer from the fact that a large payment is accepted rather than what the Generics say is their minimum, the bottom line, what they are weighing it against, that it must have been thought to have been better from their point of view and you do not need to carry out a detailed analysis which is then going to be contested with expert economists in court.

MR. MALEK: I think I understood. The other side are saying you did the analysis in the Statement of Objections and you have not pursued it and it is not in the decision?

MR. TURNER: That is right.

THE PRESIDENT: They said that they answered it and -- well, they say they demolished it and it has not been pursued. But it does not follow, just because there is a settlement with a payment, because there will be the element of risk, and you will discount it, according to the risk.

MR. TURNER: That is right. They weigh that up in the decision but what they say is that they are seeking to achieve certainty rather than -- there is actually a document in which that point is made by somebody on the Generics side, but what they are trading is certainty of

getting money in now against the uncertainty that lay on the other side and, if you wish, sir, I will find you -- seek to find you that document.

MR. MALEK: That would be useful.

MR. TURNER: I am sorry, if you go to {V/1/163}. This is our decision. This is Mr. Torben Laursen providing a witness statement to the Office of Fair Trading.

THE PRESIDENT: That is the CMA decision?

MR. TURNER: Yes. You will see a witness statement provided by the CMA by one of the representatives for Alpharma, Mr. Laursen, and he says this:

> "Ultimately, in my view, the reason for entering into the settlement arrangement with GSK was not a commercial one, but more financial. Put simply, it was to remove the uncertainty of potentially winning at a later date with the certainty of getting some money now."

And below that:

> "Entering the market independently would always entail risk, in particular uncertainty as regards the outcome of the legal action, and the agreement with GSK provided certainty -- this was key for Alpharma."

So that is perhaps understandable that that is the mindset expressly voiced by one of the actors.

THE PRESIDENT: I find it slightly an odd statement, 383. It does not say the amount of the payment equals or exceeds, it just says "linked to".

MR. MALEK: But I think you would expect that, would you not?

THE PRESIDENT: Exactly.

MR. MALEK: Because of the uncertainty~--

THE PRESIDENT: Precisely, it will always be linked in some way because that is the commercial consideration.

MR. MALEK: Yes.

THE PRESIDENT: It would be astonishing if there was not some link.

MR. TURNER: Yes, that is true.

Sir, the only other topic I was going to cover -- I do not think I need to -- is the fact that in an object restriction there is no need to identify a counterfactual.

We have already gone to paragraph 473. Unless there are any questions from the Tribunal, Ms. Demetriou will now address you briefly on the vertical agreements' exclusion order.

MR. GLYNN: Might I ask just one question: in using the concept of a more competitive outcome, were it the case that patents were valid -- and I know this is a just supposition --

then do you agree or do you think that the more competitive outcome would have been one which excluded generic entry?

MR. TURNER: At the time that the settlement agreements were struck, the point is that one did not know whether those patents were valid and therefore, essential to the reasoning process is the very fact that that lay in the future.

If, sir, you are saying, had the patents already been determined by the court to be valid and that was a final judgment, then that does alter the picture. Here the essential aspect of the CMA's case, and the Commission's, before the court is that that lay in the future and was uncertain.

THE PRESIDENT: Just a moment. (Pause)

MR. GLYNN: What I was really getting at was almost a semantic point, that in a number of cases the documents and people have spoken about the more competitive outcome with the view that that was almost by definition one in which there was more generic entry than there would otherwise have been. My question was whether you thought that, in fact, in the world in which the patents were valid, the more competitive outcome would be one in which there was no generic entry because the maintenance of the patents would have been the competitive outcome.

MR. TURNER: My primary answer is, as I have just articulated it, if you have established valid patents then, yes, we do agree that then you have an aspect of the IP bargain that you are not going to achieve a more competitive outcome overall by simply allowing the IP rights which had been established as valid and infringed to be violated. That was not part of our case at all.

Opening submissions by MS. DEMETRIOU

THE PRESIDENT: Yes, Ms. Demetriou.

MS. DEMETRIOU: May it please the Tribunal.

Both Mr. Flynn and Mr. Kon opened on the vertical agreements' exclusion order and so I wish just to address the Tribunal briefly on the CMA's position and also respond briefly to the key points that they made.

If I could remind you of the provisions -- and I will take this very shortly because you have seen it, but the order itself is at {A5/75/1}.

THE PRESIDENT: Before we go into any detail, there is also the block exemption.

MS. DEMETRIOU: Yes.

THE PRESIDENT: This is not your case, of course. It has been raised against you, but just to clarify, does that -- if the vertical -- or if the order does not apply, could the block exemption nonetheless apply?

MS. DEMETRIOU: I think one of the appellants argues that the block exemption applies; the others do not advance that argument. They have not specifically opened on it.

If it is all right, we will reserve -- we have set out our position in our skeleton argument and I was not proposing to deal with it orally now unless you want me to.

In relation to the order, that is at {A5/75/1} and you will see at the bottom of the page the definition there of vertical agreement and that is an agreement between undertakings, each of which operates, for the purposes of the agreement, at a different level of the production or distribution chain and relating to the conditions under which the parties may purchase, sell, or resell certain goods or services.

If we can go over the page you will see the relevant provision is Article 3 and that says that:

> "The Chapter I prohibition shall not apply to an agreement to the extent that it is a vertical agreement."

We are all agreed that Article 4, of which there is some reference in GSK's Notice of Appeal, does not apply. So what Article 4 does is narrow the category of vertical agreements that benefit from the exclusion but the CMA's simple point is that for the purposes of these agreements, GSK on the one hand and the generic companies, GUK and Alpharma, on the other, did not operate at different levels of the supply chain {A5/75/2}.

Mr. Flynn for his part sought to characterise these agreements as being straightforward vertical distribution agreements. Our answer to that in a nutshell is that they are not. They are settlement agreements that settle patent litigation that was all about whether GUK and Alpharma could enter the market in competition with GSK.

To that end, the agreements contain entry restrictions, restricting the freedom of GUK and Alpharma to sell paroxetine in competition with GSK.

Could I ask the Tribunal to turn up the relevant provisions of the GUK agreement and that is at {L/8/2}. It is clause 8 that I wish to focus on. What we see in clause 8(i) is an entry restriction which prevents GUK from supplying paroxetine in the UK:

> "... save as purchased from IVAX pursuant to the IVAX agreement or otherwise manufactured or marketed by [GSK or with GSK's consent]."

So the first point that we make is that even if one stops there at 8(i), what you see in clause 8(i) is a horizontal entry restriction precluding GUK from supplying paroxetine in the UK in competition with GSK, otherwise than as a distributor of the IVAX product.

That, in our submission, is enough in terms of identifying a restriction which operates as between GSK and the generic companies at the same level as the supply chain but we go on to look at clause 8(ii) and what 8(ii) says is that:

> "GUK is authorised to undertake on behalf of each member of the Merck Generics group ..."

And of course GUK is an itself a member of the generic group:

> "... and that no such group member shall make, import, supply or offer to supply paroxetine in the United Kingdom during the currency of the IVAX Agreement save in respect of paroxetine hydrochloride manufactured or marketed by SB (or with SB's consent) in the EU.

So we say that it is clear on the terms of clause 8(ii) that this is a prohibition from supplying paroxetine in the UK other than the Glaxo product -- other than paroxetine manufactured or marketed by GSK.

There are equivalent provisions in the Alpharma agreement. They are numbered 7.1 and 7.2 in the Alpharma agreement. I do not think we need to turn them up but for your note the reference is {L/11/2}.

Mr. Flynn pointed to the supply elements of the agreements but the CMA's contention is that the supply elements are the consideration for the settlement of the patent litigation and for the entry restrictions. This was precisely how the General Court characterised similar agreements in the *Ranbaxy* case.

Can I ask you to turn up the relevant paragraphs of the *Ranbaxy* case the reference is {W/2/43}. In fact, it may be worthwhile to go back to {W/2/4} because that gives you the context.

So paragraph 15 of the judgment sets out the key terms of the agreement. You see in the first of the bullet points that there is an entry restriction and then if we could turn onto to page {W/2/5}, the first bullet point at the top of the page says that:

> "Lundbeck was to sell Cipramil tablets ...to Ranbaxy Laboratories or Ranbaxy (UK) with a discount of 40% on the ex-factory price, so that they could sell those tablets on the United Kingdom market."

There is a supply element to that agreement. If we can go forward to {W/2/43} you will see how that provision was treated by the General Court. At 246 we see an argument which is similar to an argument being made by the appellants in this case:

> "The applicants submit that the agreement at issue had a pro-competitive character since it provided that they would distribute Lundbeck's Cipramil ... as a finished

product, which allowed the applicants to develop relationships with wholesalers and allowed Lundbeck to increase the sales of its product."

That is the argument that was put by the applicants. Then the court says:

"In that respect, it must be borne in mind that the applicants became distributors of Cipramil and enjoyed a discount of 40% on the purchase of Cipramil under. Article 1.3 of the agreement at issue, that is to say the same provision which provided for the payments which constituted the consideration for the obligations described in paragraph 1.1."

Then at 248:

"Accordingly, as the Commission rightly submits, it is not a separate distribution agreement with a pro-competitive character. The provisions concerning distribution were an integral part of the agreement at issue and served to supplement the consideration granted to the applicants for refraining from the production and sale of their own citalopram during the relevant period,

Our analysis of this agreement accords with the analysis of the General Court of the supply elements of the agreement in this case, essentially, we say that of course the GUK and Alpharma agreements provide for supply but that does not mean that they are simply vertical distribution agreements; the supply elements were part and parcel of the consideration for the entry restrictions and for the settlement and the patent litigation; the patent litigation was all about entering the market for competition with GSK.

That is our response to Mr. Flynn's argument. Mr. Kon advanced a different argument. He sought to persuade the Tribunal that that the CMA had found the IVAX agreement to be excluded under the order and he said there are no substantive differences between the GUK and Alpharma agreements on the one hand and the IVAX agreement on the other.

He expressly relied on paragraph B111 {V/1/539} of the decision. If you could read B110 and B111. What the CMA found there was that:

"An objective examination of the terms of the IVAX-GSK Agreement demonstrates that the IVAX-GSK Agreement was designed to be an alternative to IVAX's independent generic entry, such that (i) IVAX would necessarily defer its efforts to enter the market with a generic product for as long as it continued to purchase paroxetine under the IVAX-GSK Agreement and (ii) the IVAX-GSK Agreement would not be renewed in the event of IVAX's (and/or another firm's) generic entry."

Then B.111:

"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 the IVAX-GSK agreement was not designed to co-exist with independent generic entry by IVAX (or any other party). Moreover, as explained below, it cannot reasonably have been expected that supply under the IVAX-GSK Agreement would have been sustained, or that the IVAX-GSK Agreement would have been renewed in the event of independent generic entry by IVAX."

So Mr. Kon sought to rely on those paragraphs to argue that although the IVAX agreement did not contain any contractual commitment on IVAX's part not to launch an independent product, he said that the CMA found that it is clear that the agreement was not designed to coexist with independent generic entry and so he says that for that reason it is similar to the other agreements.

The CMA took the view when it excluded the IVAX agreement that it was necessary to look at the express terms of the agreement in order to determine whether the exclusion applies. Of course, the IVAX agreement, as everyone accepts, does not contain an express entry restriction.

Mr. Kon's point is that it is necessary for the Tribunal to discern the purpose of the agreement -- he relies on paragraph B111 -- and not simply look at their technical drafting. But our submission, and this is the critical point, is that even if Mr. Kon is correct, this argument does not take him anywhere because his submission, if correct, would lead to a conclusion that the CMA was overly cautious in excluding the IVAX agreement. What it does not do is result in the exclusion of the GUK and Alpharma agreements. He says his argument is essentially backwards reasoning, which does not work.

MR. MALEK: I think he is saying you are being inconsistent.

MS. DEMETRIOU: They are not advancing an argument of inconsistency, the question is whether on the terms of the order these agreements should have been concluded and we say plainly not and what is said against us is that the IVAX agreement was -- and you should have treated them similarly and we say there are proper grounds for distinguishing between them but even assuming against myself that we are wrong about that, it does not result in a win for the appellants on this point because it involves taking a different approach to the IVAX agreement. But the logic of Mr. Kon's argument does not result in the exclusion of the GUK and Alpharma agreements.

That was all I was going to say in a nutshell in terms of our position on the order, unless the Tribunal has any particular questions?

THE PRESIDENT: No, thank you very much. Housekeeping

MR. TURNER: Sir, that concludes the CMA's responsive opening case.

Two matters: the first is that we do not propose to swear in Mr. Reilly now. I have discussed that with Mr. Flynn and we can start him tomorrow morning, if that is convenient to the Tribunal. In fact, I do not even know if he is still here.

MR. FLYNN: I asked my learned friend if he thought we would finish in time to allow it, he said no, so we let Mr. Reilly go back to his hotel.

MR. TURNER: Which is fine.

THE PRESIDENT: In that case we will not require you to cross-examine him this afternoon.

MR. TURNER: We will call him back!

The other matter is Mr. Malek's request for the list of findings of secondary facts, alleged errors in the skeleton argument of GSK. It occurred to us that in order for that document to be useful, so that we can see how it relates to the Notice of Appeal, it would be helpful if, as well as providing a long list, that those be referred back to where it is alleged those are to be found in the Notice of Appeal also, so that one can see the extent to which, if at all, they are saying that they are relying on new matters, new alleged errors.

THE PRESIDENT: Yes, I am sure Mr. Flynn and his team can do that.

MR. MALEK: When we are talking about facts, we are also talking about inferred facts.

MR. TURNER: Yes secondary facts, absolutely.

MR. FLYNN: Plainly we are not going to, as it were, replead the case but we will try to prepare something useful which responds to the Tribunal's requests. Depending on the size of the task -- I know you were suggesting the close of business tomorrow, but it may not be possible to do it overnight which is what that would effectively require, so --

THE PRESIDENT: Do your best, if not then on Monday. We are not expecting you to set out articles; it is really a schedule and cross-referred to the Notice of Appeal.

MR. FLYNN: We will do what I can.

Can I just mention one other thing? Since we have run on a little longer than I think was anticipated yesterday and today, I know that Mr. Turner and team have something to think about, but it would not be fair to be saying to Ms. West, well, you might be required on Monday throughout the whole of this weekend and I would have thought that during the course of tomorrow the CMA ought to be able to give us an indication of where they are coming out on that issue.

THE PRESIDENT: Mr. Turner, the cross-examination of Dr. Reilly, which will start first thing tomorrow, how long do you anticipate that will be?

MR. TURNER: It is probably at least a day maybe a little bit more than a day. I would propose that when we have cross-examined Dr. Reilly that we take the decision.

I do not therefore propose, if it is sensible, that Ms. West come to be cross-examined on the Monday immediately before the hot tub either. That time can be usefully employed otherwise and that we should find a time within the remainder of the timetable when, sir, as you said, she could be interposed.

THE PRESIDENT: Her evidence is not going to effect the hot-tubbing that I can see.

MR. TURNER: No.

MR. FLYNN: No, sir, but if Mr. Turner is expecting to be say a day, a day and a bit with Dr. Reilly, then we have the whole of Monday which will only have Mr. Sellick in it and which otherwise will not be very long. Ms. West has, because we tracked her down last night, already changed her plans for next week to be available within the timetable that the Tribunal has laid down.

THE PRESIDENT: Just a moment. (Pause)

Mr. Turner what we would suggest is this, that we arrange and ask that Ms. West, who has now made arrangements for that, is here for 2 o'clock on Monday. If, by the end of Friday, there are only certain parts of the cross-examination of Dr. Reilly that affect it and you are able to say, no, she is not required, that is fine. If not, it may be only in the course of Monday morning when you finish with Dr. Reilly you can say that Ms. West is not required.

I cannot imagine, if she has arranged to come and then is told, no, you are not going to be cross-examined after all, that she will be terribly disappointed.

She will know, if it happens, it is to be Monday afternoon. You do not have to now find time later on, but it may be that you will get a welcome phone call saying feel free to do something else.

MR. FLYNN: She will not mind that at all, sir.

THE PRESIDENT: Would that be a sensible way of doing it?

MR. TURNER: The problem from our point of view is that does place quite a burden on us over the weekend additional to what we are doing and there is plenty of time, for example in the third week of this trial, devoted to the abuse of dominance side of things, when she could be interposed.

THE PRESIDENT: I think it would be more desirable to get all the evidence together and I would have thought -- just a moment. (Pause)

I think your team is sufficiently strong, Mr. Turner, that you can, between you, prepare for it. It is not as though it is a very long cross-examination with masses of documents to consider. I think we will proceed that way. I think it will assist the orderly conduct of the case.

MR. TURNER: Very well.

THE PRESIDENT: It will be for 2 o'clock.

MR. TURNER: Very well, sir, we bow to that.

We will therefore be assisted if we can see the list of the facts that they say are now in issue before that happens.

THE PRESIDENT: I think that should be -- that, I think, is a fair comment, if they are going to make that effort. You also have a large team, Mr. Flynn. You are not cross-examining anyone tomorrow, you or your junior could prepare that list tomorrow and it can be supplied, if necessary, by close of business after court hours.

MR. FLYNN: It would certainly have to be out of court hours nevertheless because people will have to be in court who will need to review that.

THE PRESIDENT: I understand that.

MR. FLYNN: We are all having a busy time.

THE PRESIDENT: It could be that you do not all have to be in court throughout the day.

MR. FLYNN: We understand that.

THE PRESIDENT: I think it is fair that the CMA team should have that benefit.

We will say 10.30 am tomorrow.