IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

27 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 (Glaxosmithkline PLC).

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

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

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

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

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THE PRESIDENT: Yes, Mr. Flynn. Good morning.

MR. FLYNN: Good morning, sir. Good morning to the Tribunal.

Sir, just for housekeeping purposes there was a note which was emailed to the Tribunal on Friday night about the discrepancy, if you remember, between the decision and GSK's records.

THE PRESIDENT: Yes.

MR. FLYNN: I am told that a copy has not reached you, and I will just make it available to Mr. George, I think.

THE PRESIDENT: Did you receive that?

MR. TURNER: We received a copy late on Friday.

THE PRESIDENT: This is tabbed helpfully. This goes into the additional bundle; is that right?

MR. FLYNN: Yes, I think so, sir.

THE PRESIDENT: This is bundle M?

MR. FLYNN: It is called DHU, I believe.

THE PRESIDENT: We will sort it out.

MR. FLYNN: I am not sure it is a matter that falls to be addressed now in closing. If necessary I can come back to it on Friday. Essentially we agree to disagree is where we come out, in that our figures are based on the audited Unison figures and we do not see a reason for using the IMS sample. That is essentially where that goes.

Sir, in respect of closing, then, what I propose to do, with the Tribunal's permission, is to follow the structure of our closing document, which I am sure the Tribunal has read, and --

THE PRESIDENT: Yes.

MR. FLYNN: And, usefully, it was page limited.

THE PRESIDENT: Yes, that was very helpful altogether, everybody's closings.

MR. FLYNN: I am glad to hear it. There will be one or two inaccuracies in it, but we may not need to dwell on those. But obviously it was a job done to a tight deadline, as it were. But essentially I will follow that document.

THE PRESIDENT: Yes.

MR. FLYNN: I will come then, at the end, to the penalty submissions after closing on the case that you have already heard. I think that is what the Tribunal would anticipate.

So in our closing submissions we make some general submissions at the beginning about, firstly, in relation to the witness evidence, factual and expert, those that you have heard and those that you have not heard, and insofar as necessary I can probably come to that in context.

THE PRESIDENT: Yes.

MR. FLYNN: You see there what we have to say about the witnesses as a whole.

In relation to the CMA's case file, which has obviously been a point of difficulty in the present case, we say -- and we have made this point -- that a full review of the documents on the CMA's case file suggests -- and we made the point also in our hand-up note on factual findings, which we stand by as a note explaining our position, we say that a full review of the documents on the CMA's case file shows that the evidence has not been properly assessed.

But we do resist the suggestion which the CMA has made that there is something deficient in our case through not calling people who have given interviews to the CMA which are backed up by severe statutory penalties or witness statements which are attested to by the statement of truth.

Nothing that we say seeks to go behind those statements, and as we say, it is quite unlikely that even if anyone had sought to call, for example, Mr. Blanksby, that his recollection would have improved over the intervening years. We say that we can properly rely on what he says there, and the same in fact goes for Ms. Rachel Parr who was interviewed by the CMA under compulsory powers and gave a witness statement in which she explains what value can be attached to her notes to self that have featured more in the skeleton, I may say, than in the closing submissions.

Insofar as that is relevant to anything, we will come back to it. In relation to the burden of proof --

THE PRESIDENT: I think the point was made about Eddie Hart, was it not? I think.

MR. MALEK: Yes.

THE PRESIDENT: Did he give a witness statement?

MR. FLYNN: Do you mean possibly Mr. Gray?

THE PRESIDENT: Mr. Gray, I am sorry.

MR. FLYNN: Mr. Gray is the GSK -- he was the person to whom Dr. Reilly reported. He was the General Manager.

THE PRESIDENT: Eddie Gray, I am sorry.

MR. FLYNN: He has not given a statement and the CMA did not use powers to interview him. I think he retired quite a few years ago, and we have relied, and we say properly relied, on Dr. Reilly who can speak to the negotiations of the agreement and to the fact that he sought approval from Mr. Gray and the hierarchy.

So I am not sure that there is a big gap to be explored there, certainly that can be laid at our door. We say a comprehensive account has been given and Dr. Reilly was able to explain to you in possibly one of the more compelling parts of his evidence, since he has been criticised quite considerably, but he explained, in my submission candidly and fully, to the Tribunal how the structure worked at the level above him and how that, at the time of the events, GSK was a merging company between SmithKline Beecham and GlaxoWellcome and new structures were being put in place, people were, as it were, jockeying for position or trying to work out exactly what their remits were at operational and European level I think he, if I may so submit, explained that candidly and I do not think there is a gap in the record there, as it were.

THE PRESIDENT: No, it is just that I think he did say -- and I see no reason to doubt it -- that he referred it to Eddie Gray, and Eddie Gray was principally the person who took the decision.

MR. FLYNN: Yes, Eddie Gray was his boss and I think that has always been clear. He was tasked with finding out what these approaches from the generics meant and what they were thinking of, what they were about and reporting back. He negotiated the agreements. He signed them, but of course he did check with his boss.

THE PRESIDENT: Well, he needed approval, I think.

MR. FLYNN: When I say check, yes, he did. He needed approval and he got it.

THE PRESIDENT: Yes.

MR. FLYNN: He got it.

There is also evidence about the value of these deals relative to approvals that were needed for higher authority and so forth. While it was clear that those above Mr. Gray would have known something of what was going on, the locus of the decision-making, we say, Mr. Gray was the person who approved it and Dr. Reilly went away and signed the agreements.

In relation to the burden of proof, sir, I do not think it is a controversial issue but it is one that needs to be borne in mind throughout the proceedings, that it is the CMA which bears the legal burden of proof at each stage of the case.

That is to the civil standard, but bearing in mind the severity of these quasi criminal penalties which are imposed upon us.

THE PRESIDENT: But for 101, paragraph 3, you have the burden.

MR. FLYNN: Indeed. In relation to infringement I should say, you are absolutely right, sir. You are absolutely right.

In relation to infringement, that is how we phrase paragraph 18 of our closings. In relation to the infringement, it is the CMA that bears the burden. We fully accept that in relation to exemption, that is the burden on the asserter. So fully accept that.

We give particular examples of how this burden applies in relation to the effects case. You cannot presume anti-competitive effects, and a potential for effects is not good enough. The CMA has to demonstrate that the effects would be likely to harm competition, and we are not required in terms of an infringement, paragraph 1 to pick up your point, we are not required to prove that these agreements enhanced competition.

To the extent this that is an issue in the case of course, and we will come back to that, we say that we have done so.

It is also the case that the test applies to the economic evidence so that the economic evidence has to withstand, as the Tribunal has said, profound and rigorous scrutiny. This in particular means that theories need to be backed up by facts at the end of the day.

Most importantly, we point out the principle, in particular given the extent of the economic evidence that has been heard in this case, both in writing and in concurrent and sequential examination, that there is to be no embroidery or ex post strengthening of the decision by reference to matters that it does not contain. So it is the four corners of the decision that have to be examined.

In relation to the factual underpinning of the decision, we make a number of criticisms. You will be familiar with these from our factual findings note as well as our arguments in the case. But we say it is a defect in the decision, for reasons which will be explained, that there are no findings on patent strength, as we have come to call it in that shorthand, nothing going beyond a genuine uncertainty finding by the CMA.

It has not sought to make any findings on the timescales that would have been expected to arise, to endure in the event of continuing litigation as an alternative to the settlement agreements, which of course goes notably to the duration of the injunctions. It does not attempt to evaluate that.

There is nothing -- and this is relevant to the submissions that I think probably we all make in relation to *Lundbeck* -- on the size of the value transfer relative to the expected profits of the generics had they entered on an independent basis. It has been explained to you more than once that the CMA tried to make that demonstration at an earlier stage in the proceedings, but was not able to bring it home. It now asks you to infer from the fact that, as it were, the generics took the shilling, that it must have been equal to the expected profits, by which they mean discounted profit, discounted by prospects of success in the litigation.

But they do not give you either the figure of the expected profits or the appropriate discount, because obviously they do not evaluate patent strength.

Those are the famous footnotes 935 and 1037 in relation to GUK and Alpharma respectively.

They also make no finding at all on whether the entry restrictions, in other words, the terms of the agreement under which the generics agreed only to take supply from GSK, were within the scope of GSK's patents. That is also relevant to the comparison with *Lundbeck*.

Lastly here, we say that it is a defect in the decision that as far as market definition is concerned, the CMA reaches no conclusion on therapeutic substitutability. As I think I said to you in dealing with that part of the case, the conclusion is that there is no conclusion. It is inconclusive and we say it should have been conclusive and it should have been conclusive in favour of a market definition of SSRIs as I defined it, that is including the venlafaxine alternative because of the SSRI mode of action.

So expanding on some of those points, in relation to patent strength you have heard a lot, and it is said to be of disputed relevance, but we say it is important. You have heard a lot about the extent of GSK's confidence in its patents, and the consistent position that we have taken in this case is that GSK was confident, it thought it had good patents, it thought they were valid and infringed. But it was keenly aware both of the risks inherent in litigation and of the downside risks that it faced.

That position, we say, was amply borne out by Ms. West, not only in her --

THE PRESIDENT: So you criticise the CMA for not making any finding about patent strength, but you ask us to make a finding of GSK's subjective belief in its patents?

MR. FLYNN: We say that based on the evidence that you have heard, you cannot safely conclude that this is a case where, on the litigation counterfactual, if it had been fully developed, this was a case that the generics would have won. That is what we say. We do not ask you to conduct the mini patent trial.

THE PRESIDENT: No.

MR. FLYNN: We are saying if you look at the circumstantial evidence and you look at the witness evidence that has been given in this case, it is impossible to say that this is a case where the deal was to cover up, make up for the defects in a weak patent or a weak patent position.

MR. MALEK: Mr. Flynn, are you saying that we should make a finding that you would have won, or are you saying you do not need to go that far?

MR. FLYNN: I am saying you certainly do not need to go that far. We are not saying we would have won; we are saying that we are confident we had a good position but we are aware of the litigation.

So it is not a case where we would necessarily have won, although, you know, one can look at that. But this is a case where it is impossible to say that the probabilities indicate that the generics -- well, this is a case where -- and the CMA has confined itself to a position of genuine uncertainty.

THE PRESIDENT: But do you agree with that? Do you ask us to come to a different position?

MR. FLYNN: We say if the test is one of genuine uncertainty, so they do not have to prove any more of a counterfactual, we have always said it was uncertain. We have never said anything different.

But compare it with some of the other cases, in particular *Lundbeck*, you can see that other things are going on. This is a case where GSK had patent, they were aimed at squarely by these generics, they were told by Mr. Justice Jacob that they could have cleared the way. This is the route they chose and GSK was prepared to defend them and did defend them in other cases.

So the point we are making is this is not a case where you can say the originator had no confidence in its patents, was not prepared to assert them, put them to the test, was trying to find other ways round. That, I think, you can usefully contrast with the *Lundbeck* case, which we will come to.

Furthermore, because the CMA does not seek to develop the position on the patent strength, it has not gainsaid what we have said about these things.

One thing that is now being said for the first time in these proceedings, possibly picking up on hints or straws in the wind, is that we cannot possibly make any of these contentions because we have not disclosed the legal advice from counsel.

THE PRESIDENT: I think it is said, if you say we accept there was genuine uncertainty, that is one thing. If you are seeking to say that GSK was confident that it would have won but there is always a litigation risk, that is a quite different thing.

MR. FLYNN: We are saying genuine uncertainty is not good enough for the legal test which we will come on to, and we are saying this is not a case, unlike *Lundbeck*, where it would be possible to say that what was going on was covering up or supplementing, trying to supplement for a weak patent position. It is a very different sort of case.

MR. MALEK: But the main point is that you are not saying that we believe that we would have won because that would not have been a very attractive line to have taken.

MR. FLYNN: No. Whatever anyone might have felt at the time, Ms. West or anyone else, that is not the case that we are making here. We are certainly not suggesting that it would be appropriate, even if it were possible, for the Tribunal to, as it were, as has been said in other cases, conduct the mini patent trial and form a view on it. That is just not there.

In relation, if I may, to the question about revealing privileged advice, our position in short on this is that we have produced evidence from, and made available for cross-examination, the patent attorney who was the point person for the case, who clearly explained to you what her role in the case was, including relaying the views of counsel in what I think she described as a continuing conversation. In my submission, she could not possibly have said what she did say about being cautiously optimistic going into the case if she had been told by counsel that she should not be.

She said management do not like surprises. She told you that --

THE PRESIDENT: Well, it is a bit difficult that -- if you are asking us to draw inferences about what you were told or not told by your leading counsel --

MR. FLYNN: Again, I do not ask you to draw the inference. I do not ask you to draw the inference. You have Ms. West's evidence as to what she was telling management and her position going into the litigation.

THE PRESIDENT: Yes.

MR. FLYNN: I am just saying that to suggest that the advice, which I think is the basis of the CMA's position, the advice from counsel might have been very different or is the only thing that can be of any guide, in my submission is not right when you have in front of you the person who was dealing with the matter from the company's perspective and, as I hope you would agree, was a good witness with good technical appreciation of the issues involved. She was well aware of the difficulties. She was candid about the drafting problems compared with the originality of the invention. She knew what was going on and yet her view was that these were good patents that were infringed by the generics in the litigation that matters.

Now, one point we do make is -- perhaps it is useful to take this now -- what happened in the *Apotex* litigation, we say, is no guide to what might have happened at the infringement level in relation to GUK and Alpharma. This has I think emerged clearly on the evidence. Apotex was an inventor as well as a generic, as it were, and they had invented their own displacement step, their own process, controlling it, I think, end to end because they manufactured their own bulk API, and Ms. West said they were clever people. You have

seen the judgments and I do not need to go to them, but you have seen the complexity of that particular case and --

THE PRESIDENT: We do not know about infringement with Alpharma because the test was inconclusive on the sample.

MR. FLYNN: Sir, yes --

THE PRESIDENT: So there was a big question mark over the process for the Alpharma product.

MR. FLYNN: Yes, there were difficulties about that process, but there is no suggestion that Alpharma, as it were, had itself engaged in research or development and invented a new step.

THE PRESIDENT: We just do not know how the process -- not itself, but its supplier -- we do not know what the process was and nor did your client, I think. That was the situation a few weeks before trial.

MR. FLYNN: Well, they had the samples.

THE PRESIDENT: They had done the experiment and it had not demonstrated apparently the infringement at that point. You had the burden of proof.

MR. FLYNN: I recognise that point. I simply say it is not, in my submission, correct to say that what happened in *Apotex* is a guide to what could have happened in any other case because of Apotex's unusual status in the world of genericisation.

THE PRESIDENT: Why is it that once Apotex comes in you give up against everybody else?

MR. FLYNN: I think the answer is, firstly, Apotex at first instance won on validity as well as infringement. So the patent was struck out. As I think you said, sir, it would have then been very difficult for GSK to apply to renew the injunction on appeal. So Apotex is in and obviously exposed to damages in the interim, but nevertheless they are in. At that point it becomes a bit of a free for all because once the patent is seen to have taken a hit, in fact a total hit, then other generics will come in, will enter at risk and the price goes down and you cannot get it back up.

MR. MALEK: So you are saying the dyke was breached?

MR. FLYNN: Precise, to coin that phrase, sir, the dyke at that point is breached. There is a flood of entrants, and an originator in that circumstance has the choice as to whether to basically become a sort of litigation factory and take on the world with all the expense, uncertainty and use of management time and external advisers that that implies, or --

THE PRESIDENT: You got an infringement initially against Apotex pending your appeal.

MR. FLYNN: We did, but then it was not renewed, as I recall.

THE PRESIDENT: Well, you decided not to continue it, yes.

MR. FLYNN: Yes.

THE PRESIDENT: But you could have continued it, you decided not to.

MR. FLYNN: Yes, I think that is correct. I think at that point recognising that it had an uphill struggle on the appeal -- I think this is a commercial matter. Whatever the theoretical possibilities at that point open to an originator, the dyke has been breached. The water is flooding in and you have to decide what you are going to do about it, and GSK it seems at that point took a decision that they had had enough. I think that is really what happened.

THE PRESIDENT: I was just thinking if you feel you have a good patent but you have one generic that has a clever way round it and others do not, you would limit your damage and say, okay, we might have to let that one in, but at least we can still keep everybody else out.

MR. FLYNN: You let one in and that is itself a wide breach. It is not as if -- it is then -- the market is completely open to Apotex, in this hypothesis. So that is already a problem, and if --

THE PRESIDENT: Anyone coming in can wreck the market, destabilise the market?

MR. FLYNN: Why not? It is only a limit of how much they can produce. So they can then price it as they would wish, and if others then follow at risk, then you do have a sort of domino effect. That is effectively what happened here.

I do not think that of itself should be taken as an indication that the company did not have confidence in the patents. The question is then whether it has confidence and the appetite in the patent system. So, you know, Apotex at that point are in. The market is therefore open. The patent has been struck down and GSK, at that point, is in trouble.

Just by way of contrast, I mean we will come to *Lundbeck* and its position in due course, I thought it might just be instructive -- I beg your pardon.

THE PRESIDENT: I just wanted to ask, I know we have it somewhere, but just help me at some point to see the actual figures for the decline in price following generic entry. We have had various percentages separately for 20mg and 30mg. There are various -- we have had percentages quoted.

MR. FLYNN: Yes. If you just give me a moment I think I do have a note on that.

THE PRESIDENT: We can come back to that, or somebody else will have it. I do not want to take you out of your stride.

MR. FLYNN: No, I have -- the sort of theoretical position is set out in 6.34, 6.39 of the decision. That is the sort of general what you would expect from genericisation. The figures are in section 3 of the decision.

THE PRESIDENT: Section 3.

MR. FLYNN: Yes, in figure 3.1, which is above paragraph 3.388. It is {V/1/169}. You will remember this graph because this is the one where the early years are wrong.

These, of course, are prices of paroxetine overall.

MR. GLYNN: That is the weighted average price of the drug taking account of the price discounts you give against the parallel traders, that sort of thing.

MR. MALEK: Mr. Flynn, I think that if you look at the third bullet point on page {V/1/168}.

MR. FLYNN: Yes, that is right. 3.387 describes figure 3.1 --

MR. MALEK: Yes.

MR. FLYNN: -- and explains how the most significant variation in price occurred following independent generic entry in December 2003. So these are indeed the average prices.

THE PRESIDENT: Yes, and that is for 20mg. Then 30mg is in 3.388.

MR. FLYNN: Yes.

THE PRESIDENT: Yes. Thank you very much.

MR. FLYNN: Then there is figure 3.3. So those are the graphics.

THE PRESIDENT: Yes, thank you.

MR. FLYNN: At the theoretical level, as I was saying, you will find that at paragraph 6.34 to 6.39 of the decision under the heading at {V/1/250}:

"Generic competition and its impact on prices," which is the expectation, as it were. If you look at 6.36, the third bullet gives some figures on the UK, again for the weighted average price reductions for medicines after generic entry {V/1/251}. Then there is some reference to contemporary expectations in the evidence.

THE PRESIDENT: Thank you very much.

MR. FLYNN: It is right to say in relation to that, since we are on it, that these are of course average prices and they do not say necessarily what happened to the Seroxat price. As I think I said in opening, when the dyke was breached -- and I shall not use that phrase again -- but at that point the originator has a choice, because there is no absolute necessity for the originator to slash its price to the generic level, and it may continue with list price or a higher price than the prevailing generic price for some time, or maybe even generally because the branded product may carry a premium.

It is obviously just feeding into what we observe from the effects of these agreements. The fact that the Seroxat price did not come tumbling down is not of itself a bad thing. That is not necessarily what you would have expected on full, independent generic entry either. What you expect is an impact on weighted average prices.

THE PRESIDENT: It would depend, I suppose, on the open/closed prescription balance, because the closed prescription, they have to dispense Seroxat?

MR. FLYNN: The pharmacist at that point does not have a choice. The doctor has made the choice for him.

THE PRESIDENT: Yes.

MR. FLYNN: But the level to which the originator in those circumstances is choosing to compete on price with the generics at the pharmacy level is a commercial choice for it.

THE PRESIDENT: Yes, sure. I am just saying the commercial choice is likely to be informed by the extent of the --

MR. FLYNN: We will obviously come back to this in another context.

THE PRESIDENT: The extent of the closed share.

MR. FLYNN: But just while we are on that, the fact that you do not see under these agreements the price of Seroxat come tumbling down to generic levels is not necessarily anything different from what you would have seen on full independent generic entry. The average price would have come down low.

MR. GLYNN: Could I just clarify. When there is a brand equalisation deal being done and the branded Seroxat is being sold at the lower price, matching it, that would affect the Seroxat price as well as the average price?

MR. FLYNN: That is the price at which they are selling to the pharmacist.

MR. GLYNN: So they are selling Seroxat both at the list price and at the lower price.

MR. FLYNN: That is what GSK has to sell to the pharmacies. It has Seroxat to sell and it chooses its price depending on how it --

MR. GLYNN: One might expect the Seroxat price itself to be reduced by the volume shift to generics and parallel importers?

MR. FLYNN: There might be some impact, there might, but it is still a commercial choice of any originator --

THE PRESIDENT: But we see the choice on the graphs you have just shown me, because that shows Seroxat as well, does it not?

MR. FLYNN: They show the --

THE PRESIDENT: In fact, once the dyke is breached, GSK slashes the price of Seroxat.

MR. GLYNN: The point I was really getting at, Mr. President, was that the list price -- I think the point being made by Mr. Flynn is that the list price might rationally be maintained unaffected and the weighted average price would come down, and if the product that is

being sold to match the importing or the generics' prices is still labelled as Seroxat, that would come up as a reduction in the Seroxat price?

MR. FLYNN: Yes, by a commercial choice of GSK. Indeed.

MR. MALEK: But what you get after December 2003, not only the price goes down but the sale volumes of Seroxat goes down 70% between December 2003 and February 2004, set out on page 172.

MR. FLYNN: Yes, you get a substantial volume effect, of course.

MR. GLYNN: Might I ask a related point at this stage, if I may.

You have mentioned that the risks that GSK faced were substantial in the event that the patent court had gone against you. At paragraph 36 in your written closing, you say that the scale of GSK's downside risk increased exponentially once markets in Europe and beyond were taken into account because of -- and then the reasons that you give.

Could you say anything more about that point? I mean, how much weight should we attach to that? How does it figure in the GSK thinking at that stage, as far as one knows?

MR. FLYNN: Well, in terms of numbers, I do not think we can take it further than Dr. Stillman's calculations which you will have seen, and we will come to those if we need to. But I think these are points that he also makes, that you do have to take into account, firstly, the signals this sends in other countries where you may have equivalent patents, either about the strength of those patents or your willingness to stand by them, which was a matter of great concern to Dr. Reilly, as you have heard.

The European price referencing point was plainly a matter of concern to them because it was one of the features in the pricing structure of the supply agreements themselves that there was a reference price, and then the marketing allowances which were taken as discounts to the price so that the headline price would be the one, if necessary, that would be picked up by those markets in other EU countries that practised the price referencing point. So I am not sure that anyone can put a figure on it, but they are clearly important.

MR. MALEK: What about the additional point that Dr. Reilly made, which was that the loss would not be £50 million a year because your sales force would be redirected to marketing other products?

MR. FLYNN: Dr. Reilly's evidence on that, we say, was off the cuff and not thought through, frankly. That is why Dr. Stillman was at pains to point out in his evidence that he had actually done a more thoroughgoing calculation of the downside risks and that the right -- I was going to come to this -- but the right number was not 50 million but more like 150

because it was three years. So it was something like 20/150, and Professor Shapiro agreed with that.

THE PRESIDENT: I think he just said if those are the figures. The 50 million, if we are on paragraph 36 --

MR. FLYNN: Well, 50 was -- I think Dr. Stillman said that.

THE PRESIDENT: Dr. Stillman's annual figure. Just so I understand it, that is from that table, is it, at {G2/42/33}? Because he takes the profits, he says, per month with no generic competition of 4.9 million, in the fourth line. As I understand it, then -- is that right? He is subtracting the generics' profits under a duopoly, just one generic, of the 0.6 in the sixth line and multiplying by 12? That is how you get the 50 million, is that right, which is about 51 million?

MR. FLYNN: You are probably right, sir. I hesitate to say that I know exactly how this table works.

THE PRESIDENT: You footnoted that as the source of it, of the 50 million.

MR. FLYNN: Which he was speaking to.

THE PRESIDENT: As I understand it, that is how it comes out.

MR. FLYNN: This table is introduced at paragraph 84 of his report, saying it is showing the parameter values that he has used to solve equation 5, which appears at paragraph 81 of the report {G2/42/31}.

I am, frankly, not the person to be able to work --

THE PRESIDENT: Yes. Well, I did not particularly wan to try and understand the equation, but I just wanted to get how the -- that is where the 50 million comes in. Equally, I think if one goes back to his figures on these, at the previous page {G2/42/33}, he says somewhere, I think ... that the generics' profits, that is under duopoly, ... (Pause)

MR. FLYNN: I am not sure I can immediately work this out, sir. I mean, his evidence to you was that 50 million, based on these assumptions, was --

THE PRESIDENT: Well, it should be --

MR. FLYNN: -- a reasonable figure.

THE PRESIDENT: Yes. It is on the next page, I think, {G2/42/34} at the top. He gives a figure for a generic's profits per month under all out independent generic competition of 0.237 million on page --

MR. FLYNN: Yes, he does.

THE PRESIDENT: So that is per month. So that is about, what, 2.8, 2.9 million a year? So that is what a generic, he says, would -- these are the figures you put forward -- make in terms of profit in a competitive market.

Have I understood that correctly? That is what he is saying, is he not?

MR. FLYNN: What is being suggested to me, sir, is that the roughly 50 million figure comes from deducting from the 4.927 million figure you see on the previous page {G2/42/33}.

THE PRESIDENT: Yes.

MR. FLYNN: You deduct from that the figure 0.761 million at the top of the next page {G2/42/34} and then multiply that by 12.

THE PRESIDENT: Yes, that sounds right.

MR. FLYNN: You will get to something roughly which we could call 50.

THE PRESIDENT: Yes, that makes good sense. I am sure that is right. I picked the wrong one.

Equally, on that same basis, the generic's profit under all out competition is 0.237 times 12?

MR. FLYNN: Yes.

THE PRESIDENT: Those are the figures you rely on. Yes.

MR. FLYNN: Specifically IVAX in the example.

THE PRESIDENT: Yes. Then if he is actually looking at IVAX's costs, I think he is taking IVAX as an example of a generic.

MR. FLYNN: Taking IVAX as the first agreement, and as I think he says, it is complicated when more come in.

THE PRESIDENT: Although this is under all out generic competition, not under -- I think that was ... yes. Otherwise if there is only one, then it is the 0.633 on the previous page {G2/42/33}, under duopoly with GSK. But once it is all out generic competition then it is 0.237. I think that is what he is saying. Is that right?

MR. FLYNN: I think that is right.

MR. GLYNN: We do not have anywhere figures for the effects outside the UK?

MR. FLYNN: I do not think we do, sir. I do not think we do. I think that is stated on the basis of principle rather than enumeration or calculation.

MR. GLYNN: Yes.

THE PRESIDENT: Yes. Sorry, I have taken you out of your course.

MR. FLYNN: No not at all, sir.

THE PRESIDENT: We were looking at that paragraph 36.

MR. FLYNN: I also raised a point somewhat out of order.

THE PRESIDENT: Yes.

MR. FLYNN: I was going to take you just very quickly to, just by way of comparison -- this just to conclude on the patent strength issue for the moment. I was going to take you by way of comparison to what happened in *Servier* where you will recall -- and we can have it up -- that in the *Servier* decision, which is {Auth-F/17/1} at paragraphs 124 to 129 -- I think those are paragraph numbers, sorry.

THE PRESIDENT: If you just give us the reference we can look at it later.

MR. FLYNN: If my note is correct it is paragraphs 124 to 129. It is volume 11 of the authorities, which is {Auth-F/17/36}. Sorry, I do not seem to have the hard copy with me.

There you will see under a heading, "The 947 patent", a description of a patent. This comes at the end of a section describing Servier's patenting policy and setting up a cluster of paper patents that people had to work their way through. This describes the 947 patent. It says it is one of Servier's most controversial patents and refers to the Court of Appeal ruling on it, and says, this patent plays a key role in the present investigation cited by all the generic companies, and so forth.

If you look at the judgment which is referred to, which is at {Auth-M/6/1}.

THE PRESIDENT: Sorry, the judgment?

MR. FLYNN: This is the Court of Appeal judgment in the *Servier v Apotex* case.

THE PRESIDENT: That was a weak, a doubtful patent?

MR. FLYNN: A highly doubtful patent.

You have the phrase that it gives the patent system a bad name, but if we just have a quick look at that at paragraph 9 of the judgment {Auth-M/6/3}. This is a case where at first instance Mr Justice Pumfrey, as it says, in one of his last first instance decisions before he was translated to Court of Appeal and then sadly died very soon afterwards, had held that the patent was invalid and obvious. He gave permission to appeal. He refused to continue an interim injunction because he thought there was no prospect of success.

I am sorry, if we just show you. In paragraph 2 {Auth-M/6/2} the appeal was opened. They had decided not to hear Apotex. The patent is then described, and the patent policy is described, paragraph 6. The judge says the fact that there were simultaneous applications for the other two forms was curious. This was perhaps a kind way of saying that Servier why simply trying to extend their monopoly in the salt.

If you go to paragraph 9:

> "The upshot of all this is that were the patent valid, Servier's monopoly in practice would last until 2020. But, as the Judge held and we confirm, it is invalid. And very plainly so. It is the sort of patent which can give the patent system a bad name."

THE PRESIDENT: So you are saying it is a far cry from that case?

MR. FLYNN: It is a far cry. He says it is a good idea to get them revoked quickly.

I just wanted to draw your attention to paragraph 10 and then we can close it:

> "It is right to observe that nothing Servier did here was unlawful. It is the court's job to see that try-ons such as the present patent get nowhere. The only sanction (apart, perhaps, from competition law which thus far has had nothing or virtually nothing to say about unmeritorious patents) may, under the English litigation system, lie in an award of costs on the higher (indemnity) scale ..."

So that, in my submission, is a weak patent when you see one.

THE PRESIDENT: Yes.

MR. FLYNN: To sum up the position on the patents, we say, as I think I have already said, that the CMA had no basis at all for any suggestion, and it does not make it, that the generics were likely to win. Therefore, we say it has no basis for a finding -- and we will come to this -- that the object of the agreement wasn't competitive or that there was a more pro-competitive counterfactual in the litigation.

I will be brief in relation to the position of the generics because I think, firstly, that is as much for my friends as for me. But in relation to IVAX, who are not here, as I understand the CMA's closing position, this now seems to turn entirely on Tillomed in respect of which we handed up a note in the early part of the hearing.

We say that makes it quite clear that at October 2001, when the IVAX agreement was signed, Tillomed did not have a product and that Mr. Blanksby's recollection, vague though it was, was broadly correct. There was not an IP problem as such with Tillomed's product because there was no patent protection in Denmark, but there was a product problem. The product had been recalled for, GSK believes, containing impurities which are unacceptable in probably any medicine, but certainly in an antidepressant medicine.

The CMA's only point on this now seems to be paragraph 33 of their closing. I think it carries an implication that GSK may have forced Hexal off the market in some way, but no, I think the position is that GSK supplied -- because of the production difficulties -- on a contract basis some product to the Danish market, presumably in response, or as a result of the product recall.

So I think that is our position on IVAX as to which you have probably heard enough.

Should I deal briefly with GUK and Alpharma, where we stand by what we have said to date based on the record, and we stress the crucial importance of the fact that at the time of the settlement agreements, both of them were injuncted. Whatever intentions or hopes they

might have had before, they were off the market. I have already said that the CMA has not estimated for how long, but they could not get in.

We have had some discussion about how long that might be using assumptions about what one knows about the Court of Appeal's willingness to grant expedition and so forth, but let us say a year on optimistic assumptions, that is how long they would have been off. It could have been longer because they were bound up in the GUK's case with the *BASF* trial, we do not know. Let us say a year.

THE PRESIDENT: The *BASF* trial, we know how long it took, do we not? There was no expedition on the appeal.

MR. FLYNN: It is the appeal, I meant to say. Correct.

THE PRESIDENT: It is you who rely on the length of time because you rely on the injunctions.

MR. FLYNN: Well, we say it is an important contextual matter that at the time of the settlement agreements they could not get into the market.

THE PRESIDENT: Yes, but if they could not get in for two weeks that would not be significant, but you rely on the fact that it would be a significant period of time?

MR. FLYNN: A significant period of time in contempt of court. Meanwhile, of course, the opportunities are slipping away from them.

MR. MALEK: But with injunctions the appeal would have been expedited, would it not, to the Court of Appeal?

MR. FLYNN: Yes, it is likely that it would have been. It is likely that it would have been. But as I say, it might have got caught up with other litigation which might not have been ready for appeal, so --

THE PRESIDENT: It would not have stopped your appeal. It is just they would not allow the hemihydrate to be joined with your case because it would have slowed down the anhydrate case.

MR. FLYNN: Exactly, to streamline it. We are not quibbling, sir. Expedition is likely and we can say about a year is not unreasonable. But that is just based on, you know, what one knows and can take judicial notice of, as it were. But the fact is that this means that our deals did not keep them off the market. They could not get in and we let them in to the extent of the arrangements, and substantially before the Apotex's judgment.

I have made the point really. The injunctions fundamentally alter the settlement dynamics from the perspective of those two particular generics.

Now, this may be more directed at others than at GSK, but I understand from the CMA's closings that they intend to make substantial play of suggesting that the Tribunal should

draw adverse inferences from the failure to produce witnesses. We have already had some discussion about that.

THE PRESIDENT: I think, as far as you are concerned, that is limited to Mr. Gray because you have produced Dr. Reilly and you have produced Ms. West.

MR. FLYNN: We have.

THE PRESIDENT: You have put in quite a bit of evidence in fact.

MR. FLYNN: Maybe I do not need to take it much further.

THE PRESIDENT: I do not think you need to address it.

MR. FLYNN: We have had a discussion on Mr. Gray. If necessary, we will come back to that later in the week.

I am just looking at the time. This would be --

THE PRESIDENT: Would this be a good --

MR. FLYNN: This would be a good moment if now is a good moment, as it were.

THE PRESIDENT: I think we need to have a break so let us have it now.

(11.43 am) (A short break)

(11.50 am)

THE PRESIDENT: Yes.

MR. FLYNN: Sir, moving on. I know the Tribunal has a busy schedule today.

THE PRESIDENT: Yes.

MR. FLYNN: Project Dyke, sir. Although a lot of time was spent in cross-examination of Dr. Reilly on this, it does not seem to go very far, in that, as I understand the CMA's closing document, they say it at best casts light on the purpose of the supply agreements. It is not suggested, I think, that -- and I think it was said expressly at one point -- Project Dyke itself shows any anti-competitive conduct.

We say, ultimately, in line with the evidence of Ms. West, who was a particular member of this internal discussion forum, that it was not a strategy-making body, it was a forum for reporting on actions taken and their cross-European implications. She said in answer to a question from the Tribunal that if it had a strategy, the general strategy of the company was to enforce the patents. She said that was not a controversial strategy and it was perhaps a stretch to call it a strategy at all, and that is {TR/6/181}.

When one considers the purpose of the agreements, the one phrase that comes up again and again in Dr. Reilly's evidence, both written and before the Tribunal is he saw the value of the settlements as maintaining the integrity of the patents. What he seems to have understood by that is, as he said in answer to a question from the President recorded at

paragraph 50 of the CMA's closing document, the patents would stay in place and there would not be a loss of the patent position.

What he means by that, in addition to not risking the outcome in the particular proceedings, is that the patents remain in place, the position is not lost, and they can be asserted against others. It is plain that he attaches value to sending out signals generally that GSK was prepared to stand by its patents and was not a company that was readily going to roll over.

The CMA says, as to the purpose of these agreements, that they are designed to protect GSK from competition, not that they are designed to give the generics real competitive opportunities. We say that sets up a false contrast. This is a compromise settlement. It is actually, surely, a bit of both. It is not the outcome that would emerge if GSK had lost, but it does introduce competition to the market and we know what the effects were, and we will come back to those. But it did give real competitive opportunities to the generics whilst not amounting to a capitulation, a complete opening of the market, as against GSK.

That is why the documents regularly talk about stability. It is natural and, we say, cannot give rise to adverse inferences that documents of that nature talk about stability. That is what a settlement is designed to achieve. Any settlement would be a career shortening move if Dr. Reilly said he had managed to negotiate a settlement which provoked great instability. That would not be regarded as a very clever way forward.

The stability that is seen is being compared implicitly with the situation if GSK had pursued the litigation to the end and lost, but it is obviously a second best situation that is in the nature of a compromise.

It is not surprising that the documents do not say "We have given the generics a really great opportunity here to improve their competitive position at our expense". Whether those effects were in fact produced is an objective question for the evidence in this case, but you would not expect to find it in the corporate strategy documents. We say it is a false comparison.

The same goes to the suggestion that these documents indicate anything very clear or certainly inconsistent with what GSK has said about its confidence levels in the patent.

A particular example taken is the 45% figure, if you recall, that was put to Dr. Reilly. I have a note. It is referred to in paragraph 78 of the CMA's closing. That will give the reference. But there was a document, if my note is correct.

You will see in paragraph 78, it was GSK's UK operating unit plan 2003. It gave a 45% probability that the supply agreements would not hold. There was a high risk, and he says that is quite high because of the inherent uncertainty around the situation.

It is important to realise -- and this is a high level business plan. This is a naturally conservative assumption in a business planning scenario, which covers a large range of possibilities, including entry at risk as well as any views on future and, necessarily, hypothetical patent litigation. So you cannot translate that on a per cent for per cent basis to GSK's confidence levels, in our submission.

We also reflect -- this is paragraph 38 of our note -- on the counterfactual which we said in our skeleton the CMA seemed to abandon. But we were told that it had not, although it did not feature heavily in these proceedings, the counterfactual of alternative deals.

We say that in line with Professor Shapiro's indication that you need evidence -- in his theory if you are going to use that alternative settlement counterfactual, you would want evidence that parties could have settled without resorting to a value transfer, we say that at least from GSK's perspective, the sort of deals that that envisages, being the early entry agreements or the royalty arrangements, were precisely the sort that Dr. Reilly said that he would not have contemplated because they send the wrong signals and show a lack of confidence in the patents and basically invite people to come along and hit you.

MR. GLYNN: Could I ask you to expand a little more on that, if you would?

If, in that counterfactual, there were, say, an early settlement, there would be an acceptance that there was a risk on both sides of the litigation, which we have got really in the agreements which we have reached, have we not? There is an acceptance that there was a risk on both sides. So could you say a little more about why the thinking was that that would be sending the signal of capitulation and it was not a possible answer from GSK's point of view?

MR. FLYNN: As I understand Dr. Reilly's position, firstly, if you take the royalty scenario, leaving aside the fact that the CMA has not expressed any views on the level of royalty, but from his perspective, just allowing people to bring in their own product and pay a royalty on it would precisely say, well, we will take some money from you, but we are not defending our patents. We are not letting them stand in the way.

THE PRESIDENT: But you are. If you are giving a patent licence, that is the basis on which you get a royalty: that we have a good patent, you can only come in with our permission on paying us money, usually based on the amount you have sold.

If you have a bad patent, you would not get granted a licence or you would get a very low royalty.

MR. FLYNN: I think at that point, as I understand what he is saying, you invite everyone else to turn up as well and, indeed, to say, well, if that is the view they are taking, we will have a go.

MR. GLYNN: But if the royalty you got was in -- assuming that GSK's confidence in its patents having some strength was not entirely misplaced, then the royalty would be not an insignificant one, and it would be a concession that there was a risk of things going the other way after time. So you would not have given up belief in your patents, you would be accepting a lower price, recognising the risk which I think is common to both sides was there?

MR. FLYNN: Yes, I entirely see that, sir. But as I say, from Dr. Reilly's commercial perspective, what I understand him to be saying is if you do that then, firstly, everyone is going to want one. You have then really lost --

MR. GLYNN: You get more royalties.

MR. FLYNN: Probably you are not going to reach a deal on the royalties is the reality. If you are confident in your patents and you want to stick by them, you are probably not going to reach a royalty level that is acceptable to a generic company, particularly one that has, as these have, substantial sunk investments that they are not going to recoup through a royalty at the kind of level that would reflect GSK's view of its patents.

THE PRESIDENT: But I think the point Mr. Glynn is making is it would be another form of commercial negotiation reflecting the parties' view of patent strength, as was this settlement.

MR. FLYNN: It would, and so would the early entry deal, which of course was even less --

THE PRESIDENT: Well, early entry may be suggesting --

MR. FLYNN: -- even less attractive.

THE PRESIDENT: -- a weakness in the patent but a royalty. I think Dr. Reilly accepted that if it is a high royalty, it does not indicate you feel you have a weak patent?

MR. FLYNN: Of course, if you can get a high royalty, then I think it is just regarded as unrealistic that you would be able to agree a royalty term. None is suggested against us, if I may say, and the evidence only suggests that a generic who considered it, as I recall, said, you know, an extremely low royalty is what they would be after.

So we simply say that there is no demonstration made that it was actually realistic that these parties could have reached such an arrangement. A big feature in that is the size of the exposure that the generics had to their suppliers and so forth, and the effect that they were already several millions in the deep means that it would have been difficult to structure an arrangement of this theoretical kind, which in any case was not acceptable, we say, to GSK.

I think unless I can help further on that ...

MR. GLYNN: It is very difficult to know how to pursue it, but you have got here agreements which are being contested because they include the value transfer to which exception is being taken. There is a certain financial cost to GSK of doing that. There would be a financial cost of a licence agreement.

I am still struggling to see why it was necessary to have the value transfer rather than the licence payment, given that in both cases you would need to achieve -- if you are going to get a settlement of any sort -- some coming together of the reserve positions of both sides of the bargain.

MR. FLYNN: Perhaps I can reflect on whether there is anything else in the evidence that I can assist you with, sir. Plainly it was not a matter that Dr. Reilly would have viewed with favour.

MR. GLYNN: It clearly was not taken seriously, but the difficulty that I am --

MR. FLYNN: As a theoretical matter, of course I entirely see that that would be a trade. I think I discussed this with Professor Shapiro. A royalty agreement with supply of specific volumes might be a different proposition from a simple royalty per pack, or whatever, which would then lead to a loss of control over what was going on in the market, and that would be GSK really abandoning itself to vagaries of that or any number of generic suppliers.

Broadly speaking, GSK was not prepared to be either a contract manufacturer or a wholesaler for this product.

THE PRESIDENT: But normally a patent licence, you are not a wholesaler, you are licensing them under your patent rights. They produce their product independently.

MR. FLYNN: Yes, indeed.

THE PRESIDENT: That is what I think Mr. Glynn is suggesting: the regular kind of patent licence, you are not a wholesaler. In this case they were a wholesaler.

MR. FLYNN: Without some understanding of volumes, I mean, as I say, the market would be flooded and you would --

THE PRESIDENT: Well, you would be competing with your licensee.

MR. GLYNN: The total market would be given by the number of people who get prescriptions of the medicine. So the total volume is there. If the royalty payment was sufficiently high, you could find it more attractive than the agreements that were in the event struck.

So in a way I am driving at this because this value transfer is an essential element of what is the case against you that I want to fully understand.

MR. FLYNN: I think you are suggesting that value could be transferred in a number of different ways.

MR. GLYNN: Absolutely, which might not have led to these difficulties.

MR. FLYNN: It might not have led to these difficulties, but I think against that we say that it is perhaps arbitrary to focus on cash transfers rather than evaluating the whole deal, and we have pointed out there are various features of these arrangements, including their early termination arrangements, which put them in a particular category, their interim arrangements, as it were, pending further developments in the market, and they include volume allowances at substantial levels.

We say that in the circumstances of this case, a cash payment was needed to, as it were, bridge the gap, and that is a point that has been substantially argued in front of you.

What is being applied against us, though, is the full pay for delay inference. That is what we are facing here. The theory is, as Mr. Turner has said, if you have a value transfer, then you have restrictions on entry for the duration of the agreement, then you are done. It is a pay for delay case.

We challenge that in a number of ways, as you will have seen. Firstly, it is not in itself a legal test. We will come back to what it does or does not show. But the source of law in this case under the treaty, and thereby the Competition Act, is the Court of Justice's/the European Court's case law on object restriction, and I am not going to go over that in great detail here.

We have set out legal submissions in relation to the *Cartes Bancaires* ruling and the tests that it lays down, and in our submission the Tribunal's task here is to apply those criteria and apply the teaching of those Court of Justice rulings to the alleged object infringement here.

What the CMA now says to you is that, well, it is not very difficult for you to do that because it is all swept up by the *Lundbeck* case. I should probably take this quite shortly unless the Tribunal wishes me to dwell on it, but we say that the facts of the case are extremely different and distinguishable, and the General Court did not endorse as the sole test that needed to be applied one that all you have to show is a value transfer in excess of avoided litigation costs and a restriction on entry.

Now, I know *Lundbeck* is an extremely baggy judgment and a difficult one to read, and possibly the reading list of paragraphs may have been exactly what Mr. Malek was hoping for, or it may have been longer.

MR. MALEK: It was exactly what I wanted. It was helpful.

THE PRESIDENT: It was helpful.

MR. FLYNN: I am glad, because it is a difficult and lengthy judgment to read.

You see what we take from it, paragraphs 46 to 51 of our note. So the essential points, we say -- I mean, I have already made the point that it is not a case that says it is fine to confine your finding to a payment above avoided litigation costs and restrictions on entry in a context that is actually quite different from ours.

As we explain there in paragraph 46.1, the restrictions that were agreed were not matters that could have been obtained through any patent litigation that had been brought even if Lundbeck had chosen to bring it. So that is point 1.

The other important difference is that the court was able to conclude that the reverse payments had paid a decisive role in encouraging the generics there simply not to enter the market, because the payments made matched or were approximately corresponding, or in one case substantially exceeded the profits that the generic concerned would have expected to make had they entered the market. Not a discounted probability weighted approach, but the profits that they would have made if they had entered.

As I said already, Lundbeck was not prepared to litigate and was essentially finding generics to settle with because it had no adequate patent coverage and no belief in the latest patent that it was seeking to rely on.

That is just not what we did. We were prepared to back our patents. So in this case, where there is no finding, no evidence that the payments exceeded the expected profits, the actual expected profits of the generics', or any suggestion that is made or properly could be made that the restrictions went beyond what GSK could have obtained if it had been successful, we say they are not market sharing agreements and you have to look a lot further than that.

The General Court did not treat, as I have already said, the reverse payment in exchange for entry restrictions as decisive. They treated it as relevant, as necessary, but says that the finding of an object restriction was justified by further factors that the Commission had examined and reached conclusions on.

Now, I do not know to what extent the Tribunal wishes me to go through the detail of this, but in circumstances where you can say in a case like that that the size of the payment replaces the "autonomous assessment of the patent strength", if you are simply paid what you would otherwise have made, why bother? Why do anything else?

That is simply not the case here, and even if there was a cash element to the deal, the major part of it took the form of supply and, indeed, supply of a new product, in circumstances

where, as we have said and you have well on board, actually the parties concerned could not enter the market at the time of the agreements.

That is a case where the authority had been able to demonstrate that it was the size of the payments which induced the entry into the agreement. We particularly commend the court's summary of everything at paragraph 500, where the Court of First Instance says:

> "Consequently, the Commission was entitled in the present case to rely on a series of factors as contextual elements -- such as the existence of a reverse payment, the size of that payment and the fact that it appeared to correspond to the profits expected by the generic undertakings if they had entered the market, as well as the absence of a clause enabling the generic undertakings to enter the market upon the expiry of the agreements at issue and the presence of restrictions going beyond the scope of the applicants' patents -- in order to find those agreements had the object of restricting competition."

{W/1/105}

We have some of those features here, but many we do not. In our submission, it is necessary to examine the agreements with which this appeal is concerned, in their context, in line with the *Cartes Bancaires* requirements and reach the court's own conclusions about --

MR. MALEK: Mr. Flynn, is not the main point in 500 that is absent here the presentation of restrictions going beyond the scope of the applicants' patents?

MR. FLYNN: No, it is the size of the payment as well, sir. It is both of those, as I think I emphasised in introducing this section. Both of those are important matters.

MR. MALEK: The payments are very substantial here, are they not? In our case, they are not small payments.

If you look at it, the existence of a reverse payment, well, we have that. The size of that payment, we also have that. The fact that it appeared to correspond with the profits expected by the generic undertakings if they had entered the market. Well, on one view it may be that this was more than they would have expected to get out of the agreements, as well as the absence of a clause naming the generic undertakings to enter into the market from expiry of the agreements in issue. Well, we have that as well.

I think the main one here is the fact that the presence of restrictions going beyond the scope of the applicants' patents, that is not present in this case.

THE PRESIDENT: That is accepted by the CMA.

MR. FLYNN: Indeed. The CMA, of course, takes the position that all of this is covered by --

THE PRESIDENT: I think the reality is the appellants all say look at *Lundbeck* carefully, it supports your position because of the sort of factors you are mentioning. The CMA says look at *Lundbeck* carefully, it supports their position.

MR. FLYNN: It supports their position if you take something off the shopping list.

THE PRESIDENT: No, I think there are paragraphs in *Lundbeck*, as you know, that would say the scope of the patent is not critical, included in the list that we have read. It says that in terms. Everyone is taking from it bits that support them.

MR. MALEK: You see, Mr. Flynn, what I am taking from this, and I have not formed a concluded view, is that there are some real distinctions between this case and what went on in *Lundbeck*, but there are some very broad statements of principle in there. The question is do we take those broad statements of principle at face value, or do we have to contextualise those by reference to the underlying facts in that case?

MR. FLYNN: So my answer to the question is the one you would expect. We have made every effort to seek to contextualise what the General Court was saying in that case in relation to the object infringement that was before it. So I think we do say you have to see that in the round. You have to see the fact that Lundbeck's patent coverage was pretty limited and the restrictions related to all forms of citalopram despite the ability, according to the facts found by the General Court, to enter without infringing any of Lundbeck's patents, which the generics knew.

We do say it is also relevant that the reason, we say, that the General Court was able to conclude that the Commission was right to say that the autonomous assessment of the generics' concerned had been overborne by the size of the payment was in relation to a finding that you just do not find here.

Obviously these sums of money are large, large to you and me, but there is no attempt to demonstrate that they correspond to what the generics would have made without having to make the effort of getting into the market, which is a clear case of being induced.

THE PRESIDENT: But we now have evidence on that of what they would have expected to make, because you put it in.

MR. FLYNN: Well, that is a calculation of the -- if you mean the calculation of the downside risk, if that is the evidence.

THE PRESIDENT: No, the expected profits of the generic. The figures you were showing us before.

MR. FLYNN: Yes.

THE PRESIDENT: Dr. Stillman's figures.

MR. FLYNN: Yes, that was a calculation of what GSK might have had at risk if there had been independent generic entry, which is a separate point.

THE PRESIDENT: Yes. But also what the generic would have met with -- yes.

MR. FLYNN: Yes. I do not think that is the same as a demonstration that for each individual generic, the amounts that they received under these agreements were as good to them as entering the market on an independent basis.

You are asked to infer that, as I pointed already. You are asked to infer that from two footnotes, the CMA having tried to make the same demonstration as the Commission made in *Lundbeck* and not been able to do so, and that is really -- and my friends may have more to say about that.

THE PRESIDENT: If we felt that *Lundbeck*, contrary to your submissions and your fellow counsel for the applicants, the statements of principle are so broad and what they say about scope of patent and so on, that would lead us to hold on this part of the case against you, but *Lundbeck* is under appeal and we do not know, of course, what might happen on the appeal, would then the appropriate course be to make a reference?

MR. FLYNN: I have understood from previous ventilations of this issue that that would be the Tribunal's preference. I mean, our feeling is that it is of course, and my submission to you has been that it is open to the Tribunal to take its own view of what *Cartes Bancaires* requires, which is a Court of Justice judgment, and decide whether or not it is persuaded by the broad statements of principle in *Lundbeck*, rather than detailed appraisals of the agreements in front of it, which as --

THE PRESIDENT: I understand that. If we did feel that course -- because otherwise -- I mean, at some point the Court of Justice produces its judgment, but not for quite a long time.

MR. FLYNN: It is likely to be quite a while, indeed.

THE PRESIDENT: That could change things.

MR. FLYNN: Yes. We understand the position, sir. I think the Tribunal itself has a choice, and I think the CMA is inviting you to say --

THE PRESIDENT: Well, I know they are.

MR. FLYNN: -- just jolly well go ahead and decide it.

THE PRESIDENT: I will ask them the same question, do not worry.

MR. FLYNN: I did not doubt that you would, I did not doubt for a moment.

But one assumes that were a reference to be contemplated, then of necessity there would be a further opportunity for addressing the --

THE PRESIDENT: Even if we did, we may well still express our views as the court has indicated they find that helpful.

MR. FLYNN: Yes, in some cases they certainly do. Conscious of the timescale, that is an important issue, and we come back -- I beg your pardon. (Pause)

THE PRESIDENT: Yes.

MR. FLYNN: So we come back later in the note to the pay for delay inference. Perhaps I should take it in the order in which we have laid things out just to ease following.

That is in relation to the objects case. In relation to the effects case, and perhaps I can take this a little more shortly, we submit that however one views their relevance of it, it is now plainly established in front of the Tribunal that there are positive effects from the entry into these agreements even if the CMA seeks to say some should be disregarded and some are trivial.

We list some of those features in paragraph 54 of our note, the first being that they created really a new product on the market with the authorised generic in substantial quantities with the generic company's own branding. It is not in any way in dispute in these proceedings as to the facts that the NHS saved a large sum of money overall calculated at over £15 million.

The parallel importers were effectively out competed, but the authorised generics not only did that, but took a substantial share from GSK.

But all of this led to a substantial overall quality improvement in the market. It provided benefits to wholesalers, not least by ensuring that they would continue to be supplied with paroxetine when GSK moved to a direct to pharmacy model.

I think it is now completely accepted that within a range pharmacy prices on average fell.

THE PRESIDENT: Can you just explain one thing to me which I just have not quite bottomed out. The saving to the NHS because of the shift to the other category meant that deals with how much they reimbursed the pharmacies, presumably.

MR. FLYNN: Yes.

THE PRESIDENT: So they reimbursed the pharmacies left and therefore saved that 15.6 million. So although one is looking at prices to pharmacies falling, in terms of what pharmacies are charged, at the same time the reimbursement to the pharmacy is falling.

MR. FLYNN: Yes.

THE PRESIDENT: So the pharmacies are not actually -- is that right: the theory is they are not any better off, they are paying less and they are getting a lower reimbursement? Is that not the theory of the reimbursement?

MR. FLYNN: The reimbursement rate fell.

THE PRESIDENT: Yes, which meant they get less money back, they pay less --

MR. FLYNN: They pay less and they get less money back. That is correct.

THE PRESIDENT: So I understand the benefit to the NHS. I do not quite see what the benefit is then to the pharmacy.

MR. FLYNN: The pharmacies, as we have said, are really an intermediary on the path between the prescriber and the patient.

THE PRESIDENT: That is exactly what I mean. The benefit -- it may not be that it is your case, really, because you rely on the NHS benefit --

MR. FLYNN: Well, we rely on that. It is also true that the prices against which reimbursement was made on average fell for a better quality product.

THE PRESIDENT: I know, but it is not a benefit to the pharmacy as such, is it?

MR. FLYNN: That is really, I think, why Dr. Stillman has always focused on the consumer, as he would see it, at least the payer, the person who foots the bill for the patient's medicine.

MR. GLYNN: There might be minor differences depending on how exactly things worked out.

THE PRESIDENT: Or a time lag or something.

MR. GLYNN: Or a time lag or accuracy of the calculations, which is done on a sample basis, all that kind of thing. But in broad terms the argument is that there is a saving that has gone through to the NHS, and that is the benefit that we should be --

MR. FLYNN: That is the substantial benefit on which Dr. Stillman has focused, and we do also say that it is clear as a result of these arrangements that there was an overall quality improvement in the market.

MR. GLYNN: Yes, indeed.

THE PRESIDENT: Understood.

MR. FLYNN: That is not --

THE PRESIDENT: That is over the parallel imports.

MR. FLYNN: Principally, yes. It is over the parallel import.

The generics with this new product on the market, which, as I think Mr. Glynn was suggesting originally, I mean, these are additional volumes and you could, depending on the circumstances, envisage more of a scrap between the generics and the parallel importers which might have played out against GSK. The way it in fact happened was that by and large the generic product won out against the parallel importers and also bit into GSK's volumes.

MR. MALEK: Just for my note, could you give me that as a percentage of what percentage was saved by the NHS, the 15.6 million? You say they save 15.6 million. What is that as a percentage? Give it to me at 2.00 pm, not now.

THE PRESIDENT: I think to have their expenditure on paroxetine would be useful.

MR. FLYNN: 15% is being whispered at me. I will find a reference.

MR. MALEK: Tell me at 2.00 pm.

MR. FLYNN: I will find you a reference at that point.

MR. GLYNN: You say that it is clear that this NHS adjustment would not have happened without the agreement?

MR. FLYNN: Absolutely. It is triggered by the "widespread availability of generic product", assessed on a basket of wholesalers and generic, five in total at the time.

The theory, obviously, is that once there is widespread availability of generic product on the market, the price is going to come down. As Mr. Scannell is saying, you will find more detail of that in Mr. Horridge's evidence, which has not been tested in front of you. It is precisely and only because of these agreements that that saving is triggered.

It is triggered because the system is set up to recognise an anticipated competitive benefit. It did also lead to falls in the pharmacy price as well and, as I have said, an overall improvement in quality which I think is uncontestable and substantial.

THE PRESIDENT: The fall in the pharmacy price is linked to the reimbursement price. The two are connected.

MR. FLYNN: The fall in the pharmacy price is because of the competition for their custom caused by these additional volumes. The pharmacy price is, if I am not misspeaking, a matter of commercial negotiation. The whole idea is the pharmacies, once there is generic product on the market, can go and choose their suppliers. Before the introduction of the authorised generic here, their choice was essentially GSK or parallel importers, and thereafter they have more people knocking on their door, with, as we say, better quality product.

So in relation to the Seroxat price, which seems to be the real focus of the CMA's concern, it is true, the Seroxat price itself moved down a bit. I think 1.5% is the figure, and Dr. Stillman fairly recognised that that is less than he would have expected ex ante, but nevertheless it was an effect. But GSK took the hit, as I said earlier, and essentially on volume.

Now, I am not, unless the Tribunal is very enthusiastic for me to do so, going to go through the blow-by-blow account of the Webster evidence because it seems, as I understand the

CMA's closing -- I will be corrected if that is wrong -- it is now accepted that within a range there was the pharmacy fall, and Ms. Webster's caveat that even that might not be substantiated, as I understand, is no longer maintained.

So there is a range -- and nobody is shouting at me. There is a range, and Dr. Stillman says --

THE PRESIDENT: There has to be some margin for error in these figures anyway.

MR. FLYNN: Of course. Nobody is saying to you: here is the number. Everyone is saying to you: there is a range, and we say it is not an insignificant matter. It is not the only matter to take into account, as I have already said, but it now seems to be accepted that within that range, whatever the mid-point or mid-point of two ranges or three ranges that you might choose by way of assessment, there was that price fall.

MR. MALEK: Just to comment. On paragraph 61, I could not see the reference back to where you deal with Dr. Majumdar's evidence. I could see where you dealt with Dr. Stillman and all the other experts, but I could not see a paragraph that deals with Dr. Majumdar.

MR. FLYNN: That is probably one of the imperfections of this document that I had not spotted before. I do not think we do actually deal in detail with Dr. Majumdar's evidence and, sir, I think you are right.

MR. MALEK: That is fine.

MR. FLYNN: That has not been done previously in this document. Sir, I think we do not. I will leave my friends to talk about Dr. Majumdar.

MR. MALEK: That is fine. You were not calling him anyway.

MR. FLYNN: We were not calling him. He had his own theories which were tested, and I think to a large extent it was thought to have been accepted, but it is possible that it was not.

So I think I am not the person to assist further. You are quite right, sir, we had not made a specific comment on the content of Dr. Majumdar's evidence. So that will lead us to conclude on the effects case, largely in the terms of paragraph 81 of our note. So to the extent that we need to, you have chapter and verse on our position in relation to the Webster issues, if I can call them that, that I will spare everyone the detail.

Our conclusion in relation to the positive effects that I have --

MR. GLYNN: Just before you do, on paragraph 69 you say that the agreements which benefited the NHS in the way you have discussed, you compare those with early entry agreements which you say would not have benefited the NHS to the same degree.

MR. FLYNN: Yes.

MR. GLYNN: Is that simply that they would have taken place later in time, or is it an order of magnitude point?

MR. FLYNN: That is a reference which probably itself could have done with a footnote to evidence of Dr. Stillman who made the comparison in what I think was called his annex 3 report. I will give a reference to that. But he made -- you probably recall, or I may be able to jog your memory at least with a reference, but he made a demonstration that if you work out what is the cross-over date at which --

MR. GLYNN: Yes, that is the point in time point that I was referring to.

MR. FLYNN: Yes.

MR. GLYNN: A related question. If we were going back to this licence agreement counterfactual, perhaps it is an unfair question, but do you have any view on whether or not that would have been as beneficial to the NHS as the agreements or perhaps more?

MR. FLYNN: I will double check, but actually the basis of Dr. Stillman's comparison was ...

(Pause)

MR. GLYNN: Fair enough.

MR. FLYNN: Annex 3, I am told, is in {G2/42/1}.

MR. GLYNN: Thank you.

MR. FLYNN: Sir, we can address that in more detail, but essentially the comparison was whether you could find an arrangement under which the NHS would be better off without the value transfer. Indeed, the answer is that it would have been months if not years later than the actual entry caused by these agreements. So that was essentially the point.

MR. GLYNN: Thank you.

MR. FLYNN: Sir, I am aware that after lunch I think I have an hour, and I will try and make it move faster.

In relation to exemption, I mean, I think we have been over abuse and I think we are all content to rely on our written submissions there because --

THE PRESIDENT: Are you on the vertical agreements order?

MR. FLYNN: If you look at paragraph 82, this is how we put it in relation to abuse. We say that we have explained the VAO point in the abuse context, and I may come back to that briefly. But otherwise we rely on the skeleton in relation to the arguments we make under abuse.

As to exemption, where, as you have said, we bear the burden, I mean, firstly, verticality under the vertical agreement block exemption, I think we are all agreed that is the same question that arises under the VAEO, and we say these are plainly vertical agreements. We

say the 30% market share limit we are under if the market is defined as we say it should be and the fact that we are under 30% has not been contested by the CMA.

The calculations are to be found in Dr. Stillman's first report on market definition at paragraph 100, and it is in table 6, and that is where you will see the market share position in the SSRI market as we say it should be defined.

So the vertical agreements block exemption point essentially turns on verticality and on market definition, both of which are probably to be decided in, as it were, other parts of the case.

But in relation to individual exemption, to repeat some of the matters we have just been over, we say these agreements did create efficiencies that could not have been otherwise produced. They brought a new kind of product to the market, being the authorised generic, which was a better product for consumers and out-competed the parallel imports for that reason, and it also led to wholesalers continuing to have access to paroxetine, which otherwise they would not have done. They would have been cut out of the picture because of GSK's move to a DTP model, and this was a matter of concern to the OFT, I think it was at the time, in the medicines distribution study that DTP models would cause problems for wholesalers.

THE PRESIDENT: They would obviously cause problems for wholesalers because they are cut out, but whether it is less efficient or more efficient, we have not had any evidence on that, whether your clients' system was less efficient. I imagine you would not suggest that.

MR. FLYNN: But it led to forms of competition at the pharmacy level that would not otherwise have been there.

I am not making any comparison between us and DTP, I am simply saying that if you have the originator going to a DTP model, then you will not have wholesaling in the system.

Under our agreements you did, and according to the OFT anyway that is a good thing as opposed to the bad thing that DTP models would lead to.

Possibly then I can --

THE PRESIDENT: But it is not your case that your move to DTP was a bad thing?

MR. FLYNN: No. It is certainly not our case. It is a good thing. We are simply saying if one wants to take an objective view of the efficiencies or customer benefits produced by these agreements, those are matters that we would point to.

I think it is the fact that there was a new and better product that was introduced to the market and could not otherwise have been, that I would lay the emphasis on.

THE PRESIDENT: Well, it is GSK's paroxetine, but it is being marketed as a generic. It is the same product; it is made by you.

MR. FLYNN: It is made by us, but --

THE PRESIDENT: It is no longer branded.

MR. FLYNN: Yes.

THE PRESIDENT: It is an unbranded version of the same product.

MR. FLYNN: It is the authorised generic version. So the source is impeccable, but the way it is sold is quite different and it enables the generic suppliers to take on GSK and the PI, which itself is also of course GSK's product.

So, you know, you can say it is a moving of things round, but actually it is quite important that this is a UK pack as opposed to PI imported, and patients clearly thought so and they were able to out compete the parallel importers.

I am told, sir, that if Mr. Glynn would like to have a quick look at how Dr. Stillman's annex 3 report works, we summarised it in our skeleton at paragraphs 7.49 to 7.52. That may be a quick way of at least understanding what the scope of the exercise was.

MR. MALEK: Sorry, what were those paragraph numbers?

MR. FLYNN: 7.49 to 7.52.

MR. MALEK: Yes.

MR. FLYNN: Sir, I see the time. I am happy to continue or happy to ...

THE PRESIDENT: You have reached where, to the end of --

MR. FLYNN: I have very little --

THE PRESIDENT: -- vertical agreements?

MR. FLYNN: I have very little to say on the exclusion order.

THE PRESIDENT: You have addressed us on that.

MR. FLYNN: You have heard plenty.

THE PRESIDENT: You have summarised it. We are sort of on page 33.

MR. FLYNN: I have a few words on the inference, on market definition and a few words on penalty then to cover when we return.

THE PRESIDENT: Yes.

MR. FLYNN: Again, market definition may be possible to be a bit quicker because we had that more, as it were, recently.

THE PRESIDENT: So we will return at 2 o'clock.

MR. FLYNN: Thank you.

(1.03 pm) (The short adjournment)

(2.00 pm)

THE PRESIDENT: Yes, Mr. Flynn.

MR. FLYNN: Sir, before lunch I was asked to provide just the references to where you would find the 15% figure.

THE PRESIDENT: Yes.

MR. FLYNN: I can give them. We can go there if we need to.

Dr. Stillman's annex D report is an exhibit to his report on consumer welfare and it is to be found in {G2/42/1}. At paragraph 10 of that report on page {G2/42/8} you will find the reference to the 15% reduction. It is 15%, to answer a question put, of the original drug tariff price. So it is a reduction by 15% overall over the period.

For the period, you can see it illustrated in figure 3, which is on page {G2/42/17} in the Magnum system, and the source for that, it is the dotted line which is the fall; the bold line is what would have happened without these agreements. The source of the numbers is given as wave data. That is also where Dr. Stillman does the detailed modeling, which I was endeavouring to outline to Mr. Glynn earlier.

THE PRESIDENT: Thank you.

MR. FLYNN: Sir, I will endeavour to take very quickly -- as I say, I know there is a lot to get through today and it is not just me. You will have seen what we have to say about the pay for delay inference in paragraphs 87 and following of our closing documents, and we essentially make three points on it.

One I think is now the uncontroversial point that the CMA relies on it and avers that that is the foundation of its case.

We criticise reliance on it for the reasons I have already given, notably that it excludes consideration of any patent strength or proper assessment of the financial imperatives on the parties, and that it is not appropriate to proceed on pure inference.

We make two groups of points about the pay for delay inference itself, the first being -- this is paragraphs 93 to 102 -- it is a theory that applies on average and applies everything on a probabilistic basis but it does not say anything about the individual case. That is a matter that was explored in cross-examination as well as in the hot tub, I believe.

So in the interests of overall consumer welfare, it sweeps up cases where, in fact, there is not a competition problem to worry about, as Professor Shapiro recognised. Basically, if the patent is justifiable then so is the monopoly, but everything is caught up in the interests of producing the best result on average.

We also criticise it because it makes the so-called revealed preference of the originator essentially drive the entire conclusion. Because if you take the position that the originator is buying off the uncertainty, dispenses the authority without any need to evaluate the litigation counterfactual, so it all turns on payment.

Of course the payment itself is not an infringement. We also say that the size of the payment is no certain guide actually to the originator's view anyway and it will vary, as Professor Shapiro recognised, with downside risk and is subject to other criticisms as well, the possibly cautious nature of the originator. We have said that if this is a deal where ultimately GSK, as it were, settled too easily, it is no part of competition law to criticise or sanction that.

What this theory effectively does is to bar a large swathe of possible ways of settling, particularly in the difficult category which lies somewhere between originator winning and generic winning; the difficult category where there is something to be said on both sides and a compromise is sought.

That is what we have here: we have a compromise and because the theory does not consider the patent strength and it does not also consider the inducement from the proper perspective, which is not that of how much was the originator prepared to take, but how much did the generic need to be overborne as per our submissions on *Lundbeck*, we say that it is an inappropriate theory to apply.

THE PRESIDENT: May I just ask you one thing. You say in paragraph 96, at the end of that paragraph:

> "One practical consequence of using the PFD theory as a standard liability is therefore to render follow-on damages claims unworkable."

I did not quite understand that.

MR. FLYNN: That was a point that I think was raised in the hot tub or the cross-examination afterwards.

If you say the infringement is caused simply because a chance has been snuffed out, how does the claimant in a follow-on case establish that it has lost? I think you mentioned the case of the professional negligence, where the court might actually need to form a view on the likely outcome.

THE PRESIDENT: Yes. Well, they might do.

MR. FLYNN: They might do, and the decision they are following on from would provide no assistance in that respect.

THE PRESIDENT: That is true in many by object infringements. If you have an information exchange agreement where competitors exchange information, it may be a by object infringement if one of their customers wants to bring a damages claim, it does not get them all that far because they will have to show it actually translated through to higher prices, and the claimant bears the burden of proof.

That is why obviously follow-on claimants much prefer by effects decisions, but that is not a reason for an authority not to take a by objects decision.

MR. FLYNN: In a case we would say particularly where what has been identified as the policy underlying the type of action is the need for the NHS and drugs bill not to be distorted by anti-competitive practices. We say it is a particularly unhelpful approach to take a decision of this nature which would not allow this hypothesis to be tested in a follow-on option.

THE PRESIDENT: It would be. The burden on the NHS would be to show that it either had an effect, or maybe persuade the court it is a loss of a chance case. I am not sure it is. But that would be a matter for argument.

But I do not see that in itself, if this is a by object infringement -- if it is not, it is not, but if it is a by object infringement, the fact that there are then certain burdens on a claimant, it is is not unworkable, it just means that instead of the CMA doing it, it may be the NHS has to get into battle strength.

MR. FLYNN: The NHS will have to do everything, and that is a particular problem of using a probabilistic approach, we would suggest.

THE PRESIDENT: I see.

MR. FLYNN: The other point that we make generally is the point that arises because in this particular case not only do you have the problem of working out whether it is not a simple cash case, it is a case of what has been called a non-cash value transfer which requires further analysis on Professor Shapiro's own understanding of matters.

He says you have to examine whether their non-cash value transfer in the form, for example, of a distribution agreement, may create pro-competitive effects such as sales at prices lower than previously prevailing, which is what happened here. We have given you our view that it is a non-cash case because even the promotional allowances were taken as supporting the supply price.

Again, in this particular case, the focus on price is not helpful either because, as we have explained or sought to explain, there is a substantial quality improvement as well as the lower prices. So it is a particularly difficult case for the evaluation of the non-price element.

We conclude, ultimately, and I probably am repeating the material that we have already given on effects, that whereas there was reference to the welfare pie not being expanded, we say it was actually stretched and more stuff was put in the pie in the form of the extra competition, and the new product that I have already mentioned out competing parallel import, the removal of substantial risk elements for all parties and the loss of volumes to GSK, which you have seen.

So that in short -- and it is short, and I apologise for that, but it in short covers the ground we have set out in relation to the problems as we see them of applying the pay for delay inference in its full form here.

May I say just a few words on market definition.

THE PRESIDENT: Yes.

MR. FLYNN: I will not take you through all the detail of what we have said, and as I say, this argument may be fresher in your minds or possibly it all is. We say that the forward-looking approach that the CMA has adopted here is inappropriate for an ex post abuse case, and there is no support for it except the possibly qualified support that one can see in the *Servier* decision. That is, as we have said, and it is not controversial point, but that is just a decision which is under appeal and the Tribunal can take it for what it will on that.

A particular point that I think it is perhaps worth stressing is that there was quite a discussion in the hot tub particularly about the possibility of two markets and facing two ways on the bridge.

In our submission, and we have said in our closing submissions that the experts may have muddied the water somewhat by talking in terms of merger cases, when you are necessarily doing a prospective analysis and considering whether it is a branded generic merger or branded branded, considering what would happen if a particular product, the same molecule, came under single hands.

We say, in fact, in this case the relevant market is the SSRI market, and that remains so even after genericisation of a particular originator's SSRI. Because at the time that we were talking about, for example, one of the players in the SSRI market was Eli Lilly despite the fact that its fluoxetine molecule had been genericised.

Obviously in a merger case it is different, but in our submission the image is a powerful one, but the bridge on which one might imagine GSK crossing from the time when it has patent protection to the time when it does not and its product has become genericised, on both sides of the river, we say, is an SSRI market.

It is the nature of its competition and its competitive response will change. On one side it will be detailing to doctors, on the other it will be considering whether it is worth marketing when that will lead to a sale for a rival.

THE PRESIDENT: I thought Dr. Stillman agreed that after the end of patent and full generic entry -- if I can just finish -- I thought he said that then, in that situation, he agreed the market definition would be paroxetine because the competitive constraint on GSK is from all the generics that are in the market. He was saying you cannot extrapolate that back earlier.

Was that not his analysis?

MR. FLYNN: My submission is that the discussion became a bit confused because it was swapping between merger analysis and ex post abuse analysis.

What Dr. Stillman focuses on always is how do you analyse the constraint or the effect of a particular situation, and yes, once your own molecule is genericised then what you look at is the constraint at that level.

Of course, post-genericisation the originator is not likely to be in a dominant position, so it becomes a somewhat -- I mean, it could be, but it is unlikely to be able to resist that --

THE PRESIDENT: You still might need market definition for --

MR. FLYNN: You might need market definition for other purposes, and most of it, as I say, was conducted in terms of mergers.

So the concern here is the idea that there is some kind of transitory dominance between a situation where you have on any view -- in our submission, anywhere on an SSRI market before genericisation is a flash in anyone's eye, undoubtedly then there is no dominance. Let us say unlikely. I recognise we might have a theoretical issue, but pretty unlikely to be dominance in a market if you have chosen to define it as paroxetine after genericisation.

You have this curious time on the bridge when for a moment you might be dominant.

We say that is a device that has no basis in theory and it is not supported in decision or practice, as we say, with the possible exception of the *Servier* decision.

THE PRESIDENT: Can I ask you something on market definition.

Before genericisation, as we have all used that word, considerably before, the competitive constraint on GSK with its Seroxat, you have been focusing on the other SSRIs as imposing constraint in terms of its marketing and I think it is suggested even a bit on price, but certainly its promotion. But was there not a competitive constraint on GSK in its pricing through the parallel importers, which we saw in Mr. Sellick's evidence?

All those deals on price reductions it had to agree and offer to pharmacies big and small, especially big, in order to meet the challenge from the parallel importers. That was a competitive constraint on GSK.

MR. FLYNN: I think I would have to accept that to an extent, yes.

THE PRESIDENT: That was from paroxetine.

MR. FLYNN: Yes.

THE PRESIDENT: That was the biggest constraint on them, much more than -- they reduced their price to Boots not because of Cipramil, but because of parallel importers.

MR. FLYNN: But nevertheless Boots would not be dispensing any paroxetine prescriptions if the work had not gone on in the first place to establish paroxetine or Seroxat as a viable antidepressant in competition with all the others.

At the pharmacy level, yes, there is a pricing issue there and Mr. Sellick has explained that. But the true competition comes in persuading doctors that your product is as good as or better than the others, and that is what gets it sold and that is what gets it dispensed at the pharmacy level.

MR. MALEK: Just going back to the previous point. Dr. Stillman was abundantly clear when he answered my question that he did accept that once you have independent generic entry, paroxetine is the market. That is Day 13 on page 45 of the transcript. I do not think that was related to the merger point at all. {TR/13/45}

MR. FLYNN: As we understand his evidence on that, where he has undoubtedly given his expert opinion that the relevant market is an SSRI one, for the purposes of these proceedings -- I should say "SSRI" is a shorthand for -- at least as wide as SSRIs and venlafaxine because clearly there were other types of antidepressants in the market with which GSK was also persuading doctors that this is the more modern way to go, so tricyclics and so forth. But say it on SSRIs, that was clearly Dr. Stillman's view.

He plainly recognises, and I think we all do, that in the prospective assessment of a merger then one will necessarily zero in on the product potentially to come under single ownership. I fully accept that at times he spoke of a paroxetine market, but I think he is looking at it in terms of what is acting as the principal constraint on the, let us say, hypothetical monopolist of paroxetine in those versions.

I do not think it would be fair to Dr. Stillman to say that he undoubtedly accepts that post-genericisation the relevant market has to be defined at molecule level. I will accept that some of the discussion was -- and you will say to me, sir, he is clear as a bell -- that the

thrust of it is you have to look at the effects and you have to look at what is actually operating on the originator at that point.

Nobody is doubting that at the point of genericisation, the focus shifts from the detailing, marketing and some price-related matters there, as you have said, to one of a new world in which your volumes are going to be decided by how well you pitch and price to your customers.

The CMA pleaded originally that *AstraZeneca* helped them. I think it is now recognised in their closing document that it does not and they merely say it is not against them, which is paragraph 201.

We say it is as clear as you like that if the Commission had taken the approach that the CMA has taken here in *AstraZeneca*, it would have looked at the conduct, which was misleading the patent office and withdrawing MAs for the purpose of excluding generics, and it could have gone straight to the molecule market, but it did not do that. In our view, it carried out a thorough and conventional analysis, including an analysis of prevailing prices, to arrive at a conclusion that PPIs were not constrained by H2 blockers.

So it really depends all on *Servier* for the CMA to say that it has anything that it is following or analogous with, and for reasons we have given, that may not be such a strong analogy anyway.

We say that the regulatory gap argument, that if the approach to market definition here is not tolerated by the Tribunal, there will be types of unilateral conduct which will fall through the cracks.

We say that argument cannot be accepted. It is wrong in principle because non-dominant firms can do unilateral things that dominant firms cannot. You have to decide whether they are dominant first, and it is not necessary here where the CMA has recognised that its Chapter I case is essentially a re-run of the Chapter I case anyway. So there is no conduct that is falling through the cracks, subject only to the vertical agreements exclusion order, where once again -- I am not going to repeat that -- the idea that you can drive a coach and horses through that because you do not like the conclusion that it drives you to is, we say, entirely inappropriate.

Sir, with a grinding change of gear may I address the Tribunal briefly on the penalty issue?

THE PRESIDENT: Yes.

MR. FLYNN: That starts at 152 of our note, and I suppose this is in a way opening submissions on the penalty.

This is obviously an alternative argument.

THE PRESIDENT: Sure.

MR. FLYNN: We say basically there should not have been a penalty, and if there is a penalty, no, it is not that we were not there, it is that it is too high.

There is a lot of, as we have said, ground that the Tribunal's judgment could follow, and I am not assessing that on any probabilistic basis. But it might not be an all win or all lose situation, and in those circumstances there are actually some complexities because of the way the fine has been calculated.

Notably, we have essentially been fined the Chapter II amount for the Chapter I conduct, if you like. It is a complicated picture. We have not sought to determine all the possible options and we probably could not. We say there may be a need to address the Tribunal further unless the Tribunal is of course free and able to make up its own mind because it has full jurisdiction. So you may not need that assistance, but I just put it down as a marker because it is an unusually complicated position with fines being traded off against each other, reduced and so forth.

We set out the law, and the Tribunal will be well familiar with that, in paragraphs 155 to 160.

THE PRESIDENT: In 158 you say the lowest that can reasonably be arrived at. Are you saying that is the test?

MR. FLYNN: I am saying that is a consideration, and I believe that is a quotation from the *Napp* judgment.

THE PRESIDENT: It is, but as one looks at it in context, they are not saying that -- I do not think; it is not the way I understand it -- the fine has to be the lowest that can reasonably be arrived at.

MR. FLYNN: We say it is a consideration, and if the Tribunal comes to the conclusion that the penalty is not just and proportionate or is excessive or unjust for whatever reason, there is likely to be a reason, as the Tribunal said in *Kier*, and we quote that in the next paragraph, which is probably some misapplication or misinterpretation of the guidance. But ultimately, your task is to decide whether the fine imposed is a just and proportionate one.

This is a case where, in relation to the Chapter I fines, the CMA actually itself finds that one or other of the fines would have been sufficient to deter GSK. You will remember that; that we end up being fined the Chapter II amount, which is a considerable degree higher. So those are factors which we urge you to consider in relation to the fine.

In relation to the argument that there should be no fine at all we make three separate points. One is as to the statutory test of committing the infringement intentionally or negligently.

The second is the relevance of the principles of legal certainty or administrative fairness, which we say are imported from EU law via section 60 as governing principles.

The third is the novelty, the utter novelty of the finding of infringement here. In relation to the statutory requirement, this is something that the Tribunal itself must be satisfied by. So it is something that the Tribunal must consider, and we say that what you have to do is put yourself back in the mind of someone in 2001/2002 and the state of competition law at the time.

Hindsight plays no guide here in deciding whether the infringement was committed at the time intentionally or negligently. It is not in dispute that there were no precedents of this kind in the UK or in the EU to suggest that patent settlements, particularly those that involve immediate supply agreements, were a matter of competition law concern.

We also say there was absolutely no precedent at the time giving any suggestion that GSK might be considered to be dominant in a molecule market on the basis of the test applied in the CMA's Chapter II case.

The factors which we think it is relevant to take into account when deciding whether it was something that GSK must have known or ought to have known was an infringement of competition law include the fact that these are, we say, genuine settlements of real litigation which GSK was entitled to bring, and that is no part of the CMA's case to say that we were not.

They expressly allow that GSK was entitled to bring the proceedings. They do not evaluate our prospects and the settlements as we have said many times were carefully structured or tailored to be within the scope of the patents.

In response, we are told, well, you must have known, you had a de facto monopoly for paroxetine and you decided to enter these agreements which would have given rise to less competition than if you had just conceded and let the generics enter, which we do not think is a very powerful way of putting it.

It points to the *Michelin* case particularly for saying that you do not have to find exactly the same features to know that your conduct or agreements were anti-competitive.

The question, we say, is a different one. The question is: was it clear, foreseeable? Must GSK have known or ought it to have known at the time that the form of patent settlement agreement that we entered into would be treated by a competition authority as excluding actual or potential competitors from the market when, as I have already said, apart from anything else, it provides them with supply?

So we say that is an entirely conclusory approach and it is not supported by the *Michelin* case. We quote some relevant paragraphs at 175 of our document, saying that Michelin knew everything, all the factual elements justifying the finding of a dominant position and the assessment of its discount system, which was set up deliberately, and in view of previous decisions of the Commission and judgments of the court, Michelin should have known that this type of discount system would fall within Article 102 as it now is.

It is not precisely the same system, but it was a discount system having relevant features. We say that only exacerbates the problem here, because there plainly was no equivalent decision that we could have had regard to.

It is an entirely different sort of case from *AstraZeneca* when you know you have a strategy which is aimed at keeping generics out of the market. The only question you might have is whether that could have been regarded as an abuse of dominance as opposed to some offence of misleading the patent office or something of that sort, is just no comparison between the two.

We say that the existence of the vertical agreements exclusion order, whether or not we are right about it, the very fact that it was there and the state of competition law in the year 2000 to 2003 was that vertical agreements were excluded, were not thought to be troublesome, exclusive supply, exclusive distribution, exclusive purchasing agreements, were just out of scope of the Competition Act.

The idea now that it should have been obvious to GSK at the time that the CMA 15 years later would see a difference between the GUK and the Alpharma agreements and the IVAX agreement, that is 20/20 hindsight and is completely unacceptable. We also say that the fact that the two generics in question were injuncted and not able to come onto the market on a non-contractual basis when the settlements were set up is a factor going to our awareness whether we ought to have known or must have known that the effects of the agreements on competition were such that, despite their inability to enter, we must have known that we were in some way restricting competition.

We say in short that the CMA is not asking itself the right questions here, and the Tribunal, we say, cannot be satisfied that it was intentional or negligent on GSK's part to enter into these agreements.

MR. MALEK: Mr. Flynn, on your ground 7 points, if we are against you on that, surely all those points would go to what the quantum of the fine should be? If we say it was negligent or intentional, the points you are making under ground 7, would they not be equally valid to make as mitigating points?

MR. FLYNN: I can see that. If you say, taking it at the sort of level of abstraction that the case is put against us, you must have seen that you had a monopoly in paroxetine, after all you had a patent and there was no one else, and you must have seen that these agreements stopped the generics or disincentivised them from coming in and making their own efforts, you must have seen that, and therefore there is an infringement, then I agree. Contextualising these matters back then would also be arguments for reduction.

THE PRESIDENT: You rely on novelty, on level of penalty as well?

MR. FLYNN: We do. We also rely on it on the imposition of a penalty as well, as I will come to. I will finish by 3 o'clock because I know --

THE PRESIDENT: Yes.

MR. FLYNN: Taking Mr. Malek's point entirely as made, we have a ground which has been unanswered in relation to the general principles of legal certainty and of administrative fairness. We are not saying you should imply a limitation period, we are saying that it is a breach of these general principles of law for these matters to have been investigated so long after their commission. You will have seen and understood, I think, many of the difficulties that has given rise to in the present case.

In relation to novelty, and this is in a way the flipside of the intentional negligent point, but it is a separate one, the CMA actually says it has taken it into account but the only way in which it has actually taken it into account is deciding not to increase an already substantial fine.

THE PRESIDENT: Is that quite right?

MR. FLYNN: I believe it is, sir.

THE PRESIDENT: If one looks at that part of the decision, the defining part which we have not particularly focused on so far, which is Chapter 11, I think.

MR. FLYNN: Yes, it is.

MS. DEMETRIOU: Paragraph 11.60, if that is of assistance.

THE PRESIDENT: It starts at step four at 11.50. This is page 472, I think, in the -- I am not sure which volume that is, because I have it separately.

In the decision they talk about step four and they say -- 11.51 -- they might increase it for deterrence, and at 11.52, they say we will also assess whether, in its view, the overall penalty is appropriate in the round, we may decrease it.

MR. FLYNN: Yes.

THE PRESIDENT: So they are looking at it both ways.

MR. FLYNN: Then if one looks at 11.57.

THE PRESIDENT: 11.57 they decide not to increase it.

MR. FLYNN: They have decided to consider it, and they consider an increase and they decide against it.

THE PRESIDENT: Then they consider decrease in 11.60 and they decide a 10% decrease. So they have done what they said in 11.51 and 11.52 they are going to do, and they go on and do it.

It seems to me they are decreasing by 10% because they say they are. You might say that is not enough. I understand that point, but I do not see how you can say they have not decided to decrease it.

MR. FLYNN: That is not, as we read it, done on the basis of the novelty of the infringement. What is done here is taking the lack of finding of this specific form at 11.58, when calculating the penalties, taking it in the round.

THE PRESIDENT: Is not 11.58 novelty?

MR. FLYNN: Yes, so there is no reduction.

THE PRESIDENT: But I mean, surely that is -- you say there is no reduction there. 11.60 says, having assessed the relevant circumstances set out in paragraphs 11.55 to 11.59, therefore including expressly 11.58 and 11.59. 11.58 is novelty and 11.59 is passage of time. That is exactly what they have done, is it not?

MR. MALEK: Mr. Flynn, it is slightly tangential. If you look at 11.59, the CMA is giving you credit for delay but on a limited basis. They are saying, well, it may have increased the burden on you. But is there not an argument that if you are talking about so many years down the line, the deterrent impact and the deterrent's imperative is not strong and that you should have a pretty substantial discount for delay, and not on this sort of limited basis which is saying, well, you know, it would have been more burdensome to deal with the process?

MR. FLYNN: Sir, yes.

MR. MALEK: If you look at the criminal authorities where someone has been convicted of an offence, the court does give and can give quite substantial discount for delay, but it is not on this sort of reasoning.

MR. FLYNN: Yes, sir. We do make specific points about deterrents, given how long this was. While in a way we are being told at that period we committed repeat offences in that narrow period, there is obviously quite a lengthy time since then when things --

MR. MALEK: We are in 2017. We are talking about conduct that really starts a very long time ago.

MR. FLYNN: A very long time ago, as you said, and it is probably only a debating point, but even before the first article of Professor Shapiro in the RAND journals. So we are talking a very long time ago for this theory to be re-engineered onto our situation there when there is no suggestion of a repeat problem.

So this may be another way of saying if that is the reduction, having considered whether actually it should be increased, you know, thanks very much, but that is not a very generous one. That is probably not a legal one. That is probably where we --

THE PRESIDENT: You say given those circumstances it ought to be a more significant reduction.

MR. FLYNN: We say there should not be one at all given --

THE PRESIDENT: I appreciate that point. Assuming there is --

MR. FLYNN: I take your point and Mr. Malek's point. These go to quantum as well as whether there should be a fine. I entirely accept that.

THE PRESIDENT: The novelty point, the pure novelty point on pay for delay, I appreciate you draw attention to other factors like the injunctions and the supply agreements, but the fact, that you also make, that there had been no pay for delay decision, that was also run in *Lundbeck*, was it not? You rely on *Lundbeck* under your ground 8. But it is also relevant to ground 7 in the sense that the General Court were not sympathetic to that argument.

MR. FLYNN: Once again, sir, we would say it is a very different case, and we have made that point.

You can, on the facts found by the Commission and upheld by the General Court -- I know my friends will be challenging that assessment, but as we have said in these submissions, you can characterise that as a market exclusion agreement. They did not have the coverage. They did not have the coverage and they agreed restrictions outside scope and paid large sums of money. So it is a different case.

MR. MALEK: Mr. Flynn, you have a big team. If someone in your team can look at the cases on delay in a more, let us say, general approach and look at whether it is right merely to give you credit for the increased burden on you or should a penalty be reduced merely because it is so many years down the line. Can you look at that and come back to us in reply? I am keen just to get it right. I think there are other cases in other contexts you might want to look at.

MR. FLYNN: I understand, sir, and I am grateful. We will look more generally, and given the time available, perhaps I could just point to the fact that in our Notice of Appeal at 10.25, that is where we set out cases in relation to novelty, including, perhaps the high point being

the *Compagnie Générale Maritime* case where the competition had only imposed a symbolic fine because the novelty of the arrangement under scrutiny. It is a Chapter II, 102 case. Even that was annulled by the General Court. Even a symbolic fine --

MR. MALEK: I have the novelty point. It is the delayed point I need some help on.

MR. FLYNN: I take that on board, sir. In relation to the remainder of the arguments, given where we are, unless there are points that I have --

THE PRESIDENT: There are one or two.

One other thing, in your Notice of Appeal you refer to a number of other cases, and I know it will be said every case is different and so on, but I think in 10.34 of your Notice of Appeal you refer to a number of competition cases and I would find it helpful if you could actually tell us what the percentage was in those cases.

You say, I think it is under (a) conduct -- or lower --

MR. FLYNN: We can provide a table.

THE PRESIDENT: Of what they actually were. You do refer to *Tobacco* and give the percentage there. But on the others I think ...

MR. FLYNN: Yes.

THE PRESIDENT: We do not actually get the percentages.

MR. FLYNN: Point taken, sir, we will do that.

THE PRESIDENT: Yes.

Then if one goes on to your ground 8, which is the calculation details, in 213(3) on page 70, what is the significance of 30th November 2003?

MR. FLYNN: I think that is the date of independent entry post the *Apotex* ruling.

THE PRESIDENT: I thought it was December. It may not matter very much.

MR. FLYNN: There may be an error there.

THE PRESIDENT: It is a date used by the CMA as well. I do not quite understand it. The injunction was only lifted I thought on 18th December, which prevented Apotex coming in. I could not understand where that date came from. The CMA also refer to that date.

MR. FLYNN: Yes.

THE PRESIDENT: So maybe they can clarify. But we could not see what it relates to.

MR. FLYNN: I think you are right that the injunction was continued pending the permission to appeal wrangle.

THE PRESIDENT: So they could not have come in and did not.

MR. FLYNN: So the CMA using that date, it is page 470 of the decision, {V/1/470} and it is footnote 1566. You have the reference.

THE PRESIDENT: I could not see what the basis is for it.
MR. FLYNN: That is the date used.
THE PRESIDENT: The date of the injunction was 18th December. That is right, is it not?
MR. FLYNN: I entirely take your point. That, I think, is correct. We had used the date in the decision for obvious reasons. We would not propose to extend the infringement even for two weeks.
THE PRESIDENT: As Mr. Malek says, we have to get it right.
The other thing I wanted to ask about is paragraph 216. This is on duration, I think, again.
MR. FLYNN: I think it may be the same point.
THE PRESIDENT: No, it is a different point. The third sentence, you say it -- that is the CMA:
> "... relies on the happenstance the generic companies decided to remain bound by the respective agreements until 1st July 2004 in the case of GUK and 13th February 2004 in the case of Alpharma."

But taking GUK, this was not a happenstance, was it? They had no choice. They could not come in before July 2004 because of your contracts and the contracts which you made with them.
MR. FLYNN: I will be corrected, sir, but they all had the ability to terminate once the price had dropped below a certain level.
THE PRESIDENT: I do not think so, Mr. Flynn. If we look at the GUK agreement, which is in {L/8/1}, I think clause 8 of the agreement {L/8/2}, 8(i) says:
"During the currency of the IVAX agreement GUK shall not make, import ..."
So that is the restriction that was tied to the currency of the IVAX agreement, and the IVAX agreement is defined in clause 4. It is the agreement between IVAX and GUK. So that is the agreement that we find at tab {L/10/1} of this bundle.
MR. FLYNN: Correct, it is.
THE PRESIDENT: At tab 10, that agreement on {L/10/5}, internal page 4, clause 4.4, says:
> "In the event that the market price per pack falls below £8.45 ... for at least three consecutive months in the third contract year ... then either party may terminate ..."

Now, the contract year runs from 14th March. So GUK could not terminate before 14th June 2004, in any event, even if there was full generic entry, could they?
MR. FLYNN: I will take instructions, sir.
THE PRESIDENT: That is one of the restrictive aspects of this agreement. It is not actually tied until the first effectively two and a half years, well, two and a quarter years, and that is why

of course it was only in July 2004, notwithstanding the generic entry took place in December 2003, that GUK were still kept out. It terminated as soon as they could.

MR. FLYNN: As soon as they wanted to, bearing in mind --

THE PRESIDENT: They could not let it go on, but they could not terminate it any earlier.

MR. FLYNN: I accept your point because they had the profit guarantee, as has been emphasised against us.

THE PRESIDENT: They were tied in until at least 14th June 2004.

MR. FLYNN: Subject to further instructions, sir, I do not gainsay your reading of the contract.

THE PRESIDENT: I think Alpharma was a bit different. They could give a month's notice, I think --

MR. FLYNN: Yes, I think that is correct.

THE PRESIDENT: -- and did.

MR. FLYNN: They did.

THE PRESIDENT: Perhaps not even a month's notice. Presumably GUK got its quarterly payments on 31st December 2003 and, what would it be, 31st March 2004 under the agreement with you?

MR. FLYNN: Subject to correction I think that is right.

THE PRESIDENT: Yes.

MR. MALEK: Mr. Flynn, I must say I found your closing submissions very helpful.

MR. FLYNN: I am very grateful, sir.

THE PRESIDENT: I think the page limit worked to your advantage.

MR. FLYNN: I shall not take time except to say that in one of the tabs of the UK paroxetine judgments, one finds from Lady Justice Arden possibly the authoritative source of the -- I did not have time to make it shorter -- and it is not, as someone in this court once suggested, Groucho Marx, and it is not Mark Twain; it would apparently be Blaise Pascal -- and we thank you for your assistance in making it shorter than it might otherwise have been.

THE PRESIDENT: Yes, she corrects Lord Justice Jacob?

MR. FLYNN: She does indeed.

THE PRESIDENT: Thank you very much.

I know it is a little earlier, but would that be a sensible moment to take a 5-minute break rather than interrupting Mr. O'Donoghue? We will do that now.

(3.05 pm) (A short break)

(3.10 pm)

Closing submissions by MR. O'DONOGHUE

THE PRESIDENT: Yes, Mr. O'Donoghue.

MR. O'DONOGHUE: Sir, thank you. My co-appellants have kindly allocated one of two graveyard slots for our closings.

THE PRESIDENT: We are ready and eager to hear you.

MR. O'DONOGHUE: I am grateful, but I have not quite figured out whether that is on the basis that I could do less damage during the graveyard or whether it is on the basis I could bring some life to the graveyard.

There are four or five things I want to cover today. The first is the question of the injunctions and delay in the case of Alpharma. The second is something which the CMA has been surprisingly coy about, which is its legal test. The third point is the economic evidence. I then want to deal with a number of discrete legal points which arise from the CMA's closings, and if there is time, although we have heard a bit about it already, I may say one or two things about *Lundbeck*.

THE PRESIDENT: We would be grateful just to clarify with you also the ground of your appeal, which has not been addressed orally at all and which I think you refer to as attribution.

MR. O'DONOGHUE: Sir, yes.

THE PRESIDENT: Because that concerns you only. We have heard a lot about *Lundbeck* from a lot of people, but that is something that only you can and need address because it does not affect anybody else, and it is something we just want to understand.

MR. O'DONOGHUE: Sir, yes, I will deal with that.

THE PRESIDENT: In a sense rather than *Lundbeck*, if there is other points we missed we would like to just go through that and make sure we have understood the points.

MR. O'DONOGHUE: Sir, yes.

Starting with the question of injunction and delay. This is a case where we have heard an awful lot about pay and very little on delay.

If we can start with looking at what the decision says on this point, this is paragraph 1.13 in {V/1/12}. It is the second line. Does the Tribunal have that?

> "Both GUK and Alpharma delayed their efforts to enter the UK paroxetine market independently of GSK."

Now, I will obviously only be addressing the situation of Alpharma, but in my submission it is very hard to understand in any intelligent way in what sense Alpharma was delayed.

Now, just to very quickly rattle through the factual points and the dates. So there is the court ordered undertaking on 1st August 2002 with the cross-undertaking, trial on 9th December 2002, the Court of Appeal judgment *BASF* on 23rd June 2003 which left the first

instance position intact. Apotex's proceedings issued in October 2002, where claim 11 in the Alpharma case, claim 2 in the Apotex case was a live issue. *Apotex* judgment on 5th December. Permission to appeal granted on 18th December 2003 on both infringement and validity, but the provisional interim injunction in place on 5th December was no longer pursued. Then Alpharma terminated the agreement on 13th January 2004 and then entered within a month. That is the factual position.

In terms of what the CMA says about this in temporal and delay terms, if we can go back to the decision, it is at annex D.

This is on page {V/1/616}, it starts at D.69:

> "Neither the GUK interim injunction nor the Alpharma undertaking created an insurmountable barrier to entry ... An interim injunction is, by definition ...temporary ... and the grant of an interim injunction is not based on a determination of the merits of the case."

If we go over the page to D.72 {V/1/617}, the CMA says:

> "Whilst it may have been likely that GSK would appeal ... this was not inevitable.
>
> "Similarly ... there is no guarantee that an injunction or undertaking would have remained in place for the appeal period ... Following the first instance judgment in *Apotex* case, for example, GSK decided not to seek to maintain an interim injunction while the appeal was pending.
>
> "Furthermore, even if an interim injunction/undertaking had remained in place pending an appeal, this would not affect the inherently temporary nature of the injunction ... or the fact that there was the potential ... to enter the market independently ...."

Then D.73:

> "The potential for independent generic entry would therefore have remained... " and so on.

Then just to complete the picture, in closings and this is the CMA closings, paragraph 35, the CMA says {M/6/15}:

> "The interim injunction was a temporary measure pending trial. It did not stifle the subject-matter of the litigation, and, had a further interim injunction been imposed pending an appeal following the substantive decision at trial, it was to be expected that the appeal would have been expedited."

Just to unpack that. In my submission, it is blindingly obvious that GSK would have appealed. They appealed everything. That is what they did. In my submission, it is very

likely that the injunction would have remained in place pending the determination of that appeal.

The reason I say that is, first of all, Alpharma had previously given two undertakings not to enter the market independently. So a third one, or equivalently an injunction, would have been more of the same. There would of course have been a cross-undertaking which would have compensated Alpharma in the event that it was prevented from entering --

MR. MALEK: Surely it would depend on their view of the merits. If they looked at the judgment and it was a strong judgment and they went to proper counsel, proper counsel would give them a percentage prospects, and if the prospects are sufficiently low they may say, well, we do not want to give a cross-undertaking because we will end up paying a lot of money if we lose, as we have been advised we are likely to.

Does it not depend on the terms of the judgment?

MR. O'DONOGHUE: That of course is unknown.

MR. MALEK: Of course it is.

MR. O'DONOGHUE: We will never know. What I am trying to disentangle here is the things we do know and can reasonably infer. I entirely accept that the terms of the judgment, in particular whether it concerned invalidity or infringement, may have a bearing, but it would be my submission that there is a credible case that the injunction would have remained in place pending an appeal.

MR. MALEK: You say that there is a distinction between your hypothetical case and the *Apotex* case where they lost both on validity and infringement?

MR. O'DONOGHUE: Potentially, sir. Again, one cannot be certain as this is a world that never was. But on the *Apotex* point, one difference of course is that *Apotex* was only concerned with a process patent at that stage. There was at least one product patent in the Alpharma litigation at the time.

THE PRESIDENT: Was there? Which? I understood that the amended claim on 31st July or thereabouts relied only then on claim 11.

MR. MALEK: Which is a process claim. That was all that was left, was it not?

MR. O'DONOGHUE: Sir, I may have got that wrong, in which case I obviously accept that. But it was of course a case where the patent was invalidated for the first time, which was striking. Of course, albeit for a short window GSK did have an injunction continued from 5th December to the 18th.

But the critical decision or distinction is the one picked up by Ms. West in her evidence, and of course Apotex by this stage was December 2003, and the point is that, at that stage,

unlike in 2002, there were a number of generics who were clearly on the cusp of coming into the market. As Mr. Flynn said, the decision by GSK not to seek to prolong the injunction beyond 18th December was a recognition of the commercial reality at that stage that things had changed. Because unlike 2002, two or three generics were on the cusp of entering. There was Apotex itself, but more relevantly, Waymade and Neolab.

MR. MALEK: Or it may be because counsel had told them correctly that they were likely to lose.

MR. O'DONOGHUE: Perhaps, but we are --

MR. MALEK: On the *Apotex* case, the reason why, when it came to the Court of Appeal, they dropped the injunction was probably they were advised by counsel that they are likely to lose, and he was right, was he not?

MR. O'DONOGHUE: We do not know. The only evidence put forward in these proceedings was that it was a commercial decision, and that is Ms. West's evidence.

MR. MALEK: A commercial decision probably taken in the light of legal advice. You have had counsel. He has done the trial. You have got the appeal coming. It would be pretty reckless of GSK to make a decision like that without getting proper advice.

MR. O'DONOGHUE: Sir, perhaps, but what Ms. West says at paragraph 104 {E/1/28} of her statement is something different.

MR. MALEK: Right, okay.

MR. O'DONOGHUE: She says:

> "Even if GSK were to be successful in securing extension of the interim injunction of Apotex, it would not apply to any other generic companies at risk. GSK could potentially have sought interim injunctions against all potential entrants. However, even if these had been granted in each and every instance, GSK would have been exposed under cross-undertakings for damages. The potential benefits of an interim injunction were therefore slim."

THE PRESIDENT: I did not quite understand that last sentence, "the potential benefits were slim". I mean, the benefits are everybody is kept out. The risk is you lose at trial or on appeal and then you have to pay them a lot of money. But the benefits are clear, are they not?

Perhaps she means an interim injunction against Apotex, that you would have had to get one against everybody else. I think that is what she means.

MR. MALEK: But she does recognise that she would have been exposed to the cross-undertaking of damages.

MR. O'DONOGHUE: Yes, in circumstances where for the first time the patent had been invalidated, that was a new factor.

THE PRESIDENT: Yes.

MR. O'DONOGHUE: Just to complete the point because in a sense nothing may turn on the injunction, because it is also my submission that Alpharma was highly risk averse and therefore would not have entered at risk in any event. Because the damages exposure faced by Alpharma was asymmetric in the sense that the level of compensation which would have been due to GSK in the event of a wrongful entry would have been far, far greater than any profits Alpharma could expect to make upon entering independently.

In my submission, that in and of itself may have been a further reason why Alpharma was not prepared to enter at risk, even leaving aside the question of injunction.

Now, in terms of timing, so we have the Alpharma trial on 9th December 2002. We would have a judgment, let us say, some time between March, perhaps as late as June 2003. Even if expedited, it is very difficult, in my submission, to see how the appeal would have been resolved by the end of 2003 or perhaps early 2004. We note, albeit on a non-expedited basis, that the BASF and Apotex appeals took 11 to 12 months, respectively.

THE PRESIDENT: They were not expedited because no injunction.

MR. O'DONOGHUE: They were not expedited. In my submission, it is clear in any event that we are talking at most about a potentially very, very short window between the resolution of an appeal in the case of Alpharma and when Alpharma actually entered.

My submission is that it is impossible therefore to see how Alpharma was delayed in any way at all. The CMA's --

THE PRESIDENT: Is this going to the effects case, is it? What you are addressing now?

MR. O'DONOGHUE: It goes to a number of points. It goes to a question of causation as to whether there was in fact any delay at all to Alpharma. It goes to the fundamental question of whether this was really a pay for delay.

THE PRESIDENT: But the object case -- at the time of the object case -- is looked at at the time the agreement is entered into. Nobody would know about Apotex and Apotex coming in and all of that.

MR. O'DONOGHUE: The Apotex litigation had commenced in October 2002. So it was certainly on the radar. But my point is that in circumstances where Alpharma --

THE PRESIDENT: You are right, sorry. Yes, the Apotex litigation had just commenced. But you would not know what would happen.

MR. O'DONOGHUE: No. So my overarching submission is that there is no credible basis on which it can be said that Alpharma was likely delayed from entering as a result of these agreements.

THE PRESIDENT: What you say -- let me make sure I have understood this -- is at the time of the agreement the Apotex litigation had started, Alpharma would not have entered at risk. If Apotex had lost, they would not have entered anyway and when Apotex won they did enter.

But I suppose what might be said against that is the only issue in the Alpharma trial was infringement. So if it had been tried and they had been found not to infringe, then they would have entered irrespective of Apotex. Because it was about their process.

MR. O'DONOGHUE: Of course then we have the appeals, or an appeal. In my submission, any realistic way you look at this, there is no credible case that Alpharma was delayed in any sense in entering compared to what actually occurred under the agreement.

So you have mentioned the point, the agreement was terminated on one month's notice. In reality Alpharma's litigation was tethered in particular to the *BASF* case because it was the molecule supplier and was also in a sense directly related to Apotex because the claim 11 in the *Alpharma* case was claim 2 in the *Apotex* case. So all these were related.

As I said in my closings, Alpharma did not make this product, it was Delta. Delta's API supplier was BASF. In my submission, it is not very surprising that what Alpharma wanted to do was to hold the coat of other people who were fighting, because it was their molecule or their product and it was waiting in the wings.

MR. MALEK: I understand how this fits in with the effects case, but are you saying it fits in with the objects case in that the objects case relies on a pay for delay inference and you say there was no delay?

MR. O'DONOGHUE: It does. The predicate of the pay for delay is that someone has been delayed. A question the President put to Professor Shapiro is that his models assume the resolution of the litigation very quickly.

Now, in this case the ultimate resolution of the litigation was at least a year away. So the inference in the factual, in my submission, simply does not work here. There was no delay.

MR. MALEK: Yes, but the CMA's case is you are being paid off for not coming in on the market independently, and that in itself is what they call delay. You are saying no, they are addressing it from the wrong angle. You have to show that there was some delay and you say there was not any delay; is that right?

MR. O'DONOGHUE: No. I am not positing a counterfactual world. I am saying that in a factual, an unavoidable fact, where Alpharma could not enter and, in my submission, could likely not enter until January/February 2004 in any event, there is no pay for delay.

Sir, moving on to my second topic which is the CMA's legal test. Sir, we picked this up at various places, but the explanation advanced in opening by Mr. Turner -- this is on {TR/3/54}, lines 7 to 12. I do not think we need to bring this up. I can read it.

He says:

> "... an unexplained reverse payment in a patent settlement agreement allows you to infer that this is a deal that disrupts the competitive process. Similar to paragraph 352 of the Lundbeck judgment. If cash is handed over by the originator as part of securing an entry restriction, the inference applies then and there."

Now, in my submission there are four fundamental problems with this as a legal test. The first problem is that if one accepts the submission from the CMA that litigation is merely a competitive process in which the only reason a patentee can make a payment to a generic is if that payment is less than the patentee's avoided litigation costs, anything else is an unlawful bringing to an end of the competitive process according to the CMA, that is true of all settlements in a litigation context because all of those settlements will by definition bring to an end the competitive process.

Now, in my submission, that cannot be a sufficient basis for liability.

THE PRESIDENT: I think it is said it is part of a competitive process in the pharmaceutical industry, litigation between generics and originators, which is echoing the Commission in *Lundbeck*. So it is not all litigation.

MR. O'DONOGHUE: Sir, that is said, but it is very hard to see how that is correct. Because what the competitive process is a proxy for, in the CMA's world, is that as an outcome of the litigation, consumers in terms of surplus are entitled to the same benefits through the litigation as obtained in the settlement.

When one views it in that way, then all litigation in a sense --

THE PRESIDENT: I do not think they are saying that, I am sorry. That is not the way I understood it. I think they are saying it is a way in which generics are competing with originators by challenging their patents, and that this goes on all the time.

MR. O'DONOGHUE: The same is true of any litigation, business to business, in which, as an end product of that litigation, one can posit that consumers in terms of surplus might benefit in some way. Any horizontal litigation involving businesses which one can posit a consumer

benefit as a plausible outcome of that litigation, that is a competitive process they say cannot be terminated. There is nothing special about patent litigation.

THE PRESIDENT: Except that I think you will find that generics, and including some of the generics here, are frequently challenging originators' patents with some success, and that this is a process that is going on all the time in our patent court, in the patent courts in Holland and Germany, and that is not true of other areas of business.

MR. O'DONOGHUE: It is a matter of degree, in my submission.

THE PRESIDENT: Well, maybe --

MR. O'DONOGHUE: Any horizontal business-to-business litigation which one can posit a consumer surplus benefit as an end product of their litigation, that is conceptually identical to patent litigation because ultimately all this is about is that one can posit a drop in prices dependent on the outcome of the litigation.

It is not difficult to think of examples in a pure B2B context outside of patents where that might also be true. All this is essentially a proxy for consumers gaining something as a result of litigation that they lose through the settlement. In my submission, a whole range of B2B litigations, including outside the patent context, are the same.

So if the bringing to an end of a competitive process is a sin, that is a sin which is not confined to patent litigation. On that basis that cannot be a sufficient criteria for legal liability.

MR. GLYNN: I understood that is not what the CMA is saying exactly because they are saying that if it is brought to an end on terms which reflect the probabilities of the litigation having been continued, then they would have no objection to that, as I understand it. It is the value transfer that brings the harm into the situation in their view.

MR. O'DONOGHUE: They do say that because they have to say that. But the value transfer is simply a proxy for a consumer welfare harm. That is all it is. Because you are saying that by being paid money, someone is --

MR. GLYNN: They are saying that --

MR. O'DONOGHUE: -- induced not to continue the litigation, and thereby consumers are deprived of the benefit.

But exactly the same is true of any litigation in which you can posit consumers might gain as an end product.

MR. GLYNN: In which there was an unexplained value transfer.

MR. O'DONOGHUE: In my submission, that is by the by. That is simply a test by which you understand whether the consumers likely lose out from the settlement or not.

The same principle will be true of any B2B litigation where consumers lose out, because ultimately all one is focusing on is the loss to consumer welfare.

MR. GLYNN: Yes.

MR. O'DONOGHUE: The payment is an indicator that that loss is present.

THE PRESIDENT: Is loss to consumer welfare the critical test for an infringement of Article 101, or is it disturbance of the competitive process? You need to show harm to consumers?

MR. O'DONOGHUE: Sir, the CMA has made the point that there is an amorphous concept of a competitive process that can be disrupted, but ultimately if one decouples that from a loss of consumer welfare, it is utterly meaningless because the process does not exist for its own sake.

The process of litigation is simply designed to bring about potential benefits to consumers; in this case, the commonly accepted reductions in prices that occur when generics enter independently.

But it is simply a consumer welfare loss. In my submission, talking about the competitive process as some great beacon that stands apart from benefits of consumers of litigation is meaningless. Now, they have said that in the sense they have to say that, but in my submission it is utterly meaningless.

THE PRESIDENT: They are not the first people to say that, are they?

MR. O'DONOGHUE: Well, apart from *Lundbeck* I am not aware of other cases in which --

THE PRESIDENT: There is quite a lot of authority in the Court of Justice saying that. Of course, yes, it is a proxy in a very broad sense for consumer welfare, but not an immediate harm to consumers, but that over time competitive process is thought to bring benefits. But there are, I thought, quite a lot of case law -- I may be mistaken -- where the Court of Justice has said it does not matter if you cannot show harm to consumers, it is not necessary to show harm to consumers.

MR. O'DONOGHUE: Sir, that is the *Glaxo Spain* case which they mention.

THE PRESIDENT: Well, that is one, yes. But I think (inaudible) from memory, says that. But as I say, I am speaking from memory. I do not think Glaxo was -- the previous Glaxo case, as it were, was saying anything novel in that regard.

MR. O'DONOGHUE: Sir, when one thinks about litigation of this kind where the whole point of the litigation is can someone enter independently and, if they do, it is common ground that there will be pricing benefits, then apart from those benefits to consumers, what are the benefits of that competitive process?

The CMA simply has not answered that. Now, the second related problem is that they say, well, if things are uncertain, by settling you bring to an end the uncertainty. In my submission, that is simply a further manifestation of the same problem. If ending the competitive process in and of itself cannot be sufficient basis for liability, it is very difficult to see how ending uncertainty could be --

THE PRESIDENT: Ending the litigation process.

MR. O'DONOGHUE: Yes, ending the uncertainty that is inherent in that litigation process.

MR. GLYNN: I am sorry to come back to the point, but surely the argument is not that ending the litigation process per se is a harm to consumer benefit. The argument is that ending the litigation process, seeing that as a part of a competitive process but ending a litigation process through this particular means of an unexplained value transfer is where the harm is revealed, and that from that unexplained value transfer we can have a rebuttable presumption or infer, or whatever words you want to use, that there has been an anti-competitive purpose behind it. Surely that is the argument you need to address, not the mere fact of ending litigation is seen as a bad thing?

MR. O'DONOGHUE: In my submission, these are hand and glove because the pay for delay inference, which I will come to separately, all it says is that by paying more than avoided litigation costs, the patentee apprehends that there could be an earlier entry date. What it is paying for is a delay. But all that means expressed another way is that the patentee apprehends that there are consumer welfare benefits that will likely accrue from this competitive process of litigation.

By making the payment, what is occurring is that process is being, they say, short-circuited, and these consumer benefits are being either denied or delayed. But my point is that that type of uncertainty or competitive process is replicated across a large swathe of B2B litigation. That cannot be a sufficient basis for liability. It is simply a wrong legal test.

Now, the third problem with this legal test is it involves a one-way assessment of the competitive process based on assumptions as to probabilistic outcomes of litigation that would involve the generic winning.

This, in my submission, ignores two other important facets of the competitive process. The first is that the fact that there is scope for the generic to settle the case is also a positive part of the competitive process. To maximise the incentives to generics to challenge branded patents generics should be permitted to chose not only when to commence patent litigation, but also when to terminate it and on what terms.

By giving these broader dimensions of options of settlement what you are actually doing is increasing the incentives and ability of generics to compete. The problem with the CMA's legal test is that it reduces the dimensions across which settlement can occur to an extremely narrow place. Essentially, as I apprehend their position, they deal with the easy cases of the two extremes where the patentee is bound to lose or the generic effectively has considered the case, but everything in the middle, which is most litigation, their position is that any payment above avoided litigation costs is either per se or akin to a rebuttable presumption. It seems that short of that the options for the generic are to capitulate or fight to the bitter end.

Now, Mr. Glynn quite rightly discussed the issues of the royalty payment and early entry without a payment.

In this case, first of all, why do we not look at what the CMA says about these counterfactuals in the decision. I do not think you have been shown this before. It is at {V/1/153}.

THE PRESIDENT: You are in the decision?

MR. O'DONOGHUE: Sorry, that is a wrong reference. It is actually in section 7. I think it is 7.150, I think. It is 7.109 and it is page {V/1/385}.

Now, I made the point in my closings that on the two critical parts of the effects case, the counterfactuals, this one is five paragraphs long. So when the Tribunal is thinking about have they discharged their burden of showing a proper lawful counterfactual, this is all we have to contend with.

Now, the critical paragraph is 7.109, and it says:

> "Any such settlement agreement could have taken one of a number of forms (for example, on the basis of an alternative supply agreement, agreeing a date (prior to the date of patent expiry) ... or allowing Alpharma to enter on condition that it paid a royalty to GSK). The CMA is satisfied that the negotiation of an alternative settlement agreement, including more competitive terms, was a realistic outcome in the counterfactual. For example, GUK and Alpharma both internally considered the possibility that a settlement agreement with GSK could include ... a royalty ..." and so on.

Now, that is true as far as it goes, but what this does not say is that the internal consideration given by Alpharma to a royalty was considered so unrealistic that it was not even put to GSK in the context of the settlement negotiations.

So this is a case which, in my submission, all we have in terms of support for a counterfactual in forensic terms is this. On the other hand you have got the record evidence of Dr. Reilly saying they would not have contemplated these arrangements. You have the actions of the generics which gave some internal consideration to a possible royalty, but did not think it was even worth putting to GSK.

So if one is looking at this in terms of a forensic exercise, in my submission there is overwhelming evidence that these counterfactuals are entirely unrealistic.

THE PRESIDENT: This is on an effects case, is it not?

MR. O'DONOGHUE: Sir, yes, it is.

THE PRESIDENT: But on the objects case, it is a bit different, is it not?

MR. O'DONOGHUE: Sir, yes. It may be. The four problems I am outlining apply to object and effect, or object or effect. That is entirely clear.

MR. GLYNN: The question which we were not able to get deeply into, I think, is why the alternative was seen as unrealistic. Clearly it was not put to GSK that the view at the time was they would not have wanted it, so attention moved on the agreements of the sort we have got.

But the question we need to wrestle with, I think, is why exactly that was so. If the reason was one we should accept as a valid explanation for the value transfer, then I would have thought we would go one way on the view we take. If, on the other hand, the only explanation that can be imagined is one which has an anti-competitive purpose, then clearly the Shapiro CMA case would be likely to prevail.

THE PRESIDENT: The other thing is it might have been unrealistic because GSK much preferred, clearly, the form of settlement that it achieved. That paragraph goes on to say that Alpharma did put an early entry agreement and GSK said no way. But if it is known that agreements of the kind that were entered into here are not lawful, then an originator would be prepared to consider alternatives if it wants to settle the case.

MR. O'DONOGHUE: Sir, perhaps. I mean, one comment I would make on Mr. Glynn's question is -- and it is a persistent problem with this case -- it is up to the CMA to establish its counterfactuals to the requisite legal standard. It is not incumbent on us to rebut a mere suggestion that, well, you could have had a royalty. My overarching submission is that based on the flimsy paragraph I have shown you, this does not come anywhere close to discharging a proper burden of proof of their demonstration of lawful counterfactual. They literally say the CMA is satisfied without a single piece of intelligent reasoning.

MR. GLYNN: Could I again ask a little more about that.

One of the counterfactuals is continued litigation, and that clearly seems to be a very plausible starting point. Sometimes it seems as though that was it, that really -- I read -- I understand it to be that the continuing litigation, after whatever time it took, results in either one answer or the other answer. So we have a world in the counterfactual in which we went through a period of time and then one side or the other would win.

The assumption I suppose underlying that is that the patent court would not make an error, and also that an outcome which favoured the originator would be just as competitive as an outcome which favoured the generic, because the court had not made an error and so we are having property rights respected or overturned according to what is in the long-term best interests of the consumer.

So that counterfactual, although it is only briefly expressed, seems to be inherently quite plausible and quite easy to understand.

MR. O'DONOGHUE: Sir, it is easy to understand, but it is even more hopeless in my submission, because all they are saying -- this was the point the President put to Mr. Turner in opening, which has not been answered -- is: it is all very well saying there is litigation which it is possible that a generic might win, but that is no more compelling than saying there is litigation in which the generic might lose.

MR. GLYNN: Forgive me, that is my point, that if you are happy from the public policy point of view with either outcome because patent courts cannot make mistakes, so we get to the right answer one way or the other, then there is no harm to the consumer under either scenario, is there?

MR. O'DONOGHUE: Indeed, and therefore it is not a proper lawful counterfactual because one at least equally possible outcome is that the dynamic process of competition by which patents are held is the outcome of the litigation. So, in other words, the end product of that competitive process of continued litigation is one which GSK gets to keep its monopoly, can continue charging the prices it was charging, because that is the entitlement of the ownership of the patent which has been established in the litigation.

So in my submission, any of the analysis of counterfactual would say, well, they might win, they might lose, is not a proper lawful counterfactual because the counterfactual has to be shown to be a more competitive option than the factual.

With these co-equal possibilities you simply have not done that.

THE PRESIDENT: I think what Mr. Glynn is saying, both possibilities, whichever one it is, are the more competitive outcome which they will not get.

MR. GLYNN: Indeed.

MR. O'DONOGHUE: In a competitive outcome where the originator wins --

THE PRESIDENT: That is a competitive outcome.

MR. O'DONOGHUE: Yes, which will include no generic entry at all.

THE PRESIDENT: Yes.

MR. O'DONOGHUE: It ties in with one of the points I was going to make in context of the third problem, which is the consequence of the strength of the patent may well be that all competition is excluded.

MR. GLYNN: I am sorry. If the patent is strong then preserving the patent is what should result from the competitive process if working properly in a context in which you have patents. It is as easy as that.

MR. O'DONOGHUE: Indeed. Whereas their counterfactual simply expresses this in terms of two co-equal possibilities.

THE PRESIDENT: I think we have covered the point. I do not think we can take it any further.

MR. O'DONOGHUE: Sir, the final problem with the legal test is that -- Mr. Flynn touched on this -- the test is expressed in terms of if the purpose of a settlement is to stabilise the patentee's branded prices, that is an anti-competitive object.

We see this picked up in the CMA's closings at paragraphs 49, 50 and the chart at paragraph 136, which has been reproduced multiple times.

That, in my submission, comes very, very close to saying that any settlement that does not allow independent entry, or allows a generic to distribute unlimited quantities of a patentee's product, is illegal. In other words, the suggestion that not precipitating a fall in the patentee's branded prices is evidence of an anti-competitive object, in my submission is misconceived.

So to conclude, in my submission the legal test applied by the CMA is not a lawful test. It is over inclusive, it would discourage legitimate competition, it would rule out settlement options that are not anti-competitive and it would give rise to a large number of instances of false positives. Certainly in my submission that makes it inherently unsuitable for object classification.

If I can pick up just one quick legal point from the Advocate General's opinion in *Cartes Bancaires*. This is {Auth-H/6/6}.

THE PRESIDENT: Which paragraph?

MR. O'DONOGHUE: I am just trying to find it, sir. It is the sentence:

> "It is not without a danger of the point of view of the protection of the general interests."

(Pause).

It is 54, a couple of pages on {Auth-H/6/9}.

It says:

> "First of all, the method of identifying an 'anti-competitive object' is based on a formalist approach which is not without danger from the point of view of the protection of the general interests pursued by the rules on competition in the treaty."

Should be "formalistic".

The point I wish to make on the back of that is that if one has an over inclusive test along the lines that I have suggested the CMA has in this case, what that does is that it prevents competition in the senses I have outlined from taking place. So it would prevent certain types of settlements, it would be at odds with the notion that the dynamic competition of originators securing their patents is itself a manifestation of competition, and in other words, in my submission, there is a danger that this test is in itself anti-competitive because it is over inclusive.

Now, sir, moving on to my third point on the economic evidence. Sir, this is in large part concerned with the pay for delay inference. I want to take this in two stages, if I may.

The first stage is based on the evidence as it has transpired, and my core submission would be that it should be common ground at this stage that the inference, at least in this case, does not apply.

The second section is if I am wrong about that and I have to tackle the inference head on, then there are a number of other points which emerge.

Now, before getting into the weeds on the first point, a small but important observation in my submission is that there is no reference to Professor Shapiro or his work in the decision. The decision is actually put on a different basis.

Now, if we can start with the object section. This is paragraph 6.150 {V/1/300}. If I can invite the Tribunal to read paragraph 6.150, please. (Pause)

THE PRESIDENT: Yes.

MR. O'DONOGHUE: Sir, the point I wish to make there is that the legal test as now articulated by Mr. Turner in openings, avoided litigation costs, is not something which appears at least in express terms in this object section of the decision.

If I can ask the Tribunal a couple of pages on, 6.164 {V/1/308}. (Pause)

THE PRESIDENT: Yes.

MR. O'DONOGHUE: I think it is over the page {V/1/309}. It is the second bullet.

So it says:

" ... Alpharma's entry onto the market had no discernible impact on market prices ..." That is part of their object case.

Then just to complete the legal test for effect, in the case of Alpharma, it is at page {V/1/359} and it is paragraph 7.66. Again, the Tribunal can perhaps read that at its own leisure, but I make the same point which is that the legal test, as articulated by Mr. Turner in opening, does not appear in this articulation of the effects case.

It is fair to point out that at paragraph 6.115 in the case of GUK, and 6.176 and 6.177 in the case of Alpharma, there is some limited discussion of the question of litigation costs. I have been asked to go to 6.179 as well, again in the case of Alpharma.

So there is some discussion of litigation costs, but it is in a rather different context, discussing a litigation cost along with a number of other items. In other words, if the CMA's test really now is that a payment by a patentee above avoided litigation costs gives rise to a rebuttable presumption for purposes of object and effect, that is not something expressed at least in terms in this decision.

In any event, that is a small point, which is that the pay for delay inference as it has emerged in this case seems to be on somewhat different terms to the decision, or at least is put on a much more pointed basis.

THE PRESIDENT: Although it might be said that the overview at the very beginning of chapter 6, it does not refer to litigation costs but the general approach is very much Professor Shapiro's approach.

MR. O'DONOGHUE: Sir, yes, I entirely accept there is some discussion of litigation costs. But the point is that one needs to infer a certain amount from this decision to get to that conclusion. It is not a major point, but it is a presentational point that, in my submission, is not a trivial one.

In any event, my core submission is that the pay for delay inference as now articulated is not relevant on the facts of this case because it was common ground that if the settlements produced a competitive benefit that was not de minimis, the inference does not apply. It was agreed by the CMA's experts, at least in the case of wholesalers, the competitive benefits were material and they were competitive benefits. They were benefits of competition.

Pausing there. Of course a clear defect in the decision is that those material competitive benefits at a wholesale level simply do not feature in the decision. This is a striking admission given that the joint expert reports accept that wholesalers are direct customers, accept that a material price discount to a direct customer would be a competitive benefit and

accept that ordinarily for direct customer benefits its own direct customer would also benefit too at least to some extent.

If this case were a judicial review, in my submission the decision would be struck down simply on the basis that it failed to consider a material consideration.

Now, this is a merits appeal, but in my submission it would be surprising if the CMA is in a materially better position by not having engaged with this issue at all.

THE PRESIDENT: Well, there is the difference: that we can consider it.

MR. O'DONOGHUE: Sir, you can. My overarching submission is that on that point alone we win.

Now, sir, I obviously in this case do not have an expert. So what I will do is I will give you the references to the CMA's experts where they have accepted the points I have outlined, and in my submission that is the end of the pay for delay inference at least in the context of this case.

So for Ms. Webster it is {TR/11/59}, lines 10 to 32, {TR/11/60}, lines 1 to 18, and {TR/11/61}, lines 1 to 20. For Professor Shapiro, {TR/8/88}, lines 18 to 26, {TR/8/89}, lines 2 to 4, {TR/8/85}, lines 33 to 34 and {TR/8/86}, lines 1 to 10.

Now, what is striking in my submission is that when it comes to closings the only point taken by the CMA in this context is that these wholesaler benefits are not the product of competition. There is no challenge to the point I have just made that their own experts have conceded, that a material benefit to wholesalers arose in this context.

I think Mr. Kon is going to address you in more detail on some of the contours of the wholesaler point. But in my submission, fundamentally it does not matter because it has been accepted that there are material benefits to wholesalers and that they fall to be regarded as benefits to competition.

In my submission, that is obviously a correct concession because if you have a certain material competitive benefit created by an agreement, then the normal thing to do would be to compare that certain benefit to any alleged possible discount.

So there is no complex principle of economics behind this. You have got a bird in the hand offering certain benefits and they are agreed to be material and they need to be assessed by reference to alleged disbenefits because that is the process of finding a restriction on competition.

THE PRESIDENT: Does it work, under Article 101, if there is a by object infringement but it says it brings certain benefits? Do they come in to the initial under paragraph 1 or paragraph 3?

MR. O'DONOGHUE: Sir, in my submission it clearly is paragraph 1 for two reasons. First of all, the point I have taken you to -- let me give you the reference. It is 6.164. So part of the CMA's object case is that Alpharma's entry onto the market had no discernible impact on market prices.

So it is an express part of their own object case that there was a lack of a competitive pricing benefit. Sir, in my submission that makes it unavoidable for the CMA to contend with these benefits in the context of both object and effect. It is part of their case that there were no such benefits.

The second reason, sir, is that in any normal analysis, the way one would test for a restriction of competition by effect is to look at the factual and counterfactual.

THE PRESIDENT: Yes.

MR. O'DONOGHUE: In this case we have the certainty of the factual, and on the counterfactual, as I submitted earlier, we have essentially nothing. We have speculative possibilities, none of which have been calibrated in any way, and in my submission we are not at the stage of a balancing exercise, we are at the anterior stage under 101(1) that a restriction of competition to the requisite legal standard has not been proven by the CMA. There is an analytical failure on their part.

So on both object and effect the material competition benefits to wholesalers are devastating for the CMA's case, even if I am wrong that they have got the legal test wrong for the reasons I have outlined.

Sir, I want to pick up a few quick points, if I may, on how one, in any event, should look at the pay for delay inference in this case, even if I am wrong on the point I have just made.

Now, I could take this very, very quickly. Sir, the first point I wish to make is that there is no general economics consensus that the pay for delay inference is correct and strong as a general matter.

I will take you to one or two points to illustrate this. But the position, as I apprehend it, is that Professor Shapiro and certain other economists think it is a good inference, at least in certain situations, but there is a relatively large body of economic opinion which thinks that the inference's disregard of a series of real world considerations means that it is not even a good economic inference, never mind a basis for a legal rule.

Now, if I can start off at {G4/86/1}.

THE PRESIDENT: You have cited a lot of this in your footnote 49, have you not?

MR. O'DONOGHUE: Sir, some, but I actually want to go to one or two other papers, if I may.

Sir, I am obviously in your hands.

THE PRESIDENT: If you want us to look at detailed academic papers, we are aware that it is a subject that there has been a lot of debate in the economic literature.

But if you want us to read any academic articles, of course we can. I think it is a little difficult to dive into one in brief in closing in this way.

MR. O'DONOGHUE: Sir, I take that point.

THE PRESIDENT: Is this the --

MR. MALEK: Were these the ones put to Professor Shapiro?

MR. O'DONOGHUE: No, they were not.

MR. MALEK: Over and above this --

MR. O'DONOGHUE: No, they were not. Sir, I am in your hands. I hear what you say.

MR. GLYNN: Do give us the other references if you wish.

MR. O'DONOGHUE: I am in the slightly awkward position where I do not have an expert.

There was a hot tub in which a certain number of things were said and conceded which, for my part, without an expert I do not accept. In a sense, what I am trying to do is give the Tribunal a more accurate picture of what I say is the lie of the land.

THE PRESIDENT: Well, if you say there is no economic consensus on it, then see all these articles, I think that is a fair point you can make. We had Dr. Jenkins who was challenging that approach expressly, and we quite understand your clients' involvement and so on, that you did not want to call an expert. I am not sure we can take various articles as sort of a surrogate expert who has not been questioned, and Professor Shapiro did not engage with them directly.

MR. O'DONOGHUE: Sir, I understand that.

THE PRESIDENT: If you wanted to put an article to Professor Shapiro and say, well, look at this, how can your theory stand up with that.

MR. O'DONOGHUE: Sir, we did have limited time to do that.

First of all, sir, I have given certain references in my closings to some of the articles. You can read those at your leisure. But in a sense I am making a more fundamental point, which is that in my submission it is not good enough in a judicial proceeding that an economist comes along with a theory when there are N number of economists all around the world who disagree with that theory to a greater or lesser extent. In the same way that it would not have been sufficient for me to trot out an economist saying: these agreements are legal for the following economic reasons.

One needs to take a rounded view. It is not an opinion poll, but in my submission, the balance of economic evidence is a very, very long way indeed from suggesting that this inference is a robust one.

MR. MALEK: But we had Dr. Stillman and he gave very clear evidence. Certain articles were put to Professor Shapiro and he was able to respond to them and put them in a context which I would not necessarily have picked up just reading the articles.

The difficulty we have is that you are now referring to further articles which none of the experts have relied on and has not been put to the expert. There is plenty of expert evidence to factor into our decision; we are not short of material.

MR. O'DONOGHUE: Sir, I appreciate that. Again, we had a limited window to put these materials. I am in a difficult position not having had an expert and having had limited time. Anyway, I hear what you say, sir, and I will move on.

I do stand by the submission that as a matter of economics this inference is a long, long way from having gained a degree of acceptance that it should even be contemplated as a basis for a rebuttal presumption, still less for an object infringement.

The second point I wanted to make, which is a slightly different point, is that the inferred subjective views and motivations of the patentee on its prospects in the litigation have no necessary connection with the objective assessment of the consumer welfare effects of a settlement.

So the pay for delay inference is that when one sees the payment to a generic in excess of the patentee's avoided litigation costs, you must infer that that payment is buying off an entry delay or other restriction that would not be secured by the continuation of the litigation. That is the inference. In other words, the payment reveals that insight. That is the inference.

But in my submission, you simply cannot assess the consumer welfare effects of patent evidence without some understanding of the probability of generic entry absent the settlement. In other words, a payment reflecting the patentee's subjective views or inferred subjective motivations is not an input into the consumer welfare equation.

It implicitly but clearly assumes that the patentee knows it is going to lose and is prepared to pay more to buy off that probability. But that is not a good inference in the real world because the outcome of patent litigation is not a singular or objective fact and nor, therefore, is settlement value.

It is certainly not to be decisively decided or inferred from the patentee's subjective views.

If I can just pick up one article, if I may, which makes this point rather well. It is at {G4/86/15}.

THE PRESIDENT: There is Dickey, Orszag and Tyson, is it?

MR. O'DONOGHUE: Sir, yes.

MR. MALEK: The Annals of Health Law.

MR. O'DONOGHUE: Yes, sir. That famed publication.

THE PRESIDENT: You say at page 15.

MR. O'DONOGHUE: Yes. So at figure 2 he has what essentially is a version of the pay for delay inference in diagrammatic form.

Then the second sentence:

> "Indeed, what seems to be a clear distinction between pro-competitive and anti-competitive in these diagrams in fact can be quite difficult to distinguish in the real world. Recall that our example assumes a 50% chance that the generic manufacturer will win the patent litigation and that everyone knows that probability. In reality, the precise strength of the patent is unknowable to the anti-trust analyst or even to the parties themselves. It will depend on a wide range of factors that affect the outcome of litigation, including the documentary evidence, the quality of presentations by counsel, the testimony of company witnesses, the testimony of expert witnesses, and the particular judge and jury assigned to the case. Whereas settlements with entry after Year 5 could harm consumers under the assumptions we have presented, such settlements could in fact be pro-competitive if the generic manufacturer's chance of winning the patent litigation was only, say, 30%."

It makes three points. First of all, the pay for delay inference as a matter of theoretical economics may not translate well into the real world for considerations to do with real world litigation. It makes the point in particular that very often one is dealing with something unknowable: who would win and on what terms, invalidity or infringement?

It makes the point, which is the last sentence, that ultimately one cannot get away from the essential question in the litigation, which is patent strength. It is the patent strength which informs and dictates the effects on consumer welfare.

In my submission, this inference is not a good proxy for those consumer welfare effects. It is conflating something subjective, the motivation for the payment, with the objective question of what is the consumer welfare impact of a settlement.

Now, just to wrap up this point. Sir, in my closings I highlighted one of my submissions, a number of surprising implications or features of the pay for delay inference. First of all, it seems that buying off any probability of generic entry under this inference is a problem. Second, it seems that as soon as you have exceeded the patentee's avoided litigation costs, then the level of excess above that does not seem to have any material bearing, which seems surprising, and it apparently takes no account of judicial error.

Now, in the litigation all of you would be familiar with, a very good case is maybe 70% because things can and do go wrong. Where in the inference does this fall to be taken into account? It seems that it is entirely irrelevant. That seems surprising to me.

Now, sir, if I can pick up very quickly three discrete legal points, which is my fourth section.

Sir, in openings by Mr. Turner you asked him for an authority for the proposition that a merely possible counterfactual is a good counterfactual and the answer he gave was that the *Visa Europe* case.

Now, I will take you to one or two paragraphs in that case, but the overarching point is that if it is being suggested that that case for the first time, or at least as a material development, brought forward a new type of counterfactual, one would expect to see that in very clear terms in either the Commission decision or the court's judgment. One does not see that.

In fact, what one sees is something altogether more prosaic, which is the argument made by Visa was, well, the Commission wrongly focused merely on intent to enter, and that is not sufficient as a legal test.

The court's answer to this was short and sweet. It said that was wrong as a matter of fact because in addition to intention, the Commissioner had relied on ability.

At paragraph 173 of the General Court's judgment, which is in {Auth-G/24/49}, the court said that the applicants themselves, as they expressly acknowledged at the hearing, do not challenge the Commission's assessment of Morgan Stanley's ability to enter the market in question.

Not only had the Commission separately analysed the question of ability, but Visa themselves did not dispute that Morgan Stanley had that ability.

Of course, pausing there, the ability of a competitor to enter a market that is not subject to the legal barrier to entry is a very different thing to this case, where the entire object of the litigation is to determine whether there is a legal barrier to entry.

In any event, even on its own terms the *Visa Europe* case does not go anywhere as far as Mr. Turner would have us believe.

Now, two final points on this. The first is the E.ON case, which has been touched on briefly. We can pick this up in authorities {Auth-G/27/1}.

MR. MALEK: Where do you deal with this in your closing submissions, the E.ON case?

MR. O'DONOGHUE: I have dealt with it in openings. I have not dealt with it in --

MR. MALEK: That is why I have not picked it up, that is fine.

MR. O'DONOGHUE: Just to run through very quickly, we can pick this up at paragraph 17 of the judgment {Auth-G/27/4}.

You will see it was a 1975 agreement whereby gas piped from Russia was imported into Germany and France. Then down at 21, there were 13 side letters that went with the MEGAL agreement. Then at 22 and 23:

> "[GDF] undertakes not to deliver or supply directly and indirectly any gas in connection with the [MEGAL] agreement to any customer in ... Germany."

So essentially they were reciprocal non-competes by the German and French monopolists in each other's territories in respect of the gas imported from Russia.

This came to the Commission's attention and they were fined EUR 553 million for market sharing.

If we move on a few pages to paragraph 83 {Auth-G/27/11}, two points were made by the appellants in respect of the French and German markets. In relation to Germany, the argument was that the parties were not potential competitors in Germany before 2000, and in France before 2002.

Then at 89 {Auth-G/27/12} over the page, it says on the French market there was a monopoly de facto until 2003. But the deadline for transposition of the gas directive was 10th August 2000.

Then in 92:

> "Ruhrgas was therefore able to penetrate the French market as of August 2000. The fact that such penetration concerned only a limited group of customers, as is apparent from recital 12 of the contested decision, is not sufficient to consider that the applicants were deprived of a real concrete possibility of entering the market.
>
> "Consequently, the Commission was right to find that Ruhrgas and GDF were potential competitors in the French market as from 10 August 2000."

The situation in Germany was different. We see this at 97 {Auth-G/27/13}. There were two distinct periods, from 1980 to 1998 and from 1998 to 2000.

Starting in the first period, from 80 to 88, there was common ground that there was demarcation agreements which granted exclusive concessions, and these were exempt from domestic German competition law.

Then in paragraph 100 {Auth-G/27/13}, the demarcation agreements:

> "... had the effect of establishing de facto a system of areas of exclusive supply within which a single gas undertaking could supply customers with gas, although there was no legal prohibition against other companies supplying gas."

At 101, this is described as a de facto monopoly.

MR. MALEK: We have the wrong paragraph on the screen. Can you go back.

THE PRESIDENT: 101?

MR. O'DONOGHUE: Yes, 101 to 102, forgive me.

MR. MALEK: Thank you.

MR. O'DONOGHUE: For the earlier period, it was not a legal monopoly, it was a de facto monopoly.

Then at 106 {Auth-G/27/14}, the statement:

> "... that GDF had not only the legal right to sell gas in the territory traditionally supplied by Ruhrgas, but that that was factually possible (despite significant barriers to entry), cannot, as such, constitute a sufficient demonstration of the existence of potential competition. The purely theoretical possibility of GDF's entry into the market is not sufficient to establish the existence of such competition."

In my submission, what we get from that judgment is three things. First of all, where there is a legal barrier to entry there cannot be potential competition. That is the French example.

Second, where there is a de facto barrier to entry, that also precludes the existence of potential competition. Analogy might be made with the injunctions in this case and a de facto bar on entry.

Thirdly, at the very least a competition authority must contend with the existence of a legal or de facto barrier to entry. In other words, it is not sufficient to say, well, there may or may not be a legal barrier, there must be a concrete analysis in the case at hand. That has not been done in the present case by the CMA.

THE PRESIDENT: You are referring to the injunctions now, are you?

MR. O'DONOGHUE: Yes. Because the point put against us is, well, in the E.ON case it was clear that there was a legal monopoly for certain periods. But in fact the judgment is broader than that, and it also deals separately with the situation of a de facto monopoly for a different period in Germany.

So the first argument is simply not an answer to the injunction point in this case. The concept of the non-existence of potential competition is broader.

Sir, finally, the last legal point I want to deal with is the Apple example which was put to Dr. Jenkins in the hot tub. Perhaps we can bring this up just to remind ourselves of what it says. It is {TR/8/54}, internal 52.

THE PRESIDENT: Bottom of the page.

MR. O'DONOGHUE: Yes.

Ms. Demetriou says:

> "Let us say Apple, for example, decided to try to enter the market for cars and Apple had, let us say a 45% chance of entering the market -- of successfully developing a product and being able to enter the market and then Ford paid Apple to stop its efforts and to stay out of the market for cars. In those circumstances too, are you saying that there would be no restriction of competition because the most likely counterfactual is that Apple would have failed to enter the market anyway?"

In my submission, the short answer to that example is the one that Dr. Jenkins gave. This example is not dealing with a situation in which Ford may have a full legal right to exclude Apple's market entry even if Apple otherwise has the ability to enter the market. In other words, even if Apples has the necessary assets and know-how to enter the market, the point of crucial distinction is that there may be a legal right of Ford to stop that entry, and it is dealing with a very different situation in my submission.

THE PRESIDENT: You accept in that example it would be an anti-competitive agreement, is that the point you are making, but you are distinguishing the present case --

MR. O'DONOGHUE: Sir, not necessarily. I think one needs to be a bit more precise. I mean, if it were the example in this case of, say, paying someone not to even obtain an MA, I can see that. But even in a case of potential entry outside of a legal prohibition, there are still further questions to be asked.

Now, the obvious question is: what is the time period in which Apple could enter the market? You have to form a view on that. That has to be proximate in some sense. There are cases, sir, as you will know, in pharmaceutical markets where separate innovation markets are defined for pipeline projects. That may be another assessment. But in any event, the temporal dimension of have they the physical capabilities or technological capabilities to enter plus the temporal dimension, they both have to be contended with.

It may be that if it is very distant, that one is then in the realms of an innovation market, which is a slightly different assessment.

THE PRESIDENT: But if it is three or four years away.

MR. O'DONOGHUE: Then the only option may be to define an innovation market. Because if it is not proximate, then according to the horizontal guidelines it is not potential entry in the legal sense. One can quibble about the time period -- should it be one year, two years or three years or whatever -- but what I am saying is there is a temporal dimension to that assessment that cannot be ignored.

MR. GLYNN: Listening to Ms. Demetriou putting that point I took it that what she was really getting at was making the point that it could be anti-competitive to buy off a risk of entry even if that risk was less than 50%, so you could identify an anti-competitive act even if it was, say, well under half the chance of entering it.

MR. O'DONOGHUE: Put in those stark terms, that is equivalent of burning down their plant. I mean, it may be that the question really is, if Ford were to merge with Apple or to acquire these assets, would one, in the context of that analysis, treat Apple as a potential competitor? My answer to that is it would depend on how proximate their potential entry was.

There may be a fallback position of defining an innovation market if the entry is a long way off. But outside of this purely naked case that, as I say, is equivalent to burning down their plant, one has to grapple with the temporal point and it goes back to the point in this case, that if, in fact, Alpharma would not have entered the market on any view within 12 or 14 months, in what sense has there been a delay or in what sense has potential competition been restricted?

So the Apple example, I say, is not a good example.

THE PRESIDENT: If you say Apple would not have entered for 12 to 14 months, and you make a three year agreement with them not to enter, they will not enter for the next three years; you say they are not potential competitors and, therefore, it is not anti-competitive because they could not enter in the first 14 months of that agreement?

MR. O'DONOGHUE: Sir, I think in that case the objection would be simply to the term.

THE PRESIDENT: Yes. You are looking at the agreement and saying is it anti-competitive? You say it cannot be anti-competitive unless you are potential competitors; that is the starting point is it not?

MR. O'DONOGHUE: Sir, yes.

THE PRESIDENT: Would you regard them as then potential competitors or not?

MR. O'DONOGHUE: The temporal question stands alone. You have to ask yourself, within whatever horizon is appropriate, that may be one year, two years, three years, I accept that,

but within that horizon are they a potential entrant? If the answer to that question is yes, the agreement is clearly restrictive. If the answer to that question is no, it may be that, in your example, sir, the temporal period falls to be adjusted. I accept that.

THE PRESIDENT: But here with Alpharma it was one year, extended for a second year. How does that tie in with your 12 to 14 months for the appeal? I think you said a year for litigation, a year to 14 months?

MR. O'DONOGHUE: Sir, that is a slightly different point. The point I make is that the total duration of the two agreements was about 14 months.

THE PRESIDENT: That is because Apotex won its case, but we are looking at it as an object restriction. It was at one year, extended for a second year. When it was extended for a second year, that took it beyond the period that the Alpharma litigation would have taken on your submissions, as I understand them, even with an appeal.

MR. O'DONOGHUE: Sir, that is where the context becomes important because as I said earlier Alpharma was, in a sense, tethered to the other litigations and the reason it had a provision allowing termination within one month was, the way it put it was as soon as our competitors have penetrated GSK's defences we can enter. That is exactly what they did. In my submission, the presence of a one month termination clause in both agreements was always expected from the outset to lead to a situation in which Alpharma could come in essentially at will.

The way I put this in closings is that it was as if the agreement contained a clause that as soon as a relevant patent was declared invalid or not infringed, Alpharma could enter; it was as if the agreement contained such a provision.

It is within that context that one would have to include an assessment of the clause as part of the object content. It cannot be ignored. That was the express factual context in which Alpharma made its settlement.

Sir, I am conscious of the time. On attribution, in a sense, for my part, I have made a couple of points in my written closings on attribution which the CMA has not responded to. For my part I would rather deal with the CMA's response to those points.

THE PRESIDENT: We have got some questions on those appeals which you have not addressed us on in opening. We have got to deal with that, whatever the CMA says or does not say. I just wanted to understand them.

So if we can look at your -- because it was not really dealt with much in openings either. Really it is the Notice of Appeal that we have got, which is, if we could go please to bundle {A/3/42}. That is I think the relevant part of your Notice of Appeal. You have helpfully

annexed two diagrams, there is annex 3 and 4. Just to be clear where we are. Can I just be clear, in paragraph 113.2 {A/3/43} which is on internal 42, I think in the last sentence, is that an error? For Seroxat you mean paroxetine?

MR. O'DONOGHUE: That should be paroxetine.

THE PRESIDENT: I assumed that but I just wanted to check. Thank you. "Actavis Group hf" that is the actual name, is it?

MR. O'DONOGHUE: Yes, that is the name. It is an Icelandic company.

THE PRESIDENT: If one looks at the agreement that Alpharma Limited signed, the actual agreement itself, which is in bundle {L/11/1}. We know, as far as Alpharma Limited is concerned, that Actavis UK Limited, as represented by Ms. Ford, is the successor, that is the same new company under a new name?

MR. O'DONOGHUE: Sir, yes.

THE PRESIDENT: That is a straight line through, as it were?

MR. O'DONOGHUE: They are the signatory.

THE PRESIDENT: They are the signatory. In clause 7 {L/11/2} (ii):

> "Alpharma is authorised to undertake on behalf of each member in the Alpharma group that no such group member shall make, import, supply ..."

What was the Alpharma Group as at the date of this agreement?

MR. O'DONOGHUE: Sir, it would have included a wide range of other entities, all of whom had essentially nothing to do with human generics --

THE PRESIDENT: They are all being bound through their sister company.

MR. O'DONOGHUE: Sir, yes.

THE PRESIDENT: Is it your submission that it would have included AL Industrier would have been part of the Alpharma Group?

MR. O'DONOGHUE: Sir, yes, they were the ultimate parent company.

THE PRESIDENT: They hold the majority of the voting shares, is that right?

MR. O'DONOGHUE: Yes, it was through the class B shares. Sir, in fact, in *Lundbeck* a finding was made that AL Industrier was the ultimate parent.

THE PRESIDENT: Was it the same relationship there?

MR. O'DONOGHUE: Sir, yes, because it was the same period.

THE PRESIDENT: No. I mean the Lundbeck -- I see -- as regards -- I cannot remember which the company was in Lundbeck.

MR. O'DONOGHUE: It was Alpharma. Well, APS.

THE PRESIDENT: It was Alpharma ApS. The agreement looking at your Notice of Appeal, page 45, paragraph 116(4):

> "Agreements with a value of $5 million or more were subject to approval by the executive ... committee of Alpharma Inc."

This settlement agreement would have needed, is that right, the approval of Alpharma Inc?

MR. O'DONOGHUE: Yes, sir, we have the actual approval at {E2/47/1}.

THE PRESIDENT: Sorry, what is the reference?

MR. O'DONOGHUE: Sorry, {E2/46/1}. It is just one page.

THE PRESIDENT: Okay. So Alpharma Incorporated approved it, and the people who negotiated it with Dr. Reilly -- we saw a lot of documents on that, but there was Torben Laursen and he was Alpharma ApS; is that right?

MR. O'DONOGHUE: That is correct.

THE PRESIDENT: The other one was Brendan Magrab who was Alpharma Inc.

You say at paragraph 126 that Torben Laursen, you say, has a limited role. Then at 127.1 you say Brendan Magrab, the only evidence is he was copied on certain emails relating to the settlement {A/3/48}.

But I thought the evidence was they were the two people who actually met Dr. Reilly and negotiated it, were they not?

MR. O'DONOGHUE: Sir, you are correct that Mr. Magrab met him on at least one occasion.

THE PRESIDENT: When it was actually being concluded, did he not? There are all sorts of sources for this, but while we have this bundle open, if we go in the same bundle to Actavis' Notice of Appeal, {A/4/20} at paragraph 54 she quotes the email from Torben Laursen:

> "Brendan and I yesterday concluded the UK settlement for Paroxetine with Mark Reilly ..."

They are the two individuals who actually made the deal; one from Alpharma ApS and the other from Alpharma Inc.

MR. O'DONOGHUE: Sir, yes.

THE PRESIDENT: They are absolutely central.

What I am trying to understand if the senior executives from those two companies were actually responsible for the agreement -- of course you say nothing wrong with the agreement -- but if one is assuming for these purposes that it is unlawful, what is the legal objection of imposing a penalty on the legal successors on those two companies?

MR. O'DONOGHUE: Sir, I do not have anything further to add.

THE PRESIDENT: Yes, thank you.

MS. DEMETRIOU: Sir, can I check if they are now abandoning this argument because I want to know whether I need to respond to it.

THE PRESIDENT: I do not think it has been formally abandoned, but you need not address it. If you want to say something about *Lundbeck*, we have heard a lot about *Lundbeck*, we have read all the paragraphs and we do feel there are, as it were, bits in it for everyone and everyone is focusing of course on the bits that are most helpful. There are obviously points of distinction. There are obviously statements which have been emphasised quite rightly. There are some points which seem to us to be statements of more general application on pay for delay. There are equally some aspects where scope of the patent test is considered and said not to be critical, but then it is taken into account and so on and so forth.

I think we feel we have heard quite a lot about *Lundbeck*, to be honest, at this point.

MR. TURNER: Fair enough. I sympathise.

Sir, I make two brief remarks, if I may.

THE PRESIDENT: Yes.

MR. O'DONOGHUE: First of all, because I was Mr. Lundbeck for the appellants, I have had the misfortune of having to read all of the judgments apart from the Commission decision.

THE PRESIDENT: We can sympathise.

MR. O'DONOGHUE: I entirely accept Mr. Malek's point that there is something in there for everyone, and in fact, even between the *Lundbeck* judgments there is not full consistency. At times they say different things.

But the two remarks I would make is that to me it is blindingly obvious that in any legal case it has to be contextualised. You cannot pluck a sentence out of thin air, which is what the CMA does, and say, well, look, there you go, that is a basic analytical failure.

The particular objection I have to the CMA's approach is what they do is they make sweeping statements like "*Lundbeck* shows that eliminating uncertainty can be an object" or "*Lundbeck* shows that bringing an end to a competitive process of litigation is an object".

If *Lundbeck* said all of that, we would not have hundreds of pages of judgments. It would be two sentences. In many respects, the submissions made by the CMA in *Lundbeck* really prove too much, because the judgments would have been very short and sweet if they are indeed as sweeping as they suggest.

I think that the fair way to read those judgments is, as Mr. Malek said, there were a series of cumulative factors in those cases that seem to have been important. One can debate in this case which ones were of critical importance, but the ones I would emphasise are there was

overwhelming evidence of patent weakness in that case. There is the point about all of the settlements essentially being out of scope and there was the lack of injunctions.

Of course, *Lundbeck* does not deal with injunctions because they did not arise in that case for decision, but you certainly strongly infer from paragraph 268, the treatment of paroxetine, that they would have considered an injunction as a blocking position and therefore a contrary indication of potential competition.

In that case, as Mr. Turner said, they did not have to decide what the paroxetine judgment meant. But in this case that cannot be avoided because there are injunctions and they are absolutely critical.

The final comment I would make is that particularly *Lundbeck* itself, it really threw the kitchen sink at the appeal. No argument was too small. There is a sense in reading the judgment that having lost on the first ground, they were then on a hiding to nothing on every other ground. The court of course is responding to arguments made and it may be that a particular ground in the context of the facts of *Lundbeck* was not a good point, but I would caution against throwing out the baby with the bathwater and trying to cut and paste those findings to a case like this which, on any view, is much more complex and far less clear cut.

THE PRESIDENT: Yes. Thank you.

MR. MALEK: I have no questions of you, thank you very much. But Mr. Turner, can you look at examples of how courts deal with the situation where a party or his employees have been interviewed under compulsion, but the party does not in fact call that person interviewed as a witness at trial, looking to what extent that party can rely on what has been said in interview as exculpatory?

I am not really interested in the criminal context. I know there are authorities and the principles there are clear. I am really interested in civil context or regulatory context. You may find a fruitful area is insolvency or directors' disqualification proceedings. I am not asking about the pressed point; that is a different point.

MR. TURNER: Sir, we have notified our friends first thing this morning of certain authorities on that point. We can forward to the Tribunal the email giving the relevant paragraphs and propositions.

MR. MALEK: Yes.

MR. TURNER: I will be addressing them in due course.

MR. MALEK: Okay. So you have thought of it anyway.

MR. TURNER: Yes.

MR. MALEK: Thank you.

THE PRESIDENT: If there are additional authorities relied on, if you would like to supply us with copies.

MR. TURNER: Over the weekend we were notified that a group of new authorities were going to be relied on by the appellants. We were going to ask them which paragraphs and propositions in those we need to look at. We have also just notified them this morning, so that these can be uploaded onto Magnum and referred to without difficulty.

THE PRESIDENT: Thank you very much.

I think, Mr. O'Donoghue, you need not be concerned. Our judgment will be, when it is delivered, longer than two sentences in any event, but we look forward to hearing from the other appellants tomorrow when we start at 10 o'clock.