IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

31 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. Turner.

MR. TURNER: Sir, there is only one small loose end from yesterday if I can hand it to the referendaire. You asked me if we knew the Alpharma wholesalers took the same margin after independent entry as they had done before the prices fell.

I said to you I would get you the references afterwards. Those are the references. It is effectively just a one page and a bit note. (Handed)

THE PRESIDENT: Just a moment, let us just read that. Yes, thank you. So that goes into the file. (Pause)

The DHU bundle. Reply submissions by MR. FLYNN

THE PRESIDENT: Yes, thank you. Mr. Flynn, I think you have also provided us with a note?

MR. FLYNN: Sir, yes, we have. That was in response to a bit of homework from you, sir, with a series of starting percentages of various decisions that we referred to. Unfortunately, it has just been brought to my attention that the version that has been put to you misses the footnote, so I think someone, in making a nicer looking table for you, has missed out the footnote, and we will provide a better --

THE PRESIDENT: Is that what the asterisk was?

MR. FLYNN: Yes, that is the question that Ms. Demetriou had for me as well when she saw the table.

THE PRESIDENT: We will park that one --

MR. FLYNN: I will tell you what it says which is that they are, in some of those decisions where you have the asterisk, you will see, to take the first of those, RBS, you will see the percentages 6%, in brackets it says 18, and what the asterisk tells you is that the starting percentage in that case was under the pre-2012 guidance of the OFT, when the calibration was different. So the 6 is what it was then. The 18 is what it would be now under a rather different set of guidelines.

THE PRESIDENT: I see.

MR. FLYNN: Basically the old ones had a maximum of 10 and the new ones have a maximum of 30.

THE PRESIDENT: So for comparison, the one in brackets is the more relevant one, but was not the actual one at the time.

MR. FLYNN: Precisely so, sir. Precisely so.

So we will provide and upload a copy with the footnote, but that is essentially what it says. The other piece of homework, as it were, that we were given was also in relation to penalties, and that was cases in relation to delay at administrative level.

We have found -- I mean, there are basically quite a few in the Community law system and we would not want to overburden you. You were taken yesterday by Ms. Demetriou to cases on a slightly different point which is delay at the level of the General Court and the consequences of that, which is not the point we are on exactly.

There are plenty of cases where the court considers reductions for administrative delays and either agrees with what the Commission has done or disagrees with what the applicants are asking for or not. Two particular ones that we bring to your attention are a case involving the *Heineken Group*. That one will be now found at {Auth-M/7/58}.

At paragraphs 425 to 434 you will see the findings of the court in relation to the principles going administrative delay, and there, in that case, I think we may need to go over the page {Auth-M/7/59}. We will see that the Commission had given a rather measly flat rate reduction of EUR100,000 and the court upped that to a 5% reduction, as you can see at the end of that section, at 434.

THE PRESIDENT: Yes.

MR. FLYNN: That was for delay -- a procedure that took seven years, and that you can find from the opening paragraphs of the judgment at 5 to 9. In any event you will see that there is a seven-year delay {Auth-M/7/2}.

The next case which we bring to your attention, we have to say this is the high point, but that is why we like it, is a case in the EFTA court, at {Auth-M/8/1}. Essentially the EFTA court is applying the same principles as the European courts and indeed as this Tribunal.

This was a seven-year duration as well, and if one looks at paragraphs 275 to -- do you have a hard copy of this?

THE PRESIDENT: I do not think we have hard copies yet.

MR. FLYNN: That may not have reached your bundle. I will give you the reference for your note.

THE PRESIDENT: Anyway we can see it on screen.

MR. FLYNN: You can see them on screen and I think they will then be hyperlinked from the transcript in due course. It is {Auth-M/8/1}. There you see the case and the relevant page starts at {Auth-M/8/56}, paragraphs 275 to 286.

There if one goes down, one follows that through over the page {Auth-M/8/57}. So the court finds for various reasons that the delay is excessive, as you see at 282. At 284 you see that the Competition Authority, the EFTA Surveillance Authority, ESA, reduced the fine by 1 million in that case, which is, they say, a discount of around 7.2%.

There is then consideration of the European Court of Human Rights authorities, if one goes over the page again {Auth-M/8/58}. You will see the court reduces the basic amount fined by 20% in that case, saying that an effective remedy requires a substantial reduction of the fine well beyond the Surveillance Authority's assumptions.

Those are two cases illustrating both the principles in, we would say, a generous application.

THE PRESIDENT: They are dealing with the length -- I have not had a chance to study either of those carefully -- but the length of the investigation period, is it, the investigation proceedings taking so long, as opposed to the time since the actual infringement?

MR. FLYNN: In both cases that is true. They are looking at the start of investigative proceedings by the Authority in question. In our case, these agreements have been under investigation for a very long time but by two Authorities, starting with the European Commission, resulting from the dawn raids in the pharmaceutical inquiry back in, I think, 2005.

THE PRESIDENT: Were they actually being -- did the Commission actually start an investigation into these agreements or was it a sector enquiry?

MR. FLYNN: They had the sector enquiry, and they took cognisance of these agreements, and then they passed the matter on to the CMA in 2010.

THE PRESIDENT: But the sector enquiry could not result this any penalties as such?

MR. FLYNN: Not as such, but it could lead to proceedings being started, and that is indeed how I believe the *Lundbeck* case started, and the *Servier* case started.

THE PRESIDENT: Yes.

MR. FLYNN: What we understand is that the file was then passed on to the CMA in 2010.

THE PRESIDENT: Or the OFT as was.

MR. FLYNN: I am sorry, indeed, to the OFT. Each time we make the point that, at that point, the European Commission was time barred under the rules applying to it. That is commented on in the CMA's documents with a reference saying "(they say)". As far as we can see, that is in fact the case, the Commission was time barred. Since then, it has taken another six years plainly to reach a decision. Nobody is saying this is not a difficult case but the procedures have been characterised by the sort of chopping and changing of legal analysis, as to whether the Chapter II infringement was in or out; the basis for any Chapter I infringements changed substantially between the Statement of Objections and the supplementary Statement of Objections; the change of position ultimately on the vertical agreements' exclusion order having been maintained through two Statements of Objection and so on.

MR. MALEK: Did GSK ever make submissions to the OFT or the CMA complaining about how long the whole process was taking?

MR. FLYNN: We have had a penalty hearing and of course, indeed, at the oral hearing after the reply, the Statement of Objections, these points would have been made.

MR. MALEK: But at the earlier stage, were you complaining, saying: you are just taking far too long to resolve this whole thing.

MR. FLYNN: We did and if you require references to those, I will --

MR. MALEK: I think it would be useful just to see if there is any correspondence. If we are looking at the two periods, one is: has the administrative procedure taken too long; that is in 2010 up until 2016. Two is, as the President has pointed out, is there just -- a long time has been taken since the events in question. That in itself may be a mitigating factor, irrespective of whether or not the OFT or the CMA have taken time.

MR. FLYNN: Precisely, sir. The OFT/CMA procedure has taken six years. We have said this is a long time, but we have always said it is a long time in the context of something that goes back to 2001/2002. I entirely see there are two different points, and almost in their nature, the cases at least that we have been able to find do not concentrate on the administrative procedures of the Authority beforehand, rather than the fact that however -- with whatever diligence they were pursued, the events themselves go back a long time. But plainly they were a long time ago and the court has the point, and the court has a wide discretion in relation to these matters.

MR. MALEK: Do you have any particular submissions as to how long you say the OFT or the CMA should have taken from 2010 to reach the stage of a report or decision?

MR. FLYNN: I can perhaps put it the other way. We say it has been very burdensome for us dealing with the shifting parameters of the case, and we have had to respond to two substantial Statements of Objections. There was a point when the question of a Chapter II infringement was said to be not within the OFT's administrative priorities. It was then apparently reprioritised. You know, we have made representations about the difficulties these have caused.

MR. MALEK: I understand you have made representations about the difficulties, and we are fully aware of the data problems, but are you going to make any submission as to what you say would have been a reasonable time from 2010 to reach the stage of a report or a decision?

MR. FLYNN: I think not more than we already have, sir. I say the six years is complicated because of the -- not just because of the problems it causes us for data, which you do well

understand, and access to personnel, but because of the changing nature of the legal case and economic case that we have had to meet and that has inevitably taken a long time. I do not know what a reasonable time would have been, but it has been six years in this case to reach a decision.

MR. MALEK: You say it has not taken a reasonable time, but you are not able to give me a figure as to how long it should have taken, is that where we are?

MR. FLYNN: I hesitate to give you a figure that we have not given as far as I am aware, of a reasonable time. I mean, a three-year period one could understand, possibly a four-year period one could understand, or at least would not be out of lines; it is hardly greased lightning but these are complicated matters.

THE PRESIDENT: Just to be clear. When you said six years, the formal investigation started in August 2011. I am just trying to see where the -- where you --

MR. FLYNN: I do not know if the Tribunal --

THE PRESIDENT: -- where the 2010 -- it may be when they got filed but when was GSK told, "We are investigating this matter"? I mean the fact they received a file from the Commission, they might have spent some time thinking about it or whatever, or not dealt with it immediately, but as far as your clients are concerned, when were you notified that we are investigating?

MR. FLYNN: August 2011 was the first that GSK knew about it.

THE PRESIDENT: August 2011.

MR. FLYNN: That it was in the hands of the OFT.

THE PRESIDENT: Yes.

MR. FLYNN: As you can imagine, there is a lengthy correspondence. I am told that, having not remembered it, that there is a chapter in our reply to the Statement of Objections, chapter 11, which deals with that and that is to be found in the bundles, should anyone wish to consult it, at {A3/46/1}. I think chapter 11 starts at 312.

You see the summary. (Pause)

THE PRESIDENT: Yes, we can read that.

MR. FLYNN: As I say, that was the first Statement of Objections. There is then of course a second one which --

THE PRESIDENT: Yes. Then we get the administrative proceedings and we can get the dates for that.

MS. DEMETRIOU: Sir, sorry to interrupt, just for your note it is dealt with in the decision at annex K, starting at K.14, just so you have that reference, it is at {V/1/685} of the decision. That is where the CMA addresses these arguments.

MR. FLYNN: That is helpful.

In our Notice of Appeal this is addressed at paragraph 10.54 to 10.56, I think it is, which is {A/2/229} in Magnum.

THE PRESIDENT: Yes.

MR. FLYNN: Sir, I think that probably gives you the references.

THE PRESIDENT: Thank you very much. We will look at that. We have got those two cases.

MR. FLYNN: Thank you.

Just while we are on penalty, perhaps I would just make a couple of further points. I mean, in the same way as Mr. Malek has just put to me, the fact that as well as the administrative delay at this end, as it were, we are really talking about facts going a long way further back than that. I think the point is already made, a rather commonsense point, about the passage of time and deterrence and we have made submissions and describe, I think it is summarised in our closing submissions, about the overall approach to deterrence being confusing, we would say, and incoherent in the decision.

You will see that in paragraphs 221 to 228 of our closing document.

The examples of that are that the 15% uplift that was given by way of specific deterrence for the Chapter II penalty in paragraph 1171 of the decision takes account of all GSK's financials, as it were. But they are the same under Chapter I where the CMA had said that no applicants specific deterrence --

THE PRESIDENT: Yes, I think I asked Ms. Demetriou about that.

MR. FLYNN: Yes, and I think we have also made the point that the CMA says that a fine for either of the Chapter I agreements, as calculated, would have been sufficient to deter, and those, of course, are both considerably lower than the Chapter II fine, even before the uplift.

So we say there is an obvious point to be made about deterrence in relation to matters that happened 15 years ago, but also the decision's own approach is a puzzling one.

In relation to novelty, we had an interesting discussion the other day in relation to the 10% reduction at paragraph 1160 of the decision, when I was questioned both as to whether that was on the grounds of novelty, and whether it was on the grounds of administrative delay.

We say it is plain, and it is plain on the pleadings, that the CMA says this case is not novel. So novelty is denied.

The 10% reduction that was given is for the reasons set out in the calculations in annex P to the decision, page 706, which makes it clear that it is on the grounds of proportionality or specific deterrence, which is the box that it falls in.

It is certainly neither for novelty nor for administrative delay. The case law on novelty, I took you to hardly at all in my closing address, as we were pressed for time at that point, but we set them out, as you know, in paragraphs 10.24 to 10.28 of our Notice of Appeal, which includes the *Compagnie Generale Maritime*; case which I did mention, where the Court of First Instance, I think it was at the time, annulled even token or symbolic fines that the Commission had imposed.

Novelty goes to both the question of whether there should be a fine at all, and to the proportionality of any fine that is imposed, as we have explained in our closing. I refer you particularly to paragraphs 190 to 193 and 229 of that document.

I think I should also say that we are not barred from making points on novelty in any sense by the *Lundbeck* judgment, when we are saying, and I think it is actually pretty clear, that on the facts this is a different case from that with which *Lundbeck* was dealing.

We address that at paragraphs 204 to 207 of our closing document. Lastly, I think since I sat down on Monday, there has been some discussion of duration in relation to the period or expected period of the interim injunction, and so I think that is a point which has been taken. That is a point that we make and I think was raised by you, sir, in discussion with, I think, Ms. Ford --

THE PRESIDENT: Yes.

MR. FLYNN: It is not something that came up in my address, but is a point we make in our Notice of Appeal and which is covered in our closing document.

Turning away from penalty, I was not going to say very much more on market definition, which we had quite a discussion on in my closing, and again with Ms. Demetriou yesterday.

Simply to say that we have the bridge analogy and one of the questions was: what happens when you are on the bridge going from, let us call it an SSRI market, to a world in which your particular product is genericised, or the originator's product is genericised?

We say, on either side of that bridge and even if you wanted to define, which we say would be wrong, the market after genericisation as a molecule market, you are most unlikely to find that the originator is dominant in an open genericised market.

So the peculiarity of the CMA's approach here is that you have a sort of transitory dominance while you are walking over the bridge. The reason for that absolutely plainly is so that they can examine certain types of conduct through the optic of the Chapter II

prohibition, and that seems to us unprincipled, because we all know non-dominant firms can engage in conduct like setting up patent thickets and so forth, that dominant firms cannot. You do not need to appeal to a regulatory gap sort of argument here, because it has been admitted and it is plain that the Chapter II case here is essentially a Chapter I case. Just in terms of how you do define the market, we remain, we rest our case on the evidence of Dr. Stillman and his market definition reports, which show, if you apply the test of substitutability, therapeutic substitutability as your starting point, that there is an SSRI market; that the market is at least as wide as we have said, as SSRIs as we have defined that.

All of that is simply ignored by the CMA's approach, but actually was not ignored by the Commission in *Servier* where they likewise looked at their guidance and treated substitutability at the therapeutic level as the fundamental starting point.

The references, I do not think we need to go there, I think we may have been taken to it yesterday, but if one looks at paragraphs 2413 to 2417 of that decision, you will see that that is what the Commission did, then looked at differentiated products and one can see, in a case like *AstraZeneca*, you might say to an extent these two types of drug do the same thing but very differently, for different levels of the spectrum. So the *AstraZeneca* analysis seems to us conventional.

The bundle reference to the *Servier* decision is, as the President knows, it is volume 11 in the hard copy and it is {Auth-F/17/1}. I think those paragraphs will be found on the Magnum system {Auth-F/17/609}. That is, I think, all I wanted to say about the Chapter II case.

If I can turn to the evidence in the case, because there have been discussions about that, and who should have called whom and was there a problem in the fact that one or other party has not.

We find it strange that this is a point of debate, firstly, when so much of our evidence has been for forensic reasons, or I do not know, but simply marginalised or ignored by the CMA. If one is on the issue: should you be looking at the NHS when you are thinking about the effects case in particular, but not only the effects case does it go to; Dr. Stillman was not cross-examined. He put up his NHS flag a couple of times in the hot tub, but he was just not tested on that at all, and neither was Mr. Horridge, the person -- if anyone in these proceedings knew anything about how the NHS reimbursement scheme worked, it was Mr. Horridge (not cross-examined).

On the issue of patent strength, the CMA did not want to cross-examine Ms. West. Eventually they did and we are delighted that they did, but we were told that that evidence was neither here nor there.

If you want to know what the effects of GSK's move to the DTP system were, that is in Mr. Heath's evidence. He has not been cross-examined. On market definition and dominance you have Professor Young, one of the most distinguished people in the field of neuropharma psychology or something of the sort --

THE PRESIDENT: I do not think this criticism was directed particularly at GSK. In one sense, one witness perhaps, but it is not a --

MR. FLYNN: I understand that, sir. I do really want to emphasise that large parts of our case are there, they have had fragmentary airings --

THE PRESIDENT: Yes, as I say -- your evidence is in -- several of your witnesses, including Professor Young, are not challenged.

MR. FLYNN: Yes, I just make that point that --

THE PRESIDENT: But they were available, so as I say, there is no criticism.

MR. FLYNN: I am making a slightly different point, sir. I do not need to belabour it, but there are large parts of our evidence that have not really been heard in the room, and that I think is potentially not necessarily a problem, but it puts a bit of a burden on the Tribunal, because the evidence has not had an airing, has not had a kick around but it is --

THE PRESIDENT: No, we have not lost sight of it, do not worry.

MR. FLYNN: I am quite sure of that, I simply say in a way it adds to your burdens and it has skewed somewhat the debate which we have had in this room.

The cases that the CMA pointed to in relation to failure to call witnesses all really seem to go to cases where the OFT had been criticised for not calling witnesses and trying to use, as it were, untested statements on the files on an inculpatory basis --

THE PRESIDENT: There was also a criticism of Tesco, but I really do not think you need to address this because it does not concern you. I think you should move on, Mr. Flynn.

MR. FLYNN: I say no more than, at the end of the day, the factual disputes as to who said what to whom in any of the negotiations are, in fact, to be resolved as we have always said, on the documents on the Commission's -- on the CMA's file.

THE PRESIDENT: I think that is what we will look at.

MR. FLYNN: In relation to that, can I just make quick points on each of the generic companies with whom we engaged.

THE PRESIDENT: Yes.

MR. FLYNN: In relation to IVAX, the CMA's case now seems to turn on Tillomed, and what is essentially said is the fact that they signed those heads of agreement and ultimately another agreement under which they would not have to pay anything unless they actually got anything from Tillomed, that establishes that IVAX had opportunities; now, we say that does not meet the legal test, the burden of proof, showing that they had real concrete possibilities of entering the market independently.

It has certainly not been established that IVAX would have entered at risk or litigated, and the fact of the matter is, despite the -- some obscurities in whatever was going on in the state of Denmark at the time, Tillomed did not have a product. I think I slightly overstated the position, perhaps more than overstated the position in saying that GSK was off the market in Denmark. I think I misunderstood what Mr. Bell was saying in the witness statement that we referred to. He said they ceased, as you would in the genericised market, promoting.

So it was still being sold but there were lots of other suppliers on the market because there was no patent protection. The fact that one of those suppliers to the market encountered a problem and approached GSK for supply on a sort of temporary commercial basis does not seem to us to make a difference, and by no means establishes that that led to anything that IVAX could possibly have imported into this country. So we say the case is simply not made out in IVAX.

In relation to Generics UK, and obviously this will be as much for my friends as for me, but you put to me, sir, and I had forgotten when I was standing up on Monday, that the GUK agreement was a three-year agreement and it did not have the clause that the others do that it comes to an end when the price dropped. I recognised the point. As I said at the time, your construction of the agreements is correct.

But just to contextualise that, because the question arose, I think what you are saying, and I fully understand the point, is why did GUK lock itself in for three years when the BASF trial could have gone the other way and the patent could have been knocked out?

I think it is important to realise and to remind oneself that, at the time of the settlement, GUK was facing litigation under the hemihydrate patent as well. It was stayed, but GUK was also facing that and if you -- I do not think we need to go to it necessarily, but in our skeleton, if one looks at paragraphs 2.171 to 2.175, you will see the facts in relation to that and that also the hemihydrate issue was very much one that was operating on the mind of Mr. Urwin and where he was advised by the otherwise generally very optimistic Mr. Rosenberg, that that would be a difficult one to knock out, if you recall.

The evidence is canvassed in our skeleton, so there were two things operating on their mind at the time of settlement. So the BASF trial was not the only thing that was, as it were, bringing them to the table. Can I just point out also that under the agreement, while it does not have the price drop clause, it has clause 11. This is perhaps worth just having a quick look at that for what it is worth. That is in bundle {L/8/3}.

This clause says that if the IVAX agreement is terminated, and the IVAX agreement could be terminated by effluxion of time or otherwise, but that would include the fall in prices, so it would be likely to happen on independent generic entry, either party can then restore the litigation.

Now, if independent generic entry had been caused by a knock out of the validity of GSK's hemihydrate patent, which did happen later on --

THE PRESIDENT: The IVAX agreement of course is the agreement between GUK and IVAX?

MR. FLYNN: Yes, it is.

THE PRESIDENT: It could not be terminated on the independent generic entry, that is the point.

MR. FLYNN: I am sorry, we are talking about -- the point you are making, which is a correct one, is that the GUK agreement was for a three-year period. If the --

THE PRESIDENT: Well, no, it is for three years, and it could not be -- the restriction was tied to the IVAX agreement in clause 8.

MR. FLYNN: Yes, and by --

THE PRESIDENT: The IVAX agreement cannot be terminated on independent generic entry until after three months into year three.

MR. MALEK: IVAX agreements are defined in clause 4.

THE PRESIDENT: That is point 7. Clause 8 and 11 go together.

MR. FLYNN: I may be making a bad point, in which case I apologise, but my understanding is the IVAX agreement could fall away. The fact that --

THE PRESIDENT: If it could, then I am making a bad point, because clause 8 is also based on the IVAX agreement.

MR. FLYNN: Yes.

THE PRESIDENT: So clause 8 and 11 are just the same in that regard. The restriction in clause 8 on your independent generic entry is for the currency of the IVAX agreement. The liberty to restore the litigation under clause 11 is after the IVAX agreement has terminated. So the two are the same, the same point. The IVAX agreement is, I think, a three-year agreement, is it not?

MR. FLYNN: If you look within that tab at {L/10/1} in that file, that is the IVAX agreement.

THE PRESIDENT: It is a three-year agreement, clause 11.1. It can be terminated for material breach, but otherwise it continues subject to clause 4.4, which was the clause I was talking about {L/10/8}.

MR. FLYNN: Clause 4.4 is the market price --

THE PRESIDENT: That is right, and it is only in the third contract year. That was the whole point.

MR. FLYNN: Yes.

THE PRESIDENT: I do not think clause 11 of the -- is any different from clause 8.

MR. FLYNN: Then if that is right, then I am making a bad point. If the GSK/IVAX arrangements fell away, if IVAX was no longer taking supply from GSK, then, at that point, as a matter of practicalities, GUK would have the option to call its bluff on the patent litigation, depending on the situation at the time.

In any event --

THE PRESIDENT: If IVAX no longer gets supplies from GSK, then GUK is entitled to get them itself from GSK. That is clause 5.1. So it has covered itself fully. So it is not dependent on IVAX getting supplies from GSK.

MR. FLYNN: But in any event -- and history shows that they did stay in the arrangement until the end of that period, as you pointed out.

Of course, at that point GUK is on the market, it is supplying, it is an established generic supplier in its own livery and so forth and it can price as it wishes, it may have turned out to be a bad financial deal for GSK and a good one for GUK.

THE PRESIDENT: It certainly terminated as soon as it could.

MR. FLYNN: It terminated at that point because at that point it no longer had the profit guarantee.

THE PRESIDENT: Well, it terminated at the first point contractually it was able to do so. For what reason it did, bar a few weeks --

MR. FLYNN: One can imagine financially why that was, it was unlikely it was going to get another deal like that. If the market price --

THE PRESIDENT: It did not have to terminate, but it could have --

MR. FLYNN: GSK did not have to continue it either. So I think there is no renewal obligation. I think one can see why it terminated.

THE PRESIDENT: Okay, shall we move on?

MR. FLYNN: Yes. The only point I was going to make in relation to Alpharma, which just covers off another point which I think did come up in discussion, which is was it all

inconclusive at the time, because the Delta tests, you could not tell what was going on and I think you referred to Ms. West being in that position.

I simply point to paragraphs 2.245 to 2.253 of our skeleton which show that on the Alpharma side, when they got the results, the suggestion was that the product was infringing, and the idea of a subsequent inspection at BASF was a matter of concern for them rather than a matter of reassurance at that point.

That is the point that is made there.

THE PRESIDENT: Yes.

MR. FLYNN: So for that reason in relation to Alpharma and for the additional hemihydrate reason that I have given in relation to GUK, we say that it was the strength of our patents that brought them to the table looking for a settlement, not the other way round, of a settlement buying off a challenge to a weak patent. Indeed, as you said yesterday, I think, sir, it is not really appropriate to characterise it as a reverse payment case, which I think is itself a point of some analytical importance.

Let me just say a few words about the strength of patent point, because while we have said all along if the legal test is uncertainty, we were uncertain, of course, we do not accept that that is the legal test. We do think that it is open to the Tribunal, and we would ask the Tribunal to consider a finding that goes beyond uncertainty.

We have consistently said that we express confidence in our patents and a view that we were not confident in -- not going to win, but confident in was the consistent position and consistent with all the contemporaneous evidence. As we have said, a suggestion that that is not the case, really does put the truth of Ms. West's evidence, both written and under cross-examination, in doubt and we do not believe there is any basis for that to be done.

The CMA says wrongly --

THE PRESIDENT: Look, I am a bit concerned about this. You seem to be going back and forth on this point. I thought in answer to questions from Mr. Malek during your substantive submissions -- during your closing, rather, this is now your reply, but in your closing, you agreed that you were content with the position that it was uncertain, that you were cautiously optimistic, but one does not have to go beyond that, and that is the basis also on which Mr. Turner then addressed it.

If you are now going back on that saying, no, we should find that you were confident that you were going to win, which is rather more than cautiously optimistic, then we are going round in circles, and it opens the whole question of what actually was the advice you were getting.

MR. FLYNN: I hope we are not going round in circles, and we have said in our closing document, and you will have seen that, it is at paragraphs 24 to 27 that that is how we put the case. It is a finding going beyond mere uncertainty, it is a position of confidence, aware that litigation is always uncertain and that GSK faced downside risk. Absolutely aware of that.

MR. MALEK: But, Mr. Flynn, we went through this and you gave a clear answer both to the President and to myself on this. If you look at the transcript from {TR/14/8}. I summarised it at the end, I said:

> "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."

You say:

> "No. Whatever anyone might have felt at the time, Ms. West or anyone else, that is not the case that we are making here." {TR/14/9}

MR. FLYNN: Yes. We are certainly not asking for the Tribunal to say that we would have won. That is definitely not the position. We are saying confidence -- cautiously optimistic, which as we said in the closing documents, is where you want to be, going into a trial, we do not think this is a more measured position than has been put forward before.

MR. MALEK: For me, for my part, the terms of the agreement, the day before the trial do not reflect a huge degree of confidence that you were going to win. If you want us to make findings as to what the probabilities were, we may have to.

I thought we had come to a sensible position on Day 14.

MR. FLYNN: Well, sir, our position is as stated in the closing document. We are not suggesting that the Tribunal should say we were bound to win. This is a question of --

THE PRESIDENT: Well, not bound to win, even probability, what the probability was of you winning.

MR. FLYNN: This is a question of GSK's beliefs and views expressed, and it is mirrored by the position of the generics with whom we settled; the contemporary record suggests that they were worried about the trial and that we were confident about the trial.

THE PRESIDENT: We will make our judgment on the contemporary record of the generics, but as far as your client was concerned, which is -- and what findings you are asking us to make regarding your client, there is a distinction between saying you are asking us to find that your client felt that they were probably going to win, or that they were, you can say cautiously optimistic, but well aware of significant risks. Not just the ordinary litigation risk of the trial going wrong, but that there were real problems in the case.

MR. FLYNN: Sir, this may be terminological. I am certainly not saying we are asking you to even estimate the probabilities of what would happen in the trial. We have always said that is beyond anyone now. That question is moot. But the main point is we do say it is not -- well, legally, as you know, it is not enough to say uncertainty, and you have the contemporaneous evidence, and you have the views that have been expressed to you in witness evidence and in cross-examination, and in circumstances where we were approached by the generics for settlement, rather than on the sort of case where on a true weak patent case, it happens the other way round; we say there are conclusions that you can draw that are stronger than in other possibly cases with which we are being compared, and we say the position of confidence expressed is there, and it is borne out by the contemporary documents on both sides, on both sides. I hope we are not going round in circles. I do not apprehend that we made no -- we have changed our position on that. We have tried to be consistent.

We just say that the uncertainty level as a legal standard, as much as anything else, is a banal, uninformative matter. All the litigation -- there is very little litigation that I have ever been involved in, the present cases excepted, where we were talking about anything other than uncertainty. It does not tell you anything very much.

Can I say a couple of words. I am conscious of the time, and I do not want to take the Tribunal's time up with points --

THE PRESIDENT: Also bear in mind, you are taking time from other counsel, other parties represented if you go on too long.

MR. FLYNN: I am well aware of that, and I will not be treading on their toes, and I will be told if I have.

There was quite a bit of discussion both with me and with others, I think, about the possibility of a royalty settlement. The essential point is that this is not a matter which the CMA has demonstrated was a realistic possibility in this case, and we stand by what we said in our Notice of Appeal in relation to that.

So, the royalty as an alternative can only in this case be approached at a theoretical level. There is some evidence that internally a couple of the generics were considering royalties amongst a variety of other proposals, but they were not discussed with GSK, and for reasons which -- Dr. Reilly I think has been consistent about this, letting any third party on to the market would, he thought, be a signal of weakness. Of course if someone offered him enough money on a royalty, he might consider it, but that never happened, and I think that is probably an example of an unbridgeable gap.

Particularly when, if you had no limits on the volume, that would put the originator in a position of considerable uncertainty, and as he pointed out, GSK had a factory more or less devoted 100% to Seroxat production. So there were various matters that would have been of concern to him, even if a royalty had been under discussion, but it was not.

I perhaps do not need to go over again but it does seem to us unsatisfactory that when we and others of my learned friends explained that, in relation to the inducement, the CMA's decision precisely does turn on an inference, and uses the word "inferred" in relation to the expected returns from the market of the generics being what they might have hoped to get from it discounted by litigation probabilities, neither of which elements of the calculation are suggested; you can see that, I will just give you the reference because I think you have had them before, paragraph 6.114 of the decision and 6.178; that is the Alpharma one. Each contains a footnote, respectively footnotes 935 and 1037 which explain what the expected returns are, and the inference is clearly drawn in that paragraph.

Although one can see other --

THE PRESIDENT: Sorry, the second footnote reference? 935 and 1037?

MR. FLYNN: Footnote 1037 which is in paragraph 6.178.

Frankly, we still do not know what the inducement or being bought off test is. There has been plenty of discussion of it, but no precise definition is given in the decision. They were new terms in the decision, not ventilated in either of the Statement of Objections, and we have had submissions on the type of inducement that was found in *Lundbeck* where the autonomous assessment of the patent issues was, as Mr. Kon told you, eclipse. So completely overborne.

MR. GLYNN: If I may, on the inference point, the question to you of what was the explanation for the value transfer was clearly put a number of times. Could you re-capitulate or say at this stage clearly what is your explanation for the value transfers?

MR. FLYNN: We deal with this it firstly in our Notice of Appeal at paragraphs 525 to 543, saying that estimating what the value is under an agreement is a difficult process. Parties have various elements that they value, and it is a little hard to deconstruct that, as it were retrospectively, by simply looking at individual elements and checking their labelling, which is what has been done here.

We say that the -- however you calculate the value transferred under these agreements, and there is some cash and there is some supply, and you have seen how we calculate that, and we say that 75% of the value is the supply, where you can just take the cash amounts and

the value of the product. We say 75% of the value actually transferred as the supply agreements.

You have to compare that, and there has been some discussion of that, against the downside risk that the originator was facing over the life of the relevant patent, which in this case would be the hemihydrate patent, because that was the one that was coming up to expiry first, so you have got a sort of five-year period of money at stake for GSK.

MR. MALEK: But, Mr. Flynn, do you agree that in the absence of you agreeing not to have independent generic entry, you would not have had the value payments stipulated in the agreements?

MR. FLYNN: What we say is, as it were, this is a tautology, but the settlement is the settlement, and of course that included that they came in, but on terms, and of course that is -- the agreement would not have been done if there had not been something of mutual value to each party, and plainly not having full independent generic entry and abandoning the patents was a matter of value to GSK. That is, as it were, obvious.

As I have said to you before, sir, this was a compromise. It gave each party something of what they were hoping for. It was neither complete exclusion nor complete open entry. It was entry on terms, and it gave GSK something, and it gave the generics something, and we said you cannot just look at the amounts and see whether they were labelled "marketing allowance", or what they actually -- you know, you need an economic assessment; if you are going to say there has been a value transfer, I think, Professor Shapiro would say that too, you have to do a complete assessment of the agreement to work out what is, as it were, explained or unexplained. We say the explanations are not just confined to the labels that are put on the cash payments, because that does not tell you what value GSK is getting from the agreement.

Matters such as, as Dr. Reilly always put it, preserving the integrity of the patents and ability to assert them in their jurisdiction against others, an ability meant with the knock-on effect of showing that GSK has confidence in similar patents in other jurisdictions, avoiding the price referencing matters; there are a whole lot of things which are there which plainly do give value to GSK which -- you cannot just treat it as a simple: how much cash did they pay and what was that for?

The real comparison is against what was at risk over probably a five-year period, and when you make that sort of comparison, the amounts paid under any individual agreement may seem a lot less stark than if you lump them all together and say: how much did that represent by reference to GSK's Seroxat profits; which is what is done in the decision.

THE PRESIDENT: When you say a five-year period, why a five-year period?

MR. FLYNN: Well, I take that as a -- the five-year period from 2001 is the five years during which the hemihydrate patent still had to run.

THE PRESIDENT: But the agreement only precluded in GUK's case that they would not challenge for three years. You did not get any assurance that after the three years, they would not.

MR. FLYNN: No, but that nevertheless gives you a measure of the value, if that is the right term, that GSK had at stake. It did not --

THE PRESIDENT: That is the value it had at stake, but it is not getting -- being protected by the agreement. It is only three years of that, five years of being protected.

MR. FLYNN: In the GUK agreement and less for the others. It was not full protection. It is a compromise arrangement which, subject to the GUK wrinkle that we have discussed, was actually designed to fall apart in the event of genericisation, which everyone had in mind. This is not -- this is why we have always said these are narrowly tailored agreements. They give something to each party.

If I may, this may not be the moment, but they give something to the consumer as well. Mr. Glynn has put the illuminating comparison, the litigation can go either way and either way is a good thing, as it were, because the consumer -- it is a good thing if the patent is upheld, because patents have value for consumers, and it can be a good thing if patents are not valid and therefore the market is open.

It was put to you by Mr. Turner, I think on Tuesday, that this is a deal which cuts the consumer out of the picture and denies the consumer any share of the -- I probably should not say it -- but the pie. We have heard lots of talk about the pie, but this is probably a different pie.

In our submission the consumer is not cut out of this picture. The whole debate comes, because the pay for delay exerts, if I can put it that way without disrespect, can only see consumer value in basically immediate generic entry and the full price that you have seen on so many graphs.

These agreements were something between the two, both because they preserved the possibility of generic entry coming in later and -- I am probably approaching the end of my time -- and because of the supply arrangements. Because they did lead to generic entry, in substantial quantities, with all the benefits that I think are now beyond dispute, which we summarise in paragraph 4 of our closing document, with benefits for the NHS, wholesalers benefiting, that is undoubted and Ms. Webster accepted that at least. Reductions in prices to

pharmacies. We know they may have been squeezed at the other end but we know this is not a case about pharmacists' welfare. And a substantial improvement in quality overall, and that, Professor Shapiro accepted when I cross-examined him. The quality improvement related to a much larger chunk of the total market than any quibble one might have as between Seroxat and the authorised generics.

I think that was, if I may say so, somewhat overplayed in our discussion because the evidence of Mr. Sellick was plainly going to the contrast between Seroxat and parallel importers.

So it is true, there might be some patients whose condition means that it would be a problem for them if they were given something other than the branded Seroxat at their pharmacy, but frankly, if that is their condition, the doctor is likely to prescribe Seroxat. So that, I think, is much less of a quality issue, and we know that the authorised generics displaced not just when Alpharma came in but right from the beginning, started eating into the GSK share. That is what those graphs show. Right from the beginning. If they took share from GSK, you might say, you might quibble about a quality issue there, but the real issue is that was done on price.

So that is an increase in competition and for all those reasons -- I mean that is, of course, the main reason why we say this case is entirely unsuitable for object treatment, because you cannot assess an agreement, or the agreements that you have before you, on an ex ante basis, knowing that they have a propensity to -- whatever the *Cartes Bancaires* phrase is, and Ms. Kreisberger will put me right on *Cartes Bancaires* but knowing that they have this inherent propensity to harm competition. You cannot know that in advance.

It is not just a question of experience, although there is very little of that about. It is also actually understanding how these complicated agreements work; and these are not classic pay for delay, which so much of the discussion has been about, pay for delay. One can see it is intuitive, the simple intuitive proposition with which the CMA's skeleton opens and which is based on the early writings of Professor Shapiro.

Of course that is intuitive, but it is actually wholly different, when what you have got is an agreement which allows entry on terms in meaningful -- at meaningful levels; establishes new competitors in the market and so forth. It is wholly unsuitable for object characterisation and no proper effects case; no proper economic understanding of the nature of these agreements has even been begun, never mind established in the case in front of you. There is simply no attempt to understand these agreements or pose a realistic counterfactual. Because I probably am --

MR. GLYNN: I am sorry, there is one question I really would like to hear on briefly. The CMA case talks about the locus of competition and analyses issues quite often in terms of the competitive pressure that the arrangements were put on GSK who -- some -- the benefits you have just been talking about in a way would not put so much competitive pressure on GSK as otherwise. I would like to hear you, if I may, for a few minutes on the locus of competition, the dimensions of the competitive process which you believe the Tribunal should be attending to.

MR. FLYNN: Well, the effect on competition, in our case, that we have put forward, this is the unheard bit of Dr. Stillman if you like, that you should look at this in terms of the effects on the consumer, which is the patient or the person who pays the patient's bill, essentially the NHS.

We know that the NHS benefited from these agreements. One can see -- it is a nice phrase that Professor Shapiro used -- the locus and focus of competition being at the pharmacy level, but as I have said I think more than once in these proceedings, the pharmacists are really just a step on the way in a regulated market between the prescriber and the patient, and we are not concerned with pharmacists' welfare in this --

MR. GLYNN: I think the reason why Professor Shapiro put it in that way was that he thinks that that is the level at which we can best see the competitive constraints on GSK. That is why, as I understand it, the CMA and Professor Shapiro were using that as the locus of competition. That is the point I would like to hear your comment on.

MR. FLYNN: Yes. GSK through these arrangements plainly lost volumes, and had some pressure put on its prices, and we cannot overstate that, because it came out in the 1 to 1.5% range.

But to say that, as has been said, that all GSK is interested in is the price of Seroxat, seems a little odd when it actually lost a considerable amount of volume through these arrangements, and we say that is the result of competitive pressure put on it by the introduction of new competitors into the market. We have already had the discussion before, sir, you and me. As you said, these substantial volumes came in and one might have envisaged more of a fight with the parallel importers. That was not a matter under anyone's control. As it happens, they did not like what they saw and they seemed to have folded their tents. But those are competitive constraints which, looking at it ex ante, could have played out in a number of ways.

I think it is again a compromise settlement agreement. It is not as much competition as they would have faced on full independent generic entry if they had capitulated, settled their

case, abandoned their patents, and of course it is a lot more competition than they would have had if they had won and led to the desirable result of that.

So it is a compromise between the two. Where exactly you put the dial, I think we do not know because that has not really been examined.

Sir, I see the time.

THE PRESIDENT: You need to wind up because there are --

MR. FLYNN: I will wind up. I have two very short points, having been given the opportunity to --

THE PRESIDENT: Another five minutes.

MR. FLYNN: Yes, I will do it in less.

The first of those goes to exemption, the question of exemption and having put in all the material that we have, we say the evidential burden, any evidential burden is discharged. The CMA bears the legal burden of showing an infringement. Under the pay for delay inference itself, one has to ask whether the agreements led to the introduction of competition before you can even determine whether the value transfer is the same as cash. If you have not got a pay for delay inference capable of being drawn, we are still, as it were, in Article 101(1) territory and where the burden is on the CMA, and the burden has not shifted to us under exemption.

That is consistent with the approach that Professor Shapiro has put forward in his framework of reference. The only other point that I wish to just say a couple of words on, sir, was the issue of the possibility of a reference to the Court of Justice --

THE PRESIDENT: Yes.

MR. FLYNN: -- where we entirely understand why you suggest that and what the temptations are. Could I just make a few points from our perspective on the other side of the balance sheet, as it were.

From our side we, and I am speaking only for GSK obviously, we would prefer a full judgment on this. It has been going on an awful long time, and we recognise there are risks in asking for a judgment, as in any litigation.

THE PRESIDENT: But if you have a judgment against you, you are not undertaking that you will not appeal?

MR. FLYNN: I beg your pardon?

THE PRESIDENT: If you got a judgment against you, you are not undertaking that you will not seek to appeal?

MR. FLYNN: Certainly not, sir.

THE PRESIDENT: So it may go on for quite a bit longer.

MR. FLYNN: It may go on for longer, but we would prefer it to go on with crystallised facts.

THE PRESIDENT: We will make findings of in fact anyway, we will crystallise the facts.

MR. FLYNN: I understand absolutely where you are coming from on this, sir, and I am simply making a couple of points. We do think it is possible for you to take a view, as it were, on *Lundbeck* which we think is a very different case, and you are able to apply the *Cartes Bancaires* and other criteria to the different form of alleged object infringement that is in front of you.

From our perspective, a full judgment would also have the benefit of a ruling on penalty, which would inevitably have to wait, I think, for a return from the Court of Justice otherwise. So those are reasons why, from GSK's perspective, they are not entirely enamoured of a reference that would lead to us possibly being linked with the very different *Servier* case. Just in case, I just -- sorry, the *Lundbeck* case.

My other point is simply because it was floated at an earlier stage was whether there should be any inclusion in any possible reference of matters arising from the *Servier* decision, and we would say that really -- we would very much not -- our view would be entirely adverse to that as a possibility.

We consider that the effects case and the market definition case are matters which you are well able to decide for yourself, and you should not be inhibited by a decision which does not bind you, and where the appeal process is simply only at the beginning with a hearing for *Servier* alone as I understand it, and not even the generics. So you would be ahead of an unappealed -- or a decision where the appeal has not been determined. Those are the points we would make in reply.

THE PRESIDENT: Thank you very much. We will come back in five minutes.

(12.00 pm) (The short adjournment)

(12.10 pm)

Reply submissions by MR. O'DONOGHUE

THE PRESIDENT: Yes, Mr. O'Donoghue.

MR. O'DONOGHUE: Sir, we are following the same order as closings. I hope to be pretty brisk.

THE PRESIDENT: We made no ruling because we assume you are grown up enough to agree between you how to share the time. We assume some arrangement has been come to.

MR. O'DONOGHUE: Yes, sir, we are all grown ups. I hope to be half an hour. I think Mr. Kon who is next will be about 40 minutes. Ms. Ford has put in a bid for around 15 minutes and Ms. Kreisberger, I think, around 30 minutes. I hope on any view --

MR. MALEK: I was worried we might be sitting here at 5 o'clock.

MR. O'DONOGHUE: We may even have an early bath.

Now, sir, I wanted to cover a small handful of topics, first on the legal test, but before I get into the weeds on that, let me start with a few basic but important propositions.

Sir, the first proposition is that settlement is overwhelmingly in the public interest, and the entire direction of travel under the CPR with mediation, alternative dispute resolution, through successive reforms has been to encourage, facilitate and increase the scope for settlement in civil litigation.

We say that patent litigation in that context is a fortiori because it is complex, lengthy and very expensive. The third point is that a reduction in the scope for settlement will certainly, and certainly very likely, lead to reductions in innovation by both patentees and generics. It is the point I made in closings, that if you narrow the dimensions of settlement, particularly along the compass the CMA has now indicated, in my submission it follows that there will be less scope to settle, and there will be less scope for both innovators and generics in their own innovative way to settle.

Now, the fourth basic proposition which I will come back to is that in a case like the present one, where the generics have not entered, and they have a cross-undertaking in damages, they have a claim to damages in principle.

That is why the CMA was quite wrong from the outset in its skeleton to characterise this case as a reverse payment case.

That claim, as I understand it, has now effectively been withdrawn, at least expressed in those terms. So, in principle, generics of the kind in the situation of my client have a right to damages in the litigation.

THE PRESIDENT: They have a contingent right.

MR. O'DONOGHUE: It is a contingent right.

THE PRESIDENT: Just like the patentee has a contingent right on that basis. Each are contingent on the other, are they not?

MR. O'DONOGHUE: Perhaps. But in a situation where they have made preparatory steps, and they were prevented and then benefited from a cross-undertaking, that is something they can in principle collect on.

THE PRESIDENT: Only if the patent is invalid.

MR. O'DONOGHUE: Perhaps, but what I am really addressing is the settlement context, where the discharge of that claim in damages is under discussion. Then subject to a hopeless case where the generic has no chance, in principle they can collect something.

THE PRESIDENT: Yes.

MR. O'DONOGHUE: I will come back to that. Now, on the CMA's legal test, they have slightly pivoted in my submission. So when they opened, it was all about Professor Shapiro, and avoided litigation costs being presumptively unlawful.

Now, the only thing I have got to say about that is that, if that is their position, it is an extraordinarily narrow approach. Now, in the present case, it would mean that in circumstances where GSK was making £51 million per year in profits, the maximum that GSK could pay to any generic in a settlement was £2.2 million, because these were the litigation costs found by the CMA.

Sir, for your reference, it is decision 6.115. Now, in my submission, that cannot possibly be correct. It is extraordinarily narrow. Now, the second way Mr. Turner has put the case, more in closing it has to be said, is that the payment is unlawful where the originator is making a payment to remove that risk or uncertainty which may have resulted in the public benefit. This is {TR/16/10} lines 10 to 13. I do not think we need to turn that up. On Day 17 he described this as "suppressing the possibility of a public or consumer benefit".

In my submission, there are clear problems with such a legal test in the context of settlement. At its most basic in the garden variety case, it means that even a patentee with a strong case cannot settle with a payment to the generic defendant.

In patent litigation a defendant in the position of my clients will not settle unless it gets some compensation for giving up the chance in the litigation, and in particular, as I said, where they have a claim in damages.

But that is the very thing which the CMA's legal test says is illegal. Now, I certainly stand by GSK's submission that that test expressed in those terms is wildly over-inclusive, because essentially all the CMA admits of is that the two extremes of the hopeless patentee case and the hopeless generic case -- we can all agree on that, that is blindingly obvious, one is *Neolab* and the other is the category A settlements under the pharmaceutical sector report.

In that large middle, which is the garden variety of cases, the 70/30 case that the President put to Mr. Turner, there is a fundamental difficulty with settlement under the CMA's legal test.

Now, that certainly captures pharmaceutical patent litigation. In my submission, it would capture patent litigation more generally, and I did make a submission in closings which I apprehended the President was not entirely persuaded of, that actually in commercial litigation on a business-to-business plane, where you can posit that consumers might stand

to gain something from the litigation, that sort of principle may have some traction. I do not wish to labour that but it seems to me that in principle that could apply by analogy.

Mr. Turner is a very skilled and seasoned operator. He again tried to soften that position in closing, because he said: we did not just do Shapiro and we did not just say that eliminating uncertainty is illegal; we undertook what he called a meticulous factual examination in this case and from that examination we found out something else.

Others may touch on this. I am not going to say much more than the following: the consideration that he took you to, frankly, are the normal things you would see in settlement.

We have had this mantra of making the numbers work. Now, in my submission, in every settlement involving commercial parties, it would be extraordinary if they did not consider whether the numbers would work.

So the kinds of things that you were taken to, and which were alluded to, are the banal, prosaic normal things you see in any settlement of this kind.

If that is to be the gravamen of this legal test, then it seems to me that a lot of settlements will be condemned. There is nothing remarkable in anything you have been shown to suggest that this is so out of the norm that it merits legal condemnation, never mind as an object infringement.

Now, one of the things that I was thinking about overnight is: well, assume you get the phone call in a settlement of this kind as an adviser, what would you do? Now, according to Mr. Turner, what you need to do is, you are presented with a settlement of complex litigation; you have to interrogate all of the contemporaneous documents to find out things like inducement and so on; you apparently need some insight into what the decision-makers on the generics' side were factoring in when they thought to settle. That already seems to me quite difficult. But in addition, it also seems that for the other party to whom you have no access, you also need to understand what was the contemporaneous position on their side, what was in their mindset.

It seems to me -- well, obviously the consequences of getting this wrong are enormous. In this case, it would be a quasi-criminal sanction and object condemnation. I was thinking about this last night and this morning.

It is not a phone call that I would like to get, and I suspect if I was going to get them, I would be contacting my professional indemnity insurers. It is extremely difficult in my submission, in real time, other than to give the cowardly advice that you cannot settle;

apparently that is not the CMA's position, it is all fact specific; but when you think about this in practical terms in the real world in real time, it just does not work.

In particular, to suggest that that type of assessment done by an adviser with limited time could have the downside of not identifying an object restriction, it seems to me very, very harsh.

Now, Mr. Turner, I think realising the extremity of his position, has tried to soften it in yet another way. So this is the large, unexplained payment. Now, on that, I have got a couple of points to make. The first point is that, in my submission, that is an unlawful attempt to reverse the burden of proof. Whereas in this case the generic has a contingent right at least to damages, there is in principle in my submission a legitimate explanation.

In those circumstances, it is up to the CMA to explain why whatever payment is observed is large and unexplained. The second point is that the CMA's test of large and unexplained is itself unexplained.

Mr. Glynn asked a very direct question of Mr. Turner a couple of days ago: well, big compared to what? What is the metric the CMA is using? Now, the best they have come up with is to cobble together IVAX, GUK and my client and say: well, in a given year, that is 37% of Seroxat profits.

In my submission, that is a misconceived approach. The correct approach, certainly for my client -- to turn it another way, at the time IVAX was settling, it had no idea that GUK and Alpharma would be on the scene, so how on earth are they expected to factor in the proportion of 37% that is specific to IVAX?

Now, all my client knew is that it was settling with GSK. Now, in terms of the metrics, let me give you one. So the CMA says that the value transfer in this case for Alpharma was £11.8 million; we do not accept that, we think that double counts to the supply agreement, but let us assume against me on that. On that basis, back to my £51 million per annum on profits, that equates to about a 20% chance of losing the litigation.

Now, on the basis of that payment, it strongly suggests that GSK was very confident in its patent position and that Alpharma was not in a good position.

To me, in my submission, prima facie, that payment is neither large nor unexplained. It is the case of course that £11.8 million is a lot of money to anyone in this court, and from Mr. Turner's protestations about his indentured service with the public body, it sounds like he would be the most deserving candidate if £11.8 million were to be given to anyone.

THE PRESIDENT: Not so much from your perspective.

MR. O'DONOGHUE: I wish. I would not be slogging on my feet today if I had such a EuroMillions win. But there we are.

Anyway, in absolute terms, yes, that is a lot of money, but relative to £51 million per annum of profits, it is not, and it translates into a prospect of success, in my view, that is overwhelming in GSK's favour.

Now, a further point on large and unexplained being unexplained is, Mr. Turner was asked very directly by Mr. Glynn: well, apart from litigation costs, what else would be an explanation? Mr. Turner more or less point blank refused to answer that question. The answer he got was: well, on the facts of this case, we do not accept that there are other justifications.

Now, I infer from that that the explanations that the parties had incomplete or different information, that they had different views on prospects, that there was some level of risk aversion, that there were spill-over effects in other products and countries, that they had different risk profiles, there was concern about judicial error; as I understand Mr. Turner, all of those explanations would be inadmissible under the legal test.

If that is correct, or if some of it is correct, again, that legal test as the basis for settlement is extraordinarily narrow indeed.

So that is the first point on the legal test. I want to turn to the question of the existence of patents. Now, the CMA's position is that the patent position is neither here nor there. But, in my submission, the patent position is the elephant in the room in this litigation.

It is an unavoidable one in any competition law assessment of the settlement, because the only logical basis for an objection to the settlement is that it avoids the patent being defeated and therefore the generic coming in. That is the deprivation of the consumer benefit. Now, I see the President is looking at me quizzically. I want to be clear what I am not saying.

I am not saying that this Tribunal needs to engage in a specific assessment of patent strength. I am not saying there should be a mini trial, the *Durkan* approach that was mentioned in the *Actavis* case.

What I am saying is that directly or indirectly, certainly for an object case, the Tribunal needs to get some handle on at least inferred patent weakness, because in my submission, the only sensible or intelligent explanation for an object case is that an otherwise weak patent is being propped up.

It is in that situation that consumers are deprived of the benefit. So that is sort of what we are aiming at. Now, with that broad framework in mind, in my submission, there are a number of consequences that need to be borne in mind in that context as well.

The first point is the point I think I touched on in closings, which is that the probability of the generic ultimately winning is not a singular objective fact known with any certainty by both parties if they settle before trial.

It depends on an awful lot of different considerations. Now, if I can just bring up one document. I think it is the only one I will refer to. This is the Court of Appeal judgment in the *Apotex* litigation.

It is {D/9/5}. Sir, this is the judgment of Lord Justice Jacob in the *Apotex* appeal, where he found that the patent to be valid but not infringed.

If I can start at 14. On the construction question he expressed the same view as Mr Justice Pumfrey did, that these patents present formidable problems of construction. If we can move on a few pages to paragraph 47 {D/9/14}. There, sir, you will see -- I mean, there is a whole series of paragraphs from 47 to 50. Essentially what Lord Justice Jacob did in that case was to re-evaluate the expert evidence at first instance. Then at 59 a couple of pages on {D/9/16}, he says:

> "I am well conscious that in so holding [on the expert evidence] I am differing from the Judge on a question of expert evidence ..."

That was an unusual case, perhaps, in which expert evidence, having been heard at first instance, was effectively overturned on appeal, which in principle should be limited to a point of law.

The simple point I am making is that, if you were GSK or Apotex, having read this judgment, you might be forgiven for not predicting how the appeal eventually turned out. You might be forgiven in a future case involving Lord Justice Jacob for building in a Lord Justice Jacob discount factor.

THE PRESIDENT: You are not asking us to make that point.

MR. O'DONOGHUE: Sir, no, you have enough to deal with. I make the simple observation which is that in complex litigation of this kind, there can be highly unexpected ways in which the case is resolved.

That does factor into: what is in the mindset of the parties at the time they settled? It is a point I put to Professor Shapiro which is: what Lord Justice Jacob did in a sense was unknowable ex ante.

Now, because of this, this does mean that at best, all one can do is infer from various indicators. I make the simple point that that is not optimal clearly, and certainly is not optimal in an object case under Article 101.

THE PRESIDENT: It was pretty clear on --

MR. O'DONOGHUE: The infringement side was clearer, yes.

THE PRESIDENT: The infringement point was pretty strong, the *Apotex* case, they did not have much trouble with that.

MR. O'DONOGHUE: No, I accept that, sir.

I do accept that there may well be rare cases in which patent weakness is manifest from contemporaneous documents. I stand by the submission that *Lundbeck* in fact is such a case. The playing the losing hand slowly, in my submission, that is about as clear as it gets. But those cases would be rare, and plainly this case is not one of them.

THE PRESIDENT: I mean, if you are making a general point, in a lot of patent litigation, this is a complex field and the outcome will be uncertain, so there will be a lot of cases that are neither at one extreme or the other. I think that is common ground at least it seems to me, not something you need to push hard at, it is well established.

MR. O'DONOGHUE: Sir, I am grateful.

THE PRESIDENT: If that is the point you are making.

MR. O'DONOGHUE: I am building up to my real point.

THE PRESIDENT: We do not need to get into the details of the *Apotex* judgment.

MR. O'DONOGHUE: No, indeed, it was simply an illustration.

THE PRESIDENT: You see the amount of litigation that is not settled and goes to trial at great expense.

MR. O'DONOGHUE: Indeed.

Sir, the point I really wanted to make is that -- and it comes back, sir, to a point the President -- that you made a couple of days ago. The object infringement is objective, and the chances of the generic ultimately prevailing if there is a trial and an appeal are not objectively knowable ex ante.

Now, the President makes the point which is obviously correct that under object, you may, I emphasise may, have some regard to subjective intention. That is clearly right. But, in my submission, in a case of this kind, we are actually dealing with something quite different. We are inferring from certain indicators, in my submission, quite unclear indicators, because the CMA has not defined what it means by large, unexplained payment, and it has not defined what it means by inducement; so we are inferring from certain indicators a

subjective motivation on the part certainly of the patentee, and at least insofar as concerns inducement on the part of the generic.

In my submission, even if technically speaking, subjective intention may be relevant to object, it is quite a different matter for subjective inference to be the decisive basis of an object test.

In my submission, that would be a dramatic development of the law on object. Now, Ms. Kreisberger will address you in *Cartes Bancaires* which tells you in object what you are aiming at, and I am not going to say more about that.

The final point I want to make, and I think then I can finish, subject to any burning questions on *Lundbeck*, is the read across from the effects case.

Now, it is very clear in response to a question put by Mr. Malek that the CMA considers that even in a case where the generic was 90% likely to lose, that would, they say, still be an effect case, and logically they would say would still be an object case.

Now, although technically it is correct as a legal matter that object and effect are alternatives, in my submission, if that were to be accepted, it would turn object on its head certainly in this case, because it would mean implicitly but very clearly that a case in which the adverse effect in competition should be revealed by its very nature, the object test, in fact, it is unbelievably unlikely.

In my submission, if the effects case goes down in flames, which plainly it should, it is hopeless, that has a read across into object, because although ex ante it was open to the CMA to ride one of two horses, object or effect, where they have ridden two horses, object and effect and we have perfect hindsight as to what has turned out, it would be perverse then to allow them to revert to object, having failed to articulate even a likelihood of an effect case.

THE PRESIDENT: You say we have perfect hindsight, I am not quite sure what you mean.

MR. O'DONOGHUE: This is now 14 years ago. There is no discussion any more as to what -- we are not waiting for any effects to yet materialise. We can see what has happened in the rear view mirror. There is no discussion whatsoever as to other unknown effects that we have not received, or that for some reason did not materialise, but we have 20/20 vision in terms of understanding the effects case. In my submission, that has at least a practical bearing on how one looks at object.

THE PRESIDENT: Sorry. I am sure I am missing something, I still do not understand. If we look with hindsight, we know what happened with the patent. We know that the process, it is possible to develop process that was not infringed. We know that even though Apotex's

process was said to be unique to Apotex, at that point GSK gave up, it never -- everybody else came on to the market, even though they used different processes which might have infringed. Are we to factor that in, I am not sure what --

MR. O'DONOGHUE: Sir, forgive me.

THE PRESIDENT: That is not what you are saying?

MR. O'DONOGHUE: No. It is a point about the legal tests, which is that if their effects case and this is the express basis for it, would be satisfied where there is a 10% likelihood of the generic winning --

THE PRESIDENT: That is their submission, yes.

MR. O'DONOGHUE: That is their submission.

THE PRESIDENT: It does not mean we necessarily accept it.

MR. O'DONOGHUE: Indeed. I do not for one second. But if that is their effect test, then their object case, which in many ways should be the inverse, the object case should be the 80/20 or the 90/10 or whatever, should be the high percentage. In my submission there is a fundamental tension between an effects case which can be satisfied with 10% and a recycling of that case as object. In my submission, that is a defect in the articulation of the legal test.

So, sir, subject to any *Lundbeck* questions, those are my submissions.

MR. GLYNN: In the period after the agreements were reached and before a patent litigation would have come to an end, there is clearly -- the effect of the agreements, as was argued yesterday, was clearly to exclude the possibility, whatever size it had, of the outcome which would benefit the consumer.

So if you take that as the case against you, what is your answer to that?

MR. O'DONOGHUE: Sir, I do not shirk from that case. A possibility that is entirely unquantified, either directly or indirectly --

MR. GLYNN: Clearly unquantified, yes.

MR. O'DONOGHUE: Including indirectly, because their case is that the large unexplained payment may allow you to infer that there is a high chance of generic success.

MR. GLYNN: Forgive me, I put it slightly differently. If the fact of the settlement -- we know that the agreements led to the end of the litigation, that is absolutely clear. The end of the litigation can be described in those words, or it can be described as the removal of the chance of generic entry. I mean, those two sets of words are used by different sides, according to what they want to underline, but they mean exactly the same, I think. So we

know that the result of the agreements was the end of litigation/the removal of the risk of generic entry, and that is the effect of the agreement.

So why is that a weak effects case?

MR. O'DONOGHUE: Because it amounts to no more than saying that -- well, it amounts to saying that if you eliminate the possibility and no more of two outcomes of litigation, that is sufficient for object. The consequence of that is clear. It means you cannot settle. In other words, mere uncertainty, mere possibility, will always be sufficient. So that is a general point.

Now, the specific point in the context of my client is that --

MR. GLYNN: I know the point about --

MR. O'DONOGHUE: -- it did not end necessarily the litigation. Our strategy was very clear. We wanted to hold the coat of other people who were fighting, and when they had won the fight, we would come in. That is exactly what we did, and that is exactly why the agreement was a one year's duration.

So I do not accept even on the facts of this case that we precluded a possibility of entry that did not otherwise eventuate. That was the express strategy in the context of settlement. Because we were injuncted, we build up huge contingent liabilities by trying to enter and failing. We wanted to get those discharged as we were entitled to in the context of settlement. It was a one-year agreement. We did not apprehend, and I hear the President's point on expedited appeals, that we would get in perhaps for a year.

We were aware of the *Apotex* and *BASF* litigation. The second the path we apprehended as being clear was cleared, we terminated.

So we do not accept that in fact there was any giving up, deferral or delay of the possibility of our entry.

MR. GLYNN: Could I take you back though to the general argument. When a point like this was put to Mr. Turner yesterday, he rightly, I think, said: the case that is being made is not just that any settlement of litigation would be harmful, but it is that accompanied by the unexplained reverse significant payment, that the two together make the case.

MR. O'DONOGHUE: Sir, I have addressed you in some detail on the large and unexplained payment.

MR. GLYNN: Indeed. Nothing more --

MR. O'DONOGHUE: Nothing more to say on that. Subject to that, it does seem to me that their case was down to saying, that where the outcome is uncertain, or there are possibilities of entry, that is in each and every case sufficient for an object. I say that cannot be right,

because it means that the garden variety of litigation, the 70/30 case, cannot be settled.

Reply submissions by MR. KON

THE PRESIDENT: Yes, Mr. Kon.

MR. KON: Sir, I probably have 45 to 50 minutes. I take it you do not want an early lunch, without sounding like a cricket commenter? I will not get through my first point, I suspect, before lunch, but I am perfectly happy to continue so that I do finish that point --

THE PRESIDENT: I think why do you not start and we will stop at 1 o'clock.

MR. KON: Thank you, sir. I have four points to make in total, and as I say, the first point is quite a lengthy point, covering a number of subpoints.

The first point covers the general position of payment and inducement, which we have heard a great deal about, and I will try to avoid repeating submissions already made.

I would like to start by going back to the discussion when I intervened yesterday when Mr. Turner commented on my opening to suggest that GUK showed a complete lack of confidence in its patent position.

I reaffirmed yesterday that that is not the position, and that GUK would not have settled at any price. In other words, it would have continued with the litigation if the settlement had not been satisfactory within the limits of what was possible.

As Mr. Urwin's email said, which is {A2/15F/1} Mr. Urwin concluded pretty late in the day that settlement was the way to go, and it was the way to go as clarified yesterday, insofar as it needed clarifying, and certainly reaffirmed, that GUK's confidence was rapidly declining, and it had a real concern that it may not prevail in the litigation.

I think on any basis that emerges clearly from the contemporaneous correspondence.

Equally, the patent position was therefore an important factor in its decision to settle. I do not put it any higher. I do not put it any lower than that, but it was an important factor. But that does not mean, and this is not binary, that equally, as I conceded to Mr. Malek on several occasions on each proceedings, that the payment was not also a relevant factor in these proceedings, and nobody, including Mr. Urwin, has ever claimed that GUK would have suddenly capitulated and settled for nothing. That is not part of our case.

Therefore, I will return, albeit I know it has been fully debated -- that the decision, and something that Mr. Turner spent quite a lot of time on yesterday in closing, but the decision not to call Mr. Urwin as a witness was it would be a misguided apprehension that we required to call Mr. Urwin, because ultimately none of those matters were in dispute. I do not see what useful purpose would have been served by calling Mr. Urwin. In relation to claims, ie that we would have settled at any price because we were fatally undermined in

our patent settlement, it is not a claim that Mr. Urwin has ever made and it is not a claim that we have made in these proceedings, albeit that Mr. Turner suggested that I may have misspoken in opening or closing on that particular point.

So from our point of view, the failure to call Mr. Urwin, we say, it has taken an enormous amount of time, but it actually is unnecessary to actually go there because nothing is in dispute in relation to these key matters.

I would only comment on this question of evidence and failure to call a witness, but I would reiterate the point Mr. Flynn made that all of the cases like *Doffman* that he referred to were essentially the Authority relying upon inculpatory evidence, whereas of course in this case, as Mr. Flynn made clear, the interview evidence and in our case Mr. Urwin's sworn witness statements, are relied upon by GUK for exculpatory purposes.

There is one other case, *Tesco* but that was a very unusual case, because that was a case where actually the witness evidence was being used for the purpose of a leniency application, and in fact one of the comments made by the court, it is authorities bundle Q5, I will not take you there, but one of the points made by the court in *Tesco* was that there was an absence, in the absence of contemporaneous evidence. But here we do have the contemporaneous evidence, and therefore GUK's submission is that it is entitled to rely upon the sworn witness statement of Mr. Urwin which addresses all of these points.

Actually, where we have finished up in those proceedings on that evidence is that we are in agreement on it and that, in fact, a great deal of the time spent has proved to be unnecessary.

I would make a similar point in relation to Mr. Turner looking at the email correspondence between Mr. Self, Rosenberg and Montgomery and the others, in an attempt to suggest that Urwin was not the decision-maker.

We say that does not take matters any further, because in fact it is clear in the terms of the decision that Urwin was the decision-maker. May I very briefly, and I will try to take you only limited authorities but I think it is important to see what the decision says on this. If we could go to {V/1/633} please.

THE PRESIDENT: In annex E.

MR. KON: E.11:

> "The CMA acknowledges that Mike Urwin was the ultimate decision-maker regarding GUK's entry into the UK paroxetine market, and that he did on certain occasions highlight that there was some risk that GUK would not prevail in the GUK Litigation."

We spent an enormous amount of time in these proceedings debating that very proposition and referring to either the witness statement or the contemporaneous materials, but it is actually acknowledged in the decision, and our case does not require us to go any further than that, and that is what we have done.

Now, it becomes clear, as a result of that debate, however, and as already Mr. O'Donoghue and Mr. Flynn have submitted to you, that the case being advanced by the CMA on the back of all this unnecessary evidence they have reviewed is the starkness of the CMA's position. Based on what Mr. Turner said in the last two days, the CMA's position appears to be that an inducement is in itself established, unless you can demonstrate that you settled for no payment. That ultimately, I think, is the stark nature of the submission that he puts forward. An inducement unless you can establish that you would have settled for no payment is indeed unlawful. That goes back to where I started in this particular submission, that GUK has never said that it would have capitulated in the litigation and actually just walked away without the satisfaction of the various elements which I am going to come on and consider. So that demonstrates the binary and extreme nature to serve the objects case, and we say that that cannot be sustained, and we say it cannot be sustained because you need to weigh up all of the relevant factors. The payment is of course -- we do not resile from this -- one of those factors, but it is only an explanation that goes into the balance, and we say that there is nothing in the decision to demonstrate that it overshadows other factors.

When looking at other factors you cannot do so, we say, and again this is an error we think the decision has fallen into, you cannot do that just from the view of the originator. Indeed, some of the submissions we have heard today I think demonstrate that; there are different perceptions, there are asymmetries in the evidence.

But we say that one of the problems with the CMA's approach in the analysis of this evidence on inducement and the payment, is that it is looking at it principally from the point of view of the originator, and actually if you factor in what drove the generic companies to settle, speaking for my own client, for GUK, it is quite clear that this balancing exercise was precisely what they undertook.

If you do not look at it from the point of view of the originator, you finish up with a very myopic approach. There was a raft of explanations we have given, and the CMA's myopic analysis became clear when Mr. Turner, we submit, was asked by the Tribunal what the CMA would regard as a valid explanation. Frankly, he was unable to provide any answer in a satisfactory manner to the Tribunal.

Indeed, there was a debate which involved members of the Tribunal. In particular Mr. Malek drew the distinction between assertion and explanation. This is Day 16, internal page 47, that was on Wednesday by the way, line 33, and the Opus reference for that is {TR/16/49}.

What Mr. Turner actually said in response, I do not need to go to the transcript unless you wish me to, it goes on in fact for several pages, the debate, what Mr. Turner said is that there was an absence of legitimate expectations. That is the way he put his case. We say that is just not good enough. It does boil down to the submission that I made to you, which is that on their analysis, the CMA say the payment trumps all.

THE PRESIDENT: When you say legitimate expectations or explanations?

MR. KON: Sorry, explanations, forgive me. Thank you, sir. Forgive me. That the payment trumps all, and once you have the payment, you do not need to look beyond it. You do not need to look at the reasoning for the originator, other than within the context of the payment itself, and you do not need to look at any of the other motives that may have driven the generic company. In the case of GUK, we believe that the evidence is actually very, very clear, that the evidence is that there were a number of very compelling explanations why they settled.

First of all, as I have already submitted to you this morning, there was a diminution in GUK's confidence, and a concern of not prevailing in the litigation. I do not think on any fair and balanced reading of contemporaneous evidence, one could say anything other than of course there were mixed views within the company, as I have already submitted to you. Those who were more invested in the project said: let us get on with it and go for it; but at the end of the day there were concerns.

The desire to get into the market with a substantial volume of paroxetine was genuine, and again a lot of the correspondence we have seen, and I took you to the GUK attempts to increase the volumes that they were getting, and the concerns they had over the credibility with their customers after they had to leave the market following the grant of the injunction. I say leave the market, they never entered into it. After they had to withdraw from their efforts to get into the market.

The heavy investment in the cross-undertaking was again the "which", and again Mr. Turner very skillfully put a pejorative interpretation on this, the use of the word "monetise" by Mr. Urwin. Again, we do not resile from that.

He wanted to monetise the cross-undertaking. It was clearly an important factor for GUK. Mr. Turner suggested yesterday that this was not supported by the contemporaneous

evidence, and I refer you to support that -- again, I do not need to take you there {TR/17/13}. He said not supported by the contemporaneous evidence that we took into account the cross-undertaking in our thinking --

MR. MALEK: Mr. Kon, if you rely on the monetisation of the cross-undertaking point, are we meant to infer something from that as to the views as to who was going to win and the strength of the case? Because if you are likely to win, then the cross-undertaking could be relatively valuable. If, on the other hand, as Mr. O'Donoghue was saying: look at the maths; on the maths, looking at it from GSK's point of view, they must have assessed they only had a 20% chance of losing. Are we to read anything into that point or not?

MR. KON: I think what we are to read, sir, is that in any litigation, two parties have different views as regards -- you will recall I took you to the calculation -- the internal calculations as regards the cross-undertaking, and equally the work done by the economist RBB in relation to that.

I think essentially that the process that would have taken place, and the way to interpret the cross-undertaking, is both parties felt they had claims on each other, that GUK believed they had a claim in respect of their cross-undertaking, because they hoped they would win the litigation. GSK had the degree of confidence in the litigation that you have heard and was characterised earlier today by the President. Both parties felt they had a decent claim, and therefore both parties were involved in a giving and taking in what they felt they were able to in order to reach a compromise, because neither party ultimately felt sufficiently compelled that they were going to win, that they felt compromise was the right thing to do. Sir, I do believe, of course I heard very loud and clear the President saying: well, it was just a contingent claim; but all litigation is essentially a contingent claim --

MR. MALEK: We both know that even if you do call upon the cross-undertaking, it is generally very difficult to prove significant loss --

MR. KON: I suppose, having had the misfortune of having to actually try and enforce cross-undertakings in the past myself, I cannot disagree with you on that in principle, but what I would say is that the normal way that that is resolved, I think if you look in the law reports and try to look for how many cases there are where cross-undertakings have actually been enforced by legal -- by judgment, relatively few. But if I put it to you that I would say very many are settled -- God knows whether those settlements could be anti-competitive at some point, given the way these proceedings are going, but how -- all I can say to you is that in my experience many cross-undertakings are settled, and they involve a compromise along the lines that we discussed when I was closing.

So that would be the mindset of GUK at the time. They would have said: we have a claim, we are not going to recover fully on the cross-undertaking but do we have a claim, is it worth something, should we be monetising that? I think the answer is yes.

I can either take you now, sir, there are a couple of pieces of evidence, in fact one judgment that I would like to refer you to. I can either do that now to finish this point or I can --

MR. MALEK: Can I go back to the cross-undertaking point.

MR. KON: Yes, of course, that is what I was going to --

MR. MALEK: One of the issues you have already addressed is, you know, is it incumbent upon you to call a witness, when you need to really focus on what are the issues and do you need a witness to prove your case one way or another. But if it is your case that a substantial proportion of, let us say, the transfer value is in relation to the cross-undertaking, would you need a witness to say that or not?

MR. KON: The answer is I believe we do have very good evidence to support that in contemporaneous materials.

MR. MALEK: So you say that the documents prove it, and so you do not need a witness to prove it.

MR. KON: I would go further than that, sir. I would say that the CMA have been aware for some material time of this position. It is very, very clear from contemporaneous documents which I will take you to in a moment that the cross-undertaking did figure. If they question that, or if they believe that Mr. Urwin is behaving in a pretextual manner in the evidence he gave in his witness statement, there is absolutely no reason why a request could not be made to this Tribunal by the CMA to call Mr. Urwin. It is not unprecedented, as I understand it, under rule 22. A request may be made to the Tribunal to call a witness. I am not suggesting --

THE PRESIDENT: It would be very unusual.

MR. KON: It is unusual --

THE PRESIDENT: I do not think, as far as I am aware, that we have ever done it, but I may be wrong.

MR. KON: If I may say, sir, with the greatest of respect, that would not be a reason that one should exclude it.

THE PRESIDENT: It would normally be for an appellant to call from within -- an executive working for their company or supporting their case.

MR. KON: If I could, and perhaps this would be a good place to break, and I could return to the evidence after. But if I could just say one thing on that, I accept that entirely from the

President, but this is a situation where on these points, you not only have the interview evidence to which you are very familiar, but we also have a sworn witness statement from Mr. Urwin, which has never been replied to by the CMA and that is, in my submission, a very significant element. Even in cases like *Tesco* the absence of sworn evidence, as against the circumstances that the evidence was given in those cases, which included lawyer interviews, was something that the court considered was significant.

Here you have a sworn witness statement. It is not dealt with, it is not challenged in the Notice of Appeal, it has not been challenged at all before these proceedings, other than obviously the *Sumika* point which we have debated, and I think Mr. Turner conceded yesterday, it was a peripheral point --

THE PRESIDENT: When you say not challenged in the Notice of Appeal --

MR. KON: Forgive me, not challenged in the defence. Therefore, from our perspective, if you consider it from a GUK perspective, we have a witness who has given a sworn witness statement in relation to some of the relevant material, and nothing has been suggested that would require us to call him to simply confirm his witness statement, whereas the CMA have chosen to take issue with that, and if that was something they considered significant, I accept that it is a bold submission, but I, nonetheless, do not resile from it, that it was always open for them to call him at any stage in these proceedings if they are questioning his sworn witness statement. They have chosen not to do so -- I should say to request the Tribunal.

THE PRESIDENT: You could not put in a witness statement with your appeal and then say it is not open to the CMA to cross-examine the witness, the Tribunal should accept the statement because it is sworn.

They would then have a right to cross-examine him, and it would be no answer to say: he said it under oath, that is that.

MR. KON: I can only return to what I said in closing: that it seems to be the wrong way round, this; that, surely in this situation, quasi-criminal sanctions, that the GUK is entitled to a presumption of innocence in relation to a situation where there is a sworn witness statement. That is something which the *Napp* case, which I referred you to in closing, establishes very clearly. Therefore, if there is a situation where there is a question where unrebutted sworn witness evidence is available to the Tribunal, and nothing has been done to challenge that, to presume that that is actually incorrect is a very bold position to adopt on the part of the CMA.

THE PRESIDENT: You say, in any event, that the position is clear from the contemporary documents.

MR. KON: I believe that is the case, sir, and that is a very firm submission on my part.

THE PRESIDENT: Yes, in which case no reason to call him.

MR. KON: Precisely.

THE PRESIDENT: Would that be a good moment?

MR. KON: Thank you, sir.

THE PRESIDENT: We will come back at 2.05 pm.

(1.05 pm) (The short adjournment)

(2.05 pm)

MR. KON: Sir, I was just finishing my submissions on contemporaneous evidence on the cross-undertaking and I mentioned there were two pieces of -- one piece of evidence and a citation from a judgment that I wanted to refer you to in that context and I will try to do so quickly.

The first one is the document that Mr. Malek alerted us to some days ago now which is {Z/155/1} which Mr. Turner also referred you to for different purposes.

This is an email chain between -- (Pause)

This is the correct document, it is from Richard Saynor as you can see, to a number of people, all of whom are familiar.

That is Richard Saynor writing on Monday, 31 December, clearly a New Year message for his troops. He is talking about the litigation and he is saying:

> "... we [are] confident that we can win the case and seek damages on the 18th of March then we should go ahead on our own.
>
> "Although GSK's offer would deliver a similar bottom line ..."

Which is of course what Mr. Turner relies upon this for:

> "... this does not include recovery of active [ingredient that is] and any damage such an action may have with Sumika. Also we would also expect to recover substantial damages from GSK."

From GSK, and he goes on to ask several questions, including how long would BASF take.

We rely upon that as contemporaneous evidence, and you will recall that we showed you an earlier email as well in opening and closing, that clearly the cross-undertaking in damages was very live in the mind of GUK at the relevant time, and that is entirely consistent prior to the settlement at the time of the interim injunction proceedings of Richard Saynor in his

witness statement in the GUK litigation. It is at {A2/15K/15}. This is a witness statement for which again the CMA relies for other purposes.

It is the paragraphs -- sorry, paragraph 17. Sorry it appears to be a bad reference in my -- can you scroll back to paragraph 15. I do apologise. {A2/15K/5}. Sorry, something has gone wrong with this reference.

It is 17, sorry, at the very bottom, "our customer base". He is talking about having approached customers. This is obviously to resist the interim injunction on the balance of convenience. He is saying:

> "Our customer base may be small, but, as our sales representatives speak to each customer on a weekly basis (or more frequently), a high volume of orders was placed during this short time."

That is during the short time they were able to advertise the product before being injuncted:

> "The new product was only offered to about 43 of our 80 account holders, and yet we have still generated a large number of advance sales. This demonstrates the demand for the generic product. The orders we have taken would amount to approximately £5.5 million in sales for the month of October. A selection of customer orders ... Some of our customers have also indicated their estimated monthly requirements of the product for the next 6 months and in total this would amount to about £35 million."

That is contemporaneous evidence as I say. I am the first one to accept that it was an optimistic view, perhaps, of the market, but it gave you an indication of the volume of business that GUK felt it was foregoing as a result of the grant of the interim injunction. While of course I understand it is a relevant consideration in many ways in terms of seeing what, in the event of independent generic, may have been available, because of course GUK would have been the first generic on the market, nonetheless for present purposes we rely upon that in terms of the cross-undertaking in damages, and the fact it was a sizeable payment that we are talking about here and not just -- indeed there was active evidence that orders had been generated and there was business. That is of course exactly the sort of evidence you would use if you were seeking to claim under a cross-undertaking in damages, in other words what the potential business was that you lost as a result of a wrongfully granted cross-undertaking.

So just to go back to this before lunch. All of this is obviously within the context of what is the position on the payment and the inducement. We say this is a case where there are perfectly valid explanations for the decision to settle and for the value transfer that was

made. We believe obviously the cross-undertaking point was significant, but the other reasons that we advanced before lunch, such as the confidence issue and the concern of not prevailing in the litigation and of course importantly the whole question of patents and how vulnerable we were in relation to the patent litigation; all of those are relevant factors in our view in determining why we settled, and to simply treat it all as solely a payment transfer being the inducement that we suggest is inappropriate and not the correct approach to take on -- in particular on an objects case.

The final point I want to raise in relation to inducement is the point made by Mr. Turner in relation to internalisation of consumer benefits.

What Mr. Turner said, and this was on Day 16, and the reference, we do not need to go there unless the Tribunal wishes me to, to {TR/16/11}, Mr. Turner submitted that all the benefits from the settlement were internalised in a way, these are his words, "that cut out the interests of consumers".

The argument here is essentially that the value can only be transferred to the generic by way of an early agreement or by way of a royalty licence, and there are three points I would like to make in relation to that.

First, we are not disputing and we have never disputed that an early entry agreement can, and I would emphasise the word can, deliver consumer benefits, but we would equally say that that is not a given, and that it does not follow automatically that as long as you have an early entry agreement, that that delivers consumer benefits.

Let me give you an example. A situation in which a patent has a long period to run as in this case, where there is a 50/50 chance in the litigation, and in the end a deal is done that the generic agrees to come on to the market five years into that remaining long-term patent. In the meantime there is litigation, not altogether different from the situation in which we find ourselves with BASF, where some litigation involving another generic and the generic goes through and the generic wins, invalidates the patent and comes on to the market with its own product. So the dyke is breached in that case. Say in the litigation it takes a year to unfold. One year and there is still another four years to go before this early entry agreement kicks in.

In those circumstances, the early entry agreement would have delivered no benefit at all. It would have been far better for the generic to enter to a different sort of settlement agreement involving, for example, a distribution agreement and getting on to the market immediately and supply the product, even if there was a limited number -- volume of product that was made available under that sort of agreement.

That is an example where it does not follow automatically that an early entry agreement is fine and a distribution agreement has a negative impact on competition. The reverse is applied, and I would add that of course even in an early entry agreement, there is absolutely no reason, and I do not understand the CMA's submissions to be suggesting that that would be unlawful, for the royalty agreement to be accompanied by a volume restriction.

The only reason for raising this example, and I am sure there are other hypotheticals that one could create which go the other way, but that in a sense would just reinforce the point I am making, that ex ante it is unpredictable which form of settlement would deliver the most consumer benefits. That was exactly what the parties had in mind in this regard, that they did not know it was unpredictable and therefore to treat this as an objects restriction in those circumstances, we say, is entirely misconceived.

Which leads on to my second point, and that is there are forms of settlement other than early settlement agreements that can deliver consumer benefits. We say that is what happened here. Because under the supply agreements, the generics were able to bring substantial volumes of paroxetine to market and this delivered significant benefits to wholesalers, which I will of course be turning to in a moment in reply to Mr. Turner.

Indeed, that is no longer in dispute. So my point is a really simple one, we should not assume that early entry agreements or royalty licences of the sort envisaged by the CMA, as we understand it, are the only forms of agreement that can create consumer benefits. There is no automatic inference to be drawn here.

My third point is really in relation to an early entry agreement or royalty licences in this case, which is that it was not one of the options here. Now, Mr. Turner took you to several provisions of the IVAX agreement, to suggest that IVAX was not a constraining factor as far as GSK's opportunities to have a royalty payment agreement.

But the fact is that GSK had appointed IVAX as its exclusive and sole distributor, as the President pointed out in argument yesterday. Had GSK allowed GUK to come on to the market with its own product, it is our submission that this would render the IVAX agreement completely unsustainable and, in fact, Mr. Turner did not succeed --

THE PRESIDENT: I think he was dealing with a point you had made, as he understood, in suggesting that in closing that it was -- they were contractually precluded from doing it. That was the point he was addressing.

MR. KON: Thank you, sir, for that clarification.

I think in terms of, if you like, the object of the submission, that may have been right. But the gravamen --

THE PRESIDENT: That is accepted that there is no contractual --

MR. KON: Well the gravamen of my submission, I think, in closing was very much that there was a fundamental incompatibility between what IVAX had committed to GSK and vice versa, in terms of IVAX being the sole and exclusive distributor, and GUK entering the market on the basis of a royalty-based agreement, an early entry agreement. Mr. Turner did not explain at all how the two would have coexisted or could have --

THE PRESIDENT: As I say, I think he was answering the point you made, which I think was that they could not have done it, because they had signed a contract which prevented -- I say, that I think was the -- I understood --

MR. KON: I think that is a fair response, sir, but I think I relied upon, if I remember rightly, clause 2.1 of the IVAX agreement, and that is what he was referring to.

THE PRESIDENT: Yes.

MR. KON: But I would nonetheless remain of the strong conviction that the whole object of the Norton IVAX agreement and the GSK agreement was for GSK to deal in the generic market, if I can call it -- put it that way, with their own product but genericised, as we discussed before, through Norton IVAX. Everything flowed from Norton IVAX. I do not think I am saying anything other than is consistent with the consistent evidence that GSK has put forward in relation to this. I think all I am saying is that while there may not have been a provision in the explicit terms that perhaps I would like there to be, which says: GSK undertakes not to enter into a royalty bearing licence agreement with a third party, there is a fundamental incompatibility in terms of the nature and effect, if you like, applying a purposive interpretation to the overall agreements.

I do not need to, I do not think, put it any stronger than that. Insofar as Mr. Turner was responding to my textual analysis of the agreement, then I am perfectly happy to accept it. Our argument is that co-existence would have been commercially unsustainable, because GSK could not have allowed GUK to come on to the market on more competitive terms than IVAX. It is as simple as that. In practice, this means that GUK's only route to market, because of the terms of this distribution agreement, was to become a subdistributor -- because one thing is clear, it seems to me, that if IVAX was -- if GUK was going to become a distributor, it would have needed to have become a subdistributor of IVAX. I do not think it was conceivable that GSK, given the subdistribution provisions of the IVAX agreement, I do not think it would be possible for GUK to become a direct distributor of GSK.

THE PRESIDENT: When you say a distributor, you mean ...

MR. KON: As a distributor of IVAX. The only point I am making is there was only two alternatives, I guess, on the CMA's interpretation: one of them was that we would be granted a royalty bearing licence, which I say was -- that sort of co-existence was not tenable or economically sustainable. The other one is for us to become a distributor of GSK origin product, paroxetine product, and that would have had to have been under -- I do not think it is compatible again with the terms of the GSK IVAX agreement, because there were provisions for IVAX to appoint a subdistributor and therefore --

THE PRESIDENT: Instead of being a --

MR. KON: It was the sole and exclusive distributor --

THE PRESIDENT: I do not think that -- I think the point -- I do not think that is the kind of alternative settlement envisaged. It is a settlement that allows independent generic entry. So whether you are a subdistributor of IVAX or a direct distributor --

MR. KON: Agreed.

THE PRESIDENT: -- it would not make any difference from your point of view.

MR. KON: My only point is that GSK would not have granted GUK more competitive terms than IVAX. I do not think I need to put it any higher than that.

I should, therefore, like to go on to the wholesaler benefits side. That is the end of my first submission. Although it feels like a very long first submission. The others, I can assure you, are much shorter.

The second submission is wholesaler benefits and why these are of material relevance to the object analysis and should not be relegated to a 101(3) analysis. Mr. Turner, of course, over the last few days, he has debated whether the benefits delivered by the agreement, in particular the wholesalers, solely fall to be assessed under Article 101(3) or whether they should properly be assessed under Article 101(1).

I refer you in that regard, I do not think I need to take you there, to {TR/16/62} where Mr. Turner posited that particular question.

In many ways this discussion in itself by Mr. Turner in closing shows that the debate has moved on, and that he is no longer seriously disputing that substantial benefits were conferred on the wholesalers.

THE PRESIDENT: Just going back to the -- you say that the point you made about the royalty could not coexist with the IVAX agreement.

MR. KON: Yes.

THE PRESIDENT: I think what would have happened is that IVAX could have terminated the agreement with you. That is what would have happened.

MR. KON: With us? With GUK?

THE PRESIDENT: No, with GSK.

MR. KON: Absolutely.

THE PRESIDENT: They would have been able to terminate. So, if GSK chose to give you a licence, then IVAX would have had a right to terminate the agreement.

MR. KON: That may be right but there clearly would also be a pretty serious breach of that agreement by GSK, because it had appointed IVAX as sole and exclusive distributor.

THE PRESIDENT: No, that goes back to the contractual point. I thought you just accepted, there would not have been a breach because there was no contractual prohibition. There is only a breach -- breach means breach of contract. If they appointed you a distributor, yes, but if they gave you a licence under the patent, you are not distributing Seroxat at all.

MR. KON: They would have had to terminate obviously in accordance with the terms of the agreement, and initially it was for a one-year term if I recall, and it was then extended to a three-year term.

THE PRESIDENT: But I think if market price -- I do not know, it depends perhaps how any party reads it was a continued agreement.

But it may be that IVAX -- I think it must mean anyone, yes, that if the market price of paroxetine, not Seroxat --

MR. KON: The 8.45 price.

THE PRESIDENT: -- the 8.45 price fell below 8.45, any independent supplier who was charging pharmacists below 8.45, then IVAX could terminate.

MR. KON: Yes, absolutely. But I am looking at this obviously from the optic of what the position was in March 2002, and at that time particular time, there was no question of that, absent independent generic entry. But my point, sir, just to go back before I revert to the wholesalers, is that -- and my submission is that the two do not coexist.

THE PRESIDENT: No, I think they would not have, because IVAX would have terminated.

MR. KON: Perhaps. Perhaps.

THE PRESIDENT: I think you are right, they could not commercially coexist, and that is no doubt why that right of termination was included in the contract, so that IVAX were not tied in, if there was an independent generic on the market.

MR. KON: Yes. I mean, Mr. Humpe says to me: the real question that raises is was GSK constrained in any way by the Norton IVAX agreement, given that basic incompatibility. Short of giving evidence on that, I cannot answer that, but I would suggest perhaps that is the case. I have just given evidence --

THE PRESIDENT: Yes.

MR. KON: Jolly good.

So I will move on to wholesaler benefits. The question I was raising before we reverted to IVAX is the question of whether those benefits fall for consideration under 101(1) or whether, as Mr. Turner submitted, it is within the context of 101(3). I was saying that in many ways, this debate has moved on somewhat from the opening, because now it is no longer seriously disputed that there were benefits. The only question is whether they fall for consideration under 101(1) or 101(3). I will emphasise three points in response to Mr. Turner, to which I do not believe he had any response during his closing.

First, we say that the benefits -- the wholesaler benefits were the consequence of a competitive process, because there was competition to supply wholesalers, and the wholesalers switched to the generic product from, of course, parallel imports because it was -- again, I think the debate has moved on in relation to this, and I do not think Mr. Turner resiled from this, because the generic product was a better and cheaper product than the parallel imports. These were therefore competitive benefits.

I do not believe in fact that there was much between anyone on this by the end of the debate. Secondly, and again, Mr. Turner had no real answer to that, but these benefits accrued to GUK's customers. Their direct customers. That does go back to the point Mr. Glynn raised, and others have raised, including Mr. Turner in his closing, and that is why, therefore, is the locus of competition pharmacists rather than the direct customers, and even Professor Shapiro acknowledged that direct customers are an appropriate source of focus when it becomes a question of assessing the competitive effects for the supply such as this.

The third point which is of particular relevance in my submission to the objects case is that these benefits were entirely predictable ex ante. They were bound to result from the agreements. They are, if you like, a necessary consequence of the agreement, and as you heard from GSK, in relation to the drug tariff, and the fact that pharmacists may not have benefited in the way that -- in the same way as wholesalers; now, I do not want to make any submissions to you on that other than one, and it is a very simple submission and I think it is an uncontroversial submission, which is the whole object of the reimbursement system was not to reimburse pharmacists overall in excess of the price which they bought their medicines from their suppliers. In other words, the object was that overall, pharmacists should be reimbursed as closely as possible to the price at which they bought the medicines that they dispense.

Therefore, the pharmacist essentially is nothing but a service provider, and gets paid a dispensing fee. That is how the pharmacist makes its money in pharmaceuticals. If I may, sir, I would like --

THE PRESIDENT: Although I think, as Mr. -- that is the headline theory, that that is how one would have hoped. What is striking, certainly to me, as explained by Mr. Horridge, is that, in fact, parallel imports were not brought into the calculation, although as we saw, they were very significant, and the explanation he gives is that it was designed to incentivise the pharmacists to try and negotiate good terms and reward them for the benefit of their negotiations, and so subject only to a potential clawback, they could keep the advantage. He explains it very clearly.

MR. KON: Sir, perhaps I could either give you the reference, or perhaps I can just take you --

THE PRESIDENT: I am not trying to stop you giving the reference. I am just observing the point you made.

MR. KON: I would like to respond to that based on my understanding of the parallel import scenario, because I think I am able to do that --

THE PRESIDENT: If you can, I would appreciate it.

MR. KON: -- without giving evidence but just to explain to you how I understand that dynamic. Perhaps I could first take you, to make good my general proposition, to {B1/1/11} which is an NHS document on the reimbursement system from the relevant time. You have already been taken to this before.

THE PRESIDENT: We have seen this, yes.

MR. KON: Simply, frankly, I do not need to go much beyond the bottom heading there, that this is the objectives in terms of reforming the reimbursement system. In other words, the object of the reimbursement system is to reimburse pharmacies and dispensing doctors who are essentially pharmacists for this purpose overall as closely as possible to what they actually pay for the medicines they dispense under the NHS. You can see the question you posit is actually the subject of this paper. It goes into the category A and category C distinctions and the question is --

THE PRESIDENT: They say it at 3.9.

MR. KON: Yes, exactly. You will see from 3.8, the question is whether the reimbursement price, less the deductions resulting from the discount inquiry, which is the imperfect system for trying to correct these profits being made by pharmacists, closely reflects the average prices paid by community pharmacists and dispensing doctors.

I think it is also -- perhaps we could go in the same document to paragraph 6.22, {B1/1/20} to complete it:

> "The reimbursement price would therefore be set in a way which best reflected the real market prices paid by pharmacies and dispensing doctors for each generically available preparation. In most cases we envisage that the NHS price -- reflecting the latest market prices of unbranded generics -- would be the most appropriate basis."

This is actually trying to -- I think Mr. Glynn referred to it as an imperfect system. It is an imperfect system and this is an attempt on the part of the NHS to investigate how it can be improved.

MR. GLYNN: Is it clear in this document that parallel imports are not counted in this clawback --

MR. KON: I do not think it is, sir. The background to the parallel import conundrum is quite simply that parallel imports started -- to some extent I am giving evidence, it just so happens I happened to have some involvement at the relevant time. Parallel imports started whereby small individual traders were literally importing, I will not say in the back of their cars but it wasn't much shorter than that, parallel imports and selling it obviously at a discount to wholesale pharmacists; and wholesale pharmacists were making quite a lot of money as a result of that. That became commercialised after a period of time, whereby large and sometimes full line wholesalers -- there was an enormous amount of opposition, and I could refer you to umpteen cases where parallel imports were being challenged as being not equivalent and goodness knows what else. But in the end they became established as part of the supply network in the UK, whereby the full line and the small line wholesalers were supplying them.

But they did, as the President has suggested, escape the net of the reimbursement system, and so retail pharmacists suddenly saw the opportunity of being able to dispense much cheaper products, in other words their supply price was much cheaper, and putting it crudely, pocket the difference.

This is an example of attempts by the NHS to address that anomaly, but they were an unpopular product for the reasons we have discussed during these proceedings.

MR. GLYNN: Did you happen to know the date on which the parallel import prices were included in the full line --

THE PRESIDENT: This is a proposal to improve it, is it?

MR. GLYNN: Yes, that is the purpose of this --

MR. KON: I do not know, sir, but I could certainly find out for you --

THE PRESIDENT: But it was after the time we are concerned with?

MR. KON: It certainly is. One thing I would mention just in passing insofar as it is relevant, that actually a number of reimbursement systems in other member states actually fixed the reimbursement price by reference to the parallel import price. They did so for two reasons. Firstly, because they did not want retail pharmacists to actually benefit in a way that our retail pharmacists were benefiting, and secondly because of course it would have the impact of driving prices down more generally, because the branded companies would then have to essentially compete with their own parallel imported products in terms of the price. Therefore on occasions -- and that is one of the reasons why you see some concern on the part of GSK in relation to reimbursement generally in Europe, because it was approached in a substantially different way, and parallel imports were part of the equation in those member states.

THE PRESIDENT: Yes. It seems like the (inaudible) was paying over the odds for some time.

MR. KON: Yes, one of the great advantages of the generic products is of course that that was part of the system, and so the fact that the NHS was able to benefit as a result of generics replacing parallel import was a real benefit to the NHS, because whereas parallel imports went under the radar, and therefore it had no effect on the reimbursement systems, once generic products were introduced as we discussed, it had the opposite effect.

THE PRESIDENT: That is the 15.6 million that Dr. Stillman --

MR. KON: Precisely, exactly so.

When one comes to an objects analysis, putting all of this into context, we say that the locus of competition cannot be pharmacies, because at best what one is doing is praying in aid an anomalous situation. A situation that should not -- in other words, one is to some extent pleading one's own wrong by trying to rely on parallel import -- by trying to say that pharmacists lost because of the parallel import situation, whereas in fact the situation was the reverse. It was a regularisation of the irregular system that parallel imports created, an irregular process that parallel imports created.

So can one say in these situations whether the agreements in themselves created a sufficient harm to competition so as to make an effects analysis redundant? That is paragraph 49 of *Cartes Bancaires* which I am sure you are going to be addressed by others.

We say that we cannot, in the light of this background, possibly analyse this as an objects agreement, because I have struggled and I have looked, and so has Mr. Humpe, to see whether we can find a case where a market entry has been facilitated by an agreement; it has produced consumer benefits, certainly consumer in the sense of wholesalers, your immediate customers, it is bound to deliver benefits as we have said ex ante; and yet we

have not found a single case of an objects infringement, where in those circumstances where new market entry has been facilitated; and yet it is found to be, by its very nature, harmful to competition to a sufficient degree.

This would be an unprecedented case. We say that simply is a massive point of principle that arises in these cases. The only reason that the CMA puts forward to justify such a position is that the payment was made to induce GUK, and we have already given you our submissions on that, and that payment created an anti-competitive effect. We say that is an entirely binary and extreme proposition which ignores all of the other factors which have to take place, and we say it cannot be in the context of an objects infringement. We say the objects case must fail.

I am not going to say a lot about effects. I have got nothing more to say about objects, but if I may turn to effects very briefly, sir, unless I can address you further on objects.

MR. GLYNN: Could you just clarify for me, you started by saying you were interested in whether or not these kind of issues should be addressed under 101(1) or 101(3).

MR. KON: Yes.

MR. GLYNN: Repeat for me, if you would, why they should not be considered under 101(3).

MR. KON: Put simply, we do not believe you get to 101(3), because you cannot establish by an object that these agreements are infringements.

MR. MALEK: By virtue of the fact that they say it should be under 101(3)?

MR. KON: They obviously, without wanting to repeat myself, name all of these factors.

MR. MALEK: They do, yes.

MR. KON: They simply say the inducement converts it into an objects infringement, you can only consider it -- that becomes obviously a self-fulfilling proficiency at some point.

MR. MALEK: It is one of the interesting things about this case, that the appellants and respondents are applying and looking at completely different things, and you say they ignore your points, and they say you ignore their points.

MR. KON: Yes, I suppose, that is what makes good litigation.

MR. MALEK: It does.

THE PRESIDENT: Uncertain outcome, yes?

MR. KON: Exactly. Uncertain outcome, precisely. I think I can vouch for that.

So, sir, can I assist any of the Tribunal further on objects? I want to say very little, literally two minutes on effects. We say the objects case fails, and therefore requires a proper effects analysis, and we say that is exactly what Mr. Turner fails to do, because he does not really produce any meaningful counterfactual analysis.

It is interesting, I noticed he did not reply on the new source counterfactual analysis in *Synthon* that I put forward. There was no reply to that, which was his latest attempt to try and come up with a viable counterfactual analysis, and as far as the other counterfactual analyses are concerned, I can only repeat what I said in closing, which is his cupboard is bare.

As far as *Visa* is concerned, unless you wish me to, I do not intend to address you further on that. We have our submissions in both our written and oral closings and we just do not believe that Mr. Turner's submission on that is tenable. We just do not think it is a correct interpretation of the facts or the laws put forward by the CJEU in that judgment.

Sir, unless I can help you further on effects, I would not want to take more time on that.

There is a third submission I need to address, and I am very conscious that this is a submission where strong views have been expressed already by the Tribunal, and that is the three-year duration point under the GUK agreement. Interestingly again, as far as I can see from reviewing the transcript, this was not something actually that Mr. Turner made submissions to you on. It is something obviously, Mr. President, you yourself have addressed, and my point on that, in that context, is this is not a point that is taken anywhere in the decision.

It is not a point that has been taken by the CMA at any time. It was not raised in the Statement of Objections and it has been not raised as far as I am aware and I am happy to be corrected, as far as I am aware it is not a point that has been raised by the CMA before the Tribunal.

THE PRESIDENT: Does that preclude us from relying on it?

MR. KON: It is a good question. All I would do, sir, is go back to what I submitted to you in opening in relation to the *Napp* case, is that this Tribunal and indeed those making submissions to it should remain within the broad framework of the original decision.

THE PRESIDENT: But this is something -- if it is on the face of the agreements, I mean, one of the issues is comparison with *Lundbeck* and so on --

MR. KON: I think the problem --

THE PRESIDENT: We are entitled, of course, to take any decision --

MR. KON: Of course, of course.

THE PRESIDENT: One would not want to do that on a whole lot of new evidence, but this is a bit different, is it not?

MR. KON: Of course I understand that, and having thought about it because I anticipated that may be something you would put to me, it does create an inherent unfairness because we

have not been able to put forward any evidence at all on the reasons for this provision in the agreement. I know you may say: could you treat it as an objects infringement; or you may take any view you like. But on the fact of the matter is we have not been given an opportunity at all in any of the written pleadings, in any of the evidence in any way whatsoever to address this particular point.

THE PRESIDENT: What sort of evidence, I mean it is a fact that --

MR. KON: For example, to be hoisted by my own petard here, we might have wanted to call Mr. Urwin to give evidence on this particular point.

THE PRESIDENT: But the reason --

MR. KON: In order to ask why, because I say unashamedly that I do not know why Mr. Urwin --

THE PRESIDENT: But it is not about the reason. It is just simply what it does. There is a restriction of a duration.

MR. KON: Perhaps, sir, I could make my other submissions on this point, and I am happy to return to that. Because I would say, secondly, and in any event, I mean essentially when you stand back from the objection that is being made to the three-year term, we would say that it is in any event necessary and ancillary to the supply agreement. I mean, if you look at the -- as I submitted in general terms to you -- guidelines on vertical restraints, in a distribution agreement, essentially which is a vertical agreement, a three-year non-compete is something that is perfectly permissible.

If, for example, we had entered into this distribution agreement after the BASF --

THE PRESIDENT: It is not that it is a three-year term that is a problem.

MR. KON: It is the non-compete is what you are referring to.

THE PRESIDENT: No, it is the fact that you cannot terminate on full generic entry, unlike Alpharma. That is the agreement that they got, which was also to supply, did not have --

MR. KON: You are very much ahead of me on each one of these submissions, because my next submission is going to be for the possibility that GUK could walk away from the agreement is not excluded, and I would like to make good that proposition.

I mean, IVAX obviously, as we have already suggested, under 3.1 and 3.2 of the IVAX agreement, could actually give notice itself under the agreement.

That would have meant that we would have reverted to direct supply as we have heard already today from Mr. Flynn, from GSK. We would say, in that event, that GUK, as would under clause 8 of its agreement with IVAX, with Norton IVAX, it would have been entitled to -- forgive me, clause 6 of the settlement agreement with IVAX.

THE PRESIDENT: Sorry, GUK under which agreement?

MR. KON: With the settlement agreements.
THE PRESIDENT: With?
MR. KON: With GSK.
THE PRESIDENT: Not with IVAX.
MR. KON: Because we would have reverted to the terms of that, absent another agreement.
What clause 6 says is -- essentially it provides a means for GUK to walk away with minimal consequences.
"In the event of a repudiatory breach ..."
It is unattractive to consider that but presumably --
THE PRESIDENT: Sorry, you are looking at?
MR. KON: 6 of the GSK agreement.
THE PRESIDENT: Right so this is {L/8/2}. Let us look at it. I have lost my feed.
Clause 6.
MR. KON: Essentially the consequences for GUK of breaching this particular provision is:
"No further payments under paragraph 1 and 2 above shall be payable ..."
Those are the payments we are familiar with.
"Any payments under paragraph 3 shall be repaid..."
That is the 50% of GUK's legal costs in the litigation, because it would restore the litigation scenario, because of course this was all on the basis that the litigation had been stayed.
Secondly:
"SB shall be under no obligation to return any Stocks to GUK."
Which is exactly what you would anticipate.
So, my submission to you is that if that scenario had occurred, while it was an unattractive proposition, GUK was left with the option of repudiating the agreement with minimal consequences --
THE PRESIDENT: You say minimal consequences, it is still liable for damages. This is not --
MR. MALEK: This is over and above.
THE PRESIDENT: -- a liquidated damages clause.
MR. KON: It is not a liquidated damages clause, but I think it is perfectly arguable that it sets out the term -- it does not say it is the only damages requirement.
THE PRESIDENT: Clearly not.
MR. KON: May I put it to you like this, sir: what damage would GSK have suffered in the event that it was trying to claim damages under, for example, its patent agreement? There would be no other agreement in place between GSK and GUK, because the distribution agreement

was with Norton IVAX. So there was no other damage that it would have suffered as a result of its patent being invalidated, which is the scenario I think that you put to us.

As Mr. Humpe is reminding me, the three years was under the IVAX agreement, and that would have fallen away, because of course in the scenario under consideration, either we would have repudiated that agreement, but I think the scenario you are looking at is that IVAX would have actually terminated.

THE PRESIDENT: In any event you did not.

MR. KON: We did not and it did not. It just did not happen. But my submission to you is, this is not -- I am the first to acknowledge, I can say this because I had nothing to do with this agreement, but I am the first to acknowledge that it is not a very happily drafted -- or the two agreements. I suppose the distribution agreement on the face of it is fine, but why concluded in this way, I can only put it to you in this way, that it is clear from the evidence of the file that the agreement was completed, was signed at 9.00 am on 14th March with the parties going into court at 10.30 that morning to litigate.

While I am the first to accept that some aspects of this agreement are unattractive, I would suggest to you that it was never intended, and it would be a strange outcome, given that I spent most of the last four weeks kind of considering how commercial GUK may have been in relation to this, that these were not commercially naive parties, that they would have entered into an agreement for bad reasons to tie themselves up for three years on the back of an invalidated patent.

To repeat my submission in this regard, I think what would have happened in practice if the patent had been invalidated, the Norton IVAX, as you pointed out to me, would have had the right to terminate. GUK would then have been obliged to take those supplies in principle from GSK, but in practice what they would have done would have been to repudiate the agreement, work on the basis that there is a limited exposure that they had, but rather than be left out.

There is one other point I would make to you in terms of our state of knowledge in relation to the reasons for this, which is that you have mentioned when GUK terminated the agreement, but I would remind you, sir, that when GUK did finally enter the market, it did not do so -- independently, that is -- until August 2004. In other words, it did so some time later.

It did so on the basis of the 30mg product, not on the basis of a 20mg product, and it did not actually enter the market with a 20mg product until February 2005. If I may, I will refer you to table 3.3 at page 165. I do not think we need to go there, but if I can give you those

as references for that submission. Therefore, there was something going on in relation to the delayed market entry of GUK, post the introduction of independent generic competition, and we do not know, and we have not got evidence as regards why there was such a significant delay.

So, the reason I am making that point is reverting to my earlier point, that we just do not have evidence on this, and there is nothing on the file which we have searched scrupulously to see if we can assist you further. It tends to suggest, for example, and I am speculating here, we do not know for example whether it is possible that GUK still had a source of active ingredient, whether another party had taken its Sumika supplies. We just do not know the background to this.

But my primary submissions are firstly that GUK could have repudiated the GSK agreement with minimal consequences, and that is what would have happened if Norton IVAX had fallen away, and secondly, that therefore the three year term with opportunities to terminate only in the third year, it was clearly contemplated, based on my closing submissions to you with Mr. Urwin's evidence, that he did not anticipate coming on to the market much before the end of 2003/early 2004. There clearly was some assessment made as regards how long it would be before they would be able to enter the market independently.

You heard from Mr. Flynn today that the hemihydrate patent was also of serious concern to GUK, and the evidence is clear on the file and contemporaneous evidence that that was a real concern for GUK. I know it is something that has been trodden upon lightly in these proceedings, but there was a hemihydrate risk. We were sued under the hemihydrate, and those proceedings were still hanging over us.

Putting oneself in the mind of Mr. Urwin at 9 o'clock on that fateful day in the morning, I would say firstly that there was some attempt to address this issue, albeit not in a very elegant way, and I am the first to accept it, and secondly it most probably reflected an assessment on the part of Mr. Urwin that that is how long it would take him to enter the market, and it was better to have continuity of supply --

THE PRESIDENT: Who terminated the GUK-IVAX agreement?

MR. KON: GUK-IVAX agreement?

THE PRESIDENT: Yes.

MR. KON: I do not know if I can help you on that.

THE PRESIDENT: It may be in the decision. I know the date when it was terminated.

MR. KON: Perhaps I can look at that and revert to you before we close this evening.

I have one further point to address which actually is a response to a question raised of me by Mr. Malek in closing which Mr. Turner addressed incorrectly in his reply and I would just like to correct that and deal with it. That is the question as to whether or not wholesaler benefits were something that arose at the Statement of Objections stage at the OFT proceedings.

Mr. Turner submitted to you that it had not been addressed at that stage and I am afraid to say that is an incorrect submission. Firstly, it has always been GSK's case, as you know, that more competition was introduced into the supply to wholesalers or in the supply of their customers, and this was addressed specifically in the SO response.

As regards the benefits to wholesalers, that point was made in the response and if I can take you to paragraph 6.9(c) of the GUK response to the Statement of Objections. That is at {A5/83/79}

Where you will see at (c) at the top of that page -- this is in response to the SO as regards talking in terms of why the settlement was not an infringement:

> "The settlement gave rise to customer benefits by giving customers [obviously in our case our customers were wholesalers] a cheaper option than parallel imports as well as providing the scope for customers to negotiate lower prices with other suppliers using the threat to switch to GUK as a bargaining tool..."

That was in response to a Statement of Objections in the reference identify just given you. If that is not clear enough, it was dealt with in terms in the RBB report as well, the RBB report, which was annexed to our report in the Statement of Objections, annex 1. If I may take you to that, I think the easiest reference I can take you to is at {A2/6A/15} please. If you look at the bottom of the page --

THE PRESIDENT: This is, just to be clear, what this is -- this was annexed to the document we have just seen?

MR. KON: This was a RBB economic report.

THE PRESIDENT: That was annex to the document you just showed us?

MR. KON: To the GUK response --

THE PRESIDENT: The one you have just shown us?

MR. KON: Correct.

THE PRESIDENT: This is A2.

MR. KON: Forgive me the reference is {A2/6A/15}. That is the Opus reference. You can see the internal page is 14. At the bottom of the page it says:

"Figure 1 below shows the wholesale price of paroxetine sold by GSK, IVAX, GUK, Alpharma and parallel imports between October 1999 and December 2003 (when Neolab and Waymade entered). It is clear that following its entry, GUK (in particular from August 2002) consistently priced below GSK (Seroxat), IVAX, and parallel imports; GUK also typically priced below or on a par with Alpharma. It was only when entry occurred in December 2003 by Neolab and Waymade that GUK lost its place as the lowest priced generic distributor..."

Then if I could take you again to {A5/83/68}

This is again --

THE PRESIDENT: That is the response again.

MR. KON: I am going back to the original document now. This is in the objects section of the response.

If you read (c) about seven lines down in (c):

"The OFT's case, in any event, fails to recognise that GUK's entry into the market was associated with a reduction in the price of 20mg paroxetine ...."

That is all I need to say:

"in the absence of the settlement ..."

I do not need to read all of this.

THE PRESIDENT: Just a minute. (Pause).

That is paragraph?

MR. KON: (c).

THE PRESIDENT: Can you just --

MR. KON: Page 68 internal numbering.

THE PRESIDENT: Sorry, can you just scroll up the page please. {A5/83/67}. It is 5.7(c).

MR. KON: I would point out to you, sir, this was not being put as a 101(3) point, it was put as a reason why it was not an objects infringement.

THE PRESIDENT: Right, thank you.

MR. KON: Sir, that brings me to the end of my submissions. There is only one further point I have not addressed you on, much to your relief I am sure, which is *Lundbeck*.

There are only two points I wish to make about *Lundbeck* and the first is that in no sense is the *Lundbeck* judgment Acte clair neither internally nor in terms of the statement of law it advances.

I think it is notable that I just learnt yesterday that, in fact, the UK government has applied very late in the day to intervene in the *Lundbeck* proceedings and that, in itself, demonstrates I think that it feels it has an important role to play in that regard.

THE PRESIDENT: You do not need, speaking to myself, to persuade me that it is not acte clair, that is clear.

MR. KON: Sir, you asked me the question who terminated the agreement, I think I can give you that now to save bothering you later. The answer is GUK terminated the agreement and it is an email to Richard Darnell, who I guess is at IVAX, dated 25th June 2004.

It is document --

THE PRESIDENT: You need not show -- I thought it was GUK.

MR. KON: Yes, it is GUK. Sir, unless I can assist any Members of the Tribunal further.

Apologies I have gone on a little longer than anticipated.

THE PRESIDENT: Thank you very much.

MR. KON: Thank you.

THE PRESIDENT: We would like to take just 3 minutes. (Pause).

(3.03 pm) (A short break)

(3.11 pm)

MS. FORD: Sir, I understand there may be a short point of factual clarification.

MR. TURNER: There is a very short point of factual clarification but we can mention it at the end if the Tribunal prefers. It is just that it arose out of what Mr. Kon said.

THE PRESIDENT: No, do it now.

MR. TURNER: It arose out from the discussion about the NHS and how the system worked, and we raise it only to give completeness to the point. Mr Kon, this is page 102 [Draft] of the real-time transcript, finished:

> "... whereas parallel imports went under the radar, and therefore it had no effect on the reimbursement systems, once generic products were introduced as we discussed, it had the opposite effect."

The question was to what extent does the NHS reimbursement system take account of parallel imports?

THE PRESIDENT: Yes.

MR. TURNER: It does. First, the clawback arrangements are very definitely or they were then a regular part of the system, and I will simply give you the references for that, but in the document that we were looking at, the 2001 paper, {B1/1/10}.

The penultimate bullet at 3.1. Mr. Horridge says that himself in quite clear terms in paragraph 18 at {E/4/6}. So that is the first point. Discount enquiries were taking place, I think he says not every year because it would have been too onerous, but once every two years.

THE PRESIDENT: Two to three years.

MR. TURNER: Those were fairly regular occurrences. But then the specific point is that the evidence produced by GSK also rightly shows and emphasises that the parallel import purchases were built into those discount enquiries and were a significant part of them. This, I can show you very briefly if it will assist, it is in Mr. Horridge's exhibits. You have those on the Magnum system, the first at {K/58B/1}. It is a letter from Mr. Horridge to somebody at the department, Mr. Kevin Guinness, 20th June 2003.

You will see from (iii) that:

> "[Pharmaceutical Services Negotiating Committee] did endorse a new discount inquiry covering branded and PI products ..."

Then this is repeated if you go to {K/58C/1}. This is an article by Mr. Horridge and in the right-hand column, towards the bottom you will see letter (e):

> "Discount in PIs:
>
> "This is calculated in the same way as for generics ..."

Do you see that in the final column near the bottom? Again, in Mr. Horridge's exhibits at {K/58G/1}, this is Mr. Horridge writing in the trade press, "Clawing back that cash".

If you see what he says in the first column under the heading, "Collecting the data":

> "The clear objective of a discount inquiry is to quantify the discount on purchases of proprietaries, generics, and parallel imports dispensed ..."

That is towards the bottom of the first column.

MR. GLYNN: This is all 2003, is it not?

MR. MALEK: This is 1999.

MR. TURNER: This article is 1999.

MR. GLYNN: Thank you.

MR. TURNER: But it relates to that.

MR. GLYNN: The system was in place throughout all the relevant period.

MR. TURNER: Yes.

MR. GLYNN: I thought it was.

THE PRESIDENT: He refers to these in his witness statement, of course.

MR. TURNER: He does.

THE PRESIDENT: Because he is exhibiting them. Yes.

MR. TURNER: Sir, that is all.

MR. GLYNN: Thank you. Reply submissions by MS FORD

THE PRESIDENT: Yes, Ms. Ford.

MS. FORD: Sir, I have just got some brief observations to make on the question of the test for object infringement.

Mr. Turner has sought to reassure the Tribunal that the CMA has not applied what he described as a wildly inclusive sweeping inference for unlawful settlement agreements, and rather he sought to persuade you that the CMA has applied a test which is actually fit for purpose, in the sense that it effectively distinguishes between settlement agreements which are pernicious in competition terms and settlements which are legitimate.

In particular, he emphasised that the CMA had carried out a meticulous factual examination of the evidence to see whether payments had induced the generics to accept entry restrictions.

In relation to Alpharma in particular, he took you to three documents to show inducement. I do not propose to turn them up again, because they are documents that we have seen fairly frequently throughout these proceedings. But it was submitted what you could see from those documents was first of all that Alpharma had used the possibility of its early entry on to the market as a lever in settlement negotiations. That was the submission that was made on the first document.

Then it was said that they had considered what was the minimum payment that they were prepared to accept in settlement. That was the submission that was made on the second document. Then it was said that when it came to the renewal of the agreement, they engaged in an exercise of weighing up the benefits of supply by GSK and supply by Delta.

In my submission, you would find documents of this sort, documents of this nature in the communications of any undertaking which is contemplating settlement of negotiations and settlement of litigation. In any case where an undertaking is thinking about settling, you will see it trying to negotiate the best deal it can with the other party to the proceedings, including by emphasising the downside to that other party if they were to lose.

You will also see the undertaking in question considering the minimum payment it might be prepared to accept in settlement, and you will see it assessing and weighing up the pros and cons of settling and of not settling.

If that really is the correct test for inducement, then, in my submission, it is not a satisfactory way of trying to distinguish between a settlement which is legitimate and a settlement which is not.

In my submission, that takes you no further than the sweeping inference that, where you have a payment and an entry restriction, then you must have been induced. It is really the inference again by the back door.

Mr. Turner also referred you to the evidence of Mr. Laursen as to the rationale he advanced for entering into the settlement agreement with GSK. He took you to that in the decision. It is {V/1/324}. You can see it at 6.202. He says that the reason he entered into the agreement was to remove the uncertainty of potentially winning at a later date with the certainty of getting some money now.

In my submission, what Mr. Laursen is saying is exactly what any businessman would say if they were asked the reason for entering into a settlement agreement. It is absolutely standard that they are looking for certainty and they are prepared to take certainty now as opposed to uncertainty later.

So, in my submission, again, this sort of testimony does not provide you with any comfort at all that this is a test which can satisfactorily distinguish problematic settlement agreements.

On a related point, I have made the submission that Alpharma decided unilaterally to settle, and the factual basis for that submission is the email which is at {A9/184/75}. This is the email where Alpharma is setting out its -- the settlement approach that it is planning to take when it approaches GSK.

It was suggested by Mr. Turner that my claim needs to be, that is the way it was put, that Alpharma would have walked away without payment or it would have capitulated completely in the litigation in order for it to be in any way relevant that Alpharma decided that it wanted to settle.

Now, to be clear, first of all, I am not making the submission on these facts that Alpharma would have walked away. That is not the submission that I am making. But nor, I say, do I need to make that submission for this to be a relevant fact.

If you are asking the key question which is: was this undertaking induced to accept entry restrictions; surely it is relevant that that undertaking has resolved, on the basis of the merits of the litigation, that it no longer wishes to pursue the litigation and that it wants to approach the other side and see whether it can obtain terms of settlement which it considers to be fair and reasonable. Surely that is a relevant fact.

It is materially different in my submission from a circumstance where an undertaking is not dissuaded by the merits from pursuing the litigation but then is persuaded by means of a payment.

This is precisely what we are trying to get to the bottom of. It does not matter, in my submission, that the undertaking may have a point where it says: no, I am going to walk away from these settlement negotiations. It does not matter that it is not prepared to settle without any payments at all, because in my submission, very few undertakings that resolve to settle would actually walk away with nothing. So once again, this is a situation that does not distinguish between legitimate and illegitimate. It is imposing an artificially low threshold for what is permissible conduct here.

THE PRESIDENT: Part of the difficulty it seems to me, I quite accept your point, it is pretty rare to say that, you know, we will walk away with nothing. It is equally pretty standard with expensive litigation, of which the outcome is not certain, that one party or the other explores whether there is any scope for settlement.

MS. FORD: Sir, indeed.

THE PRESIDENT: That is fairly standard. It does not mean that they have decided they no longer want to pursue the litigation. It just means that they want to see if there might be scope for a commercial deal.

MS. FORD: Indeed.

THE PRESIDENT: I am not sure it goes really that far either, to say -- when you say it is relevant that they no longer wanted to pursue the litigation. I am not sure if the fact that they are exploring the scope for settlement -- does not mean they no longer want to pursue it. Many parties to -- as you know well -- to commercial litigation, unlike an appeal like this, will always as it gets closer to the time say: well, is there a commercial way out?

MS. FORD: Sir, my submission is that the difficulty arises because what you see on these documents is by no means out of the ordinary. For that reason these documents cannot be the basis of a case which applies an appropriate test for determining whether this settlement agreement is legitimate or not.

There is a related matter, which is that a question was raised about what was the evidential basis for a submission that I made in writing, that the CMA's over-inclusive test would preclude a large and commonplace category of settlement agreements. It was suggested that I did not have an evidential basis for that submission.

To be clear, I am not seeking to make any sort of submission about the incidence of patent settlement agreements with authorised entry arrangements, or anything of that nature. The

submission I am making is really quite a lot more prosaic than that, and it is essentially the one that the President made in {TR/16/9} starting at line 21.

Starting at line 21:

> "But that makes these settlements very difficult ..."

Leaving aside, you are saying, sir, all these questions about information asymmetry and such, if you simply assume:

> "... that the patentee considers they have a 70% chance they would win and the generic also thinks that they have an only 30% chance that they would win, the generic might not be willing to give up its challenge without some compensation for giving up that 30% chance."

You said, sir:

> "That is the normal bargain that would be struck and the payment will reflect -- they have got a 30% chance of making a certain amount of money, so they are not going to give it up; they are not too worried about litigation costs because the costs are dwarfed by the 30% of likely profit, so they are prepared to take their chance, and the only way they will not is if they get some compensation financially for the possibility foregone."

You went on:

> "In those cases then, that is the obvious way those cases would be settled."

I gratefully adopt that formulation as what I was attempting to say, which is that, essentially, this is an absolutely normal state of affairs. So to point to these sorts of scenarios and say: aha, that shows you were induced; that is simply not an appropriate test.

Mr. Turner also went to show you various documents that he says shows Alpharma had not given up the ghost by the time of the settlement agreement. I have already explained that I do not seek to claim that Alpharma had given up the ghost, and I do not need to show that in my submission. But there is another reason why that sort of submission is problematic.

You can see that from the witness statement of Mr. Laursen. This is {A7/154/6}. Paragraph 6.2, he says:

> "... I note that the relevant litigation between Alpharma and GSK continued for several months after this point. In my experience, it would be normal to continue with the legal proceedings for as long as possible because the moment you stop them, you are telling your counterparts at GSK that you are surrendering."

Now, again, in my submission, what Mr. Laursen says here is not at all surprising. When you are negotiating a settlement, you do not -- you cannot simply cave in and stop

litigating. You have to push on with the litigation in the background, because of your negotiating position. Once again, to point to documents which say: look, Alpharma was still litigating, it was still continuing this litigation; does not tell you in my submission anything about whether or not this is a problematic settlement agreement.

Sir, in summary, in my submission, there remains a real concern that although the CMA has told you that it does not rely on a sweeping inference, and that actually it has conducted a very careful review of the facts, in fact, the test it is applying is not fit for purpose to identify pernicious agreements and not to identify perfectly legitimate ones.

Sir, unless I can assist you further, those are my submissions.

MR. MALEK: That is very helpful, thank you.

THE PRESIDENT: Thank you, very clear, Ms. Ford.

Reply submissions by MS. KREISBERGER

THE PRESIDENT: Yes, Ms. Kreisberger.

MS. KREISBERGER: Thank you, sir.

I was proposing to address only the object restriction, and I have -- well, I had four short points. I think I have two additional ones that have just arisen as a result of some of the debate this afternoon.

Principally four short points. They really pick up on the point that Mr. O'Donoghue raised last, which was the read across between object and effect and that is my overriding topic which I would like to develop a little more fully.

Now, in my submissions, I focused throughout on the concept of object restrictions, which I say cannot accommodate the CMA's theory of harm in this case, in summary because for an object restriction, what is required is a primarily textual analysis of the agreement, which must demonstrate a sufficient degree of harm.

That is the *Cartes Bancaires* return to orthodoxy. You look at the agreement and you see the pernicious infringement. You exclaim: mine eyes dazzle with this malign infringement.

So coming to my first point on this. Sir, if I could just summarise in fact the four principal points I have. They relate to the legal test; the application of that test to the settlements; the outcomes which are produced by the CMA's test, just very briefly; then, lastly, the question of incentives.

So turning to the first of those. The legal test. I would like to take you back for one last time to a passage of *Cartes Bancaires* and the reference is hard copy 19, if you do not know that already and that is {Auth-I/51/12}.

The paragraph numbers are 49 to 51. That seems to be -- if you could start on the prior page {Auth-I/51/11}. Thank you.

Just reading there, and this is really coming back to basic principles. The Court of Justice at paragraph 49, it is really 51 that I am going to focus on but just to put that passage in context. The court begins that:

> "... it is apparent from the Court's case-law that certain types of coordination ... reveal a sufficient degree of harm ..."

So that there is no need to examine their effects. That is 49. They say at 50:

> "That case-law arises from the fact that certain types of coordinations ..."

Are regarded by their nature as harmful to the functioning of competition.

Then one turns the page to {Auth-I/51/12} paragraph 51 and this is the one I want to focus on:

> "Consequently, it is established that certain collusive behaviour, such as that leading to horizontal price-fixing by cartels, may be considered so likely to have negative effects, in particular on the price, quantity or quality of the goods and services, that it may be considered redundant, for the purposes of applying [now 101] ... to prove that they have actual effects on the market ..."

The key point I would like to emphasise there -- this is a very well established formulation, and one sees it in many of the object cases and it is reiterated here -- the key point I want to emphasise is the reference to actual effects being so likely.

So the Court of Justice says that is really the nub of the sufficient degree of harm test. It is a question of degree for the object finding of likelihood, and actual effects are of course demonstrated by reference to the counterfactual.

As I say, I am really getting back to basic principles here.

What this means in my submission is that the basic insight, the underlying premise as to why any particular type of agreement is anti-competitive must be the same for each category, object and effect, for a particular type of agreement.

Article 101, in short, does not compel the demonstration of effects where effects are "so likely" to arise. That is the basic principle underlying all of this.

Now that applies equally if one is looking at purpose in order to establish object. Objective to establish object. It must be a purpose which, if achieved, that purpose is so likely to have negative effects that they need not be proven. The test does not vary because you are looking at purpose.

I would like to illustrate this point, the broad point on likelihood effects, by taking the President's example of yesterday --

THE PRESIDENT: Just before you do that. In *Cartes Bancaires* they go on at paragraphs 53 and 54 to deal with the various matters that can be taken into account, as well as the content of the agreement: the economic and legal context, which it forms part, the nature of the goods and services, the conditions of the functioning of the market and the parties, not necessary but can be taken, the subjective intentions.

In deciding whether it is object, you can look at a lot more than just the terms of the agreement, it is not that the terms of the agreement hit you and you say: it is anti-competitive; or no, it is not obvious; in which case that is the end of an object examination. Indeed, the *Allianz Hungaria* case, which I think you criticise in your closing, but it is another decision of the Court of Justice, does that. So it is a broader enquiry than might appear from just taking the words in paragraph 50 sort of on their own, without looking at what the follow-on is.

MS. KREISBERGER: Sir, I accept everything you have just said, and it is dealt with very clearly in all of my submissions on *Cartes Bancaires*. So I paraphrased at the beginning of my reply, but I accept and actually I have advanced the proposition that of course it is appropriate that you look at context. If you remember my key submission on how you approach object is, this is one of those cases where I think it would be appropriate to look at subjective intentions, to understand the payment.

So it is not my submission that you do not go beyond the agreement, and I am sorry if I have given that impression. I do stand by all my submissions; that was purely simplification. But that does not in any way, in my view, impact on paragraph 51. There are just two points on that.

First of all, *Allianz* is cited there for the broad proposition. I stand by my criticism that the actual analysis in that case probably would not hold good today following *Cartes Bancaires*. That is my submission, but the broad principles set out here are correct. One does go to context and that is precisely why I say one looks at the settlement objective. That is the main consideration of context.

Paragraph 51 -- of course, the distinction I have drawn in all of my submissions on this in opening and closing, written and oral, is that -- and that is on the face of this judgment -- you can look at context but you cannot go on to assess effects, and I think that is something that comes out very clearly from this judgment. But the point being made in paragraph 51 is, you look at the agreement, in its surrounding context but let us be clear, that is an

abbreviated analysis. It is not a full assessment of impact. It is abbreviated. So you look at the agreement. You look at its permissible surrounding context and then you say: is this so likely to have negative effects? I do not mean to be glib, but the paradigm example of price fixing does leap from the page, but there is more scope for analysis. I hope that is clear, sir.

MR. MALEK: Presumably you rely on paragraph 58 as well, do you? {Auth-I/51/13}.

MS. KREISBERGER: Very heavily, yes.

THE PRESIDENT: You said you relied on that before.

MS. KREISBERGER: Absolutely front and centre of the case, absolutely.

So I was just about to turn to the President's example of yesterday, which I thought was a very helpful one in relation to information exchange. It is an example you put to Mr. Turner, sir, yesterday. That was in relation to the CMA's case on effects.

If it is helpful, the reference is {TR/17/47} line 21. If I might just quote, you said, sir:

> "[it is] a restriction by object because, if the parties had not exchanged information, it may be that the prices that they would have charged or the way they would have marketed their product would have been different from the way they were as a result of the information exchange. The way in which they competed was changed. But that does not make it a restriction by effect."

That was your point, sir.

In my respectful submission, I would suggest some refinement of that. I can show you that, illustrate the point by reference to the Commission's horizontal co-operation guidelines, which are at {Auth-K/10/16} paragraph 73. That is the one. If one goes to paragraph 73, it says:

> "Exchanging information on companies' individualised intentions concerning future conduct regarding prices or quantities is particularly likely to lead to a collusive outcome. Informing each other about such intentions may allow competitors to arrive at a common higher price level without incurring the risk of losing market share or triggering a price war ..."

What this illustrates in my submission is taking that example, the reason why information exchange is characterised as a restriction by object is because of the likelihood of effects. It is a central part of the test.

It may be trite to say that the object category is obviously not a shortcut for cases where there is difficulty in establishing effects. It is precisely the reverse. The presence of such difficulty should give pause for thought before branding something a restriction by object.

Those are -- that is the basic principle. If I could move on to my second point, which is applying that principle to the patent settlements.

THE PRESIDENT: But it would not make any individual information exchange, just on that basis, an effects case, just by saying: well, it is likely to lead to a collusive outcome.

MS. KREISBERGER: No, sir. And that is not my submission. My point is when one is asking the question: do I put this type of agreement into the object box; the question --

THE PRESIDENT: You say as a generality are they likely to --

MS. KREISBERGER: Exactly, sir, precisely, sir, are they so likely.

THE PRESIDENT: Therefore one can put it in the object box and allow a shortcut, even though in a particular case that goes in the object box, you might not be able to establish effect.

MS. KREISBERGER: That is right, sir. I am not saying it is universal, but it is the underlying premise. It is the reason for allocating that type of agreement to the object box, and not on an individual basis. One would not expect to -- one does not have to demonstrate it in the individual case, but the assumption is one does not need to, because those affects will be so likely. If one thought that as a generality those effects were not so likely --

THE PRESIDENT: They can be quite hard to demonstrate, once you get to the follow-on damages case. It actually has to be demonstrated, it is not straightforward.

MS. KREISBERGER: Nonetheless, it is the operative reason.

THE PRESIDENT: I see your point.

MS. KREISBERGER: Applying that approach to patent settlements, remembering this is the first time the Tribunal is asking itself the question: should it go in the object box? In my submission, the question that the Tribunal must ask itself is: are these types of settlements which feature the characteristics on which the CMA relies, pay for delay, are they so likely to give rise to actual restrictive effects that it is appropriate in this case to allocate them to the object box? Does it satisfy the so likely test?

In order to answer that question, one must first ask: how do you go about assessing the effects of these kinds of settlements? Because that is the logic that provides the foundation for allocating them to the object box. One cannot skip ahead. There must be a reason for likelihood of effects. So my essential proposition is that they will only lead to actual restrictive effects at all where it can be shown that the counterfactual is more competitive, which on a continued litigation counterfactual means that the generic would have won on a balance of probabilities. That is just taking effects, parking so likely, balance of probabilities.

That is a question which, in my submission, is perfectly capable of investigation. It may not be easy, but much is not, particularly in competition law, but there are different ways of approaching this question and I have already suggested some. Contemporaneous evidence; magnitude of the payment; nothing in my submission precludes one from looking at the payment and seeing it and analysing it as an indicator of patent strength, and engaging with the underlying merits in certain cases.

In certain cases, depending on the facts, it may be appropriate to get into underlying merits.

On that last point, I thought the paragraphs of the *Servier* decision which Mr. Turner took you to on Wednesday were actually highly instructive. He relied on them for a different point, but if we just pull them up, it is {Auth-F/14/36}. It is paragraphs (124) to (128).

That may be a bad reference, I may just need to check that.

It is hard copy 11 I think.

THE PRESIDENT: I think it is {Auth-F/17/1}.

MS. KREISBERGER: Sorry, that is what I thought I had said. That is at {Auth-F/17/36}. You see there at paragraph (125) we have the reference from the Court of Appeal to this being the sort of patent that can give the patent system a bad name.

If one goes over the page {Auth-F/17/37} you see reference at (128) to:

> "The view of many generic companies ... that the ... patent was not valid."

There is also reference, sorry, in the paragraph above to *Servier's* view about the merits. In that case, that led the Commission to conclude there was uncertainty, if they wanted to carry on the thinking, the logic that is being set out in all these decisions.

One could take that evidence, direct evidence, in relation to the underlying merits and say: I think it is more likely than not in this case that continued litigation would lead to generic entry. So I am not suggesting one makes a finding on these facts, but I am giving the example of a case where one might grapple with the underlying merits. There may be evidence. If you do not think this is strong enough there will be other facts.

MR. MALEK: That is on the basis of irrespective of what the parties thought the merits were, you are just looking at this coldly and you say to the court or Tribunal: you decide whether on the balance of probabilities if the generics would have won, or whatever way you want to look at it.

MS. KREISBERGER: That is right, because it may be very clear from their views, and also the views expressed by -- there might be a first instance finding that can be relied on. I think -- the point about an effects analysis is that nothing is excluded. Each case will fall on its own

facts and should fall on its own facts. There may be a range of evidence, we do not have it here.

That is the only point I am making here, that there are different ways of cracking this nut and these are matters that should be looked at in the round as part of a full effects analysis, not the abbreviated contextual analysis that we were just discussing under object. So that is effects on the balance of probabilities.

Now, if the Tribunal is with me on that, then the same logic must apply to the assessment of object. Then the question becomes: in what circumstances is a patent settlement so likely to give rise to restrictive effects that it can be properly deemed an object infringement?

Now you already have my submission on that, that this analysis provides further support for the approach that I have been advocating, where there is clear evidence that the parties were united in a belief that the patent would fall down as invalid or not infringed, so that the settlement was designed to stop that process which was expected to lead to competition. That, in my submission, would tick the object box.

I accept the President's point that subjective intentions are not enough, but they can explain contractual terms.

I claim in support of that the case of *AXO* that I have already taken the Tribunal to, on which the CMA relied in written closings at least, that you need evidence that loss-making was part of a plan to eliminate a competitor, where it is open to different explanations.

So if you are treating the payment here as your hook, you need evidence. It does not suffice on its own, because the reason for payment is open to different interpretation. I am going to come back to that.

Mr Malek suggested during the course of my closings that I was being rather bold in suggesting a threshold. My submission is this really is in line with orthodox principles on object infringements. Likelihood on a balance of probabilities for effects, a much greater likelihood for object.

Mr. Malek just flagged the paragraph in *Cartes Bancaires* that I rely on very heavily. You need proper limiting principles under the restrictive approach, and the inference in this case is simply too shaky a foundation.

Now, the upshot of all of that is that the essential conceptual justification is that it will avoid an outcome which involves competition law striking down settlements under patents that are likely valid.

Where there is no restriction of lawful competition, there can be no effect and no object. In my submission, that is a simple proposition and it is rooted in principle. If I might remind

the Tribunal, without taking you there one last time, that that is the focus of US anti-trust law, where this whole idea has come from, and where, as the President has pointed out, the effects are far starker because of the Hatch-Waxman 180-day period of exclusivity.

The approach there explicitly has been to root out the settlements where a monopoly has been preserved by agreement which, to quote *FTC* was likely invalid and should not be shielded from anti-trust attack.

For your note, that is *FTC v Watson* {J/5/46} hard copy 19. Then on appeal in the same case in *Actavis*, the Supreme Court said you can look at the payment itself to test the effects, and treat the payment as a proxy or a workable surrogate for a weak patent.

In both cases, subject to appeal and final appeal, the objection was the same. The objection was that the patent is weak. We see in the same case different approaches to arriving at the same conclusion. The first based on evidence relating to the case, the second relating to the magnitude of the payment. Neither has been done by the CMA here, either on object or effect.

In my submission, Mr. Turner was quite wrong yesterday when he said that the test which I am proposing, I think he said in relation to GSK but it was essentially the same point on weak patents, proceeds from no obvious principle. That is simply not right.

I say it is the CMA's case which is unprincipled, because it assumes restrictions of competition where there are none. This is very stark, because Mr. Turner and the decision itself yesterday made explicit the objection to the parties splitting the monopoly profits. That is the basic objection here.

Of course that is perfectly legal if the patent is valid. The whole purpose of the patent is to give the patentee monopoly profits for the innovation.

On a different point, Professor Shapiro insisted that the agreement not to enter on the part of the generic was a restriction of competition. He was very clear about that. That is an equally wrong assumption, because if the restriction is within the scope of the valid patent then it is perfectly lawful. That is the inquiry that has to be conducted. So the CMA's approach is essentially based on a fiction. It assumes too much.

THE PRESIDENT: If you are right about all this, and you are putting it at a level of high principle very clearly, does that mean that significant parts of the reasoning of the court in *Lundbeck* are wrong?

MS. KREISBERGER: I accept that.

THE PRESIDENT: It seems to me that follows.

MS. KREISBERGER: Absolutely. I think that is clear in the submissions we made on *Lundbeck* in the replies. There has been debate about whether you can actually distinguish.

THE PRESIDENT: Yes --

MS. KREISBERGER: Merck's submission has always been that *Lundbeck* was wrongly decided and Merck is an appellant, so of course, I am happy to make that submission --

THE PRESIDENT: Yes, you are one of the parties appealing.

MS. KREISBERGER: So we accept that absolutely and we rely on that. My third point is a very brief one, and it is one which Mr. O'Donoghue touched on, and that is the result that one gets, one obtains on the CMA's test. Now, just to put that in context, you will gather from what I have said, that, in fact, sir, that was your point in referring to *Lundbeck*, that the mere snuffing out of the possibility of a successful claim does not amount to a restriction of competition, on the approach I just laid out, whether by object or effect. It is not an appropriate foundation for actual effect so it cannot be for object.

Now, the Tribunal expressed some surprise yesterday at the strange result you get on effects, according to the CMA's test on effects, which I will describe as false positives, and Mr. Malek suggested an uncertain patent dispute, and the patent subsequently upheld. I think I set out a similar scenario in opening. Effects are deemed at the same time both likely and unlikely. That is the logical impossibility. Precisely the same objection applies if you transmute that to object, only with more force.

Effects are so likely and unlikely at the same time. So a more surprising outcome. I am not sure if you can have degrees of false positives, but if you can, this is more a false positive than for effects. It is very false.

That brings me to my fourth and final point on object. Mr. Malek asked me in closings whether I accept that the originator has an incentive to preserve its patent, and I fear my response was not sufficiently clear. So I want to clarify in case there was any lack of clarity.

Not only do I agree, it was the premise of the hypothetical scenario that I advanced in written closings, and which the President subjected to some scrutiny during oral closings. It is the premise of my case that there is this basic asymmetry of risk and reward in this sector, which means that settlements with payment can be in both parties' interests, even though the patent is likely to be upheld.

This explains how payments arise. So, in my submission, I know an oddity of this case is that the CMA rely on this feature as an anti-competitive aspect.

I say it is relevant to purpose, and parties should not be condemned as infringers because of this basic facet of commercial reality.

Now, the President, I think, accepted the CMA's submission that the fact that it may be commercially rational is irrelevant because price fixing is commercially rational. In my submission, the Tribunal should not be so ready to dismiss the basic commercial realities which operate here. They are relevant. The analogy with price fixing, with respect, I would suggest is not a good one.

Price fixing is a direct restriction of competition and established to be quasi-criminal conduct. Settling a case has never been branded as such. Mr. O'Donoghue covered this in some detail. It has always been considered as being in the public interest. Merely having incentives to settle in this sector cannot be helped and is not prohibited conduct. It is a fact of life but it is not a restriction. There is only a restriction if lawful generic entry was delayed.

This, in my submission, underlines the need for a correct threshold, which only strikes down settlements with anti-competitive effects, where the effects are either so likely, looking at the agreement and surrounding context, or probable, based on a full assessment.

MR. MALEK: You have the same incentive whether or not you have the case which is that a patent is likely to be upheld or a weak patent or, as here, it could go either way.

MS. KREISBERGER: Absolutely. The incentives, they do not tell you anything. It is a fact of the price differential between generic products and branded products.

I think it would be artificial --

THE PRESIDENT: I am getting a little confused. If you say you could have an effects case where it is likely, and you can deduce from various pieces of evidence of the kind you describe, that the patent is likely to fail or the generic is likely to succeed, and then if they settle, you could say there is an anti-competitive effects case, but the fact that they have the incentive to make that agreement is irrelevant.

MS. KREISBERGER: It does not help you decide whether there are effects. As Mr. Malek says, it is simply there. I think it would be incorrect for you not to take account of that, that that is a feature of the sector which we are talking about. That is commercial reality. Therefore, you do not condemn the parties purely on that basis.

THE PRESIDENT: I think one was not saying they are condemned for having the incentive to settle or the incentive to make such a transfer, whether the patent is strong or weak.

MS. KREISBERGER: I think my point is the incentives do not give you the answer to whether the patent is strong or weak, and it is only those cases where lawful generic entry is delayed,

that competition law should intervene, because that is a restriction of competition acting on incentives; a payment which arises out of incentives is not a restriction of competition, it is a function of the realities here, the asymmetries. You need something more.

Therefore, you have to engage with patent strength and that is the conclusion that has been arrived at in US anti-trust law. You have to engage with patent strength, whether it is via payment or via some other approach.

MR. GLYNN: Against you, the argument is that whatever the probability of the patent coming out one way or the other, if the result of the agreement is to eliminate the chance of -- the way you are characterising it, you are assuming that the generic victory is the more competitive outcome. As you know, I would not quite agree with that, but that does not matter for here.

But the point from the CMA is that it is the elimination of the risk that is the harm you need to get -- and you are eliminating the risk by the settlement. That is still left as a standing point against your argument so far, I think.

MS. KREISBERGER: I do not accept that --

THE PRESIDENT: I know.

MS. KREISBERGER: -- because that is not a restriction of competition.

MR. GLYNN: It is a restriction of potential competition.

MS. KREISBERGER: For the same reason that I understood the Tribunal to be struggling with that argument on effects, because the effects test is are effects more likely than not, probabilities, then the same approach applies to object. You have to grapple with the question of whether there is an effect in the market. I do not accept the basic proposition that the mere loss of a chance of a court ruling, which has the possibility of leading to generic entry, is a restriction on competition. That is central to my case. I do not accept that.

THE PRESIDENT: For the originator to pay off a generic challenger, number 1, number 2, number 3, number 4 is fine~--

MS. KREISBERGER: I thought you might come back to that, sir.

THE PRESIDENT: Because in each case the chance is only 20%.

MS. KREISBERGER: Let me put it this way.

THE PRESIDENT: Unless of course it is an abuse of dominance.

MS. KREISBERGER: That was one point I was going to make, it may be a abuse.

THE PRESIDENT: Which Mr. Flynn says they are not dominant. You may not have to engage with that.

MS. KREISBERGER: I will not engage with that. If there is an abuse of dominance, that is one way of approaching it.

In my submission, sir, your point is very similar to Mr. Turner's point when he said yesterday: there are alarming consequences for the public interest if you have to treat the grant of a patent as valid because consumers are set out from the benefits of a challenge and you are positing a particular illustration of that in relation to one patent.

My answer is this: these are concerns about consumer welfare that do not fit within Article 101. Article 101 is not your tool because in the example that the President scrutinised me on a couple of days ago and has raised again, there is, in my submission, no restriction of competition because the patent is more likely valid than not. It is a very simple proposition.

Now, I think what one is really saying is that there are concerns about the public interest because of these basic features of this sector, this commercial asymmetry.

Now, I do not think that those concerns which, looking broadly, may arise are a matter for competition law. We are dealing here with the intersection of two separate tools which point in different directions for protecting consumer welfare. Patents, sorry to get back to basics again, which are a lawful monopoly to reward innovation, and competition, which protects consumer welfare through achieving, effectively, lower prices here by means of generic entry; they are different approaches to protecting the public interest.

If there is a separate concern that because of the incentives to settle there is an impact on consumer welfare, and that there is a difficulty in many cases in evaluating the underlying merits of the patent dispute, then that is a concern that needs to be addressed directly. But, in my submission, you cannot call that a restriction of competition because competition is only restricted where lawful generic entry is delayed or precluded. Article 101 is not your tool.

It is entirely unprecedented to say: excluding a mere possibility of a particular outcome which may be less than 50% sounds in an infringement finding. This will be the first case, save for *Lundbeck*, which makes that finding.

In my submission, that is wrong at a level of basic principle. There is no restriction in the market. So you need to distinguish between public interest, in my submission, and consumer welfare and restrictions of competition in the market.

MR. GLYNN: So you would object to the point that was put about Ford buying off the potential --

MS. KREISBERGER: I do.

MR. GLYNN: Why exactly do you think that is not an anti-competitive move?

MS. KREISBERGER: I reject it on the separate basis that there was no right to exclude because there is no patent, but I do not think that is what you are asking me about. I do not think it is comparable for that reason, but I understand you say, just taking a case where you are precluding a 45% possibility.

MR. GLYNN: Yes, you are buying off the risk of a competitor. That is the question that I am getting at.

MS. KREISBERGER: I understand that, sir. I think that is not the counterfactual analysis for precisely the reason that the Tribunal articulated yesterday. The question is, very basic level of principle, the way one approaches it as a matter of the legal test is: are anti-competitive effects more likely than not compared to the "but for" scenario? I am afraid that does mean you have got to work out whether the "but for" scenario is more or less restrictive and a below 50% possibility -- and of course there are all the other objections, which is at what point do you draw the line if not 50%, the traditional legal approach? 10%, 5%, 1%? That is not a defensible bright line and particularly not for restrictions by object. If one cannot stomach it for an effects analysis, it cannot be the basis for an object finding which demands a restrictive approach and likelihood of effects. It is not good enough. That is my clear submission on that. I do not accept it.

Unless the Tribunal had any further questions on that, I have two discrete points that have arisen really this afternoon.

The first one is just really to remind the Tribunal since Mr. Glynn questioned Mr. Kon, I think, about Article 101(3) and the assessment of material benefits.

So I just remind the Tribunal that my submission on that is, one has to bear it in mind in ascertaining objectives, the purpose. So one reads the agreement, one sees that that is an apparently pro-competitive objective, and in my submission, one then has to do further work which cannot be done within the ascertainment of object. It requires an effects analysis, because one of the obvious questions is what were the effects, and we spent a lot of time on that and that is relevant -- so one cannot assess this on an object basis. That is why I say early entry is relevant to the object analysis and takes one out of the object box into an effects assessment.

The other point I wanted to raise on an entirely separate topic is the point which the President has raised about the construction of the term of the GUK settlement.

I gratefully adopt all of Mr. Kon's submissions on that point. I would like to add one on behalf of Merck, which is Merck's approach to this appeal has been consistent throughout,

since its Notice of Appeal, which I have raised before, which is that Merck accepts the primary facts in the decision.

It does so because it took the view that conceptually the decision was bad. I am instructed that I can say it did attempt to make some enquiries about the underlying issues, and I am sorry to have to say this because it is certainly not an issue with my friend Mr. Kon, but co-operation was not forthcoming from GUK prior to the launching of the Notice of Appeal. It has certainly not been an issue since we have been in front of the Tribunal.

That influenced Merck's approach to its appeal. Now, had this been an issue, it may be that Merck might have taken a different approach and wanted to investigate matters and bring forward evidence. Now, we have not had the opportunity to give this much consideration, but the Tribunal would need to be very sure indeed that there are no objective, for instance objective contextual factors relevant for the construction of the GUK settlement which would not have been advanced by evidence.

I make the broad submission that I cannot say, standing here today, that it would have had an effect that it well might to Merck's approach to this appeal in terms of evidential enquiries. So I would invite the Tribunal not to take a decision which could unfairly prejudice Merck. I should just remind the Tribunal, I say this because Merck divested itself of GUK many years ago, and hence that is where the problems arose.

THE PRESIDENT: Can you go any further and say what sort of --

MS. KREISBERGER: It just occurs to us that, as Mr. Kon says, this was a settlement on the doors of the court --

THE PRESIDENT: I mean, the IVAX agreement, the two agreements, they might have been agreed on on the door of the court, it might have been negotiated, for all we know, over a week. It was not clearly just written out at the door of the court and we all know if you tell the judge: we have reached agreement but we are going away to finalise the detailed terms; parties will be given time to do that. So the fact that -- it is not as though this was a phone call. It was a detailed contract. Indeed, the IVAX agreement, which where this term is, is a quite carefully drafted agreement.

MS. KREISBERGER: All I can say is I think Merck would have wanted the opportunity to consider the matter, speak to people and it might have affected its entire approach to the appeal, which is an expensive appeal. So there are all sorts of implications. So we say there is a real risk of unfairness here.

Sir, those are my submissions unless I can assist further.

THE PRESIDENT: Thank you. It is a sign of how efficiently this case has been conducted that on the last day, unless you are about to launch into further submissions --

MR. FLYNN: I am not going to spoil it, I just wondered whether I could clarify the clarification that Mr. Turner gave --

THE PRESIDENT: On the NHS --

MR. FLYNN: Simply to say, the fact that the parallel -- purchases by pharmacies played any part in discount inquiries in the clawback rate, just so you are clear, have no impact on the reimbursement matters that we have been talking about.

That would have been factored into the clawback rate at the time when the reimbursement was under the list price, which covers parallel imports as you said, and the same rate applied after the 12 and drifting down to 15% reduction. So it makes absolutely no difference, and we know that there was no discount inquiry after these agreements were entered into, and we know from Mr. Horridge that none would have been expected after. That is simply the point I wish to make. Thank you, sir, and I apologise for taking an extra minute of the hearing.

THE PRESIDENT: It is still a finish, 13 minutes ahead of time on the last day of long appeals, which I think is an tribute to the efficient way it has been conducted. We would like to thank all the parties' representatives for the clarity and elegance of their submissions, which have given us a lot to think about. If we do decide to make a reference, we will nonetheless deliver a judgment, and indeed may express our views, even on any questions that are referred. We obviously give the parties in that event an opportunity to consider the questions.

We have one request before you think you can now forget all about the case until you get to judgment, which is that we would please like a schedule in chronological order of all the documents that have been -- the contemporary documents, not the authorities, and obviously not the notices of appeal or skeletons, that have been referred to during the case, just in chronological order with the hyperlink to the Magnum system.

I am told that this should not be too onerous, given the way one can search the transcripts, but if we could have that, please, before Easter, that would be appreciated, and that is something for you to do together, and I trust that does not present any problems, and I hope that can be accommodated.

MR. TURNER: Sir, we will collaborate on that.

THE PRESIDENT: Thank you very much. I would also like to thank on behalf of the Tribunal, but I think on behalf all parties, the silent heroes of the past few weeks of hearings who

have enabled the case to be conducted with much greater efficiency than would otherwise have been possible; that is to say, our transcribers who have operated the Magnum system. They have not fallen prey to the mistake of PriceWaterhouseCoopers of providing the wrong document. If any mistakes were made in that respect, it was done by the requesting party and it has been of great assistance. Thank you all very much. You will be informed when the judgment is ready.