IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

6 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, before we resume with Dr. Reilly, the Tribunal sent us a letter. You wrote asking about whether in the administrative proceedings the CMA had asked GSK to supply copies of internal papers about the approval of the settlement agreement, and if so, what was Glaxo's response.

We have handed up a clip, which I hope each of you will have either on your desk or with the referendaire.

THE PRESIDENT: Not yet. (Handed)

MR. TURNER: If I may, it will be convenient just to address your question first before resuming with Dr. Reilly.

THE PRESIDENT: Just pause.

MR. TURNER: You should have an indexed clip, and just so that you can see what happened, on page 39 of that clip, if you go to that first you have the first formal information request which was sent by then the Office of Fair Trading, called a Section 26 notice to GSK.

THE PRESIDENT: Sorry, this is in section?

MR. TURNER: Mine is not divided into tabs, but it should be paginated at page 39 continuously through.

THE PRESIDENT: I see, 39. Yes.

MR. GLYNN: Yes.

THE PRESIDENT: This is dated 12th August 2011.

MR. TURNER: So here you have the first formal information request. If you turn the page and go to page 41 of the external numbering, you will see that the company was asked at 2 and 3 questions concerning the production of the documents.

At 2 they were asked, with respect to each of the agreements:

> "Please provide all documents that consider the advantages and disadvantages of entering into those agreements and the terms that should be included."

3 concerned cash flow forecasts that relate to paroxetine and that informed the decision to enter 1into the agreement and in particular cash flow forecasts relevant to any of the following scenarios:

> "(a) no other company supplying generic paroxetine in the UK;
>
> "(b) other companies supplying it as distributors or subdistributors of Glaxo and ;
>
> "(c) other companies supplying paroxetine where any such supply was independent of Glaxo."

Then, at paragraph 10, on page 43, there was an information request, as opposed to documents:

"Please say which individuals took the decision to enter into the agreements."

THE PRESIDENT: Yes.

MR. TURNER: Go to page 29 of the continuous numbering, you have Glaxo's first response in writing. It did not provide the documents requested at that early time. It said it will provide that information later, but if you go to page 35, you see that they did provide immediately an answer to question 10:

"Which individuals took the decision?"

There they said:

"Mr. Eddie Gray, at the time general manager of Glaxo, now President Pharma Europe, supported by Mark Reilly, then finance director of the UK Pharmaceuticals business."

So the answer given was that the relevant decision makers were limited to those two. After that a number of documents were provided to the Office of Fair Trading by way of response to the information request or in on-site inspections, but the documents provided did not include board approval documents or financial projections and so the Office followed up with a further information request on 23rd March 2012.

You have at page 3 of this clip Glaxo's response which was given on 20th April 2012. You can see from that the questions that were asked on page 3. So at paragraph 2 they report the question 6:

"In conducting the relevant searches of documents to respond to the Office's Section 26 notice of 12th August 2011, please confirm the following document sources were searched: documents which were provided to or produced by the board of GSK, including but not limited to agenda board submissions or minutes of board discussions and correspondence with the contracted auditors. If the sources were not searched, please provide a copy of all documents within those sources which are responsive to the initial section 26 notice."

The answer given under A4 documents, at 2.1, the second sentence:

"In responding to the initial notice, Glaxo did not search documents provided to the board. This was not specifically requested and the value of the agreements with the generic suppliers was below the level typically considered by the board."

Then, in 2.2, go to the third line, the second sentence:

"The UK's pharmaceutical business would have reported to the European pharmaceutical management. In particular, GSK believes that discussions concerning the proposed agreements with the generic suppliers will have taken place with Chris Viehbacher, head of the European pharmaceutical business at the relevant time. However, as stated in response to the initial notice, the decision as to whether to enter the agreements was taken by Eddie Gray, supported by Mark Reilly. The matter would only have been reported to the board if it was sufficiently material."

If you turn the page, 2.3 says that there was a materiality threshold and you will see from the last sentence:

"GSK would not expect the agreements to feature in GSK -- "

THE PRESIDENT: Just a moment. We have had a technical crash, Mr. Turner. We will take this with us and read it to ourselves while that is sorted this out.

MR. TURNER: If the Tribunal reads --

THE PRESIDENT: We will read this document, shall we?

MR. TURNER: Yes and the answer to question 7 over the page.

THE PRESIDENT: We will read the whole document.

(10.37 am)

(Short break due to technical crash)

(10.40 am)

THE PRESIDENT: Yes, Mr. Turner, we have read that.

MR. TURNER: So the only parts, then, to note briefly are paragraph 2 on page 4.

For completeness, 2.4:

"Glaxo said that they conducted an electronic search, but it did not result in -- "

THE PRESIDENT: We have read it.

MR. TURNER: And 3.3. As these points were to some extent addressed on Friday with Dr. Reilly, it may be sensible to revisit them briefly with the benefit of this material when he resumes his evidence.

THE PRESIDENT: Some of it really is rather what he told us, namely that he said he did not have authority but he got it from Eddie Gray, who also referred to Chris Viehbacher, so I understood what he was telling us, and that there was nothing done in writing, but he spoke to them and got approval from them was his evidence.

MR. TURNER: Yes. So if we call Dr. Reilly back to give evidence. DR. MARK REILLY (continued)

Cross-examination by MR. TURNER (continued)

MR. TURNER: Dr. Reilly, you should have in front of you a copy of the transcript of Friday's hearing somewhere. You just heard us talking about a small clip of documents containing your company's answers to the Authority's information requests. Do you have that?

A. I assume it is this?

Q. That is the transcript. Yes.

THE PRESIDENT: Will you be referring to the transcript?

MR. TURNER: I will be referring to the transcript as well. Do you have any hard copies?

THE PRESIDENT: We may not need them in hard copy.

MR. TURNER: We have hard copies here.

THE PRESIDENT: We may not need it in hard copies.

MR. MALEK: It is on the screen.

THE PRESIDENT: It will be.

MR. TURNER: So Dr. Reilly, very, very briefly, may I just confirm what you said on Friday about the approval of the agreement in this case.

On Friday at page 93 of that transcript, lines 17 to 25 {TR/5/93}, in the middle of the page, you see that? At 17 the President asked:

"Did you have authority yourself to agree those amounts or did you have to get clearance?"

You said:

"Answer: No, I had no authority. I was there to listen ..."

A. Sorry, I do not have it. Could you repeat?

Q. Yes, do you have the transcript at page 93? Bottom right it should say "TR/5/93"?

A. The bottom references are not printed properly, I'm afraid.

Q. In the internal reference, do you have page 91 at the bottom in the middle?

A. That is this one?

Q. That is it. In the middle of that page at line 17, the President:

"Did you have authority yourself to agree those amounts or did you have to get clearance?

"Answer: No, I had no authority. I was there to listen and to carry the messages into the team and then the team would discuss and then Eddie would escalate those discussions up to Europe.

"THE PRESIDENT: Who would actually have to sign off to tell you, yes, you can sign to that?

"Answer: That would be Chris Viehbacher, David Redfern and somebody from Europe legal."

Then if you have the little clip of documents and if you go in that to page 39.

A. Sorry, clip of documents?

Q. That is the documents that you also had loose. (Handed)

A. Thank you.

Q. If you go page 35 in that, you will see at paragraph 10 the company was asked:

"Which individual took the decision on behalf of GSK to enter into the agreements?"

They said:

"Mr. Eddie Gray, at the time the general manager, supported by Mark Reilly."

Now, without casting doubt on the point that that will have been discussed with Chris Viehbacher, the head of the European pharmaceuticals business, on reflection, was your answer on Friday about the individuals who took the decision entirely right?

A. I believe what I said on Friday was correct.

Q. Thank you.

Second, please can we confirm your evidence on Friday in answer to Mr. Glynn's question that there would have been documents giving financial forecast of the losses that GSK would suffer if it did not enter into the contested arrangements with the loss margin of the £14 million.

If you have the transcript again and go in it to page 66 of the bundle numbering {TR/5/66}. If it is obscured on your copy the internal number in the bottom middle is 64.

Do you have that?

A. 64, yes.

Q. In the middle. Then line 26 near the bottom, Mr. Glynn asks:

"Did you put a number on the second set of calculations to compare with the 14 million?

"Answer: Sorry?

"MR GLYNN: When you said the alternative would have been more costly --

"Answer: Yes.

"MR GLYNN: -- did you put a number together which would compare with the 14 million?

"Answer: We would have had a number yes.

"MR GLYNN: Do you recall what it might have been?"

Over the page { TR/5/67} if we pick it up at 21:

"MR. GLYNN: Would there have been a document which set out these calculations on the alternative scenario?

"Answer: There would have been some documents, yes, backing up --

A. Sorry?

Q. This is your answer on line 23.

A. Sorry, which page?

Q. Page 65 if you are looking at the internal numbering of the document, page 67 if you are looking at the bottom right.

A. Okay, 65. On line?

Q. 21.

Mr. Glynn asks:

"Would there have been a document which set out these calculations on the alternative scenario?"

"Answer: There would have been some documents, yes, backing up what you are seeing here which was just the summary."

It carries on:

"MR GLYNN: I meant, there is the documents backing up the 14 million you have just described to us very interestingly how you would think about the alternative position, which would have been more than 14 million?

"Answer: Yes.

"MR. GLYNN: Was there a document which draws those thoughts together?

"Answer: There would have been, backing up this document, the detail behind it. Where it is now I cannot say unfortunately because of the passage of time.

"MR. GLYNN: Thank you.

"Answer: But it would definitely be there."

Now, if you turn back to the clip and go to the --

A. Sorry, are you asking a question about that?

Q. I am about to, yes. Before asking the question, if you go back to that clip that was handed to you by the referendaire and go to Glaxo's response of 20th April, which is at the top of that clip, beginning on the third page, if you go to page 5 in the bottom right numbering and

you look down to answer 3.3 on page 5, Glaxo was asked about the absence of financial forecasts produced to them and said:

"Second, GSK has discussed the matter with Mark Reilly, the key GSK business person directly involved in the negotiation of the agreement."

It should say:

"Based on this discussion, Glaxo does not believe that any financial forecast documents were created in relation to the decision whether to enter into the agreements."

So putting these two together, were you mistaken in 2012 when you said that no financial forecast documents were created, or were you mistaken on Friday when you said there would have been forecast documents?

A. 2012 you referred to?

Q. Yes, that is the date of this document from your company where they say -- based on discussions with you.

A. I am afraid I am not familiar with this document. I am not familiar with the questions that were asked in it, but I -- what I said on Friday, I believe to be the case.

Q. Yes.

A. So where the other point was raised, I am sorry, I cannot comment.

Q. Thank you. So put that away.

A. I am sorry to stop you for a minute, is it possible to have some water, please?

THE PRESIDENT: Yes. On its way.

A. Thank you. Just wait a moment.

MR. TURNER: To conclude the commercial deal in each of these cases, each of them included agreements by your company, GSK, to pay sizeable sums of cash to the generics.

A. I do not think cash is the right characterisation.

Q. Money.

A. Mm?

Q. Money.

A. I believe there was a settlement agreement.

Q. Let us turn to your CMA interview. In your bundle it is cross-examination bundle tab 2, but for everyone else it is at {E1/12/20}. You should have this loose on your desk. It is the same one we were looking at yesterday (sic). It is your interview with the CMA.

A. It is not in here, it is loose?

Q. Yes, it was the one we were looking at yesterday --

THE PRESIDENT: On Friday.
MR. TURNER: I am sorry. Friday.
A. This one?
Q. That is it.
A. Do I need the transcript again?
Q. It is your transcript. Not of Friday; you can put that to one side.
A. Sorry, there are some other documents here. Do I need these?
THE PRESIDENT: I think the problem is it is getting a bit cluttered up there for Dr. Reilly. If you are going to be referring to Friday's transcript?
MR. TURNER: We are going to be mainly referring to the transcript, so that should stay.
THE PRESIDENT: Which transcript?
MR. TURNER: Of the CMA's interview.
THE PRESIDENT: The transcript of Friday's hearing -- I think it is loose anyway, it has not been bound.
MR. TURNER: That can be put to one side.
THE PRESIDENT: Could someone help by taking it from Dr. Reilly?
MR. TURNER: Yes. He may need it again later, but --
MR. MALEK: Take it for now.
THE PRESIDENT: Take it for now. It is very difficult when you are giving evidence to have a whole lot of different documents in front of you. The clip that we have just been looking at, can that be put away?
MR. TURNER: That can be put away.
THE PRESIDENT: If you can give that to the referendaire, you will not need that again. What you have, I think this is the interview to the CMA, is it?
MR. TURNER: That is right.
THE PRESIDENT: To Mr. Moore.
A. I am sorry, I appear to have two witness statements. Do I need two? Are they the same?
MR. TURNER: I do not know what those witness statements are.
THE PRESIDENT: You will have your one in this Tribunal, you should keep that with you, which is in this case, and the other one is the one you are about to be asked about.
MR. TURNER: The one you made to this Tribunal, put to one side. You will need that. If you look at the transcript of your interview to the CMA.
A. Sorry, they both appear to be the same. Are they not?
Q. Keep the loose one and put the other one away please. (Pause)

We were talking about the payments. If you go to page 20, using the bundle numbering as we did on Friday, and read at the top.

THE PRESIDENT: Which is internal page 19; is that right?

MR. TURNER: Yes.

THE PRESIDENT: The document where the first word top left is "helpful"; do you have that?

A. I have that one, thank you.

MR. TURNER: So on the second line down, Mr. Moore asks:

"... is it fair to say that there were significant payments made by GSK to the generic companies, would that be a fair, factual characterisation?"

Your answer:

"There are some payments, in the agreements characterised, as part of the commercial terms for doing the arrangements."

"MOORE: Absolutely. Would you characterise those as significant payments?

"REILLY: Yes, I mean they are fairly sizeable, some of them."

Now, you were asked then what you got in return for the money in the next question from Mr. Moore who wants to understand:

"... precisely what GSK got out of that, as it were."

Your answer refers to two things:

"It got agreement to come into the GSK supply agreements and therefore GSK maintained the volumes ..."

First point. And two:

"... and maintained the integrity of the patents."

So the supply agreements gave you stability, yes? "Maintained the volumes", gave you stability?

A. Is that your word, is it?

Q. I am asking you whether you agree with it?

A. I think what I have said there is fair.

THE PRESIDENT: Can I just understand it. What do you mean by "maintain the volumes"?

A. That would have been for the factory, in terms of the overall factory volumes for the UK production, rather than those volumes switching to a different factory.

THE PRESIDENT: You mean a factory of --

A. Of GSK in Crawley. It was almost a dedicated factory to Seroxat production.

MR. TURNER: But you mean somebody else's factory, 1not your factory.

A. No, the Crawley factory.

Q. But you are saying if you had not maintained the volumes there would have been competition and other people would have taken those volumes?
A. Those volumes would have had to have been supplied from somewhere else.
Q. Another company?
A. Possibly. If the patents were not in place, then there would be supply from a different company, or many different companies probably.
Q. And your volumes, therefore, would have been less leading to the impact on the factory in Crawley.
A. That would have happened in genericisation.
THE PRESIDENT: That is what you mean by "maintain the volume"?
A. Yes.
THE PRESIDENT: I understand.
MR. TURNER: Then we turn to your second point on what you got from these payments: maintain the integrity of the patents. In other words, again --
A. Sorry, where does it say what I got, or?
Q. Just above your answer, Mr. Moore says he wants to understand quite precisely what GSK got out of that "as it were". Do you see that?
A. Could you just point me to that?
Q. Yes, just above your answer --
A. It is quite difficult to come in halfway through --
Q. Of course it is.
A. -- this discussion, so I want to be clear, please.
Q. You are quite right and we will take this more slowly.
A. Thank you.
Q. A third of the way down, Mr. Moore says:

> "So I am just trying to be absolutely clear, sort of the commercial rationale for sizeable or significant payments and just understanding, quite precisely, what GSK got out of that, as it were."

Your answer is responding to that question.
A. Sorry, I am not being difficult, but I cannot find it.
THE PRESIDENT: Are you on the page which says, top left, the word "helpful"?
A. Yes, I am.
THE PRESIDENT: Then below that paragraph against your name it says:

> "There are some payments ..."

A. Yes.
Q. Then Mr. Moore says:
"Absolutely. Would you characterise those as significant payments?"
And you say:
"Yes, I mean they are fairly sizeable, some of them."
Then Mr. Moore says:
"So I am just trying to be absolutely clear, sort of the commercial rationale for sizeable or significant payments and just understanding, quite precisely, what GSK got out of that, as it were."
A. Got it, thank you.
THE PRESIDENT: That is your answer.
A. Yes.
THE PRESIDENT: That is what we have been looking at. It got agreement to come into the GSK supply agreements, and therefore GSK maintained the volumes, and maintained -- and you have just explained that -- and, secondly, "maintained the integrity of the patents".
A. Right.
MR. TURNER: We are on that last bit, "maintained the integrity of the patents".
Does that mean that you avoided the risk that the High Court would find your generic products would infringe your patent or that the patent was invalid?
A. It was a settlement agreement, so they agreed that they would not carry forward in terms of their court action. So that was it.
Q. The risk that you were avoiding was what I have just described?
A. The risk, it was a settlement agreement.
THE PRESIDENT: That does not quite answer the question, Dr. Reilly. You have explained "maintaining the volumes". I think it is a very simple question. When you say "maintained the integrity of the patent", just explain what you meant by that.
A. So, essentially, the proceedings versus the generic company to eliminate the patents were ceased in terms of the agreement and they did not continue forward.
THE PRESIDENT: So the patents remained in place?
A. In place.
THE PRESIDENT: Yes.
MR. TURNER: The benefit that you derived from them remaining in place, was what I have just been referring to?
THE PRESIDENT: I think we have got the point.

MR. TURNER: We have the point. We will move on.
THE PRESIDENT: I think it is fairly clear what Dr. Reilly means. He has just explained it.
MR. TURNER: Dr. Reilly, you were the finance director. Did you count up how much payment in total you were making to IVAX, GUK and Alpharma under these agreements? Did you count that up?
A. In terms of the value of the agreements?
Q. In terms of the sizeable payments that you were making, did you count up how much it amounted to?
A. For the settlement agreements we measured that in terms of the overall volumes that would have been supplied and the impact on the profit and loss.
Q. I understand you went through a weighing exercise, but did you count up how much it all added up to?
A. Sorry, what do you mean "count up"?
Q. The sizeable payments under each agreement --
A. That is your phrase, "sizeable payments --
THE PRESIDENT: It is actually your phrase, Dr. Reilly.
A. Okay. I think this came from the initial lead in terms of sizeable payments, I said some of them are fairly sizeable.
THE PRESIDENT: Yes.
A. So your point?
MR. TURNER: It is a question. Did you add up the sizeable payments under each agreement and realise how much in total it amounted to?
A. We did an assessment of the value of the agreement to settle the outstanding litigation. Does that answer your question?
Q. No, it does not. Perhaps if we go to the --
MR. MALEK: The witness did say: we looked at the impact on the profit and loss.
THE PRESIDENT: Yes.
MR. MALEK: You cannot do that without assessing the financials, can you?
A. Thank you.
MR. TURNER: Without assessing the financials, that means adding up and therefore appreciating the amount of the payments.
THE PRESIDENT: Let Dr. Reilly explain.
A. I do not think you should quite characterise everything from a financial perspective just as adding up. Please, it is a little more sophisticated than that.

MR. TURNER: Do you have a copy of the CMA's skeleton, or is that only available to you on screen? Can you look for this one on the screen, please -- I hope that will be sufficient -- at {S/6/11}.

MR. MALEK: Before you do that, I just want to go back.

When you say you looked at it and you assessed the impact on the profit and loss, can you just take us through what that process entailed? I know it is not a straightforward (inaudible).

A. What we were trying to do, of course, was look at what the overall impact would have been. There is not a straight financial impact on the factory particularly because that did not sit within the overall P&L from a UK pharma perspective. But the factory was very closely aligned to the GSK business, so obviously that was something quite large in terms of consideration.

But the overall modeling was done in terms of what would the volume have been supplied? What would the margins be? How was the deal constructed? So, yes, there would have been a financial assessment done on it and the impact on this year's financials.

MR. MALEK: Yes, of course. Thank you.

MR. TURNER: Would it have been a written financial assessment?

A. There would have been some documentation for the plan, yes.

Q. Let us look at what you should have on the screen there. This merely lists the amounts of money, the payments that were made in each case which are not disputed in these proceedings.

Paragraph 24, you will see in relation to GSK paying GUK £13.7 million paid; for Alpharma, £5.9 million, adding up the payments under that agreement; and for IVAX, underneath that, GSK paid IVAX £10.15 million.

The total in direct payments, let us call them, was £29.75 million. So that would have been something that you took into account in your analysis, that degree of payment you made?

A. I do not know. I have not seen this document before, I have not had a chance to review it. It is a significant amount of time has passed since these numbers were reviewed, these settlement agreements were done, so I do not think you can expect me to remember exactly the numbers as they stand.

If these are not disputed, fine. I really cannot comment on them. But what I would say is also they were not paid at the same time. These were not kicked off at the same time. They did not end at the same time, or they may have ended at the same time, but there was

different phasing. So the impact within the years would have been different. So it is a bit more sophisticated than this.

Q. When you prepared for this hearing did you refresh your memory by looking at details of this kind?

A. No, I deliberately did not because I wanted to give my impression and answer the questions as best as I possibly could.

Q. Well, these are the figures taken from the contracts which are referred to in this document. You do not need to worry about not having seen this document before.

May I then pick up Mr. Malek's line of questioning. Did you carry out across these three agreements, supply agreements, settlement agreements combined, the sort of cost benefit analysis that Mr. Glynn was first asking you about on Friday?

THE PRESIDENT: Can I be clear, when you say "across these three agreements --

MR. TURNER: Taking them together.

THE PRESIDENT: They were entered into at different times.

MR. TURNER: Yes.

THE PRESIDENT: When entering into the first one, obviously, one would not know what is in those that had not happened. Are you saying when the third one was done, did Dr. Reilly sit down and look back at the previous two and do an overall picture? I am not quite clear what you are asking.

MR. TURNER: Before completing the deal on the three, which may have been between --

THE PRESIDENT: The deal on three was not one deal, was it? There were at different times.

MR. TURNER: They were at different times. However, as you have seen from the reference to joining the supply agreement, there was a consideration of the three together at the end. There must have been, presumably, Dr. Reilly, some consideration of the three agreements in total, or was there not?

A. I must say I am saying I think exactly the same thing, that when these agreements were entered into, of course there was an assessment of each one, but they went at different times, there was different clauses etc. So --

Q. Do you recall whether there would have been any cumulative consideration of them, or were they considered, to the best of your recollection, only as individual stand-alone items?

A. Of course when you have only signed one, you can only do one, so there is not a cumulative assessment at that point, if that is what you mean.

Q. No, no.

A. Looking forward? It does not make sense.

Q. If you come to the end of the process did you consider them all together at any point or did you only consider them as stand-alone items?
A. They would have been considered as stand-alone separate items, but of course they would have been closely aligned. So by the time you had entered into three, you would be able to assess what the impact of those was within that year.
Q. To the best of your recollection, would there have been a consolidated appreciation of the effect of all three of them when you came to the end of the process and you were dealing with the third agreement?
A. Sorry, explain that again, please?
Q. Would you have considered the impact of the three as a whole at any point in your consideration?
A. I think I have just said when that would happen. You would take each individual agreement, obviously, calculate that out and then you would make sure you aligned the years for the year assessment. Does that answer your question?
Q. It will do for now. That is the payments that were made under these agreements. Each of them also provided for the supply of fixed amounts of product, paroxetine, to the generic companies, yes?
A. It was an agreed volume. I would not say a fixed amount.
Q. It was an agreed volume, and each of them concerned only the supply of 20mg paroxetine?
A. Yes. For manufacturing purposes.
Q. None of them concerned 30mg of paroxetine?
A. No.
Q. Although that was an important separate product?
A. Much smaller.
Q. In fact, the agreements prevent, or prevented, that product being provided at all by anyone other than GSK?
A. Because 20mg was the major product. That was what the generics were interested in.
Q. They were not interested, is your evidence, in the 30mg product?
A. Well, all I can say is that they were more interested in the 20mg.
Q. If it is all you can say, we will leave that there.
On Friday, we saw from your slide presentation, in February 2001 --
A. Yes, it was not just my slide presentation.
Q. Your slide in the slide presentation which related to the IVAX threat, that you set out there the projected negative financial impact of the supply agreement that you contemplated on

your company progressively from 2001. Shall we go back to that and look at that again, please?

A. Sure.

Q. It is at tab 11 of your bundle. For everybody else it is at {B2/37/4}. Do you have that?

A. I do.

Q. Now, the negative sales profit impact added to £16.8 million over the period to 2004, we saw that before.

A. Did we agree that that was the number?

Q. 16.8 million is the figure in your slide.

A. I am not sure I would agree it is to 2004 necessarily. It is very difficult to say from that slide what it actually references. That is only a handwritten number in terms of 3/1 plan, so it does not actually say what it references.

Q. We also see from the Alpharma note after the final settlement meeting with you, which was on 22nd October 2002, but from Alpharma's point of view the value of the supply agreement was thought about, by them, in hard money terms.

Go to tab 35 in your bundle, which is {E2/26/1} on the Magnum system. Do you have that?

You will remember at paragraph 2 referring to the UK settlement being concluded with yourself and Cynthia Robinson.

In the third line of paragraph 2, they, that is GSK:

> " ... will be ready to offer 500,000 packs of the 20mg ... pack at a transfer price of £8.45. The value of this offer is app £2.5 million on a 12 month basis."

So they had in mind the transfer price and they had in mind a retail selling price based on what you had told them in the previous meeting was the prevailing generic selling price.

We can go back to that if you like?

A. They would have calculated that out themselves, I am sure.

Q. Do you recall that we saw on Friday that you had given them the prevailing generic selling price?

A. I think that is what they mentioned. They would have done their own assessment, I am sure.

Q. Did you also work out for your own purposes, in your cost benefit analysis, the total profit sacrifice that your company was making, not just on this IVAX agreement but eventually under all three of these as a group?

A. We would have --

Q. The impact on your company of the three, the distribution agreement with IVAX and the two subdistribution agreements?
A. No.
Q. Your company never looked at that?
A. How could we? Unless we were looking into the future, predicting a future that would have those particular agreements in, and that is not the case, as you know.
Q. Right. If we may return, perhaps on the Magnum system, to {S/6/11}.
MR. MALEK: Can I make sure I understand this. Every time you entered into one of these three agreements, you did your assessment, as you explained.
A. We did our assessment.
MR. MALEK: Then once you have done three agreements, when it comes to do your projections on an annual basis, you will take into account what you have already done in the three previous agreements, would you not, the impact on the figures?
A. Yes, of course. They are cumulative. You would take into consideration for the year what the impact of the agreements would be.
MR. MALEK: That is clear. I have understood what you said. Thank you very much.
THE PRESIDENT: You do that for the year and also in any forward projections?
A. The forward projections, of course, on this were very difficult because of the environment.
THE PRESIDENT: Yes.
A. We were not expecting generics to come along so early because we thought the patents would be in place for such a long time. Then, when one agreement was dead we did not know how long it would be before another challenge came. We thought we would go to court, we thought there would be some hearings, so there was inherent uncertainty within the nature of this particular market at that point.
THE PRESIDENT: Yes. I mean, forward projections, particularly when the patent is challenged, are terribly difficult.
A. Very difficult.
THE PRESIDENT: I imagine it is one of your skills that you had to manage that somehow as best you could because you had to do projections, I suppose, within a margin.
A. We had to do some projections moving forward given what else could happen.
THE PRESIDENT: Yes.
A. Then particularly with the threats, because, as I am sure we will come to, with GUK it was almost in the hearing before a settlement was done. We actually were projecting, because we were not expecting them to come back, that that would be the case, that there would be a

launch at an early stage. We did not expect to get the interim injunction. So, again, that was a surprise.

So all of these things happening make that particular point around Seroxat very difficult to forecast into future. It was one of the things I was working on, that if we had generic competition on Seroxat what were the alternative strategies that the company could make, such as buying new products, expanding the portfolio, investing in other products in the portfolio that were under optimised etc.

We did lots on work on that and lots of planning on that.

MR. TURNER: None of which appeared in any documents produced to the Office of Fair Trading.

THE PRESIDENT: That is not Dr. Reilly's fault.

A. I cannot comment.

MR. TURNER: Let us go back to this line of questioning, Dr. Reilly.

We saw from your slide, February 2001, that there, for IVAX, you contemplated --

A. We have gone back to which tab?

Q. This is where we were before. In your bundle it is tab 11.

A. Because we are now on 35, so back to 11?

Q. You can take it from 35 at the moment. There you did calculate or estimate sales profit impacts on entering into that agreement, and we --

MR. MALEK: Can we have it on the screen?

MR. TURNER: Yes, {B2/37/4}.

THE PRESIDENT: The slide, yes.

MR. TURNER: You set out in money terms estimated negative financial impacts of entering into that supply agreement that you were recommending establishing. You see that?

A. Financial terms for a possible agreement, one source of a strategy.

Q. Yes, you did. Now, did you do the same thing when it came to GUK and Alpharma, or not?

A. A little difficult because we were not aware what was going to be happening, as I said, with that particular agreement. But there would have been some estimates in place, of course, but probably both scenarios -- well, definitely both scenarios.

Q. There were estimates?

A. Both scenarios.

THE PRESIDENT: Sorry, what are the two scenarios?

A. The two scenarios would be either going into a supply agreement or one of the generics coming on at risk onto the market for genericisation.

MR. MALEK: While we have this document up, the manuscript writing, you do not know whose that is, do you, at the bottom of that page?

A. No, sorry.

MR. MALEK: It is not yours anyway?

A. It is definitely not mine.

MR. TURNER: Now, if we go back to the CMA document {S/6/11}, which you should now have on your screen, this summarises, as well as the payments, what I have called there the straight cash payments taken from the contracts, the sacrifice in profit margins that form part of the CMA's decision.

For GUK, that was at least 7.5 million; for Alpharma, 5.9 million; for IVAX, at least £7.7 million. Now, are these figures that you have considered at all?

A. No.

Q. These figures --

A. I mean, how could I? Because I have talked about the inherent uncertainty of the situation here. So how could I project out to get to these numbers when actually you do not know how long these agreements are going to last, what is going to happen, who is going to come next.

I have referenced in my witness statement that I would draw your attention to the number of generics that were out there making a lot of noise, saying they were going to launch at risk, saying they were going to come into the market. There were lots of suppliers, lots of providers talking to a lot of generic companies.

Q. Dr. Reilly, I do not want to stop you, but in the interests of time all we are talking about here is figures reflecting the profit margin that would have been sacrificed by you, the impact on your company, of transferring product under supply agreements to other companies.

A. Sir, with due respect --

Q. Therefore, all I am asking --

THE PRESIDENT: Let counsel finish his question then he will be quiet.

MR. TURNER: What I am asking you is whether you have estimated at least numbers similar to that even if you do not recognise these numbers.

A. No. Could not possibly have happened.

Q. Sorry, your evidence now is that you would not have estimated similar numbers to what you did in relation to IVAX?

A. How could you estimate similar numbers to this? With all due respect, it is not easy to forecast an inherently uncertain future.

Q. With IVAX what we saw was that there were certain numbers there reflecting a possible sales profit impact. Do you recall that?

A. What I see here is not a cumulative three-year plan. I see some numbers representing some impacts over a forecast and maybe the next year.

Q. Dr. Reilly, I think --

THE PRESIDENT: Let Dr. Reilly finish.

Did you want to say something?

A. So when you put together a forecast, you have to make an assumption about the future. When that future is inherently uncertain, it is inadvisable to continue forecast out. If you talk to any financial director they will tell you you have to operate on that basis.

Q. Dr. Reilly, in each case you transferred agreed volumes, yes?

A. So you are changing the question now?

THE PRESIDENT: Just answer the question.

MR. TURNER: Please answer my question.

A. Can you give me the question, please?

Q. In each case, in each agreement, you transferred agreed volumes?

A. There was a volume provision of transfer to them, yes.

Q. In each case there was a transfer price, £8.45?

A. Yes.

Q. In each case there would have been an understanding as to what was the prevailing selling price, yes?

A. They would have estimated that, yes.

Q. Using those factors, one could arrive at an estimate of the profit that they would derive, yes?

A. They could do that, yes. That would not be how we would do it, but that is how they could do it.

Q. Tell us how you would do it?

A. The impact on us is slightly different.

Q. Of course it is.

A. I think, as I explained quite clearly on Friday, it is a different factor to calculate the profit impact to GSK.

Q. Yes. Yet you --

A. So these would be different numbers, different calculations to the ones you have here for some reason.
Q. Did you or did you not make such calculations, to be clear?
A. We estimated our profit impacts, as I have said many times this morning.
Q. Good. Now, if we take --
A. On an individual agreement basis. Okay?
Q. Let us then take the totality of these three agreements. We have in totality almost £30 million in direct payments under them, yes?
A. I do not recognise the totality agreement. So if you want to talk about each individual agreement then we can do it that way.
THE PRESIDENT: What you are saying is that is not the way you calculated it at the time?
A. That is right.
THE PRESIDENT: Yes. As a matter of fact, it adds up to about 30 million, just simple arithmetic, for what it is worth.
A. Yes. Okay. That is not the way we looked at it, but that is fine. If you say they add up to that, I have not personally added them up.
MR. TURNER: In relation to the profit sacrifice under the supply agreement, we do not have any figures here to speak of, but that will have been a significant figure at least in terms of millions of pounds as well, would it not?
A. We would have calculated that for each of the agreements, yes.
Q. If as a matter of simple arithmetic, one sums these, we have a figure which in the decision is put as at least £50 million given up by your company in total under these settlements over the period of the agreement. Are you aware of that?
A. I cannot comment on that one, I am afraid.
MR. MALEK: Can I just interject, because I understand what you are saying about these figures and it is clear that you would have done an assessment of the anticipated cost to GSK of each of these agreements at the time you entered into them. It would not be an exact science for obvious reasons and we do not know what volume they are actually going to take up etc, but can you just explain to me in relatively simple and short terms what that assessment would have entailed. What would it have been looking at? I do not need the precise figures, but what would that assessment have entailed?
A. The assessment in terms of the --
MR. MALEK: The cost to GSK for each of these agreements.

A. The cost to GSK, as we discussed on Friday, would be the differential between the selling price, less discounting down to parallel trade and the amount that was sold to -- the price it was sold at to the generic company. So the volume times that differential is the profit impact, and then on top of that there would have been the provision for marketing allowances and any other payments that were made.

MR. MALEK: That is fairly simple. Thank you very much.

MR. TURNER: Now, on Friday we were discussing a company presentation which referred to a £14 million downside looking at more than one of these agreements and with a view to another party joining the supply agreements. Do you remember that? If not, I will get you the reference.

It is on the Magnum system, {B8/269/2}; tab 16 to you.

Do you recall us discussing this document on Friday?

A. Yes, I do.

Q. You can see there that the author of this document, at paragraph 2, refers to the fact that:

> "Settlement has been reached [then] with IVAX and GUK ... and a supply agreement has been established with IVAX ... A key strategy to maintain market stability for Seroxat across the Plan period. In the plan it is assumed that one further party joins the supply agreement."

You see that?

> "The plan assumes that growth of the Seroxat molecule will achieve £4.3 million, while the lost margin as a result of the supply agreement will be £14 million."

Now, do you recall on Friday Mr. Glynn asking you questions about the level of company business that you were protecting by making those payments under the agreements?

A. Yes.

Q. Do you have that transcript of Friday? I am sorry, that is the one you would have put away. There is one further reference in it.

THE PRESIDENT: It has to come back to him. Dr. Reilly, does not have it at the moment.

(Handed)

A. Thank you.

MR. TURNER: To prevent you messing further with that, why do you not put that, if it is hole punched, at tab 41 in your bundle, which should be loose, and you can just slot it in there.

Now, looking at internal numbering, page 64, with the external numbering page 66, from line 26 we have Mr. Glynn's question {TR/5/66}:

"Did you put a number on the second set of calculations to compare with the 14 million?

"Answer: Sorry?

"MR. GLYNN: when you said the alternative would have been more costly --

"Answer: Yes.

"MR. GLYNN: -- did you put a number together which would compare with the 14 million?

"Answer: We would have had a number, yes.

"MR. GLYNN: Do you recall what it might have been?

"Answer: It would have been substantially more than this number, but not as large as you might expect ..."

Line 8, Mr. Glynn asks:

"So when you thought through those business responses you would have come to a figure that would be significantly more than still the 14 million?

"Answer: It would have been bigger than the 14 million, yes. But not 50 million because actually the sales force savings, etc, were quite considerable ..."

{TR/5/67}

You said then that the downside that you were avoiding would not have been as much as £50 million?

A. Correct.

Q. Was that on an annual or a total basis?

A. That would have been -- what does the 14 -- what are we comparing to in terms of the 14?

MR. MALEK: Can we go back to this document on the screen, please?

MR. TURNER: Yes. It is in tab 16 of your bundle, and for everyone else it is {B8/269/2}.

A. Tab 14?

Q. Tab 16 of your bundle on the second page.

A. So it seems to me there, reading that, that seems to be an estimate for a three-year period because this is a three-year plan.

Q. When you said in your evidence on Friday, "not 50 million because of the for sales for savings" were you talking, therefore, about a three-year period?

A. Probably.

Q. That is what you meant?

A. I would have thought it would not be that large over that period of time.

Q. Now, Dr. Reilly, if you had paid amounts of money, both directly in terms of the payments, almost £30 million, and in terms of profit margin sacrifice on top, which at least the authority estimates at over £20 million, if you had paid that amount of money in the settlements in question, in order to avoid a downside over three years of less than £50 million, does that not suggest a lack of confidence in the strength of your patents in court?

A. I do not really see the numbers that you are quite coming up with there because I think that is a bit unfair to ask me to make estimates on a plan that was for -- this is for 2003. So the basis for the 14 is very difficult for me to understand just from this document. The 50 that you have referenced was a number that you asked me to estimate on Friday, which I kindly gave to you, but the basis for that was just a discussion.

Now, you are asking me to tell you whether there is some correlation between those numbers that suddenly can be talked about in terms of patent confidence? No, I do not agree --

Q. If you pay very large sums of money --

A. Sorry, can I just finish?

Q. Of course.

A. I have stated many times, in both my witness statement and in the CMA discussions that we have had, that we were confident in the patent position and we were willing to go to court to fight that if settlement had not -- could not have been reached at a reasonable number.

Q. I understand that Dr. Reilly. I am asking you to draw an inference --

A. I do not think I can say any fairer than that.

Q. Well, perhaps you can just answer this question and then we will move on. If you are prepared to pay very large sums of money, over £30 million, possibly up to 50 million or more, in return for a downside risk of under £50 million, according to you, does that not suggest that the prize of maintaining integrity of the patents, as you have called it, suggests a lack of confidence in them winning in court?

A. I am sorry, but I do not agree with your numbers. I just do not agree with the numbers. I am sorry, you would have to explain to me the 14 and where you get the other numbers to come from. I think it is a little unfair for you to put those sorts of numbers to me. If you want to talk about the strength of the patent, I am happy to do that.

Q. I think we will leave that there rather than prolong the debate on this.

A. Okay.

MR. MALEK: Before we leave this document, can we just look at the top of the page, top of the document, would you have had input into this document at the time?

A. The executive summary?
MR. MALEK: Yes.
A. I would have had.
MR. MALEK: You would have had?
A. Yes.
MR. MALEK: You are saying 13 years later, it is slightly different.
A. Yes. It is a long time and to pick out a number of 14 million and to ask what is the context for that particular number, I would have to go back to the underlying documentation to see how the 14 was actually come up with and there would be documents at the time that existed to back that up. They may not be able to find them now, but certainly they did at the time.

So, I could do that, but now from the top of my head, without any knowledge, looking at this, I am sorry, I cannot do it.

MR. GLYNN: Could I ask one further question. When you are thinking about maintaining the integrity of the patent, are you thinking about the UK market exclusively or are you also taking into account any ramifications for any other parts of the world?
A. No, just the UK; only the UK piece.
MR. TURNER: Well then, in that case, let me conclude with this, Dr. Reilly, leave aside any attribution by you or your company to the profit margin that you would sacrifice under the supply arrangements and focus only on the direct payments mandated under the supply agreements, which as a matter of simple arithmetics sum to around £30 million and stop there.

For that money alone you are referring to a downside risk in your evidence on Friday of less than £50 million. What I am asking you is whether, if you are paying such large sums of money relative to the value that you say you are seeking to protect, that does not suggest to you a lack of confidence in your patents in court?
A. Okay, I have said many times in many witness statements, in many forums, over many years, actually, that we were very confident in the patent and we were happy to go into court to fight those, which we almost did. We wanted to do agreements, if that could take away the risk of something going wrong in the patent hearings.

So, if you want to calculate out what the actual protection of the overall deals were giving, you would have to take the sales over the whole period of time, the gross profit, and calculate it out properly as well as re-allocating all of the sales force costs. Now, it could be done, but I do not have the numbers to do that right now.

Q. So the less than £50 million downside risk that you referred to on Friday, taking into account the savings on the field force and so forth, that is not a reliable number?
A. You asked me for an estimate in terms of from -- bear in mind this is 2003 -- you asked me for an estimate. I gave an estimate.
Q. Right. Let us leave that there.
I will ask you perhaps one more general question and then it may be a convenient time to have a short break.
These agreements, Dr. Reilly, the three agreements, were connected, were they not?
A. Connected in what way?
Q. They were part of a single arrangement, IVAX was a distributor and GSK arranged the subdistributions?
A. I would not describe them as connected.
Q. IVAX did not have a free hand as to who it wanted as a subdistributor because GSK set it up so that GUK and Alpharma would be the subdistributors?
A. GUK and Alpharma eventually became the subdistributors on the agreement.
Q. By agreement with your company?
A. That is right.
Q. Each of the agreements with GUK and Alpharma, in fact, required the signing of agreements between them and IVAX as a condition precedent to the settlements, did they not?
A. They did for manufacturing purposes.
Q. For the purpose of the settlement more generally?
A. Yes.
Q. Yes. All right. Sir, it may be a convenient moment. I am going to come to the specific terms of the agreements next.
THE PRESIDENT: Yes. We will take 5 minutes.
(11.40 am) (A short break)
(11.50 am)
MR. TURNER: Dr. Reilly, I want to turn to the specific agreements and begin with the IVAX agreement. Can you open your main witness statement for these proceedings, which you should have there, and turn in it to paragraph 22 on page 7.
At the bottom of the page, just refresh your memory. You recollect that David Blanksby of IVAX approached GSK in mid-2000 and he was threatening to bring a paroxetine product to market and he told you that they had sought some marketing authorisation in Ireland.

If we go to paragraph 27 over the page, page 9, you say this:

"With the benefit of the documents that have now been shown to me -- that have been shown to me now, I see with hindsight from Simon Clark's witness statement that IVAX in fact did not consider it had a non-infringing product, they were bluffing."

The only specific document you refer to that was shown to you was the witness statement for the OFT by Mr. Clark of IVAX there. May I ask were you also shown the witness statement of Mr. Blanksby himself that was given to the authority, or not?

A. I think I have seen that. I may have seen that.

Q. Shall we turn to it. It is at tab 22A of your bundle, and for others it is {K/51/10}. This is a document that we have seen before in Mr. Flynn's opening.

The document begins at page 1, so you can see that there. Dr. Reilly, this is Mr. Blanksby's statement. If you go to page 10, then you will see what he says there at paragraph 5.7 concerning the Tillomed product:

"I do not recall being aware of any issues with the Tillomed product at the time, specifically any IP issues. I cannot remember what I knew at this particular time, about the Tillomed product, however I do not believe that I would have signed the heads of agreement with Tillomed if I considered that there were reasons to believe that Tillomed would not be able to supply IVAX. However, I also suspect that I was not free from doubt about Tillomed's product ..."

Does this come back to you now?

A. Yes.

Q. So you see there that there is something which does not appear to be bluff in terms of being able to bring a third party product to market there. So you would have seen that at the time with the documents that you were shown; is that right?

A. Seen that at the time?

Q. When you were shown this for the purpose --

A. Fairly recently.

Q. Yes.

A. Yes.

Q. If we go to paragraph --

A. So after preparation of this.

Q. You saw this after you had done your main witness statement, but not before it?

A. I think that is correct.

Q. Does it change your view?

A. It does not really change my view, I do not think.
Q. Does that not suggest to you that IVAX were not bluffing about the availability of a third party product?
A. At the time, they were very convincing that they had a product. They would not reveal the source and they were very aggressive in terms of bringing things to market, and they said they had an MA coming in Ireland.
Now, there is very little transparency about how these MAs are progressing, so it is very difficult to know whether that is the truth or not. So you have to go through those discussions.
Q. Now you see this document, do you on reflection think that your evidence in your witness statement that it is now clear to you that IVAX was bluffing is incorrect?
A. I had not specifically gone through this in detail. I do not know what the Tillomed product they are referring to is. Presumably that is from Hexal.
Q. Do you remember GUK speaking to you about the Tillomed product, or not?
A. No.
Q. Could you turn over the page to page {K/51/12} and read paragraph 6.4:
"Whilst I cannot fully recall the discussions, I believe that I may have said to Mr. Reilly that I was talking to GUK and Tillomed regarding possibly taking supply of paroxetine."
A. IVAX were discussing with GUK, I know that. Tillomed, I cannot -- I mean, they were not sharing with me what companies they were or were not talking to. They were talking to a lot of different companies. There were a lot of different suppliers out there, as I have said many times.
Q. Do you at least accept that the statement you made in your witness statement was based on incomplete appreciation of the documents because you only saw this afterwards? Would you at least agree on that?
A. So, about them bluffing?
Q. Yes.
A. Well, I think that is what Simon Clark had said.
Q. I am asking you now that you see this as well, whether you accept that there were other documents that you had not seen which give a different picture?
A. It is very difficult for me to say. Simon Clark is saying they may be bluffing. David Blanksby appears to be saying something different, I do not know.
Q. It is not therefore clear whether they were bluffing, is it?

A. I am not sure about that situation. I would have to go through each document. I only have my recollection at the time, which is that they made a very strong case that they had a legitimate source of supply.

Q. Good.

Now let us turn to the IVAX agreement itself, which is at tab 23 of your bundle and, for everyone else, at {L/1/1}. Do you have that?

A. Sorry, which reference?

Q. This is tab 23 of your bundle. At the top it says:

"Supply Agreement.

"This agreement is made this third day of October ..."

Do you see that?

A. Yes.

Q. Now, I am going to deal with some of its terms. So keep a thumb in that, please.

If you could turn over to tab 24 while keeping a thumb in that, which for others is {B1/11/1}, here we have a note of a meeting that you attended with the Office of Fair Trading in December 2011. If we go in that to page {B1/11/5}, at the top you have paragraph 19, and you are recorded there as having said -- "MR" being your initials:

"MR said that IVAX had obtained certainty from its supply agreement - although there was a limited volume of product supplied."

That is a fair description of the arrangement for the supply of product, is it not?

A. Sorry, this is the OFT meeting?

Q. That you attended.

A. Yes, I did. Bear in mind this is several years ago. It is December 11. So you are asking me to comment without reading prior --

Q. I am asking you to agree with that description which it appears you yourself gave.

A. I gave in 2011, yes.

Q. That is an accurate description?

A. It seems to me, I think.

Q. Then let us turn back to tab 23 of your bundle, for others {L/1/9}. Here we can see the orders for the product, and we see that IVAX was to provide GSK with a 12-month forecast of likely sales volume requirements with estimated monthly requirements. Clause 7.1?

A. Sorry, where are you now?

THE PRESIDENT: Where are you?

MR. TURNER: Page 9, 7.1.

THE PRESIDENT: Let Dr. Reilly find it.

A. "Orders for the Product".

MR. TURNER: Yes. You see from 7.1 that IVAX was to send the 12-month forecast of their requirements, and so forth.

A. Okay.

Q. You see also, if you read down to 7.3, that:

"For technical reasons the quantities ... [were not to] exceed 770,000 packs unless otherwise agreed"?

A. Yes.

Q. Those technical reasons are not explained in the agreement, but you refer in your witness statement for these proceedings to practical reasons to justify that provision. That is at paragraph 90 of your statement, {E/2/23}.

If you go back to your statement, which is where you talk about the practical reasons.

A. Okay.

Q. Those are the technical reasons, these practical reasons?

A. Yes, they appear to be.

Q. There was no technical reason why GSK could not produce more than 770,000 packs, was there?

A. What do you mean "technical reasons"?

Q. There were no technical reasons preventing GSK from being able to produce substantially more than 770,000 packs for these supply agreements, was there? There was nothing about that figure that had any magic to it?

A. No.

Q. Indeed, we know that GSK made amendments to the supply agreements and they increased the volumes without any technical difficulties to enable supplies to be made to GUK and Alpharma.

A. Mm.

Q. Through the second addendum, which, if you turn to your tab 23 -- you should have a green tab. If you go behind that. For others, it is {L/4/1}.

The amount of the product was increased directly up to 1,520,000 packs a year. We see that from clause 2.6 {L/4/4}. For technical reasons now we are enabling IVAX to manufacture 1,520,000 packs. You see that?

This document, of course, on page {L/4/5} was signed by you?

A. Okay.

Q. Then if we go to in tab 23, the third addendum which should be, for you, behind a red tab, {L/5/1} for others. Again, the total amount of the product now rises to enable IVAX to manufacture 2,020,000 packs per year, which we see from the bottom of page {L/5/2}, clause 2.3. This document is not signed by you; it is signed on behalf of your company by Cynthia Robinson.

A. Okay.

Q. The IVAX agreement requires IVAX to provide you with a 12-month forecast and to keep you updated throughout the year, as we have seen.

Dr. Reilly, there is no reason why forecasts on a rolling basis could not have addressed the problem of planning, was there, bearing in mind the way in which these levels could be increased to accommodate other supply agreements in that way?

A. The production planning process, given enough time, that is fine.

Q. If we go back to your statement, page 9, paragraph 29 {E/2/9}, you say there -- give me a moment to turn it up, page 9, halfway down:

> "... I recall IVAX did not agree to any restriction on their sourcing paroxetine from an alternative supplier, either explicitly or implicitly."

If I can use one of your words "incentives", they would not have had an incentive --

A. Sorry, incentives came from?

Q. That was a word that you use in your witness statement that we were discussing on Friday, but --

A. Did I use it in that context?

Q. Do not get hung up on the word, please, but just to answer the question, IVAX did not have --

A. So why use the word?

Q. I do not want to spend time going back to another part of your statement, but Dr. Reilly IVAX did not have incentives to challenge you by drawing on alternative sources of supply of paroxetine, did they?

A. They could have done.

Q. Did they have motivation or incentives to do that when they were under this supply agreement? Was that your evidence?

A. They could have done, because if other generics had come into the market then they could have taken their choice.

Q. What if other generics had not come into the market, did they independently have an incentive to take supplies from an alternative source, or not?

A. They could.
Q. Did they have an incentive to do that?
A. They would have an incentive depending on what they thought was going to happen in the market. So if they thought the patents were going to be weak and were going to be broken, then actually they could.
Q. Was it something that was envisaged that they would do or might do as part of this agreement?
A. It was something that was discussed as a risk, yes.
Q. Let us turn to your CMA interview again, which is at tab 2 of your bundle {E1/12/29}. Do you have it loose?
A. It appears I do. 29?
Q. Yes. Do you have that?
A. Yes.
Q. Let us look at the top of the page.

Mr. Moore asks you:

> "Turning to the actual ... the detail of the IVAX-GSK agreement. What was your understanding as to whether IVAX was permitted to enter the market with its own product during the period of the IVAX-GSK agreement?"

You said:

> "It was not envisaged, although I do not believe that there was a provision stopping it coming to the market; it could still have come to the market as far as I was aware. But again, it would be at risk because we had the patent protection in place and we were protecting that IP."
>
> "MOORE: Yeah. Could you just talk to me about 'it was not envisaged' and why was not it envisaged?"

Your answer:

> "Well, they were on the market selling a product, so why would they challenge us from a legal perspective, which essentially is what they would be doing by coming into the market?"

In other words, Dr. Reilly, you were recognising that the terms of this agreement would satisfy their profit requirements?

A. No, that is not strictly true from a commercial perspective. I agree, everything I have said there is fine but I think you are interpreting it slightly wrongly.
Q. Why?

A. Because they could have come onto the market. At the time this was signed up, we did not have an injunction in place. Injunctions had not been granted at that point, so the market dynamic could have been very different. So I do not think it is fair to say that there was no motivation. There could have been a motivation for them from a commercial perspective, and they could have done it.

Q. What would have triggered them to motivate them to do that apart from other generics coming onto the market first?

A. If they felt that somebody else was going to come on quickly, they could get in first. Being first on the market for the generic companies was something that they were all striving to do, something very important to them in terms of their business. So there is a lot of drivers, a lot of things that they may have wanted to do to be first onto the market, first to get that position, if they thought genericisation was coming.

Now, of course, there are still patents in place, they are still subject to legal challenges from GSK.

Q. If IVAX had launched its own product, let us take what you have just said, that would have caused, leaving aside you challenging them, a reaction in the market, would it not?

A. It would.

Q. In your witness statement, at paragraph 71 {E/2/19}, your evidence is --

A. Can we just down the pace a little bit, please, a little bit slower.

THE PRESIDENT: Let Dr. Reilly catch up with where you are.

A. Thank you.

THE PRESIDENT: It is paragraph 71.

MR. TURNER: Four lines down.

THE PRESIDENT: Give Dr. Reilly a chance to read the paragraph. (Pause)

A. Okay.

MR. TURNER: Any entry to the market independently risks provoking wider generic entry, yes?

A. Yes.

Q. As we have discussed, prices then fall dramatically, yes?

A. If there is a lot of generic entry at the same time, a lot of generics coming on.

Q. It would lead to that?

A. It depends how many want to take the risk.

Q. You would agree that generic entry would lead to this dynamic taking place, would you not, prices falling in the market?

A. Possibly. Because if one generic comes on, that is a different dynamic to lots of generics coming on. Entering at risk is a pretty -- well, it is at risk, so there is financial penalties if the product is found to be infringing. So they would have to be very confident.

Q. If others do come in and if prices fall, let us then remind ourselves what the agreement says. If you go to tab 23 of your bundle, for others at {L/1/3}. Do you have clause 3.2?

A. Yes.

Q. The termination provision.

You will recall there that if:

> " ... during the term of this agreement ... the average price offered by any party to retail pharmacists over an average period of three (3) consecutive days for a generic product (other than Seroxat or the product) having paroxetine hydrochloride as its active substance reach £8.45 per pack or below IVAX shall have the option to terminate this agreement forthwith."

So the likely drop in prices would have led to termination of this supply agreement, would it not?

A. If there was full genericisation, yes.

Q. In your CMA interview, if we can go back to that, please {E1/12/42}, you explained there that you would not see any point in renewing -- let us look at the top of the page, Mr. Moore's question to you.

A. Page?

Q. Page 43, bottom of page 42. I am looking at the bundle numbering, not the internal.

THE PRESIDENT: I am not sure Dr. Reilly has the bundle. I think he has the statement loose. In the statement, are you on page 41?

MR. TURNER: I am not in the statement, I am in the transcript of the interview.

THE PRESIDENT: The interview, yes. The internal numbering, is it 41?

MR. TURNER: The internal numbering is 41.

THE PRESIDENT: The page that begins "Yes, yes".

MR. TURNER: That is it, and at the bottom of that page --

THE PRESIDENT: Just a minute. Let Dr. Reilly get the page.

Do you have a page where Mr. Moore at the top says "Yes, yes"?

A. Got that.

THE PRESIDENT: Near the bottom, Mr. Turner, you want to ask about something there.

MR. TURNER: You begin by saying:

"But certainly you pointed out other possibilities for IVAX, in terms of there was no stop to them launching their own generics. There was other companies out there so lots of things could have happened."

Mr Moore, top of the next page:

"Yes and how would that particular point about, IVAX no prohibition in the agreement as it were. How would that impact upon the renewals provision just so I understand that, on the possibility of options arising?"

Your answer:

"I think that would remain to be seen. But I would not, if they launched their own, I would not see there would be any point, but I think that would have to be reviewed."

In other words, you were saying that there would be no point in renewing the IVAX agreement in the event that IVAX launched on their own, yes?

A. They would be challenging a patent if they launched on their own.

Q. There would be no point in the renewal?

A. Well --

Q. It is obvious?

A. If they have launched their own product.

Q. Yes.

A. So, yes.

Q. It would be the end of this arrangement.

Now let us turn back to the IVAX agreement {L/1/6}, which you have at tab 23 in your bundle, please. If you go in it to page {L/1/18}, very simply you have the supply price, £8.45 per pack?

A. Sorry, which page?

Q. Page 18.

A. Right.

Q. Your evidence in paragraph 31 of your statement -- you do not need to go there; we can if you like -- is that this was a low price which would have provided IVAX with substantial margin to compete for customers. Yes?

A. 31?

Q. Paragraph 31 of your statement {E/2/9}.

Do you remember saying that?

A. I see it here, yes.

Q. So that was your evidence.

Now, it was not envisaged by you that IVAX would undercut the existing prices paid by customers as you confirmed on Friday, was it? It was not envisaged that they would undercut, in their marketing behaviour that they would not seek to undercut to win business?

A. They would have to to a degree. They would have to take the prevailing market price and compete with that, as we discussed, and that is notably the parallel trade.

Q. Yes. This is an area of evidence we covered on Friday. Do you remember going over that on Friday?

A. Yes, I do.

Q. Do you wish to change any part of your evidence on Friday?

A. Is there something you want to show me?

Q. No, no, no. If you remember it, I am just wondering whether we need to revisit it or whether you agree with what you said on Friday about the likelihood of them competing or setting their price at the prevailing price.

A. Well, they would have to compete in the marketplace.

Q. We will show you just one document to refresh your memory about what you said at tab 20 of your bundle, for others {A2/15L/2}.

This was, if you remember, your witness statement in the GUK litigation. You will remember what you said there, which you agreed with on Friday, at 2.6. Do you remember that:

> "... Norton will want to maximise its return on the price which it pays ... and so is unlikely to want to undercut the existing prices paid by customers"?

Do you remember that?

A. I think I am saying here, expect Norton to be selling at a similar price to parallel importers, which is below the UK pack price.

Q. Meaning your own Seroxat price?

A. Yes. So they have to compete with the parallel trade.

Q. Now, let us turn to the question of promotional allowances. You deal with that in your main statement, I am not asking you to turn it up now, at paragraphs 34 to 36.

If we can go to the IVAX agreement again at tab 23 of your bundle, for others at {L/1/6}. If you go, please, to page 6, you have clause 5. You will recall from the first line your agreement to pay IVAX:

> "... a promotional allowance of £3.2 million ..."

You see that?

A. "SB shall pay to IVAX a promotional allowance ..."
Right?
Q. That was a substantial sum in circumstances where generics do not need to have substantial marketing expenditure, is it?
A. As I have mentioned in several interviews and also with regard to my statement, that this should be viewed with regard to the overall biggest lever that they have, which is price.
Q. Could you explain that?
A. So this is essentially, as we discussed, they can offset this versus the price of the pack in their own accounting.
Q. Your evidence is that these funds were for IVAX and, indeed, for the other generic companies to treat as they wanted, was is not? They could decide what they wanted the funds for?
A. They could decide if they wanted to use it for rebates and pricing issues. They could -- if they wanted to use it for some marketing purposes and promotional purposes, they could.
Q. If they wanted to do it for anything else or, indeed, for neither of those purposes, they could?
A. Well, it is probably what they would do, but the marketing and promotional campaigns for generic companies, as we discussed on Friday, they exist, they are legitimate, but they are smaller than for an R&D pharmaceutical company.
Q. You said a moment ago it is probably what they would do, but you expected the generic would price at the parallel import level.
A. Mm.
Q. If they price at that --
THE PRESIDENT: I know you said "mm". You have to say "yes" for the recording.
A. Sorry.
MR. TURNER: Yes, and if they price at that level they do have a healthy margin on top of the £8.45 transfer price giving them headroom to discount, do they not?
A. Agreed.
Q. So there is no need for a marketing allowance to be used to fund discounts, is there?
A. But they could.
Q. Let us turn to the side letter. Go to your statement, paragraphs 37 and 38 {E/2/11}, and remind ourselves what you said there. Do you see that?
A. Yes.

Q. So this is the arrangement where GSK would compensate IVAX £3.2 million in a number of scenarios depending on outcomes in GSK's litigation with GUK.

A. Yes.

Q. The side letter itself is at tab 27 of your bundle, for others at {L/2/1}. We see from this, if you turn the page to page 2 {L/2/2}, clause 2 provides that if you obtain judgment against GUK, that you will seek to recover damages and the amount of the damages so recovered will not exceed £3.2 million, and that is payable to IVAX.

We also see from clause 3 providing for a similar result if GSK ceases to prosecute the claim as a result of a settlement, and that is compensation paid by GUK to GSK and up to an amount not exceeding £3.2 million again.

This is a side letter of course that you signed, as we can see from the bottom of it?

A. Agreed.

Q. So you were familiar with its terms and its purpose?

A. As I said in my witness statement, I remember the discussion, I remember it being a big deal -- a big important issue for IVAX in terms of GSK continuing to enforce its patent position.

Q. Now, as well as --

A. Sorry, GSK.

Q. Yes, and as well as enforcing the patent position, this is an arrangement for paying further money across to IVAX in certain circumstances, is it not?

A. Only if GSK did not enforce its patent.

Q. In the event that you do enforce your patents, rather, and you obtain judgment or you obtain money under a settlement, if you do do that and you obtain money, you will pay up to £3.2 million to IVAX. You see that?

A. I understand that this is quite poorly drafted, but it was if GSK did not enforce its patent, there would be an amount payable. It was IVAX just wanted to make sure that that was an incentive to do that.

THE PRESIDENT: Sorry, I did not quite understand. Are you saying what the agreement says, that if you get a judgment against GUK in the action, then you must get damages from GUK and pay out of those damages up to 3.2 million? That is what the side letter says.

A. If we get damages -- sorry --

THE PRESIDENT: Just one moment. So if you get damages, that means you are enforcing your patent. Is that not right?

A. Your concern for IVAX --

THE PRESIDENT: Pausing there a moment. If you get damages, that is through enforcement of your patent, is it not? Is that not correct?

A. It would be through enforcement of the patent post-generic entry.

THE PRESIDENT: Yes. Well, it would be for infringement.

A. Exactly, for infringement.

THE PRESIDENT: Yes. But you would be enforcing it by getting a judgment?

A. Agreed.

THE PRESIDENT: You were not expecting an injunction, you explained, so this is the way you would expect to enforce it?

A. Yes, agreed.

THE PRESIDENT: Yes. Then you pay 3.2 million?

A. Agreed.

THE PRESIDENT: Yes.

MR. TURNER: Dr. Reilly, nothing in the side letter avoids your other obligation under the main agreement to pay the 3.2 million promotional allowance, does it?

A. It was the same.

Q. Well, it is obviously not the same.

A. My understanding was it was the same.

Q. If the side letter was -- well, you signed this -- triggered, IVAX would be entitled to both the promotional allowance and the money provided for in this side letter?

A. A slight moot point, but my understanding was it was supposed to be the same.

Q. What was your understanding based on?

A. My discussion at the time with David Blanksby and Cynthia, who was there.

THE PRESIDENT: Can you just explain to me, if you look at the promotional allowance -- are you able to turn back to that in the agreement? It is clause 5.

MR. TURNER: Tab 23, Dr. Reilly, page 6.

THE PRESIDENT: Page 6, yes. This is the clause about the promotional allowance:

"SmithKline Beecham shall pay to IVAX ..."

Do you have it? It is on page 6.

A. I have it.

THE PRESIDENT: Clause 5 {L/1/6}:

"... a promotional allowance of 3.2 million in recognition of its promotional activities required to support the distribution of marketing the product. This sum shall be

payable by way of monthly instalments of ... (£450,000) in the first month and thereafter eleven payments [and so on] ... by electronic transfer ..."

Once this agreement comes into effect, which it did pretty quickly, the payments start being made monthly?

A. Agreed.

THE PRESIDENT: The side letter is envisaging something that had not happened yet, because you had not even -- I think at that point you are talking about October 2001. Any question of any judgment against GUK would be quite far in the future for damages.

A. Sir, actually the injunction was in the October time. The October time was very significant in terms of the date. So I think the injunction was in the same month. The concern was if we did not get the injunction against GUK, they would launch and that actually the --

THE PRESIDENT: Then you would have to get damages.

A. Then we would have to get damages. But if they launched, a lot of people came onto the market at risk, then we would have to -- the prices would drop, that was the concern.

THE PRESIDENT: I understand that. But getting damages from them, on 3rd October you did not have the injunction yet.

A. No, we had not.

THE PRESIDENT: If you had to get damages from them in a judgment, that legal process, as you know, it takes quite a while. It is not very quick.

A. Yes.

THE PRESIDENT: So that would be months if not a year away to get damages.

A. But the concern was from IVAX that GUK would launch very quickly in around the October, so actually their supply agreement would not get going and would effectively terminate very quickly.

THE PRESIDENT: So what you are saying is that if the supply agreement terminates, you still have to pay a promotional allowance, do you not?

A. If it terminates I think we would -- they would be stopped.

THE PRESIDENT: That was not how I understood clause 5, if you go back to it. I am looking at the last sentence of clause 5:

"In the event that this agreement --"

Do you have clause 5?

A. Hang on, I will just get there now.

THE PRESIDENT: Sorry, you are having to jump between documents, which is always --

A. Clause 5.

THE PRESIDENT: Yes. Do you have clause 5? The one that is:

"... allowance of 3.2 payable monthly ..."

And then the last sentence:

"In the event that this agreement terminates before the 12 month period has expired, other than ... 3.3 ... 3.4," which is about liquidation and company takeover, "then all outstanding instalments shall remain payable for the remaining month during that 12 month period."

So you continue to pay 450,000 a month. It does not stop, you see?

A. My impression was that this was the -- well, at least the discussions led me to the conclusion that this was the same 3.2 million and they were just making sure that that is what they got for the period of time in the same way.

THE PRESIDENT: Did you get assistance from lawyers --

A. Cynthia Robinson.

THE PRESIDENT: -- for the drafting of the agreement and the side letter?

A. Yes, she drafted it.

THE PRESIDENT: You would have told her what you expected?

A. Yes, well, she also had a discussion with the IVAX lawyer to come up with these form of words.

THE PRESIDENT: But as far as GSK was concerned, you were telling her what your understanding was.

A. Yes, that it was just one.

THE PRESIDENT: Yes, thank you.

MR. TURNER: In the interests of time, let us move to the next agreement, Dr. Reilly, the GUK agreement which you deal with in your main statement at 39 to 47. If we go first to what you say on page {E/2/13} of your main statement, paragraph 47.

Do you have that?

A. 47.

Q. Paragraph 47. You say how the discussions with GUK, who were at a very advanced stage, in the paragraph above, had taken almost six months and had been broken off twice with GUK returning to the table each time.

Now, GUK declined a series of offers, each one of increasing value, from your company to settle, did they not?

A. I would not characterise them as offers, they were discussions and negotiations about whether a possible settlement could be reached.

Q. At different levels of value that were referred to in each of those?
A. Different types of deal, yes.
Q. Yes. After those rejections, you expected GUK to go to court, did you not?
A. Well, they were going to launch.
Q. You expected them, you said there is no more deal, they are going to go to court, they have rejected our final offer; is that right?
THE PRESIDENT: When you say "go to court", I mean, I am not sure it was expected. Do you mean it was expecting GUK to start proceedings for a declaration, or do you mean to launch, so that GSK would have to go to court? They are two different things.
MR. TURNER: Yes. To end the settlement discussions and simply pursue the litigation to a conclusion.
THE PRESIDENT: To launch at risk, do you mean?
MR. TURNER: No, to pursue the litigation to take the court case forward is the thesis. Perhaps I will show the witness this --
THE PRESIDENT: I do not think your question is quite clear, what you are asking.
MR. TURNER: That they would no longer be interested in pursuing a settlement agreement, but would instead simply prosecute the court case to see what the outcome would be.
A. It would launch.
Q. Let us go to what you said. If you go to tab 29 of your bundle, please. For others it is {E1/23/1}. This is an email that you sent on 2nd January 2002. Do you have that?
A. I do.
Q. Do you remember this?
A. Yes.
Q. Was this in the bundle you were shown before you came to court?
A. This was, yes.
Q. Now, you addressed this email to David Redfern in your company, Cynthia Robinson and Cameron Marshall, and you copied it to Eddie Gray. You also addressed it to the two patent lawyers from Simmons & Simmons, Rowan Freeland and Paul Inman. Yes?
A. Yes.
Q. Were you in direct communication with them?
A. No, I was not, generally speaking.
Q. But for the purpose of this email you were, yes?
A. Yes.

Q. Now, with the benefit of seeing this email, it does seem to be that there was a line of communication with those individuals, but you were saying a moment ago that there was not any more wider communication with them than you could have seen from this email. Is that right, or was there a line of communication that you did have directly with Simmons & Simmons?

A. Simmons & Simmons were in periodic conversation with me with regard to witness statements etc.

Q. But did they discuss the merits of the case with you as the finance director of the company, or --

A. A little bit, not a huge amount.

Q. A little bit?

A. When they came in to discuss witness statements etc, there was one or two meetings, as I said, that Cynthia had organised. There were not a huge amount of meetings with Simmons & Simmons.

Q. But they did discuss those matters with you a little bit?

A. Mm.

Q. Now, in this email from you you begin by saying:

> "I have received confirmation from Richard [presumably Richard Saynor] this afternoon saying that Merck Generics have rejected the offer of a commercial settlement for Paroxetine. They are clearly only interested in a European deal. I could not negotiate away their requirement for assurances of further European deals."

Then you said:

> "As they have now rejected our final offer they will now go to court."

What did you mean by that?

A. Well, they had two opportunities in terms of discussions. One was up to October when they could have -- they were going to launch but we got an injunction against them, and then when we had the injunction against them then they would go to court in terms of the patent litigation.

Q. So they would take that patent litigation on to its conclusion, that is what you meant?

A. Yes.

Q. You then say after that:

> "David", presumably David Redfern?

A. Presumably.

Q. "... I will call you on Monday to discuss possible financial implications."

So those financial implications include the financial implications of losing the litigation?

A. Of course.

Q. In GSK's proposals, the figures for sales and marketing costs that you were putting to them in your settlement proposals were used as alternatives to giving them packs of paroxetine per annum, were they not? The two were used as equivalent value items? Different ways of packaging the same value offer?

A. It started off with settlement around volume. The marketing allowances only came in with regard to after the first agreement when the 8.45 pack became a requirement because of some issues around European pricing and international pricing.

Q. But you agree that those were different ways of giving them value, different ways of packaging the value offer? A very simple question.

A. I would not quite characterise it that way. But it was a discussion in terms of how many packs could they have etc, what were the commercial terms for those agreements.

Q. Yes, to give them the minimum that they would accept?

A. Well, to discuss what was a reasonable settlement for the risks that we were facing.

Q. Yes, to give them the minimum that they would accept to settle?

A. Well, it was something that had to be negotiated. It was a mutual agreement to settle the patent litigation. If we could not reach that, they would have gone to court, as I have said, and they fully intended to, they say.

Q. Yes, they did.

At paragraph 43 of your statement {E/2/12}, go to that, you suggest that the granting of the interim injunction against GUK, that is October 2001, caused a change in GUK's attitudes in the negotiations. Do you recall that?

A. It did, yes.

Q. Now can we turn to your CMA interview, which for everyone else is at {E1/12/49}. Just look at the top of the page; see what you said at that stage on this point.

Taking it from Mr. Moore's question to you three lines from the top of page 49:

> "Were GUK more aggressive, less aggressive; was there any impact arising from that particular granting of the injunction?"

Your answer:

> "Obviously it was a bit of a shock for them because they were not expecting it, because not many injunctions had been granted. So yes it was a, a proof that particularly in this environment not everything was going to go their way, but it did not hold them off for very long."

That is right, is it not? It did not hold them off for very long?

A. Well, it was a shock to them. There had not been an interim injunction granted previously, so that was something that was unexpected.

Q. It was. But the last part of this, which I am focusing on, was "it did not hold them off for very long", and you would agree with that as having happened, that they then continued?

A. They then continued to make preparations and we were going to go through a litigation.

Q. Yes. They did.

Now, let us turn to the terms of the agreement. For others it is at {L/8/1}, for you, Mr. Reilly, it is at tab 29 of this bundle. Or is it in tab 30? It might be an error.

A. 30.

Q. 30. So this is the agreement that was signed and which entered into force on 13th March 2002. Again, you are the signatory.

Now, in the interests of time, I am going to restrict the questions about this. Start with the volume restriction and look at clause 3.1, please.

A. You mean the volume allowance?

Q. {L/8/2}.

THE PRESIDENT: You are in L?

MR. TURNER: I need to go not to this, but to the GUK-IVAX agreement which contains --

THE PRESIDENT: GUK-IVAX agreement?

MR. TURNER: Yes, because that contains the provision.

THE PRESIDENT: Yes. That is a different one.

MR. TURNER: That is at {L/10/1}, apologies, which is tab 32 for you, Dr. Reilly.

So here we have the provision that {L/10/4}:

> "Unless GUK notifies IVAX otherwise ... GUK shall order and IVAX shall supply in each contract year 750,000 packs."

So that is the level agreed as the volume in this agreement. Do you see that?

A. I see that.

Q. In your witness statement at paragraph 89 {E/2/23}, you said that you do not recall -- if we go to that -- any direct request from GUK or Alpharma for additional volume either.

Is it your evidence that they at no stage had wanted more volume from your company?

A. I am not aware of any request.

Q. Well, let us turn to tab 33 in your bundle, which for others is {B1/18/1}. Here we have a letter from Mr. Saynor of GUK to IVAX, and we see that as of January 2002, GUK was informing GSK and IVAX -- let us read it together from the second sentence:

"As you know, one of the principal sticking points has been that GlaxoSmithKline, through yourselves, has been unwilling to meet our required demand of 1 million packs per year (your latest offer amounting to 550,000 packs)."

Dr. Reilly, that rather suggests that your company had been unwilling to agree to a higher requirement of £1 million per year, does it not?

A. I think I am clear in my witness statement, and what you are showing me now at tab 33 is not something I have seen at any point.

Q. It may not be something that you have seen; does it not suggest that your company was unwilling to meet the requirement?

A. No, I see that Mr. Saynor has written to Simon Clark.

Q. But it is not something that you can assist with, is what you are saying?

A. That is true.

THE PRESIDENT: So when he says "GlaxoSmithKline have been unwilling to meet our required demand of 1 million packs", that has no recollection for you?

A. I am afraid that has no recollection. It was not raised to me.

MR. TURNER: Let me go straight to the profit guarantee. There was a specific provision in the GUK agreement, which you do not mention in your statement but which I do want to cover, and for this you will need to go to tab 32; for others it is at {L/10/5}.

This is the supply agreement that GUK enter into with IVAX. 14th March 2002. If you go in it to clause 4.3 on page 5, you will see -- have you seen this before?

A. I have not seen this agreement.

Q. You have not seen this?

A. No.

Q. Well, it provides for IVAX to pay GUK if the average selling price of a pack goes below £12.25. Then, although you have not seen this, let us go back to tab 30, which is {L/8/2} for others, which is the agreement between your company and GUK, and remind ourselves that you signed this agreement on page {L/8/3}.

Look at paragraph 5.1. You will see there that:

"If the exclusive distribution agreement between SB and IVAX is terminated SB agrees to perform certain of IVAX's obligations ..."

If you read down you will see this refers to the obligation:

"... on IVAX to maintain GUK's minimum level of profit over the term of the IVAX agreement in accordance with its terms."

5.2:

"If IVAX is unable to fulfil its obligations under the IVAX agreement SB agrees to guarantee those of IVAX's obligations under ..."

Which were identified in 5.1.

So do you recall now this agreement and linking it in that way to the profit guarantee?

A. I have not seen the previous agreement, but I do --

Q. You recall this now?

A. No, I am saying I do not recall the supply agreement that you just referenced. Why would I see that? But this, the profit guarantee, I remember being a discussion point at the time. Now, I think also if you recall from my witness statement, I was not in the final negotiations with this particular deal, although I did sign the agreement.

Q. Dr. Reilly, given the existence of this sort of guarantee, it would have been very dangerous for your company to compete actively on price against the generic companies, would it not, to take the price down, because that would trigger the profit guarantee?

A. It would trigger -- that was one of the issues, yes. It would trigger the profit guarantee, agreed.

Q. So that rather suggests it was not envisaged that your company would be competing on the price against GUK, does it is not?

A. Not necessarily, but there would be a cost to doing that.

Q. Why not necessarily?

A. Because it depends what happens in the marketplace.

Q. Can you explain?

A. If the patents have been invalidated or if somebody enters at risk, then that is a different position.

Q. Absent that position? If that were not to happen?

A. If that were not to happen?

Q. If the patents had not been challenged and overturned in court, then what?

A. Then there would be some drop in price, but it would not be as dramatic as with regard to for genericisation.

Q. And your company would not have been motivated or incentivised to compete on price against GUK, would it?

A. There was some competition on price but not a full genericised position.

Q. Let us turn to the Alpharma agreement, the third agreement. If you go to tab 36 of your bundle, for others it is {L/11/1}. Do you have that?

A. Yes.

Q. If you read clause 2, you see the provision stating that GSK shall ensure that it provides IVAX with 500,000 packs of 20mg to allow IVAX to supply Alpharma.

A. Agreed.

Q. Now, if we go to tab 37 of this bundle, which for others is {B1/24/1}, here we have a document containing Alpharma's internal emails of May 2003. Have you seen this before?

A. No, I have not.

Q. If you go to the third page {B1/24/3}, we have an email from a man called Russell Howard of Alpharma and he is writing to his team on 20th May. You will see the top of page 3 what he says:

> "Paroxetine, we will not get any more at this stage - GSK are 'quite happy' with limiting the market - but we should be getting our agreed share. This needs to be continually pointed out to IVAX."

Dr. Reilly, your company was quite happy with giving limited volumes to the generics, was it not?

A. We had agreed volume allowances as per the settlement agreements. There was no request for further volumes coming through. I am not aware of the people who are in the emails you are referencing from Alpharma or why they would write that.

Q. No, I am asking what your attitude was.

A. My attitude was --

Q. Quite happy to limit --

A. -- supplied them with volumes up to the allowances and they could have asked for more. Nobody asked for anything, that I am aware of anyway.

Q. Let us turn to a different topic now. In your statement at paragraph 69 {E/2/18} and following you give your views on possible alternatives to the settlement agreements that the CMA had identified.

A. 69?

Q. Yes. From paragraph 69 forward in your statement. It is under the heading in your statement "The CMA's comments on alternative courses of action". Do you see that?

A. Yes.

Q. Now, please can we go to tab 24 in your bundle, which is {B1/11/6} for others. Dr. Reilly, if you would go within that -- well, first of all let us see what the document is.

A. Sorry, which tab?

Q. This is tab 24. You will see this is the meeting we have looked at once before already between the OFT and Glaxo on 19th December 2011, which you attended for your company. Yes?

A. Yes.

Q. If we go to page {B1/11/6}, there was an exchange, you will see, about this matter. If we go to paragraph 24:

> "DM [Mr. Moore] asked whether payments would normally be part of supply agreements. MR [that is you] said that the normal process would be for a patent to expire and then for generics to come into the market. Any arrangements would be sorted out then. MR said that this was the only deal of this type that he had seen - and that this was due to GSK's patent position at the time which was considered strong."

So you said there that normally a patent expires and then the generic comes onto the market and then makes a supply arrangement; is that right?

A. Not necessarily. I do not think that is what I am saying. What I seem to be saying there is that --

Q. Any arrangement --

A. -- this is an unusual situation with regard to the data exclusivity, as we discussed on Friday.

Q. When you said "any arrangements would be sorted out then", were you talking about supply arrangements, or not?

A. They could have some supply arrangements there, I am not familiar with any deals of that type, but you could have.

Q. Indeed, why would generics make arrangements with you after patent expiry rather than sourcing independently?

A. There are a number of commercial strategies that you could use. You could do a supply agreement to -- it is an alternative to brand equalisation deals -- to supply into the market. It depends on your penetration in the market and it depends on the type of product.

Q. So you are referring, you think, to supply arrangements which would be made out after generic entry, after patent expiry?

A. That is what I seem to be saying here.

Q. You have said that this is the only deal of this type that you have seen and that was due to GSK's patent position being strong; is that right?

A. That is right.

Q. I put it to you it is the other way round, Dr. Reilly. If GSK thought its patent position was strong, then it would not have made these sacrifices five years before patent expiry, would it?

A. Yes, it would because there was an unusual situation, as I have mentioned many times, with regard to the data exclusivity point. That makes a big difference.

So the patent position was considered wrong -- was considered strong, but there are some risks because generics could enter the market at risk.

Q. If the patent position is considered weak, it would be more plausible that one would make arrangements of this kind to prevent the patents being challenged in court; would that not follow?

A. That is your theory.

Q. Would that not follow?

A. That is not the case here.

Q. Let us turn to the question of alternative settlement agreements. If these agreements had not been an option for you because they raise competition problems, and the payments that you made to secure stability had not been allowed, you would still have had to offer different terms to the generics if you wanted a settlement and to avoid them going to court, would you not? You would have needed different terms?

THE PRESIDENT: Just to understand, are you saying if this sort of settlement was prohibited by law, is that what you are saying?

MR. TURNER: Yes.

THE PRESIDENT: If GSK wanted to settle it would have to make a different kind of agreement?

MR. TURNER: Yes.

THE PRESIDENT: That is just logically obvious. If they could not do this one and they wanted to settle, they would have to do something else.

MR. TURNER: Without a term which was prohibited.

THE PRESIDENT: Whatever was prohibited they could not do it. I do not see the point of the question.

MR. TURNER: Dr. Reilly, your claim was that a royalty-based deal was not commercially feasible; is that right?

A. That is right.

Q. That is because it would have undermined the patent position, a royalty-based deal, you say, because it would signal to the market that GSK had allowed an infringing product onto the market?

A. That is always the problem. If you have a strong patent position, why would you do that? That would encourage other people to enter the market.

Q. I see. Is your evidence that as a general and invariable rule, royalty-based deals of that kind are not made by originators?

A. No.

Q. Is it your evidence that GSK never entered into that sort of arrangement?

A. No, I am talking about some of the problems in the marketplace, as I see it.

Q. Are you aware that GSK has entered into that sort of arrangement?

A. I am, actually.

Q. Shall we look at one?

A. You could do. Is it relevant?

Q. Yes, it is, because it shows that it is commercially feasible.

If you go to tab 38 of your bundle --

A. Does it match the patent position in this particular case?

Q. Dr. Reilly, in the interests of time, would you please answer the questions. If you go to tab 38 in the bundle.

MR. MALEK: Please give the document reference?

MR. TURNER: Which is {B2/61/1}. Here we have an internal GSK document from January 2004 entitled "Synthon STP".

Is this a document you have ever seen before?

A. No, this is not a document I would have seen or had seen.

Q. Let us look --

A. It is rather complicated, if you do not mind me saying.

THE PRESIDENT: What is it? Dr. Reilly has not seen it. What is this document?

MR. TURNER: This is an internal document of GSK. The author is over the page. But if you read halfway down the first page, you see a very short extract which simply records a position that I was going to put to Dr. Reilly.

Halfway down:

> "GSK settled an out of court agreement with Synthon in the USA at end December. As part of the settlement, two patents were said to be infringed - paroxetine hemihydrate (post ingestion) and paroxetine mesylate. A settlement was reached on ... hemihydrate of 5% royalty for life of patent to December 2006. Still waiting outcome of patent interference to determine validity of mesylate patent ... If GSK win then

Synthon to pay decreasing royalties per year of 9%, 7%, 5%, to low of 3% which will continue to end of US patent in 2019."

Dr. Reilly, we see there a settlement agreement in relation to paroxetine in which a settlement is reached on a royalty basis for the life of the patent in the period that is relevant to these proceedings.

A. The date on this is 2004.

Q. Yes.

A. Yes, and? These pre-date this by quite some time.

Q. Yes. Dr. Reilly, your evidence in your witness statement, which we can go back to --

A. I am aware you have read it out once.

Q. Shall we go back to it so we can see the question I am putting to you. It is at paragraph 73 in your statement {E/2/19}:

"Royalty-based deal."

You make a specific observation:

"... [this] would not have worked. It would have undermined the patent position."

Over the page you say {E/2/20}:

"If we had agreed a royalty-based deal in these settlements the way it would have looked in the marketplace in my view is that we had allowed an infringing product onto the market ..."

Now, the same is true in relation to this settlement, is it not?

A. So I am very happy with what I say in my witness statement and I stand by that. Turning now to this Synthon STP, could you explain what the patent position was with regard to those products to see what are the similarities that could be applied or do not apply to this particular case.

Q. Dr. Reilly, I am putting to you --

A. This is also US market.

Q. I am putting to you that for this sort of arrangement, a royalty-based deal was made that does not merely therefore signal in the marketplace you have allowed in an infringing product making it commercially infeasible?

A. You cannot say that when you do not understand the patent position on which you are facing. I am sorry. Unless you can give me details on the case it is very difficult to say.

THE PRESIDENT: Can I try and understand something. You say if we had agreed a royalty-based deal in the settlement, the way it would have looked in the marketplace, in my view, is that we had allowed an infringing product onto the market particularly with a small

royalty, which it was explained to me was contemplated internally by each GUK and Alpharma.

I am sure GUK and Alpharma, if they were going to pay a royalty they were going to want it to be as small as possible.

A. Agreed. Yes.

THE PRESIDENT: I can see if it is a small royalty -- a royalty-based deal is about licence, is it not? That is what they are talking about?

A. Agreed, yes.

THE PRESIDENT: If it is a high royalty, why does that suggest your patent is weak if you are able to extract a higher royalty?

A. Because essentially if you are putting a -- allowing a product onto the market you are showing some weakness. The view around the commercial team at the time when we discussed this was that actually it would encourage people to come onto the market because there was so many people offering supply and threatening to come onto the market in any case.

THE PRESIDENT: It would only encourage them to come on at risk if that --

A. At risk, agreed.

THE PRESIDENT: But if you were able to extract a higher royalty payment from a patent licence, in other words what people have to pay to get your permission to sell, does that not indicate a stronger patent? Is not the measure of the royalty an indication of the strength of the patent, is what I am trying to ask?

A. The degree of the patent.

THE PRESIDENT: Yes.

A. I would agree with that. But it does indicate if you allow anything onto the market that there is a reason for doing that, and that reason could be linked to the strength of your patent. Again, the discussion was we did not want to indicate there was any weakness in the patent position, we actually were rather going to fight that in the courts.

THE PRESIDENT: Yes, I understand, but if there is a licence and a royalty, then where it ends up is a reflection of the parties' perception of the patent strength.

A. I agree with that.

THE PRESIDENT: Would that be a sensible moment?

MR. TURNER: Yes, it is.

THE PRESIDENT: 2.05 pm.

(1.10 pm) (The short adjournment)

(2.05 pm)

THE PRESIDENT: Yes, Mr. Turner.

MR. TURNER: Dr. Reilly, just a few more questions and then we are done.

A. Okay.

Q. You say that a royalty-based deal, as it were, sends out a signal of weakness to the marketplace?

A. That is my opinion.

Q. The same would be true, would it not, with the supply agreements that you made in this case so long before the date of patent expiry?

A. No, I do not believe so because there is a fundamental difference between authorised generic, which is essentially manufactured by GSK, and another product that is allowed onto the market.

Q. From the perspective --

A. Given that we have patent positions.

Q. From the perspective of the marketplace, why would it not appear to be a signal of weakness that you had agreed these supply arrangements so long before patent expiry?

A. The patent expiry is a different position because of the nature, as I have explained many times, with regard to the market authorisations and the data exclusivity. So it is a very different position.

Q. Just to ask my question once more, from the point of view of third parties, why would their perception be any different with these agreements? What would they see that would be different to distinguish these supply agreements for third parties from the royalty-based deal?

A. They see that one product is essentially on the market, an authorised generics, as opposed to another product which is allowed onto the market. The patents remain in place.

Q. As they would be with the royalty-based deal?

A. No, because that is -- allowing them on with a royalty given the point about the magnitude of the royalty, which I accept, it is a very different message that you are sending to the marketplace, in my opinion.

Q. Precisely what was the message to the marketplace with these supply agreements that would have indicated the strength of GSK continuing after you had made them? What was it?

A. It is the patent position is still in place and we will take action to uphold our patent rights. Very simple.

Q. Let us ask you one question or two about early independent entry, so before the date of the patent expiry, allowing a challenger to come onto the market at a predetermined date. Do you say again that as a general and invariable rule, an originator such as your company do not enter into that sort of arrangement?

A. Sorry which? Are you referring to my statement again?

Q. I am asking you a general question.

A. Okay, could you repeat that, please?

Q. Do you say that as a general and invariable rule, originator companies such as GSK do not enter such agreements providing for early entry before patent expiry?

A. It depends on the circumstances.

Q. Yes, all right. Thank you very much.

A. Specific circumstances.

Q. I am going to ask you finally some questions on a slightly different topic. We were discussing on Friday the way in which competition takes place for the business of pharmacies and how much of that happens at the level of discounts and rebates from the list price, yes?

A. Right.

Q. If you had observed drug tariff prices rising during the terms of the supply agreements, let us say after Alpharma had come in, but the drug tariff going up, would you have said that that was a sign of competition?

A. Drug tariff going up?

Q. Yes.

A. From?

Q. From the level it was before. If you had seen that, would you say "Aha, that must be linked to competition in the market"?

A. I think you would have to analyse out what is the cause or the causal factor of that particular movement in drug tariff.

Q. But you would not say, would you, that that was going to be affected by competition?

A. Well --

Q. You would not infer that directly, would you?

A. You would not -- well, I do not know. The drug tariff is a very complicated calculation. There is lots of different lag factors in there. So you really have to take a look at each individual component.

Q. So one could not conclude from observing, let us say, a particular movement upwards in the drug tariff that that had been affected by competition resulting from these agreements?

A. No, that is not what I am saying. I am saying I would have to look at the dynamics broken down in a little bit more detail than just your finger pointing.

Q. Yes, and does the same apply in reverse, that if you saw a very slight decrease by a certain date, you again would not be able to infer directly that that was the result of competition, would you, by the same logic?

A. Obviously the drug tariff, in its components, is responsive to the average prices in the marketplace over a given period of time. So you would have to calculate out what is happening there.

Q. So the answer to my question is, yes, I am right, that you cannot infer directly from observing a slight change that that resulted from competition in the supply agreement --

A. You would obviously have to understand what is happening to the drug tariff.

Q. Yes, thank you.

If we turn to paragraph 95 of your statement, the last paragraph {E/2/25}, you will see that:

> "The drug tariff price from 2001 to 2003 has been shown to me ... This shows that the drug tariff price fell from GSK's list price ... £17.76 to £15.66 in June 2002 ..."

That was the IVAX effect that we know about:

> "... and £15.21 by November 2003, just prior to independent generic entry."

Therefore after Alpharma's entry.

There you said:

> "Those falls clearly resulted from the introduction of generic paroxetine under the settlement agreements ..."

Dr. Reilly, that second movement, for the reasons that we have been discussing, cannot be attributed without knowing a great deal more about the drug tariff to competition, can it?

A. As I said, you would have to analyse out what 15.66 to 15.21, what are the components within it.

MR. TURNER: Sir, I have no further questions.

THE PRESIDENT: Mr. Flynn, do you have any re-examination? Re-examination by MR. FLYNN

MR. FLYNN: Yes, thank you.

Dr. Reilly, just a couple of points to follow up on. On Friday -- it must seem like quite a long time ago -- you were taken to a table in the CMA's decision, which is in the decision file, which I think is {V/1/218}. I believe it would be in a tab in your file, but I am afraid I

do not know the tab number. Maybe someone from the CMA can help there. It is up on screen.

THE PRESIDENT: It is page 218 of the decision.

MR. TURNER: Tab 5.

THE PRESIDENT: Mr. Turner, which tab would that be?

MR. TURNER: That is tab 5.

MR. FLYNN: You either have it in front of you or on the screen, Dr. Reilly.

A. I have both.

Q. Just a couple of questions on that. You see on these two tables, 4.2 and 4.3, there is a column that says "GSK profits" in each case?

A. Yes.

Q. You see there is a profit figure for each of five years given: 1, 2, 3, 4, 5 --

A. Yes.

Q. -- and a total? Would you expect the total to be the total of the figures above it?

A. That is what is inferred.

Q. Yes. Just eyeballing it, do you think those are the totals?

A. It looks lower if you add it up.

Q. Yes. Take from me that if you had a calculator in front of you, you would be able to establish those totals are not in fact correct.

A. Okay.

Q. I can give the numbers. I see I have two different numbers here so I have not done it properly myself, but the first one is either 85.2 or 82.2 and the second one is 70.

You will see at the bottom of those tables, Dr. Reilly, it says:

"Source: CMA calculations based on annex 4 of GSK second response, part two."

A. Yes.

Q. You commented in relation to the second table, which is Seroxat 30mg profits, that the figures did not seem right to you. Is that right?

A. Yes.

Q. Do you recall that?

A. The profits do not seem right to me, they seem very high, particularly on the 30mg.

Q. The figure for sales also, did those seem right to you? I am looking at the 30mg table.

A. Yes, the 30mg table seems to be very overstated in my recollection. Obviously it is going back a long time.

Q. This is not a document that you have in front of you, but it will come up on the screen, the GSK response which is cited there. For the Tribunal's note it is probably in various places in the bundle, but one is at {G1/14D/6}.

I am sorry, it is G1/14C/--

THE PRESIDENT: 14D looked right, Mr. Flynn.

MR. FLYNN: Sorry, it probably was then.

I do beg your pardon, the tabs have perhaps got mixed up in my file. Seroxat UK data, and if you look down on the first table there, the Seroxat tablets 30mg line, you see the figures given there for 2001 and 2002?

A. Yes.

Q. On that basis, can you explain the figures given back in the decision at table 4.3 that we were looking at earlier? Perhaps I should ask you this: do those figures look reasonable? Do those figures look right to you?

A. That is much more my understanding of the situation. So they are significantly lower.

Q. I think that is fine.

THE PRESIDENT: Just one second. (Pause)

So 2003, 2004, 2005 are the same as in the table, but for 30mg, Dr. Reilly. In other words, in 2003 there were 25.9 of the 20mg and 22.6 of the 30mg. In 2004, there were 7.7 of the 20mg and 10.1 of the 30mg. Does that seem right to you?

A. So bear in mind --

THE PRESIDENT: It is a long time ago --

A. But the 2000/2001 numbers, the proportions seem right to me. That was more than I would have had in my mind.

THE PRESIDENT: As opposed to the later years?

A. To the later years, yes.

MR. FLYNN: Would you have been involved in the business in the later years?

A. No.

Q. So for the years that you can recall, the figures in this table on the screen --

A. Seem right to me.

Q. -- are more in line?

A. Are more in line with my memory.

Q. Thank you.

THE PRESIDENT: When did you cease being involved?

A. 2003, early.

MR. FLYNN: Unless the Tribunal has further questions on that point?

Then, Dr. Reilly, I think we are now into today, so possibly more recent memory. It was put to you that IVAX, as the head distributor, did not have a free hand in who it took as subdistributors. Do you recall being asked that question by Mr. Turner?

A. Yes, I do.

Q. Could we have a look, please, at bundle {E2/28/1}.

MR. TURNER: Tab 9.

A. Thank you.

MR. FLYNN: I am grateful to my friend.

This is your witness statement in the Apotex proceedings. If you look through that to paragraph 6.9 {E2/28/6}, Dr. Reilly.

A. 6.9, right.

Q. You see there:

"GSK understands that IVAX has appointed two subdistributors. The first, Hexal AG, agreed, through its UK associated company, Tillomed Limited, to become a subdistributor of IVAX in October 2001."

Did IVAX have a free hand over appointing Tillomed?

A. There was no discussions with GSK.

Q. Then, more recently, I think probably just before lunch, you were asked about the volume allowances.

A. Yes.

Q. Given to the generic companies under the agreements. You were asked whether you recalled any requests coming from them for additional volumes.

A. Agreed.

Q. If I have your evidence correctly, you said you did not recall any such?

A. Right.

Q. Then a letter was put to you at {B1/18/1}. Again, I do not know which tab that is in your file. Perhaps my learned friend Mr. Turner can tell you that.

MR. TURNER: Tab 33.

MR. FLYNN: You see that. You recall being shown that letter?

A. Yes, I was shown that letter this morning.

Q. Could you just note the date of the letter, Dr. Reilly?

A. 24th January 2002.

Q. Do you recall offhand the date of the agreement made with GUK or the GUK-IVAX agreement?

A. Not offhand. I am very tired.

Q. I can well understand. It is in bundle {L/10/1}. I do not know if that was made available to you. That will come up on the screen.

MR. TURNER: Tab 30.

MR. FLYNN: Are you there, Dr. Reilly? If you just look at the front page.

A. So March 2002.

Q. Yes.

A. So it was actually before that.

Q. So what is your evidence about requests for additional allowances under the agreements?

A. My evidence is the same: nothing ever came to me.

MR. FLYNN: Sir, I have no further questions for Dr. Reilly. Questions by THE TRIBUNAL

THE PRESIDENT: I will not keep you long because, as you say, you are tired, you have been giving evidence for a long time, but just a couple of things.

You talk in your witness statement -- we can turn it up if you want to, but I do not think we particularly need to -- about parallel imports.

A. Yes.

THE PRESIDENT: You say one of the benefits of the agreement, the settlements was around parallel imports you and explain why parallel imports are a headache, and so on.

The discussion there, and I think maybe also in some answers you gave, was that the supply agreements that you made to these Generics would displace the parallel imports.

A. Agreed.

THE PRESIDENT: Can you just explain, I did not quite understand, why would they displace the parallel imports. Why do they not come on, as it were, on top of the parallel imports and you have both?

A. Obviously there is competition in the marketplace and the pharmacist has to decide which it is going to dispense, and the problem with the parallel import pack is that sometimes it is over stickered; it has Greek or French or Spanish writing on it.

It does not look as good, and particularly for these types of patients with depression and particularly depression with anxiety, they need -- they like to see the same pack. They like to know that the tablet format is the same because it is something that they actually rely on. If you suddenly get put a parallel imported pack that has "Deroxat" on it, for example, then it can be quite upsetting for those patients. So they do not like the product and they will not

accept it because they want the same pack they had last month, and that is why it gives the pharmacist a bit of a headache, so if they can get supply that they can trade on and it is UK pack, then they are very happy with that.

THE PRESIDENT: I can see why they would prefer the generic supply under these agreements to the parallel import, but would not the parallel import still come on top of that? After all the parallel import is worth sending to pharmacies because they are cheaper, presumably, than Seroxat?

A. Yes.

THE PRESIDENT: Is there not additional volume, parallel imports?

A. Yes --

THE PRESIDENT: Which you were anticipating --

A. We were anticipating there would be some additional volume and also some displacement. So we thought it would be a mix. We did not know what the response of the parallel traders would be because there is different prices across Europe, and if they could secure a source of supply, and you cannot stop supplying, it does not matter who it is, so they would supply, if they could get a cheaper price in, let us say, Spain or Greece, then the overall price would come in would be lower, and there was possibilities of price cuts across Europe at that time. So the overall price of parallel imports could keep coming down, and that was something, again, we discussed.

MR. GLYNN: Would it be fair to say, following on from that, that the parallel traders were competing between themselves and the first parallel traded product would be roughly the same price that they would achieve from the pharmacies?

A. It depends on their source of supply. So if they were predominantly Spanish traders, obviously that would come from Spain, Greek traders. Some bigger companies were getting multiple sources and then were seeking the best source that they could get at any particular month.

MR. GLYNN: The amounts that they could get from these other sources would be in some sense limited?

A. Not really.

MR. GLYNN: Not really, no.

A. No. You cannot constrain that supply so it was made available to them.

MR. GLYNN: So when you had these generic additional supplies becoming available, did that amount to a material increase in the potential supply to the market?

A. Yes. That was incremental. Again, we had thought there would be some parallel traded impact that would act as a disincentive, but we did not know how much at the time we signed the deal.

MR. GLYNN: Thank you.

I am sorry, one final question. There is no suggestion that there was any business relationship between any of the generic companies and parallel traders; none of them were involved in parallel trading, none of them had business associations, as far as you know?

A. Not at this time. Later on some of these traders did get into parallel trading and they started to offer, side by side, generic plus parallel traded pack.

THE PRESIDENT: The other thing I wanted to ask was something completely different.

You talked about GSK's confidence in its patents and you made the point that it was not just the anhydrate patent, it was also the hemihydrate patent in particular which you regarded as a strong patent.

A. Yes, from the information that was given to me, bearing in mind I am not an expert.

THE PRESIDENT: Obviously you get the advice and that is what you were told, and then you adjust your commercial strategy according to the advice?

A. Agreed.

THE PRESIDENT: You do the settlement with GUK, you later agree a settlement with Alpharma. Alpharma, under the terms, are entitled to give a month's notice if there is a generic entry. Then Apotex, it goes to court, fought out and the judgment comes I think in December 2003 that Apotex succeeds. It then enters the market or Neolab, related to Apotex, enters the market. But that case, that judgment against Apotex, that is only on the anhydrate patent. Then Alpharma says, notice it terminates the agreement and Alpharma enters the market. But you still have your hemihydrate patent. You do not seek to enforce that against Apotex. You do not seek to enforce it against Alpharma. Why not?

A. I think there were ongoing proceedings that subsequently happened, and I think, again, this would be a question for others within GSK, and bearing in mind I had actually left at that point so I do not get to see the final issues as they were resolved, unfortunately.

THE PRESIDENT: We know Alpharma came in, I think. Are you aware of any judgment against Apotex on the hemihydrate?

A. I do not know. I would have to ask, I am afraid.

THE PRESIDENT: I have seen nothing to suggest any steps taken to enforce the hemihydrate patent, but you cannot help on that?

A. Because I was not in the business at that point, sorry.

THE PRESIDENT: Would it be fair -- I appreciate you had gone, but knowing how the business is run, that if it was felt it was a good weapon to stop generics, it would have been used?

A. Yes.

THE PRESIDENT: Is that a fair inference?

A. My understanding was there was still some discussions going on and there was some patent litigation around the hemihydrate later on, was my understanding.

THE PRESIDENT: Would it be a fair inference, if it is a good weapon it will be used?

A. Yes, agreed.

THE PRESIDENT: Mr Malek may have some questions.

MR. MALEK: Can we have up on the screen the document that had £14 million in?

MR. TURNER: Tab 16, Dr. Reilly. For everybody else {B8/269/2}, second page.

MR. MALEK: We looked at this document earlier. Could we look on the second page of this document at {B8/269/2}. It has a heading:

"Key Sensitivities."

A. Yes.

MR. MALEK: Then there is one passage:

"Genericisation of paroxetine. Assumptions of supply agreement holding are high risk. Significant further margin erosion (£10 million) is possible as further potential suppliers approach the UK market."

Can you just explain that to me?

A. Again, that would be based on some degree, it is not specific around the degree, but some degree of further genericisation, somebody entering the market at some point in the future.

MR. MALEK: Then if we go to the top of the final page of that, which is page {B8/269/3}, it is headed "Primary Care".

Then it says:

"Seroxat: supply agreement not successful."

Then he has 10 million. Is that the same --

A. That is the same.

MR. MALEK: Then someone has assessed that at 45% probability.

A. That is a tabulation of that particular comment, and the probability is quite high because of the inherent uncertainty around that situation.

MR. MALEK: You, or someone, thought that the risk was sufficiently high to give it a 45% marking.

A. Yes.

MR. MALEK: The other point I want to note, you were shown various documents. You said that document had been shown to you recently in a bundle. Can you explain what that process was? Were you just given bundles of documents and told just look after yourself and prepare for the hearing, or what?

A. Essentially, I was given a bundle of documents that go through all of my witness statements in the past etc and some associated documents that were referred to, and yes, I have just been told to have a look at these and spend some time making sure I am more up to speed than I would be.

MR. MALEK: That is fair enough. I just wanted to know what the process was.

THE PRESIDENT: Anything arising out of that?

MR. FLYNN: No, sir.

MR. TURNER: No.

THE PRESIDENT: Thank you very much, Dr. Reilly. You have been giving evidence for a long time. You are now released. You can leave if you wish.

A. Thank you. (The witness withdrew)

MR. TURNER: Sir, the next witness will be Vivien West, as we were discussing last week, and Ms. Demetriou will take this witness in cross-examination.

MR. SCANNELL: May it please the Tribunal, it will probably be appropriate for me to call our witness.

THE PRESIDENT: I do not think it was being suggested that Ms. Demetriou was going to call her, but was just that Mr. Turner will not be dealing with her evidence. MS. VIVIEN WEST (affirmed)

Examination-in-chief by MR. SCANNELL

THE PRESIDENT: Thank you. Do sit down, Ms. West.

MR. SCANNELL: Good afternoon, Ms. West. I hope that you have been handed a bundle of documents. It may be blank on the outside or it may have the letter E on it. In any event, could you open the bundle, and the first document in it is dated, I hope, 4th April 2016. Do you recognise that document?

A. Yes.

Q. Is that your first witness statement in these proceedings?

A. Yes, it is.

Q. Could I ask you then to turn to page 29 in the bottom right-hand corner of the same document. Is that your signature below the statement of truth?

A. Yes.

Q. Ms. West, does that remain your evidence in these proceedings?
A. Yes, it does.
MR. SCANNELL: Thank you.
Cross-examination by MS. DEMETRIOU
THE PRESIDENT: Yes, Ms. Demetriou.
MS. DEMETRIOU: Ms. West, good afternoon. You should have in front of you a bundle of documents which are the documents that I am going to be taking you to when I ask you some questions about your statement.
We are about to hand up to the Tribunal and to the other parties in the case some additional documents which are in that bundle, but which are not on the Magnum system. (Handed)
Ms. West, I want to start with some questions about your role generally at GSK, and I do not think anything is going to be controversial but I want to put your evidence in context first by reference to your role.
If you could go to the witness statement that you drafted for these proceedings and go to page 1 of that witness statement. That is in tab 1 of your bundle. Do you have that?
A. Yes.
MS. DEMETRIOU: For the Tribunal's reference, it is at {E/1/1}.
If we look at paragraph 1 of your witness statement we see that you are a chartered patent agent and European patent attorney. Then if we go over the page {E/1/2}, so we are looking at page 2 and paragraph 5 of your witness statement, we see that from there that at the time of GSK's settlement agreements with the generic companies, your position at GSK was senior patent counsel in GSK's corporate IP department.
You are not, just to be clear, a solicitor or a barrister, are you, Ms. West?
A. No, I am a patent attorney.
Q. You have been employed now by GSK or by its predecessor companies since 1986, so something over 30 years?
A. At the time I signed the witness statement I had been employed for that long. Since then I have retired.
Q. I see, thank you.
During the time that you were employed by GSK or its predecessor companies, your role would have included responsibility for many different patents?
A. That is correct.
Q. If we look at paragraph 5 of your statement, what we see there is that you were responsible for what you call the paroxetine hydrochloride patent prosecution, and then you go on to

explain what that is. So you say that this includes drafting and pursuing applications for patents, including dealing with opposition to those applications.

Then we also see that you were the first point of contact for the external lawyers instructed by GSK in a number of countries, including the UK.

We see that you gave factual witness evidence in the GUK and Alpharma patent litigation proceedings. In fact, you drafted the application that became the European hemihydrate patent, did you not?

A. I drafted the European patent application, although it was based on two earlier UK patent applications which were not drafted by me.

Q. Thank you. That was in 1986?

A. That is correct.

Q. If we go to the second tab in this bundle that I handed up, which is a witness statement you gave in the BASF litigation -- do you remember that? You may be looking at the wrong bundle, Ms. West. Is that the bundle your solicitors gave you? I think you need the other one, the black bundle.

It is tab 2 of that bundle. That bundle also, just for future reference, contains your witness statement at tab 1, so you do not need to switch between two of them. At tab 2 do you see your statement dated 27th March 2003? For everyone else this is at {Z/98/1}.

A. Yes.

Q. This is a statement you made in the BASF litigation. If you could turn to page {Z/98/3}, we see there at paragraph 7 the reference to you being asked to draft the application which became the European patent. That is the point that you were just explaining to the Tribunal.

Then at paragraph 8, just below that you say --

THE PRESIDENT: Just one moment. This is dated March 2003.

MS. DEMETRIOU: Yes.

THE PRESIDENT: I am just trying to understand this. This is in which litigation? This must be in the Apotex litigation.

MS. DEMETRIOU: It is in the BASF litigation. So we see that from the High Court number.

THE PRESIDENT: But I am just trying to ... maybe Ms. West can help us. The BASF litigation, the judgment was in July 2002.

MS. DEMETRIOU: That is right. Then there was a Court of Appeal procedure, of course, which finished in June 2003.

THE PRESIDENT: But this is not the Court of Appeal, or is it?

MS. DEMETRIOU: This is an application. If we go to the end of the statement {Z/98/7}, it is an application to amend the patent.

THE PRESIDENT: I see.

MS. DEMETRIOU: It is in the context of the BASF litigation, and you are quite right that it is after the judgment of Mr Justice Pumfrey.

THE PRESIDENT: Yes, there was an application to amend the patent following his judgments.

MS. DEMETRIOU: Yes.

A. That is correct.

THE PRESIDENT: Sorry, I understand. I was a bit confused.

MS. DEMETRIOU: I was looking at paragraph 8, and you explain there that in January 1987 you handed over the file to Brian Russell, who had taken over John Blake's position and you had no further involvement with the prosecution of that patent.

Then you say:

"The granted patent came back within my area of responsibility when I took over responsibility for the paroxetine patent portfolio in July 1997."

A. That is correct.

Q. You were responsible for the amendments to the anhydrate patent, which were contemplated by Mr Justice Pumfrey in his judgment. That is right, is it not?

A. That is correct.

Q. Going back, if you will, please, to your statement, which is at tab 1 of this bundle, and to paragraph 5, so we are looking at {E/1/2} on the Magnum system, going back to that, we see there that your role involved taking part in patent litigation. We see that about a third of the way down.

So:

"... responsibility for paroxetine patent prosecution (ie drafting and filing patents and handling oppositions and patent litigation) ..."

That is right, is it not?

A. Yes.

Q. You also say, as I have indicated before, that your role included acting as the first point of contact for the external lawyers instructed by GSK.

What I want to do now is ask you a few questions about how, in your time at GSK, GSK generally handled patent litigation. I am not for a moment asking you about the patent litigation issue in these proceedings, I just want to establish the general position first and I want to establish the general position when it came to handling patent litigation concerning

significant products where the outcome of proceedings was potentially of commercial significance to GSK, what would generally happen in those cases.

So where GSK was contemplating patent litigation of that sort, then you presumably used to instruct external lawyers?

A. Yes.

Q. That would be solicitors in the first instance, would it?

A. In the UK, yes.

Q. So I am looking at the UK at the moment. So just confine your answers to the UK, it will make it simpler.

Then after that you would instruct counsel, or perhaps at the same time?

A. Or perhaps at the same time, yes, depending on the circumstances.

Q. Generally leading counsel for important cases?

A. It would not normally be up to the primary attorney to choose counsel. That would be a matter for more senior members of the patent department.

Q. But what was the general position while you were there and involved handling this patent litigation? Would you generally instruct leading counsel for important cases?

A. I think it was felt desirable that we should have best representation for litigation concerning patents that covered marketed products.

Q. So what sort of cases would you just instruct junior counsel? Would those be less important cases?

A. I probably do not have sufficient broad litigation experience to give you many examples, but I can think of at least one instance where we had a hypothetical question about a particularly knotty question of naming of inventors and in that situation we instructed junior counsel.

THE PRESIDENT: For advice or for litigation?

A. That was just for advice, because in that case it related to whom we should name on a patent application.

THE PRESIDENT: When cases involving important patents came to court -- I appreciate it may not have been your decision, but was the general pattern that GSK would use a QC?

A. In my experience, yes.

MS. DEMETRIOU: Now let us take a case where GSK is considering applying for an interim injunction. Presumably at that stage when you are taking advice from the counsel you have instructed and the solicitors you have instructed, presumably at that stage the key question then is do you have an arguable case of infringement and what is the sort of damage that

would result? What is the balance of convenience? Those would have been the two questions that you were primarily concerned with at the injunction stage; is that right?

A. Yes, that is correct. The two questions that are classically posed are: is there a colourable case of infringement and validity of the patent, and if the injunction is not granted, will the damage to the plaintiff be of such a nature that it cannot be reversed by the usual remedies available?

Q. That is right. So on that question, once you had instructed your leading counsel, you would take leading counsel's advice on those questions, presumably?

A. Yes, that is correct.

Q. Once you have got the interim injunction, assuming you get it and you are heading towards trial, it is right, is it not, that there is the usual process of obtaining disclosure and then expert evidence?

A. That is correct.

Q. And your barristers, your leading counsel and your solicitors would want to see that factual and expert evidence before forming a view on the merits of the case, would they not?

A. Yes, every member of the team, including the patent attorney and outside counsel would want to look at the evidence on a continuing basis.

Q. On a continual basis, to assess it continuously through the process because it changes over time, does it not, things come in from the other side and you want to continually assess how that places your position in the litigation?

A. That is correct. It is an evolving situation.

Q. It is your job then, as the point of contact with the external lawyers. So it would have been your job to ask them for their advice on the merits taking into account the evolving situation and the evidence which you had got?

A. Yes.

Q. Ultimately it is right, is it not, that the most important question for the company to know is how is the court likely to answer the question of validity and infringement when it comes to litigation? That is what the company wants to know?

A. Yes.

Q. That is the advice that you are asking leading counsel to give you? That is part of the advice at least. An important question for leading counsel when you instruct them is: what is the court likely to say on validity and infringement?

A. Yes, that is what the litigants would like to know as soon as possible.

Q. Would you generally speaking get that advice in writing from leading counsel?

A. I think that this varies. If there is a very specific question like the one I referred to earlier about the naming of inventors, then advice in writing is useful. But in a real world litigation scenario, where you are working with a large team of outside counsel, in-house patent attorneys -- I was not working alone -- and also scientists, then it is more usual in my experience for there to be a continuing conversation which took place through a series of meetings with the lawyers and with the scientists.

Q. Thank you. In relation to that continuing process -- at the moment I am focusing on the question of external counsel's view of the merits -- how would you convey that advice back to the company? Presumably you would need something in writing, would you not, to show other people in the company what leading counsel thought?

A. No, in my experience I would not normally need that because other senior members of the patent department would be involved in these discussions, at least part of the time, and they would also trust me to inform them as to how the litigation was proceeding and what we considered our chances to be.

Q. Now, presumably, when it comes to important pieces of litigation, presumably in some cases the litigation is so important that the board would need to approve a decision to continue, to go to trial and continue with the litigation?

A. I have to confess that I do not recall what the exact rules were. Earlier on Mark Reilly referred to a value threshold. From my perspective, I did not have the authority to start litigation and therefore if I wanted to do that then I would speak to my manager, and if he did not have the authority, he would speak to his, and at that time his manager was the head of the patent department. So he would have had quite significant decision-making authority.

Q. That is very helpful, Ms. West. So when the decision is being elevated up depending on the importance of the case, how did you convey leading counsel's advice to the ultimate decision-maker? There would presumably have been some kind of written document, either summarising that advice or encapsulating it in some other way?

A. Are you now asking me about the paroxetine --

Q. No, I am not. We will come to paroxetine, but I am asking you about important litigation generally. So you have just given an example, you have just said that there may have been decisions that had to be taken at quite a high level because of the importance of the litigation, and what I am asking you is how leading counsel's advice on the merits of that litigation would have been conveyed up to the ultimate decision-maker within GSK.

A. Okay. Almost all of my litigation experience was with paroxetine so I can only give a vague picture of how the rest of the department might have operated. But I know that there were different ways of conveying this information. You could get a written counsel's opinion or you could brief a relevant client directly, visit them and walk them through the patent situation, tell them what your advice was as a qualified attorney.

Q. Ms. West, it would not just be your advice, would it, because if it were an important piece of litigation and you had gone to leading counsel, you would want to convey leading counsel's advice too to the decision-maker, would you not?

A. I think perhaps you are giving the impression that the advice of counsel is something that the patent attorney obtains and carries to the relevant client and says "Here it is, this is what leading counsel thinks". But in reality internal clients want the advice of the patent attorneys, the patent department, and we use outside counsel as a sounding board and of course a reality check.

Q. Well, Ms. West, we are talking about here -- you have said already, you have explained very helpfully how with important litigation you would instruct solicitors and generally instruct leading counsel, and you have explained that leading counsel would want to look especially at the expert evidence that comes in, the disclosure, to form a view as to the merits of the litigation. So they presumably would convey that view to you; is that not right? You were the point of contact with those external lawyers?

A. Yes. They would convey that information to me, but probably not only to me but also to other patent attorneys within GSK's patent department.

THE PRESIDENT: You were in a team, as it were; is that right?

A. I worked in a team and different members of the team had responsibility for different aspects of the product and different countries. I was responsible for the English litigation.

THE PRESIDENT: When the solicitors went to see leading counsel, would you go along with them?

A. Yes. I would.

THE PRESIDENT: Would you make notes then of what was being said for yourself, or would the solicitors make notes and send them to you? What was the general way things were done? We know solicitors take an attendance note.

A. What tended to happen was that we would decide what we were going to do. So, for instance, if we were talking about the merits of the patent claim and decided that an amendment would be a good idea, then what would come out of the meeting would be a draft amendment.

MS. DEMETRIOU: You accepted the most important question in patent litigation is what is the court going to decide in relation to validity and infringement. Now, in relation to that question, leading counsel's advice is the most valuable advice, is it not? Not the advice of the patent attorneys. Because it is a question of law.

A. It is true that it is good for GSK if counsel agrees with GSK's internal patent attorneys about the merits of the case.

Q. Ms. West, if leading counsel disagreed, is that not advice that you would have to pass back to the rest of the team?

A. I find it hard to imagine a situation so extreme. You have to remember that the question "Will we win on validity and infringement?" is usually followed by the words "Give me a percentage", and the answer is "Well, it will either be 100% bad or 100% good, but we do not know which yet".

Sorry I seem rather flippant, but all that we could really tell the client in a situation like this is we believe that the patent is valid and infringed, but we do not know whether the judge will agree with us.

Q. So Ms. West, what I am trying to establish, that question about whether the judge is likely to agree with you or not, that is primarily a question for leading counsel, is it not, because it is a question of law?

A. I think that does underplay the role of the patent attorney and scientist, which is not to say that I do not agree that leading counsel's opinion is very useful.

Q. Very useful. So with the very useful opinion you would have conveyed in some shape or form back to the decision makers at GSK, would you not? You would not surely have instructed leading counsel to get their views and then not conveyed those views back at all?

A. Well, in a situation where we have decided that we wished to go ahead with litigation --

Q. Can I pause there, because the question I am positing to you is precisely that question. I am not assuming at this stage that you have decided. I am at the stage where the expert evidence has come in and precisely the question you have got to decide is whether to pursue the litigation to trial, and that depends on the view the court is likely to take on infringement and validity.

What I am asking is on that very important question, would you not convey back to the team at GSK leading counsel's advice?

A. I do beg your pardon. What I meant to say was in a situation where the patent team has determined that there appears to be an infringement of a valid GSK patent and that, therefore, legal action is possible and likely to be desirable, in that situation if we need to

ask for authorisation by, say, the head of the patent department, then yes, he will ask what do outside counsel think and he will take into account what they say.

Q. If you then, at a later stage of the litigation, get in an expert report from the other side which looks very powerful and leading counsel gives you his or her views about the impact of that report, again, that is the kind of matter that you would convey back to the relevant people at GSK?

A. Well, now you are talking about a situation where the litigation is already underway. There is an exchange of disclosure and there is an exchange of experimental evidence, at least in the case that this relates to.

At each stage, anyone involved in the litigation may look at a new piece of disclosure or a new piece of experimental evidence and think "We need to follow up on this, we need to get other scientific advice, or we need to amend our pleadings", or whatever. This is part of the fine detail of the progress of the litigation and unless it makes us think this is completely new, we are definitely going to lose this, then we would not be going to a senior person within the organisation.

Clearly, if it did completely turn the case on its head, then that is the first thing that we would do because senior management do not like surprises.

Q. Thank you, Ms. West.

Now I want to now look at the parts of your witness statement that deal with your views on the strength of the paroxetine patent, so I am now moving away from generalities to look at paroxetine.

Could we turn to paragraph 37 of your statement {E/1/10}. Do you have that?

A. Yes.

Q. You say:

> "The settlements concerned the allegations of infringement of the anhydrate patent and/or the hemihydrate patent. In my view, the patent claims in these patents covered good inventions."

Let us break that down a little bit.

When you talk about allegations of infringement, there are in principle two issues, are there not? One is whether the patent is valid and the other is if it is valid, whether it is infringed?

A. Yes, that is correct.

Q. In the GUK litigation both of those points were in play?

A. That is correct. At the time that we brought the action against GUK, the patent had been challenged by BASF, so we both had to show that GUK infringed the claims and that the claims were valid in the face of the BASF challenge.

Q. In the Alpharma litigation, the question was whether there was an infringement of process claim 11 of the anhydrate patent, so that was an infringement question?

A. At the time that we filed the Alpharma case, we were alleging infringement both of the process claim and a product claim. It followed after that that the product claim was struck down in the BASF litigation and we therefore amended our claim in relation to Alpharma. So at that point we were only asserting the process claim against them. However, the BASF decision was appealed, and at the time the Alpharma settlement was signed, there was still a possibility that the product claim would be reinstated.

Q. Ms. West, just to take you to paragraph 50 of your witness statement, which is at page {E/1/14}, here you are explaining the point I just put to you. Do you have that?

A. Yes.

Q. You are saying that logically three options were open to the generic companies. The first was to attack the validity of GSK's patents; the second was to introduce a product which did not infringe GSK's patents; and then for completeness you say at (c) that there was a third option which was to:

> "Introduce a product which did not infringe GSK's patents by using a different salt ..."

You say:

> "As far as GSK knew, each of these salts would be pharmaceutically acceptable."

You go on to say at the end of that paragraph that that is in fact what Synthon did do. So those are the options open to the generic companies?

A. Yes.

Q. Going back to paragraph 38 of your witness statement {E/1/11}, you say there, at the end of that paragraph:

> "I considered, and still consider, that both Form A and the process for its production were novel and inventive, and this view was upheld twice by the Court of Appeal in the later litigation in relation to the process."

Just to be clear about that, Mr Justice Pumfrey in the BASF litigation held that the product claims were invalid; that is right, is it not?

A. That is correct.

Q. GSK did not appeal against the judge's conclusion that claims 1, 2, 6 and 10(ii) were invalid. So you did not appeal that finding?

A. Excuse me for a moment while I look at those claims. This is the Form A patent.
Q. What may be simpler is we take it from the Court of Appeal judgment, which will come up on the screen in a moment {D/8/2}. It should be set out there. It is paragraph 2.
It says there:
"SB have not attempted to overturn ..."
Do you see that sentence? Do you remember that?
A. Yes.
Q. So GSK's appeal to the Court of Appeal concerned the construction of claim 3 and that appeal was dismissed. Do you remember that? That is the judgment you are referring to. If you go back to your statement in paragraph 38, you footnoted a judgment at footnote 1. That is the judgment you are referring to there {E/1/11}.
A. Yes.
Q. In relation to the process claims, it is correct that the validity of these were confirmed by the Court of Appeal following an unsuccessful outing for you before Mr Justice Pumfrey. But in the Apotex litigation, the Court of Appeal and the judge below indeed both held that Apotex did not infringe those claims. That is a fair summary, is it not?
A. That is correct. The final conclusion was that the process claims were valid but that Apotex did not infringe them.
Q. Just to go back to a question that you heard the Tribunal put to Mr. Reilly at the end of --
THE PRESIDENT: Just before that. So when you say, in your witness statement at paragraph 38, the sentence that you were referred to:
"I considered, and still consider, that both Form A and the process for its production were novel and inventive, and this view was upheld twice by the Court of Appeal in the later litigation in relation to the process."
The process was held to be novel and inventive, but the product was not, was it? I was just puzzled that you say you still consider both Form A and the process, but I thought Form A, the product claims, had gone?
A. Yes. Okay. So Form A is made using a displacement process.
THE PRESIDENT: Yes.
A. Which was invented as a result of our scientists' inability to recreate an old anhydrate which we named Form 2. So immediately before the priority date of this patent, no anhydrate existed because it could not be made. They invented the process and then it could be made. Unfortunately, when we were before Mr Justice Pumfrey, we realised that we had a problem with claim 3, the claim that -- yes -- in that the claim had been amended. It contained a lot

of detailed technical information, infra red specks and so on and so forth, and it specified that the product was substantially free of bound isopropanol and it specified that because that restriction had been carried forward from an earlier claim which had been crossed out and the rules require you not to expand the scope of a claim when amending.

THE PRESIDENT: Sure.

A. But what it should really have said is substantially free of all bound solvent, because solvates other than isopropanol solvate were actually known in the prior art. If you take one of those and dry it down very thoroughly, you will get an infra red specs, and x-ray and solid state NMR, and so on, which look very similar, although not exactly the same, as Form A.

So this was literally a drafting error originally on the part of the person who had drafted the claim and failed to appreciate that there was a disclosure of solvates other than isopropanol solvate in the prior art.

I am sorry, this is a very long-winded explanation, but this is my way of saying that Form A, as an entity, in my view, was new, but Form A as claimed in the claims, was not supportable because the claims were not very well drafted.

THE PRESIDENT: But you could not expand the drafting then, could you? That would be quite -- well, quite tricky.

A. We could not expand the scope, because that is against the rules, but we also, in the end, decided that the process claims were more important, and on the basis of a bird in the hand we stuck with those.

THE PRESIDENT: What you mean is Form A, if the patent had been drafted as it should have been, the claim would have been valid? Is that what I understand you to be saying?

A. Yes. I do not want to suggest that my predecessor was incompetent, but he did not know about things that we later found out about. Some of these things did not become apparent until we saw the evidence at trial.

MR. MALEK: At the end of the day you accept that Mr Justice Pumfrey got it right?

A. Well, we did try to make an argument on the basis of purposive construction, which was very well supported in terms of the specification because the patent specification contained a great deal of exemplification of products that were crystallised from solvents other than isopropanol and then subjected to the displacement process.

But at the end of the day, it was his decision and his discretion, and patent attorneys should never expect to be excused for errors just because it is not fair.

MS. DEMETRIOU: Ms. West, I just wanted to pick up on one point you may have heard the Tribunal ask Mr. Reilly about, and I think you are better placed to comment on it.

It is correct, is it not, that after the judgment of Mr Justice Pumfrey in the Apotex proceedings in 2003, GSK did not sue any of the Generics under the hemihydrate patent, did it?

A. As far as I recall, that is correct. Yes.

Q. Moving on to paragraph 40 of your statement, you say there that, you recognise that:

> "Patent litigation can be complex ... It is particularly risky ... I was confident that GSK's patent claims covered good and clever inventions, but there were features which made this case particularly complex and so presented even more litigation risk than usual."

I do not think it is necessary to get into the fine detail of the complexities, but I just want to ask you a couple of points.

You say at paragraph 41, the first feature that you identify in paragraph 41 that presented more litigation risk than usual was the question whether Form 2 constituted prior art. You say there that this was and still is an unanswered legal question.

The relevance of that, if I can just see if I have got this right, is that if Form 2 did constitute prior art, then GSK's position on the merits would be weaker because it would have to show that Form A was distinguishable from Form 2. I think that is the upshot of what you say in paragraph 41?

A. That is correct. If Form 2 was prior art we would have to prove that it was different from Form A.

Q. Then you refer in the last sentence of that paragraph, you say:

> "A related legal point concerns whether ... GSK could justifiably claim Form A as a product irrespective of how it has been produced, when we had only invented one way of producing it."

I am not asking you to comment on what that means exactly, but the point I would like you to comment on is that these questions, these questions that you have identified in paragraph 41, I think it is clear from there, but they are difficult questions that go to the answer that the judge may take. So they are questions that affect the likelihood that a judge would find the patent to be valid. That is right, is it not?

A. Yes.

Q. Just going over the page {E/1/12}, I am going to summarise, I hope not unfairly, what you say at paragraphs 42 to 45.

What you say in summary here is that as far as the process claims were concerned, you could not tell whether the process patents had been infringed simply by testing the product. So it was difficult to get information to help you discern whether or not the process patents had been infringed?

A. Yes, that is correct.

Q. Again, this is a point which goes directly to the question of GSK's prospects of proving an infringement of its patents. It is a question the courts would have to grapple with?

A. I think this differs slightly from the previous point in that it is not a fundamental legal issue, it is a practical problem. If we have purchased a sample on the open market and analyse it, it is not possible to tell whether it infringes. The only way to find out is to enter into litigation and obtain discovery, and even then it might not become clear straightaway until you have actually taken the litigation some way.

From the practical viewpoint, you were going into the litigation blind.

Q. So what you are saying is that it raises a difficult evidential question?

A. It is a difficult practical question.

Q. A question of evidence ultimately because the court has to decide on infringement and this is a point that goes to evidence?

A. Yes, because the claimant has to prove on the balance of probabilities that the process has been used, and the onus would therefore be on the patentee.

Q. Then just for completeness --

THE PRESIDENT: Of course, I suppose the defendant has the advantage. A bit unfair for you as patentee because they know, the defendant, how it is made in many cases whereas you, as you say, cannot find out until you get disclosure and maybe inspection, and so on.

A. Yes. In many cases they do know more than the patentee, but in practice it did seem that some defendants did not know as much as we thought they would about how the product was made.

THE PRESIDENT: It might depend on whether they themselves make it or get it from someone else.

A. Whether they are having it supplied by someone else and also whether they bought in the bulk and made their own tablets or not.

MS. DEMETRIOU: At paragraph 46 {E/1/13} , you say you considered at the time:

> "... the possibility that BASF or someone else might be able to prove that Form 2 in fact still can be made; or that a process described in the prior art inevitably leads to Form A ..."

Again, that is a point that affects the relative strength of the anhydrate patent. It was a point in play that was uncertain at the time?

A. Yes. This is, as you say, a point about evidence. The patentability of Form A depended on the fact that the previously described process for making the anhydrate no longer worked, and if in the first instance BASF were able to prove that in fact they were able to make the process work, then that would invalidate the claim without a doubt. In practice, they were unsuccessful.

Q. That is very helpful. Thank you.

Going back to paragraph 46 your statement, when you talk about even more litigation risk than usual, what you are referring to, and we have seen it quite clearly, are difficult points of law and evidence that might undermine GSK's position in court. That is a fair summary?

A. They were features that made this an interesting case.

THE PRESIDENT: In my experience the last thing clients ever want to hear is what you say: this is an interesting case. Is that a fair comment?

A. Very fair, yes.

MS. DEMETRIOU: More than an interesting case, Ms. West, you are saying these were features which were uncertain and unclear and led to more litigation risk than usual. That is what you say at paragraph 40?

A. I think it is very hard, as I said earlier, to quantify litigation --

Q. Let us stop there. I am not asking you to quantify the risk.

A. But you have asked me to say whether or not the litigation risk is greater or less than a notion of a risk.

Q. I am not asking that, I am just going back to your statement and the last line of paragraph 40 where you say these features presented even more litigation risk than usual. All I am asking you to do is accept that we can interpolate in that sentence these features, which concerned difficult questions of law and/or evidence, made this more risky than usual?

A. Yes, I think it is fair to say that this case did have unanswered legal questions and questions of evidence for which we did not yet have the information.

Q. Thank you. No doubt your views over this period were influenced by events. Presumably your confidence levels were affected, for example, by the judgment of Mr Justice Pumfrey in July of 2002 where he found that the product claims were invalid. That would have had an impact on your views?

A. Mr Justice Pumfrey's decision did not change my view on the patentability of Form A because he was satisfied that the process was patentable and the patentability of the process

was tied intimately to the impossibility of carrying out the prior art process, which meant that Form A was still novel.

As I explained earlier, however, the Form A claim failed to include all the right data to encapsulate that and we failed to persuade Mr Justice Pumfrey that a purposive construction could be put on the claim to take into account what was described in the specification. So at that point I felt that the decision he had come to was fully supportive of our view on patentability of the invention, but it had highlighted problems with the patent specification.

Q. Problems which then had an impact, did it not, on your strategy because when it came to the anhydrate litigation you dropped all the anhydrate patent product claims?

A. Yes, we dropped the anhydrate product claims shortly before the Apotex hearing, although it was not directly connected to that. As it happened, Apotex were using a displacement process, although the judge in that case decided that it was not sufficiently close to our displacement process to be an infringement.

THE PRESIDENT: It was a question of the construction of the process claim, was it not?

A. Well, this was another interesting aspect, because the process -- the patented process is a displacement process which starts with the solvate and ends with an anhydrate which is substantially free of solvent, and the exemplification that we used was water or carbon dioxide.

Now, Apotex did a very clever thing, and Apotex is a generic company which does on a lot of its own chemical research, and they manufactured their own bulk Form A, and they did it via crystallising first of all from one solvent, either isopropanol or acetone, I forget which, then carrying out a displacement with a mixture of the same solvents. To my mind it was a development beyond the GSK process.

I do not know whether they knew about the GSK process when they invented it, but to my mind they fell within its scope, but was a clever development. The judge seemed to feel it was sufficiently different and sufficiently clever that it should be regarded as a different invention.

THE PRESIDENT: There was also the question of substantially free, was there not, what that meant?

A. Well, that came up for discussion at the first trial, the BASF trial, and although at the time it looked a bit knotty, I think by the end of that everybody was agreed on what it meant, although it did result in some problems with the claims in relation to products other than Form A which I will not trouble you with because all of the infringements were Form A.

MS. DEMETRIOU: Sir, I was going to move on to another topic, so if that is a convenient moment for the transcript writers.

THE PRESIDENT: Yes. I do not know if you have been in court earlier. We take a short break for the transcribers, a 5-minute break.

(3.27 pm) (A short break)

(3.35 pm)

MS. DEMETRIOU: Now Ms. West, I want to move on to look at some of the events leading up to the settlement agreements. If we can just start again with paragraph 5 of your statement, which is in your first tab. For everyone else, that is bundle {E/1/2}.

You say there, and I am looking at the penultimate sentence:

"I was not involved in the drafting of the settlement agreements themselves."

A. That is correct.

Q. I want to take you to an email which is at tab 11 of this bundle. For everyone else, that is in the separate clip because it is not on Magnum, and it is tab 1 of the Tribunal's bundle.

Now, this, as you see, is an email dated 25th September 2001 and it is from Cynthia Robinson to you.

THE PRESIDENT: So sorry, Ms. Demetriou, where is this?

MS. DEMETRIOU: You should have a separate clip and I am hoping it is in tab 1 of that clip. It is an email dated 25th September 2001.

THE PRESIDENT: Sorry, I am looking at the wrong clip. Yes, I have it.

MS. DEMETRIOU: So Ms. West, do you see that that is an email from Cynthia Robinson to you? Can I just first of all understand how it worked in terms of reporting.

Did Cynthia Robinson report to you? Is that how the professional relationship worked, or did you report to her? How was it?

A. No, neither of us reported to the other. We were in, what were at that time, separate departments. Cynthia was a solicitor, I was a patent attorney. I was instructing Simmons & Simmons in relation to the patent litigation and --

Q. If we can just take it in stages. That is all I wanted to establish at the moment, the reporting structure.

This email says:

"Vivien, I attach the first draft of the proposed side letter ..."

You see the subject is "Norton side letter":

"... and would welcome Simmons' comments as soon as possible. We are proposing to meet with Norton on Thursday, so a reply by close of tomorrow will be very much

appreciated. It is likely that Norton will substantially amend, once they see the text, to cover all eventualities."

So here Cynthia Robinson, who is GSK's in-house lawyer, was asking you to get, as the point of contact with the external lawyers, Simmons & Simmons' comments on the draft side letter. That is right, is it not?

A. That is how it appears, yes.

Q. So the external lawyers, Simmons & Simmons, were involved in advising on the IVAX side letter?

A. I do not remember seeing this before. Obviously I have seen it before, but I do not remember as far back as 2001 and I do not recall seeing it during the preparation for these proceedings.

Q. No, but do you remember Simmons & Simmons advising on the IVAX side letter?

A. It is clear from this that Cynthia did ask for Simmons & Simmons' comments on this side letter of the IVAX Norton agreement. I do not know why she has sent it to me.

Q. Perhaps it is because you were the point of contact, as you say in paragraph 5, with external advisers?

A. Yes, I was instructing them in relation to the patent litigation.

Q. This may help. If we go to tab 2 of this bundle, and there we are going back to the witness statement in the BASF amendment claim. The page on Magnum is {Z/98/5}.

Looking at paragraph 17 of your statement -- do you have that? You should have it in front of you at tab 2. It is page 5 at the bottom. I am looking at paragraph 17. You say there:

"By this time, we had started a series of regular meetings with Simmons & Simmons and counsel in connection with paroxetine generally ..."

Just to locate when this was, if you go to the previous paragraph, {Z/98/4} you see that the time we are talking about here is mid-2000. So already by this stage you are saying that you had started a series of regular meetings with Simmons & Simmons and counsel in connection with paroxetine generally. This probably would have cropped up in the context of these meetings, the IVAX side letter; it is all part and parcel of the contact you were having with Simmons & Simmons about paroxetine generally?

A. I do not have any specific recollection of speaking with Simmons & Simmons about IVAX.

Q. Right. Let us move on.

THE PRESIDENT: Pausing there. It is a long time ago and a lot has happened since. You have been involved in all sorts of other things. But looking at this email from 2001, so some 15 and a half years ago, it asks you effectively to get Simmons' comments as soon as possible.

A. Yes.

THE PRESIDENT: Presumably, even if you do not remember it, can one presume that is what you would have done?

A. Yes. I would have very likely forwarded it to them directly.

MS. DEMETRIOU: If you turn the page, you will see there the enclosure. This is the page in the separate clip, not on Magnum. But it is the next page in the same tab, Ms. West, in your bundle. You see here the enclosure and the draft of the side letter is attached.

What we see there is this:

"In consideration of Norton entering into a supply agreement with GSK for the supply of paroxetine hydrochloride, and in recognition of the lost profit opportunity in the paroxetine market through the impending launch of a third party generic product, it is hereby agreed as follows ..."

Then we have a clause saying that:

"In the event that patent litigation against GUK is successful in the UK," then Norton -- sorry I will read it out:

" ... resulting in the payment to SB of damages, or should a settlement be achieved during the course of such litigation or otherwise, then SB and Norton shall negotiate in good faith for a proportion of those damages representing Norton's loss of profit to be paid by SB to Norton."

That is a very clear statement, is not, Ms. West, that what IVAX was expecting under the supply arrangement and what you were trying to achieve through this side letter, what IVAX was expecting, was that the price of paroxetine would stay high under the IVAX agreement and that is why there needed to be some protection for it against prices dropping if GUK entered independently? That is what all that is about, is it not?

A. I am not sure I can draw any conclusions about what Norton expected of the agreement with GSK.

Q. No, but can you draw a conclusion -- sorry.

A. They are asking for compensation in the event that they lose profit, because GSK's litigation against GUK -- sorry, no. This is going the other way, is it not? They are asking for a share of the damages in the event that GSK was successful against GUK.

Q. But the statement there:

"... in recognition of the lost profit opportunity in the paroxetine market through the impending launch of a third party generic product," what that is saying is that if there

is independent entry, prices will drop and so the expectation under this agreement is that prices would remain high. IVAX would not bring down the price.

Maybe you cannot comment on that.

THE PRESIDENT: I am not sure it is something Ms. West was really involved in.

A. I am not sure that it is something I am qualified to comment on.

THE PRESIDENT: You were really on the patent side, not on the commercial side of negotiations. We can see what it says.

MS. DEMETRIOU: Let us move on.

Moving to tab 3 of your bundle, and this, for everyone else, is {Z/1697/1} on Magnum.

You see there an email. So let us start at the bottom.

You see an email from Cynthia Robinson to various people at IVAX. Do you see that?

A. It is an email from IVAX to Cynthia.

Q. I am sorry, you are quite right.

From IVAX to Cynthia, and it says:

"Cynthia.

"Please find attached the supply agreement with our proposed couple of changes which we discussed a short while ago.""

Then it explains the changes and it says their MD is leaving at 4 today and it needs to be signed and they want Cynthia to revert.

If you look at the top of the page there is then an email very shortly after that, so 15 minutes later, from Cynthia Robinson to you saying:

"Please call me to discuss clause 11. Actually, we had copied over the same warranty/indemnity from the co-amoxiclav agreement so we already had a warranty but you have not approved the wording as it refers to the 'patents' - the new wording is 11.2 and we should not be agreeing to this without further qualification.

"Could you call me to discuss asap. Thanks."

Here Cynthia Robinson is asking you detailed questions about clause 11 of the proposed IVAX supply agreement. She is asking you questions about clause 11?

A. Yes.

Q. So you were involved, were you not, in drafting the supply agreement as well as the side letter?

THE PRESIDENT: Hang on. The question is about specifically clause 11.

MS. DEMETRIOU: Yes.

THE PRESIDENT: If it is the same clause 11 as we have, it is on a very specific point, is it not, of patents?

MS. DEMETRIOU: That is right, but I am just asking about --

THE PRESIDENT: So to say you were involved in drafting the supply agreements --

MS. DEMETRIOU: The drafting of agreements, certainly involved in the drafting of clause 11.

THE PRESIDENT: Yes, clause 11, but not the agreement beyond clause 11, which if it is the same as what became clause 11, the final one, can see why because it is on a specific --

MS. DEMETRIOU: Yes.

THE PRESIDENT: And it is only fair to show Ms. West clause 11 if you are going to ask her about this email.

MS. DEMETRIOU: That is in bundle {L/1/12}. Do you see clause 11 there? Do you recall your involvement in discussion with Cynthia Robinson about that clause?

A. So it is 11.1, the patent warranty.

Q. Yes.

A. 11.2 relates to the same question.

Q. Yes.

A. Yes. Obviously, I do not specifically remember it after all of these years, but it is a patent warranty of a very common type.

Q. Then moving forward to tab 12 of your bundle -- this is tab 3 of the separate clip for everyone else -- we see there another email from Cynthia Robinson to you. This time it is dated 3rd October 2001.

It says:

"Vivien, this is the revised draft letter ..."

So this is the side letter:

" ... completely rewritten by Norton's external lawyers with now no mention of the current patent litigation, and I think Paul Inman will have an issue with some of the wording in view of his comments concerning Norton's position."

Who was Paul Inman?

A. Paul Inman was one of the solicitors at Simmons & Simmons.

Q. Again, we see that they are actively involved in drafting the side letter.

Then she says:

"We have to resolve this wording this morning as I am keen to progress it. My initial thought is the action number correctly stated; do we want such a binding obligation as stated in paragraph 1; would we want to consult Norton as stated in paragraph 2; in

paragraph 3, do we want to be bound to seek maximum recovery; in paragraph 4, is the use of the wording 'monetary consideration' wide enough to catch any subdistributorship through Norton. Do you have any comments on the draft?"

In fact, what we see here are a series of quite detailed questions to you on the content of the side letter?

A. After all this time, I cannot recall whether I did provide any comments. I think it is quite unlikely. I think that I would have forwarded this directly to Paul Inman.

Q. Right. It looks like urgent advice was required and you were being asked to phone her as soon as possible, but you think you would not have followed up on that?

A. Cynthia says:

"Could you please email Paul and ask him to call me or let me have his email address."

Q. Yes, okay.

THE PRESIDENT: You think that is what you probably would have done?

A. Most likely, yes, because these are specific questions which are relevant to the litigation which Simmons & Simmons were handling.

MS. DEMETRIOU: Again, you were the point of contact with the external lawyers so you would have passed these queries on to Simmons and reported back on the answers?

A. I think it is more likely in this case that Paul and Cynthia would have spoken directly.

Q. Okay. Now, going back to your statement, which is in tab 1, I just want to look at paragraphs 53 and 54 {E/1/15}.

What you say here at 53 is that:

"In order to obtain the information needed to take effective action against infringers, GSK set up a European-wide team, of which I was a member."

So that is Project Dyke, is it not?

A. That is correct, yes.

Q. If you turn to tab 13 of this bundle, and that is {E1/6/1} for everyone else, you will see there an extract from the response provided by GSK to the European Commission, response to a questionnaire. This is something which you exhibited to your statement. Turning over the page {E1/6/2}, there is a description of Project Dyke and its purpose. Do you see the words underlined:

"The work of obtaining the requisite legal advice and coordinating the representations was given the name Project Dyke"?

When that talks about the work of obtaining the requisite legal advice, that would include legal advice, would it not, about the validity and possible infringement of GSK's patents?

A. This would have included advice about patents relating to the mesylate, which were actually handled by another patent attorney within the department, yes.

Q. Are you saying that Project Dyke did not seek legal advice about the validity and possibility of infringements of its paroxetine patents?

A. No, I am not saying that. I am sure that that legal advice was sought, but it was not something that was done by me.

Q. No, but you were part of the Project Dyke team, so would you have seen that legal advice?

A. I was not part of the team that solicited legal advice about the validity of the paroxetine mesylate patents.

Q. I am not focusing on mesylate now. I am asking more generally whether the activities of Project Dyke included seeking legal advice about the validity or infringement of the patents we are looking at here in this case.

A. Okay. One of the reasons for including this information was to explain how it came about that Project Dyke was adopted --

Q. I think I can shorten this, because I am not asking how it was adopted, I am just asking a simple question, which is: did Project Dyke seek legal advice about the validity or possible infringement of these patents, as far as you are aware?

THE PRESIDENT: By these patents --

A. The hydrochloride patents?

MS. DEMETRIOU: Of the hydrochloride patents.

A. No, it was not a function of Project Dyke at any time to seek legal advice from outside counsel on the validity of the hydrochloride patents.

Q. All right. So can we go to tab 4 of this bundle. This is {K/15/1}. Do you see there an email dated 21st July 2000? That is an email from Martin Matthews(sic) and do you see that you are one of the recipients? Under "cc" it says "Vivien West".

A. Yes.

Q. We see the subject line is:

"Paroxetine anhydrate telecon - 28th July - legally privileged and confidential."

This was a Project Dyke telecon, was it? If you look at the recipients, can you tell us that?

A. This was not a Project Dyke telecon in the sense that I would normally have understood it.

Q. Right.

A. This is a teleconference which Martin Andrews has called to talk about paroxetine patent issues, and he has called it Project Dyke because, following the mesylate issue, he has got the impression that all paroxetine patent issues are called Project Dyke.

Q. Right, but it is nonetheless coordination or communication between various participants across GSK in different countries?

A. This particular email seems to involve only relatively senior people in central functions.

Q. Right --

THE PRESIDENT: Can I just ask, who is Martin Andrews, who sent this email? What was his position?

A. I believe he may have been the UK general manager before Eddie Gray.

THE PRESIDENT: He was quite senior?

A. Quite senior, yes.

MS. DEMETRIOU: Jean-Pierre Garnier?

A. He was one of the recipients.

Q. He was the CEO?

A. He was the CEO, or maybe at this time he was head of pharmaceuticals, but he was certainly very senior.

Q. And David Roberts?

A. He was the head of the patent department.

Q. And Hans Bishop?

A. I am afraid I do not recall.

Q. Do you remember any of the others?

A. Ray Cresswell was, and perhaps still is, a solicitor in the legal department who specialised in regulatory issues. I cannot tell you about any of the other people.

Q. This email says:

"Please find below the objectives for our telecon in case there is any confusion about the content in relation to Project Dyke."

Then we have three bullets:

"To fully understand the nature and timing of the potential anhydrate threat posed by the Norton (source thought to be BASF-Knoll)

"To review external Counsel's opinion of our anhydrate patents.

"Identify critical decision time points and criteria for engagement in third party discussions."

Then it says:

"In terms of a running order, I suggest that I kick off with a summary of competitive intelligence on the Norton situation to date, followed by an update from David on the Counsel's opinion and then discussion."

So, amongst other matters, this call was going to consider the nature and timing of the threat from IVAX. That is right, is it not?

A. That is what it says, yes.

Q. It was also going to review external counsel's opinion on the strength of GSK's anhydrate patents?

A. Yes, that is what I infer from the penultimate paragraph.

Q. At this stage, in July 2000, you had already obtained external counsel's advice. So who did you get that from? Do you remember?

A. At this point we had had some discussions at least with solicitors at Simmons & Simmons and I recall that David Roberts was involved.

Q. It rather looks like it is written advice because it says:

"Review external counsel's opinions."

So it would have had to have been recorded in writing for it to have been discussed by all these people on the call.

A. I do not think that that follows at all.

Q. Well, it would have had to have been summarised in writing otherwise how do you review it?

A. I am not actually aware of any written counsel's opinion that this could refer to.

THE PRESIDENT: It does say below:

"... followed by an update from David," who I take to be David Roberts, "on the Counsel's opinion ..." So it may be that David Roberts was going to report to the people on the call.

A. That is what I would expect from a reading of this, that Dave would present orally to the group.

THE PRESIDENT: The expression "counsel's opinion", is that used to mean a barrister's opinion or could that be a solicitor's opinion?

A. It could mean a solicitor's opinion.

THE PRESIDENT: It is not used to mean --

A. Martin Andrews was not a lawyer. So he is probably using this as a catch-all for external advice.

THE PRESIDENT: Yes. But David Roberts would no doubt have a note of the advice, whether it was written advice or not, over which --

A. He might have a written note or he might have attended a meeting and known what he wanted to say.

MS. DEMETRIOU: The use of the singular "counsel's opinion" rather indicates that it is counsel in the sense of an individual barrister, does it not?

THE PRESIDENT: Not everybody uses it as precisely as that. I think what Ms. West is saying --

MS. DEMETRIOU: Ms. West, we see from the bullets that the third bullet is to:

"Identify the critical decision time points and criteria for engagement in third party discussions".

Clearly the legal advice would have been relevant to that question, and that is why you are discussing it. Do you accept that?

A. Give me a moment to read through it one more time.

Yes, you will recall that at this point data exclusivity had not yet expired for paroxetine in the UK. It expired in December of this year.

We had not yet seen other generic manufacturers. So critical decision time points could relate to a number of different things, including responding to Norton, if they had already approached us --

Q. I am focusing more on the words "engagement in third party discussions". The simple point I am putting to you is that that would have been informed by the legal advice that you had received.

A. I do not know what third party discussions could have been referred to here other than Norton. If Norton had already approached us it could have been Norton, but at this early stage there were no third parties to discuss with.

Q. I think to be fair it is referring to Norton. So if you look at the first bullet it is talking about the threat posed by Norton, and so I think you are right to suggest that that is talking about third party discussions with Norton.

The short point I am putting to you is that you would have taken, or the team or the recipients of this email would have taken into account counsel's opinion when approaching those discussions.

A. I think it is a truism to say that we would have counsel's opinion in mind when considering what to do about Norton.

Q. Thank you.

Given that Dr. Reilly was involved in discussions with Norton, then presumably that advice would have been passed on to him, would it not? He would have had to have known about it?

A. Yes, I recall that Mark Reilly did consult the patent department and talked to us about the patent situation.

Q. If you could turn, please, to the next tab, which is tab 5 of your bundle; for everyone else it is {K/21/1}. You see here an email dated 11th January 2002.

Let us start with the email at the bottom of the page, so that is an email from Mark Reilly to David Redfern and Pascale, Pascale Richetta. Who is Pascale Richetta?

A. My recollection is that she was the commercial head of neurosciences marketing in Europe.

Q. We see the question, and the subject line is "Project Dyke - Today Meeting with Chris". Chris would have been?

A. Chris Viehbacher.

Q. "David/Pascale

> "Is any input from the UK required for this meeting as we have been in extensive negotiations with GUK? A pan-European 'card' would really help us as we cannot reach agreement on a deal for the UK alone."

Then we see further up a response from Pascale to Mark Reilly, copied to you, saying:

> "Mark, I believe Viv (West) is full up to speed with what is ongoing in UK and did plan to raise this specific issue at the meeting (if any specific point you would think of do not hesitate to give me a call before ... I do not believe a pan European agreement can be achieved, but at least some concerted moves in different markets and we will definitely check how UK could benefit of those.
>
> "We will keep you updated."

We see here that, first of all, taking it in stages, we see Mark Reilly is asking whether UK input is required for the Project Dyke meeting in light of negotiations with GUK. You see that in light of his email. He is canvassing there a European-wide agreement. You see that?

A. Yes.

Q. Then the response to you says that you are fully up to speed with what is going on in the UK, in other words with the GUK negotiations. That was copied to you. So you are being put forward as the person fully up to speed with events. Yes?

A. I think the context here is that Pascale is preparing for a meeting and Mark has asked whether she wants him to provide some information about the UK.

Q. Yes.

A. You will recall that Project Dyke collected information from across Europe about what was going on in different countries, so he is volunteering information, he is saying we are talking to GUK, shall I dial into the meeting, or whatever?

The pan-European card is something which I think Mark referred to earlier, which was that GUK were interested in a co-marketing arrangement that would apply outside the UK, and I think that is something that we could not provide.

Q. Yes. So you are the person who is being said by Pascale Richetta to be the person fully up to speed with the GUK negotiations who could report to this meeting?

A. Yes, Pascale is saying "Do not worry about dialing in, Vivien can say whatever needs to be said about what happened in the UK".

Q. Yes. So in effect, you were liaising between Mark Reilly and any others that may have been handling the negotiations and the rest of the Project Dyke team.

You were reporting what was going on with the negotiations to the Project Dyke team at least in relation to this particular issue?

A. To the extent that I would have reported into the Project Dyke team about events in the UK, it would probably be at rather a high level. The meetings were only an hour long and there were attendees from every European country.

Q. Yes.

A. If I reported, it would be at the rather high level of some discussions are taking place with GUK.

Q. Yes, so your role was not restricted to just looking at the patent position, you were looking at things a bit more widely than that, were you not, in terms of the negotiations?

A. My role in Project Dyke was as somebody who could provide other people in the team with information about what was happening with the patent and at the same time solicit information from them about, for instance, the launch of generics.

So the membership consisted of one or two patent attorneys on a typical occasion, regulatory people from all of the countries, and Pascale, who took on the thankless task of doing the minutes, and so forth.

So at a typical meeting we would have people from the regulatory departments telling us about approvals of generics in their countries, and I would pop up and talk about what litigation was happening where. So it was a forum for exchanging information.

Q. Yes, I am not asking you anything inconsistent with that. The question I was asking you is that we see here that you are said to be the person fully up to speed with what is going on in

the UK in relation to the GUK negotiations, and in particular, whether there could be a pan-European agreement. So your role extended beyond just looking at the patent position?

A. Well, I would say that my role did not extend to influencing questions about pan-European agreements. In fact, rather the opposite. Project Dyke did not tell the local operating companies what to do. It --

Q. That is not the question I am asking you. I am asking a much narrower question, which is that your role extended beyond involvement just in the patent position. You were involved, fully up to speed, in the negotiations more generally. I am not asking about the role of Project Dyke. Do you accept that?

A. So you are asking about my role?

Q. Your role.

A. My role was specifically a patent role. I wanted to know about regulatory information so that we could obtain samples and test them.

Q. Ms. West, I am going to put the question one more time and then I will move on.
It looks from this like your role went beyond just looking at the patent position, and that you were fully up to speed with the negotiations more generally. Do you accept that or not?

A. I do not think that is a fair characterisation of what is happening here. Mark is offering Pascale some information. She is saying "I think we know enough for now, Vivien is dealing with the UK litigation, when she is at the meeting she can tell us what is going on".

Q. Let us move on. Let us go to tab 6 of this bundle {K/17/1}. This is a presentation called "Seroxat Update" dated 11th May 2001, and you are one of the two people along with Pascale that has put this together.

A. Yes.

Q. So you co-presented it?

A. Obviously it is a long time ago, but judging from the format, the font and the content and the style of the content, I think it is highly likely that we took it in turns to present this.

Q. If we move to page {K/17/12}, please.

THE PRESIDENT: What is the EET that it is being to presented to?

A. It was Chris Viehbacher's group and he was head of commercial operations Europe, I believe. It was like a steering group for the European group of companies.

THE PRESIDENT: Yes. Thank you.

MR. MALEK: What does EDC mean? It says "EET" at the top and then at the bottom it says "EDC".

A. I am afraid I do not know.

Q. If you can't remember, do not worry.

A. One sends to suffer from an excess of acronyms from a big company.

MS. DEMETRIOU: Going back to the slide on page 12, headed "Corporate IP Strategy Europe", we see a number of bullets. The first one says:

"Assume generic competition everywhere in Europe from anhydrate."

Then:

"Enforce anhydrate patents as appropriate.

"Hemihydrate enforcement requires separate consideration.

"Deals must meet US anti-trust and EU competition law rules."

It looks from that that this was a coordinated strategy across Europe that includes both enforcement, we see that from the second bullet, and deals, we see that from the fourth bullet?

A. Right. Well, this goes to what I was saying before about Project Dyke, because this set of slides in effect is output from Project Dyke, but Project Dyke did not decide strategy, it was intended to collect and share information between the local operating companies and, in this context, to report upwards to Chris Viehbacher.

This slide, the slide on page 12, is information, it is not a set of instructions.

Q. It is more than information, is it not? It looks more like recommendations. Points that need to be followed up.

A. I believe that this is a slide which I drafted. I cannot be 100% certain, but the style looks very much as though I drafted it.

My recollection, imperfect though it may be, is that this is intended to inform and to some extent to reassure and also to warn because we know the data exclusivity is expiring --

Q. But I think we are agree on this: that from this slide it appears as though there is a strategy across Europe?

A. I think it is a stretch to characterise enforcing infringed patents as a strategy, because it is something that any patentee will want to do.

Q. Ms. West, I am looking at the title of the slide. I did not think this was going to be a controversial issue:

"Corporate IP strategy Europe."

So there is a coordinated Europe strategy.

A. It is a description of what is likely to happen. It is a warning about generic competition. It is a statement that we have anhydrate patents that we are prepared to enforce. It is a statement that we have a hemihydrate patent, and it is --

Q. It is a statement --

A. -- a reminder that any local operating companies who want to enter into agreements will need to run it past the legal department and share the information with other members of the group.

MR. GLYNN: Would it be fair to read from the fact that it is going up to Viehbacher that there is a sort of approval at the high management level for what is being done across the European countries, either implicit or being --

A. Yes, I think it is implicit that there is approval to do all of these things, for instance, to enforce patents. But that is probably not as significant as it sounds because in the case where there is a marketed product and a patent that covers it, and an infringement, it would be quite rare not to take some action.

MR. GLYNN: Not a controversial strategy?

A. It is not a controversial strategy, and it is perhaps a stretch to describe it as a strategy at all.

MS. DEMETRIOU: Can we turn to page {K/17/15}, "Next Steps". Do you have that page?

A. Yes.

Q. The second bullet:

"Explore agreement with third parties:

"- NL, Germany, UK, Ireland to draft agreements for internal approval asap.

"- All countries to identify third party players."

I will not use the word strategy, because you do not seem to accept that, but what we see is a coordinated action across Europe. Do you agree?

A. Yes. I was showing this the other day. Obviously I have seen it before, but I had not recollected it until I was shown it more recently:

"All countries to identify third party players," is obviously a reminder that the LOCs need to be alert to potential paroxetine generics in their territories.

I do not know exactly what it means when it says "agreements to draft for internal approval asap". Whether that means asap after you have decided to enter into an agreement, or as soon as possible now, I do not recall what exactly that means.

Q. We do not need to explore that, Ms. West, but the point I was putting to you, which I think you agreed with, is that this shows coordinated action to try and make agreements with the generic companies in various European countries, and I think you said "yes". Is that right?

A. It says "explore agreement".

Q. Yes.

A. I have to say that must mean that we are open to the idea of agreement if agreement is necessary. In some countries, of course, we did not have patents.

Q. We saw from the email that I have already taken you to at tab 5 of this bundle -- and that was the email that we just discussed, so this is at {K/21/1}. I do not think we need to go back to it, but just so you know what I am referring to. We saw there that you knew that Mark Reilly was negotiating a possible settlement with GUK?

A. Yes.

Q. That is the up to speed point.

A. In January 2002.

Q. Yes. If we look also at -- it is something that is going to pop up on your screen; it is not in the bundle. At {E1/23/1} we see there an email from Mark Reilly. Do you have that on the screen? To various recipients, including yourself, dated 2nd January 2002:

> "I have received confirmation from Richard this afternoon saying that Merck Generics have rejected the offer of a commercial settlement for paroxetine. They are clearly only interested in a European deal."

You see that?

A. Yes.

Q. I do not think you were in court on Friday, were you, Ms. West, when Mr. Reilly was giving his evidence?

A. No.

Q. Have you read the transcript of that evidence?

A. No.

Q. Let me take you to the transcript. That is in your bundle at tab 7. This is on Magnum, bundle {TR/5/77}. If you turn to page 77. If you look at the top of the page, the question that was being put to Mr. Reilly was:

> "Question: Was GSK's view uniform in all cases -- because these were different cases [this is his view as to the strength of the patent position] -- and at all times that the patent position was strong or did it vary at any point according to the circumstances?"

His answer was:

> "Answer: My understanding was that it was strong all through. I mean, there would be discussions going on particularly with some of the discussions around the litigation, etc, but what was communicated to me was consistently: we have strong patents."
>
> "Question: Communicated to you by whom?

"Answer: Vivien."

If you turn over the page {TR/5/78}, at page 76, and if you go down a few lines to line 8, you see a question that was being put to you (sic) there:

"Question: To be clear, Dr. Reilly, was your dialogue only with Vivien West or was it also with Cynthia Robinson or with any external counsel?

"Answer: Cynthia would have been in the discussions and Vivien would have briefed Eddie, myself, Cameron Marshall and Cynthia.

"Question: Did you yourself have any dealings with external counsel?

"Answer: No."

So that was Dr. Reilly's evidence on Friday.

Would you agree with that, that that is a fair summary? Is he right?

A. Obviously after all this time, it is hard to remember exactly how the conversation went, but it is completely believable that I would have told Cynthia and Eddie and Mark about the progress of what -- it appears to be the Alpharma inspection at this point.

Q. His point, going back to page {TR/5/77}, was that there would be discussions going on. The question asked to him was whether his view was uniform throughout. The answer that he gave was that the patents were strong, that message was being communicated to him consistently by you. That was his evidence.

A. Yes.

Q. So not on a one-off basis. You would agree with that? You were giving him regular advice during this time when the settlement agreements were being negotiated?

A. I see. The question he is specifically answering on page 76 starts:

"You are saying after the inconclusive inspection --

Q. No, if you look at the question at line 28 on page 76 {TR/5/78}, his answer is "yes" and that was being communicated to him by you. Do you see that?

A. I see something like that at the top of page 75. I don't see the dates. Can you show me again.

Q. Of course. If you look at internal page 74, {TR/5/76}, do you see line 28 at the bottom?

A. Got it.

Q. Yes?

A. Yes.

Q. So do you agree that throughout that period you were providing Dr. Reilly with advice about the strength of the patent position?

A. Yes.

Q. I want to explore with you the basis for the advice you were giving Dr. Reilly. If we go back to your statement at {E/1/17}, can we turn up paragraph 58.

We see there -- this is not controversial -- that you were the instructing patent attorney for GSK in relation to the GUK proceedings. If you flick forward to paragraph 76 {E/1/21}, you say there that you were the instructing patent attorney in relation to the infringement proceedings against Alpharma?

A. Yes.

Q. Let us start with the GUK proceedings --

THE PRESIDENT: Can I ask you -- sorry to interrupt -- how much longer you have, Ms. Demetriou?

MS. DEMETRIOU: Yes. I have about 15 minutes.

THE PRESIDENT: Yes, just a moment. (Pause)

We can do 15 minutes, but no more, and I do not know if there is any re-examination, but we will have to stop.

MS. DEMETRIOU: Thank you. I will try and be as quick as possible.

Let us start with the GUK proceedings. We know you instructed Simmons & Simmons. We see that from paragraph 60 of your statement. At some point before you commenced proceedings on 18th September you instructed counsel. Was that leading and junior counsel?

A. Sorry, can you direct me to the reference to 18th September?

Q. The proceedings began on 18th September, you see that from paragraph 61 of your statement {E/1/18}.

A. Yes, I do not recall exactly what the sequence of events was. I would have had multiple meetings with the solicitors and with the solicitors and counsel at various points in time, but after this length of time I cannot remember.

Q. Was it leading counsel you instructed?

A. As far as I recall, I did meet with a QC at around about this time.

THE PRESIDENT: Andrew Waugh?

A. Andrew Waugh took the case.

MS. DEMETRIOU: The immediate thing you did was apply for an interim injunction, and as we established earlier the key things you would have been concerned about at that stage were whether you had an arguable case on infringement and the question of irreperable damage.

A. Yes.

Q. Do you remember taking advice on those points from leading counsel?

A. We did take advice, and I recall that we were reasonably happy on both points.
Q. Once you got the injunction you were then pressing ahead towards trial. So disclosure took place and there was an exchange of expert evidence. Once the expert reports were in, it was possible to take a more considered view of the merits of the case going ahead to trial. So presumably you would have asked leading counsel for their advice at that stage?
A. As I explained earlier, it was a continuing conversation between myself, other patent attorneys and the solicitors and counsel, and junior counsel as well.
Q. At some stage before taking the decision to press ahead to trial, it would have been essential to know leading counsel's view, because his view would have been your best guide to how strong GSK's case would have been in the trial?
A. Yes, we certainly took into account counsel's views. We went along.
Q. Was that advice given in writing, do you remember, on this occasion?
A. I am fairly certain that it was not, because at the stage where evidence is being exchanged and disclosure is being exchanged, it is necessary to meet fairly often and speak fairly often, and it would just introduce a hiccup in the proceedings to suddenly say "Please can we have "a full written opinion".
Q. Sorry, for GSK, the company, to know how leading counsel viewed its prospects of success would have been a very important thing, would it not? It briefed leading counsel on the trial, so it would have been very important for the company to know what leading counsel's view was on prospects of success, would it not?
THE PRESIDENT: I do not think Ms. West is disputing that. I think she is saying once you have got into the process of going up to trial, a lot is going on. You are meeting with counsel quite a lot and talking to the solicitors a lot, you would not get -- her practice anyway -- a formal written opinion on the merits.
MS. DEMETRIOU: Right, but you would have conveyed the gist of that advice to Mark Reilly, would you not?
A. I would not be constantly reporting back to Mark.
Q. I am not asking you a question about regularity, but once you knew what leading counsel's views were you would have conveyed them to Mark Reilly?
A. If there was a change of our view on the case then certainly I would tell the client, which in this case was the UK business.
Q. At some stage after the injunction a view would have had to have been formed by your leading counsel, having seen the expert evidence, as to the merits of the case, yes?

A. The view formed by GSK in light of the evidence, disclosure and advice from counsel, formal or informal, was that we were going to go to trial and have the case heard.

Q. Yes, and that decision would have been based on advice, or at least taken into account advice of leading counsel, would it not? You were not going to take a decision like that just ignoring leading counsel's advice, were you?

A. Yes, I agree, we would not continue with the case if counsel advised us it would be a bad idea.

Q. In fact, leading counsel's advice was the most important piece in the jigsaw in terms of deciding and reaching a view on how it was likely to go in court?

A. Yes, counsel's opinion is the only indicator that we have for how likely it is that we will win the case. But it is still not, of course, a very reliable indicator.

Q. Well, Ms. West, you may take that view, but when you gave your advice to Dr. Reilly, you presumably passed on leading counsel's advice? Either expressly or by way of summary, you would have passed on the gist of that advice?

A. What I told Mark was that we considered the patent to be valid and infringed and we were prepared for trial.

Q. You would have -- in making that assessment -- passed on the gist of leading counsel's advice?

THE PRESIDENT: I think what Ms. West is saying, correct me if I am wrong, is this: GSK is an experienced patent partner, not like some other potential clients in a patent case. They have a lot of experience of pharma patents. They reached a view, they then, having got the injunction and preparing for trial, working closely with outside solicitors and counsel. If at any time counsel said "We have a problem" or "This is not looking so good for the following reasons", then you would have conveyed that back, you would not have disregarded that and gone on ahead.

A. Yes.

THE PRESIDENT: If that were not the case there would not be anything specifically of counsel's advice to report to your clients. Have I got that picture right.

A. I think that describes it very well.

MS. DEMETRIOU: I want to go one stage back because you talked about a change in position, but what I want to establish is this. Once you got past the interim injunction stage and all the evidence had come in, that is when it was possible for leading counsel to form a better view, a more informed view, as to prospects of success at trial. That must be right, must it not?

A. Yes. Once the evidence has been received and disclosure, everyone can see a great deal more about how the case is likely to unfold.

Q. So the short point I am putting to you is that that advice, you would have received advice, whether formally or informally from leading counsel about that, you would have passed it on to Dr. Reilly in some form or other, you would not have kept him ignorant of counsel's views, would you?

A. No, I think we have already established that.

Q. I can move on. If we go to tab 9 of this bundle, you see there some notes written by Rachel Parr, who was the finance director, of course, who took over from Dr. Reilly.

These were notes based on a conversation between her and Cynthia Robinson. If you go to the bottom of the page, do you see a series of bullets?

A. Yes.

Q. In the middle there is a bullet saying:

"Wk [weak] patent and stopped entering the market."

A. Yes.

Q. Now, did you tell Rachel Parr the patent was weak?

THE PRESIDENT: We do not have this note up.

MS. DEMETRIOU: It is {B1/6/1}.

THE PRESIDENT: I know we have seen it before.

MS. DEMETRIOU: Do you see the point saying "weak patent"? Did you tell Rachel Parr the patent was weak?

A. I did not.

Q. Do you have any idea why Cynthia Robinson may have formed that view?

A. I would be very surprised, because that is not what I advised Cynthia.

Q. Let us have a look at what Dr. Reilly told the CMA in his interview about the advice he was getting.

THE PRESIDENT: Just to make sure, I am a bit concerned you are rushing a little bit now, I do not know if there may be any re-examination.

MS. DEMETRIOU: I have three questions left. I am winding up.

THE PRESIDENT: Otherwise we can resume tomorrow.

MS. DEMETRIOU: If we go to tab 8 we have a transcript of an interview that the CMA case team held with Mark Reilly {E1/12/25}.

Do you see a question at the bottom of the page by Mr. Moore where he talks about Rachel Parr's note and the weak patent. It says:

"Do you have a comment on that?"

Mr. Reilly says:

"The advice we got was that the patents were reasonable and we had a fair shot at it."

Does that accurately reflect the advice you gave him?

A. Yes. I think that it does because my advice was that the patent was valid and infringed, but litigation is always uncertain and we could not guarantee that we would win, needless to say.

Q. It is more than litigation being uncertain, is it not, because we established at the outset of these questions that the particular points you went through at paragraphs 41-47 of your statement were about more than general litigation uncertainty; they were about issues of law and evidence, difficult issues of law and evidence that these cases raised?

A. Yes, that is correct. We went through earlier some of the reasons why I thought this was an interesting and difficult case. However, I suspect that if you looked at any patent case in detail you would very quickly find it has its own interesting and difficult aspects.

Q. If we turn to {B1/11/4}, it is tab 14 of your bundle. If we start at {B1/11/1}, you see it is a meeting between the OFT and Glaxo which you attended. We see your name there in the list of people present on 19th December 2011.

If we could go forward please to page {B1/11/4}, at paragraph 16 and 17, that says:

"VW said that the interim injunctions provided approval for GSK's case in that GSK had shown that there was a serious case for the generics to answer. She noted that the divergent rulings during the litigation were an indication of the 'significant uncertainty' as to the final ruling in relation to the status of the patent."

Then at 17, Mr. Moore asked:

" ... what the process was in establishing the strength of the patent. VW said that GSK believed that it had detected an impurity when developing the product. GSK was not able to make anhydrate until its research work finally resulted in several forms, including Form A. GSK therefore considered that it had a strong but narrow patent which covered a useful product and process which was not previously available. GSK was therefore 'cautiously optimistic' about the strength of the patent."

All of those phrases, going back to Mr. Reilly's summary of the advice you gave him, which was reasonable, had a fair shot at it, and the phrases you use here "significant uncertainty", "cautiously optimistic", they are all pretty consistent, are they not, and that was your view at the time?

A. Yes. I would say so.

Q. Had the advice you obtained from leading counsel been positive, then Mark Reilly would not have been saying that the patents were reasonable and you had a fair shot, and neither would you have been talking about significant uncertainty, would you, Ms. West?

A. I do not think it is correct to say that Mark's reference to reasonable and having a fair shot is inconsistent with positive advice from counsel, and the uncertainty point I think is a different point. This is about the fact that there were different rulings during the litigation, either as between BASF and Apotex or possibly as between different jurisdictions, I cannot tell what the context is for this at the moment. But what that tells us is that it would have been difficult before the litigation to predict what the outcome was, which meant there was a risk both for the plaintiff and for the defendant.

Q. Yes. Ms. West, going back to the last sentence of paragraph 17 of this interview, "cautiously optimistic", that was your view?

A. Mm.

Q. I have no further --

MR. MALEK: Yes, because that does not come on the transcript. That is yes?

A. Yes, cautiously optimistic expresses it. We thought it was a valid patent, but of course it is not over until the fat lady sings.

MR. MALEK: No.

MS. DEMETRIOU: I have no more questions.

THE PRESIDENT: Is there any re-examination?

MR. SCANNELL: I have no additional questions.

MR. MALEK: You have dealt with the difficulty of predicting the outcome pretty well clearly, but when you got the judgment on the BASF case in July 2002, that was an outcome that was not outside the range of predictable outcomes, ie it did not come as a bolt from the sky?

A. It did not come as a bolt from the sky. We were pleased with the decision on the process because BASF had made a good effort to reproduce the prior art process and failed, and we were disappointed that we lost the product claim because we had unsuccessfully argued this purposive construction point and I felt that equitably we were entitled to the claim but we had rather created a problem for ourselves with the way that the claims were worded.

MR. MALEK: What about the Apotex judgment in July 2003?

A. That was much more painful. Apotex, of course, had different experimental evidence from BASF. As I said earlier, they do their own research, they are very good and they are quite sneaky, and they were very aggressive with their cross-examination.

So the process claims fell, wrongly, we felt very strongly that was a wrong decision, and the appeal court agreed.

MR. MALEK: Thank you very much.

THE PRESIDENT: It is right to say, is it not, the appeal court agreed, but they found no infringement and if they had accepted your construction to find infringement they would have found the claim invalid; it was a squeeze, was it not?

A. No, no, I disagree. The point on whether or not Apotex infringed the claim was not actually at the point of novelty of the claim, it was purely a question of whether a claim to crystallise a solvate and then carry out a displacement could be interpreted broadly enough to cover the displacement being carried out with a solvent. But as long as the end product is substantially free of bound solvent, then it still meets all the requirements of the claim and of the process.

My feeling was that Apotex had done something that was within the claim but really super clever, and the board just could not bring themselves to find infringement when they had made such a big effort to try and get outside the patent.

THE PRESIDENT: We can all look at the judgment, but I thought they had said that if we had construed it the other way, the claim would have been insufficient.

A. Right, so you are talking about the insufficiency point not the prior art point.

THE PRESIDENT: Not the prior art. Yes.

A. Okay. Yes, that goes, I suppose, to a point I touched on in my witness statement about how much you can justify claiming in relation to what you have invented.

So what we had invented was the displacement process, but we had only described two displacing agents and, in addition, the inventive step was very much tied into the fact that one of those agents was water and it was surprising that it did not convert to hemihydrate.

In the end, the Apotex process was just far away enough from both our claim and from our examples.

THE PRESIDENT: Yes. Thank you very much, Ms. West. You are released as a witness.

A. Thank you. (The witness withdrew)

THE PRESIDENT: Can I just mention, first of all, Mr. Turner, Mr. Sellick, is he coming tomorrow morning?

MR. TURNER: He will come tomorrow morning, as I understand it. He will be short.

THE PRESIDENT: How short?

MR. TURNER: Much shorter than these witness, about 40/45 minutes.

THE PRESIDENT: We will do that first and then reconfigure for the experts. What we thought we would do is to -- we may not follow exactly the order of questions in the joint statement, but there are in the joint statement of the first group of experts, essentially three points, with various subpoints. The third one is to do with the Chapter II case of the two points, but we will deal with all the issues under point 1 tomorrow, in particular the pay for delay inference and what it means, and in general how it might apply or not in this case, and explore all that with, therefore -- not Ms. Webster, but the other expert. We will save point 2 and the issues under that for Thursday. We are not sitting, you will recall, on Wednesday. That means that Dr. Jenkins, who is not concerned with point 2, need not come back on Thursday, and that is the way we will split it up.

I do not think we will have a problem on timing tomorrow allowing for your one hour with Mr. Sellick, so we should be all right.

MR. TURNER: Thank you, sir.

May I raise two very quick operational points in relation to the experts.

THE PRESIDENT: Yes.

MR. TURNER: Which have been raised with me. The first is in terms of bringing material with them into the witness box, as it were, my understanding is that there will be available to them the joint statements and their respective reports, but that they should not bring other materials.

THE PRESIDENT: That is right.

MR. TURNER: Secondly, that they will not communicate after they have started to give evidence about the case with others, including, that is, the respective members of their teams advising them, because in some cases these are consultants supported by larger teams.

THE PRESIDENT: That is correct as well. Yes. We will do it on the basis that they will sit in the front row and they will be up on the screen, and I think we will probably go through the issues in point 1 and then you can ask questions afterwards.

10.30 tomorrow.