IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

27 February 2017

Before:

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

(Sitting as a Tribunal in England and Wales)

BETWEEN:

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

Appellants

- and -

COMPETITION AND MARKETS AUTHORITY

Respondent

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HEARING

A P P E A R AN C E S

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

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

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

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

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

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

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THE PRESIDENT: Professor Beath has asked me to thank the parties' representatives for their good wishes. He is now recovering at home after an emergency operation, although unfortunately, sadly, he will never be fully restored to where he was.

We are all very grateful to Mr. Dermot Glynn for stepping in at extremely short notice for this heavy case. You all appreciate Mr. Glynn is still reading in to the papers, but if he had not been able to step in obviously the case would have had to have been adjourned to a later date.

There was discussion at the PTR about how we will handle the hot tubbing of the experts next week. You may notice that since then we have had the screens installed in court which are intended for us to take video evidence, but they will enable the camera to be on the experts in the front row so that counsel sitting in the row behind will be able to see the experts properly giving their evidence, and we think that takes care of the issue that was discussed of counsel being concerned they could not see the experts properly.

Then, when individual counsel come to ask questions, they can come up and use the witness box as a podium and that's the way we think that should be handled. That should work well.

We thank the parties for their skeleton arguments, and we also received a document from GSK which is certainly not a skeleton argument in any shape or form. It is an extremely long and rather wordy document which, I have to say, we did not find particularly helpful but we have read it. So there we are.

Yes, Mr. Flynn.

MR. FLYNN: Sir, perhaps I could once again echo our good wishes to Professor Beath and, I think on behalf of all of us, gratitude to Mr. Glynn for undertaking a heroic task.

I apologise for the length of our skeleton if the Tribunal didn't find it helpful, but we thought that possibly with two new members of the Tribunal, it would assist to have matters set out in narrative form, and that was before we knew precisely how new the members of the Tribunal would be. But I apologise if the Tribunal has not found it helpful.

THE PRESIDENT: Well, a shorter document would have been much more helpful, and had time permitted we would have sent it back but it was not practical to do that. So there we are.

Opening submissions by MR FLYNN

MR. FLYNN: Sir, let me provide by way, then, of opening with an overview of our case, as it were a summary of what you will find in the skeleton, and just to set matters into context.

The case is clearly about three agreements by which GSK settled or avoided some complex patent litigation, and I will explain the patents and the products in due course, and those agreements were entered into in 2001/2002 and terminated by 2004.

GSK is the originator, the patent holder, the patentee. The patents that it had were over a substance called paroxetine hydrochloride and how to make it into a safe and effective medicine. It is an important part of our case that these patents were strong, they were believed in by GSK, they were asserted and they were also feared by the generic companies against whom they were asserted.

The medicine, paroxetine, is an antidepressant within a group which is described by mode of operation as SSRIs, which stands for selective serotonin re-uptake inhibitors.

If you want to know more about how they work, as much as you possibly could need to know, I think, that will be found in the evidence of Professor Young, which will not be tested in these proceedings, and sits in bundle J. He is a distinguished -- neuropsychopharmacologist I think is the proper title of his discipline, and he explains how these drugs work on the central nervous system.

There are several drugs in that category, the most famous by way of household name is probably Eli Lilly's Prozac, which is a generic name for fluoxetine. The GSK version was branded as Seroxat, and Seroxat was launched in the UK in 1991 and competed successfully within that class of drugs, SSRIs.

Now, not unnaturally it attracts attention from generic companies whose business is selling off patent medicines rather than developing their own. They can start taking an interest in these medicines once market data exclusivity has expired. That allows them to seek their own marketing authorisation using the originator's clinical trial data, and they will look to see what scope there is for working around any patents that are an obstacle.

The three Generics with whom this case is concerned are known as IVAX or Norton -- the companies change their names and ownership quite frequently; I generally refer to IVAX, but some of the documents call it Norton -- and Generics UK Limited or GUK, and Alpharma, which has certainly changed its history a number of times.

I'm pausing, sir, because I look down at my learned friends as I say this and I recall with apologies that I forgot to introduce anyone, and I do not know whether that would be helpful for the members of the Tribunal?

THE PRESIDENT: I think we should have a cast list.

MR. FLYNN: You may have a cast list, but if you find it helpful --

THE PRESIDENT: You can take that as done.

MR. FLYNN: I will take that as read for now, then.

So the decision, the CMA decision, which is in bundle V, was taken last year and finds that the agreements in question infringed competition law by object and by effect, and it also

finds that GSK had a dominant position in what it says is the relevant market, being paroxetine, and thereby abused it by entering into the agreement.

You know that the decision is extremely long and it also has a series of annexes which are said to be an integral part of the decision.

Chapter VI is the key object chapter --

THE PRESIDENT: Just pausing one moment. I think it is right, isn't it, if I have got it the right way round, that the GUK agreement was found to infringe Chapter I and Article 101, but the Alpharma agreement was just Chapter I; is that right?

MR. FLYNN: I will double check that. The Alpharma one is the later one.

THE PRESIDENT: Ms. Ford is nodding, yes. So, I mean, that affects the whole issue of block exemptions, obviously.

MR. FLYNN: Yes. That's relevant to the block exemption point.

I'm somewhat hemmed in in here, as you can tell. The infringement by object chapter of the decision is Chapter VI, and the CMA holds there that both GUK and Alpharma were potential competitors of GSK at the time the agreements were entered into and that they amounted to infringements by object in that the generic company concerned accepted restrictions on their competitive behaviour in return for cash payments and other value transfers that GSK made, and that the objective aim of the value transfers was to induce the generic company's acceptance of entry restrictions.

In Chapter VII, which is the infringement by effect chapter, the CMA's findings in the object chapter are repeated and used by the CMA to justify a finding that the likely effect of the agreements compared with counterfactuals that have come to be known as continued litigation and alternative settlement terms, or alternative deals, was to delay the emergence of independent generic competition and not to increase the actual competitive constraints placed by GSK.

In a separate decision address taken on the same day, which I think in the bundles is to be found in bundle {A3/44/1}, the CMA also took a decision -- it has come up on the screens; technology is wonderful -- took a decision that there were, as it is called, "no grounds for action", NGFA, in respect of the IVAX agreement under Chapter I because it was excluded by the effect on the vertical agreements exclusion order, and we will come back to that.

In Chapter X of the decision, the CMA finds that the GUK and Alpharma agreements did not benefit from that exclusion and they did not qualify for any form of exemption from the prohibition. At the end of the decision, in Chapter XI, there is a decision to impose substantial fines, including, as far as GSK is concerned, a fine of £37.6 million.

Obviously I'm not today addressing you on the Chapter II aspects at all, nor, indeed, on the penalties which will come later in the closing submissions as the Tribunal has directed.

THE PRESIDENT: We have all read the decision.

MR. FLYNN: Naturally. I am simply summarising it now just to situate ourselves.

Our overall submission, obviously, is that the findings of the CMA are wrong in fact and that they are wrong in law, and GSK at all times had faith in its patents and it took the necessary action to assert them in court and defend them.

The IVAX dispute was settled without any resort to litigation because IVAX didn't actually move to launch a paroxetine product. As we shall see, that was because it could not. The GUK and Alpharma agreements were entered into in the context of actual litigation instigated by GSK because GUK and Alpharma took steps that led to GSK fearing that they would be supplying products which would infringe GSK's patents. GSK secured injunctions against both of them, although formerly it was an undertaking to the court to like effect from Alpharma, but nothing turns on that. These were secured on the basis that GSK had made out a prima facie case of infringement of the patent that is sued on.

So when GUK and Alpharma settlement agreements were entered into, GUK and Alpharma were legally unable to bring their proposed paroxetine product onto the market. The form of the settlement agreements was essentially that each of the three generic companies was enabled to enter the market, bring to market substantial volumes of generic paroxetine produced by GSK. This former supply agreement is referred to as authorised generic supply. The pills were produced by GSK, but they were not branded as paroxetine. Each of the generic companies sold the medicine in their own chosen livery or get-up, and the medicine took its place in the product range that each of the Generics was offering.

That gave them access to a guaranteed non-infringing source of paroxetine. From GSK's perspective, it preserved the integrity of its patents which could be asserted against other generic companies who might be thinking of bringing what GSK would consider to be infringing product to the market.

We will come to the terms of the agreements in a short while. Just in the chronology, the IVAX agreement was the first in time and IVAX was appointed GSK's sole distributor of authorised generic paroxetine. When the GUK and Alpharma agreements were later entered into, they were appointed as subdistributors to IVAX, indeed by IVAX.

Each of these distributors was given a specific volume allocation. We will come back to those. The CMA say that they are limited or restricted. We say the important point is that

they were substantial and they amounted ultimately to around 60% of what GSK had been supplying as Seroxat.

There were also cash payments made by GSK to each of the Generics, as you will hear. But it is clear, we say beyond dispute, that the preponderate value, looking at the value secured by the generic company, the preponderate value lay in the supply arrangements. We have some calculations in our notice of appeal which I can turn up, but the proportion is 75%.

Now, it is not in dispute in these proceedings that the result of entering into these agreements was a substantial saving to the National Health Service of something of the order of £15.6 million. This is one of the many facts in the case that the CMA does not dispute, but asks you to consider as irrelevant and to focus on what happened further up the chain at the level of sale to or purchases by pharmacies. This will be explored in considerable depth in these proceedings.

The fact of the matter is that the CMA now accepts that prices to pharmacies did fall as a result of the agreement. Let me just say for the moment that GSK's case has always been that the primary focus should be on the assessment of the expected or actual effect of the agreement should be on the consumer, which is the NHS, and nobody is doubting that that impact took place and that it was in fact bound to take place because the regulatory scheme which governs the market in medicines provided for a change in the reimbursement level, the drug tariff, made to pharmacies once a particular product had become widely available in generic form.

Before that change, reimbursements for proprietary medicine is at the level of the patent owners list prices, at so-called category C. Once the drug is widely available in generic form, it is moved into category A where the reimbursement is based on the list prices of a basket sample of generic suppliers and wholesalers operating in the market.

Now, the CMA says this undoubted saving of 15.6 million is a quirk of the system and not an effect for which we can take credit. Their reason for saying that is that the system was designed to reflect the actual prices paid by pharmacies and was intended to be adjusted to ensure that that happened. It is, again, common ground that no adjustment took place. The reimbursement level was slashed without any rebalancing subsequently in favour of pharmacies.

We have a dispute, and we answered it because the CMA raised it in its defence, that it was unforeseeable at the time that the agreements were entered into that there would be no such adjustment. We have produced evidence from Mr. Godfrey Horridge, who was at the time the finance executive on the Pharmaceutical Services Negotiating Committee. He has given

evidence to say that no discount enquiry, as it has been called, was to be expected at the time. The CMA suggested at one point that they would produce evidence to counter that; they have not done so. It looked as though they might be going to make a case about the notes of a speech made by the minister at the time, but that came to nothing and it has now been decided that Mr. Horridge will not be cross-examined.

So we will wait to see what the CMA has to say about him, but in our submission his evidence stands, and at the time it was foreseeable that the reimbursement levels would not be substantially adjusted.

In any event, in our submission, it is not a quirk. The change in the drug tariff category is a recognition in the regulated system that the introduction of generic product when widely available is going to lead to price falls in the trading level of the market between suppliers and intermediaries, wholesalers or pharmacies, which, after all, in a regulated system are just a conduit for medicines from producers to patients in the NHS.

So it is a recognition that there would be that price fall, price effect in the trading level, and the aim of the reimbursement charge is to ensure that the NHS has the benefit of that change.

Now, the CMA, even in its press release announcing the decision, gave a focus, stressed the impact on the NHS, ultimately the taxpayer, and we say that it is perverse as well as legally wrong to say that it is not relevant in these appeal proceedings because the ultimate aim of competition law, so we are constantly being told, is to ensure a free and fair market for consumers. Whether, in some cases, depending on the circumstances, the focus may be on the competitive system as such, the reason for examining all these matters is to ensure that consumers are being properly treated.

The CMA's own mission statement, as far as I'm aware, is there to make markets work for consumers.

So our positive case in a nutshell is that these agreements were genuine settlements of genuine disputes under which strong patent rights were front and centre, in circumstances where no right to enter had been established and, indeed, the case of GUK and Alpharma had been blocked by the court. The agreements led to the introduction of Generics supply in substantial quantities leading to substantial savings for the NHS.

We say in those circumstances they are plainly pro-competitive. What is the objection that the CMA is raising? Investigating matters long after the agreements have been entered into and terminated, the CMA is trying to seek to persuade you -- and this is how its skeleton argument starts -- these agreements fit within a theory which had not taken shape at the time

they were entered into, which has become a source of activity and concern for competition authorities in the EU and, of course, in the US and no doubt elsewhere.

They use this buzz phrase of "pay for delay". They open their skeleton with an example of what they call a "simple pay for delay case" where a patentee, a patent owner/holder, pays a large sum of money to a generic company simply to stay away from the market that it might otherwise have been considering entering.

We say that is certainly a simple example. You can devise others, some from the real world. We have seen some cases we know of where incumbents effectively bribe someone to stay out or leave the market, and thereby infringe competition law. That certainly happens.

We do not say that it is the mere existence of the patents that prevent that sort of case being made under competition law. There may be cases, and some of them may be present in our minds, where a patentee pays a would-be challenger handsomely not to come to the market because he knows that his patents do not prevent such entry, and where a competition authority, including the pay for delay, can document that sort of situation it may have a pay for delay case.

THE PRESIDENT: You say do not prevent such entry. I mean: are unlikely to prevent such entry? Would that meet the same point? You say the patentee knows they do not prevent such entry. If they were absolutely certain of patent litigation ...

MR. FLYNN: You are never 100% certain, sir, I accept that.

THE PRESIDENT: You accept that if he thinks it is unlikely that his patent would prevent such entry, then he pays a large sum --

MR. FLYNN: Then again, there may be a case. I do not dispute that, and certainly cases which we know, you can take a view on whether they absolutely knew or whether they were pretty certain, or whatever. But I think it is not sufficient simply for it to be the ordinary risks of litigation so that the patentee says, "Well, I am sure as I can be". But obviously there are always risks in litigation, as we all know. We say, in short, just calling this case a species of pay for delay case gets it off to the wrong start. This is asserting by inference; this is asserting what the CMA has got to prove in its decision.

In the present case, unlike just about all the others that might be put to you, the patents were actually deployed and had actually blocked the entry of GUK and Alpharma.

It is striking that the CMA's skeleton does not mention the injunctions at all in the introductory setting of the seal. It is also clear, in our submission, that this is not a case of Generics being paid to stay away and not enter into the market. It is not a case of exclusion.

It is a case where they were enabled to enter where otherwise they could not. It is not a case of delay, but of immediate entry.

THE PRESIDENT: They could not until the termination of the litigation. They might have been able to depending on the outcome.

MR. FLYNN: Depending on the outcome. I am making no wider point than at the time of the entry into the settlement agreement their entry was legally precluded.

THE PRESIDENT: Yes, we have that point.

MR. FLYNN: The entry that was facilitated by the settlement agreement was with non-infringing generic paroxetine, which we say is the introduction of competition into paroxetine supply, substantial competition.

The volumes that they received displaced not only the parallel imported product, which the pharmacies may have had some unsatisfactory features, but it also displaced substantially GSK's sales of Seroxat. If you look at the NHS, the impact is clear, if you look at the pharmacy sales, then it is also clear, and not in dispute that there were price falls.

What the CMA wishes to do at every point is to compare what did happen with what would have happened if there had been immediate independent generic entry at the time of the agreements with the steep price falls that you would get on full, independent generic entry. That is what all their charts in the CMA's skeleton tend to show.

We say that leads the CMA's focus or obsession with the price falls which you get when there is an independent entry, which might happen on capitulation by the patentee in a settlement agreement. It is a fundamental error.

It may be the right comparison if you can document, as I have said, a patentee simply paying someone to stay out of the market. But it is not the right comparison when at the time they were barred from entering and would have stayed so for a good while --

THE PRESIDENT: You say for a good while. In the litigation these were temporary injunctions --

MR. FLYNN: They were interim injunctions yes.

THE PRESIDENT: If it is a period of 10 months, 11 months, you say that is irrelevant. But you are looking in about a year. If it could be said, well, in a year's time there could have been unrestricted generic entry.

MR. FLYNN: Yes, if that comparison had been made you might have a different case, but that comparison has not been made. That comparison has not been made. The CMA simply says, "Well, if there had not been the agreement". They compare it with the benefits of immediate generic entry. They say -- we will obviously be coming to the counterfactuals in

some detail, but they say, in effect, any alternative would have been better than the one that these parties looked into.

THE PRESIDENT: I may have misread the decision. I thought they compared it with continued litigation, not immediate entry.

Now, it is a question of what value you put on that. I can see the argument. But I thought that was the comparison they were making: not immediate entry, but continued litigation and uncertainty.

MR. FLYNN: Continued litigation with an unspecified chance of success by the generic company. We start by saying the case does not get off the ground on the facts, and we recall as a legal matter that the CMA bears the burden of proof here and that any doubts that the Tribunal has must be resolved in favour of the appellants, not least because this is a decision imposing substantial fines. Also we say we come back to that because of the significant delay between the facts which are behind these agreements and the CMA's analysis.

The data problems that arise in the Webster issues are perhaps an example of the problems which have arisen due to the lapse of time. That's on the facts and we come back to that.

We also say that the CMA misapplies the law governing both infringement by object and infringement by effect, and by using inference and inclusory reasoning, the burden is being shifted onto the appellants.

We say that that is an unacceptable way of proceeding. In fact, if we have the burden we say that we have satisfied it.

THE PRESIDENT: Article101(3) or the CA98 equivalent, you have the burden.

MR. FLYNN: We have the burden under exemption. This is simply on the infringement case.

THE PRESIDENT: On infringement, yes.

MR. FLYNN: Indeed. We have an argument also that this backward-looking attempt to foist onto the facts of the time of the pay for delay theory fails at the preliminary hurdle of the vertical agreements exclusion, which we say covered all three agreements and not just the IVAX agreement. I will come back to that.

We do say of course that the agreements have to be seen as a suite. They are connected agreements; they depend on each other. One might have come before the other and the system would have been just the same, and naturally, as we know, the CMA objects to the IVAX agreement as well under its Chapter II analysis.

Dealing with the core infringement case, we say that the CMA is trying to make the facts fit the theory and not the other way round. Where the facts are inconvenient they are either to be ignored or they are to be abstracted away.

We say that that forces the CMA to take some extreme positions. One is the undoubted beneficial consequences of the agreement. Another is taking the position that it does not have to have any view at all on the likely outcome of the settled litigation.

A further extreme position, in our submission, is the suggestion that this case is on all fours with the decision in the *Lundbeck* judgment of the General Court of the European Union. *Lundbeck* is the first judgment on an appeal against a permission decision in this area, and in my submission it is inherently improbable that it has all the answers to all the questions that can arise. It is as improbable as saying that the first judgment of the Court of Justice on a cartel, say, something like dyestuffs back in the late 60s, answered all the questions once and for all as to how price fixing agreements were to be dealt with under the object limb.

That, again, will be explored in detail, but we say that the facts underlying *Lundbeck* were extremely different from those underlying the present case. There are no injunctions, there was no litigation in the *Lundbeck* case and there was certainly no authorised supply agreements either. Even if *Lundbeck* had been successful in any litigation it might have brought, but did not, it could not have obtained through that litigation what it did obtain through the agreements.

That will be addressed tomorrow I think by Mr. O'Donoghue in the agreed list of topics.

THE PRESIDENT: Yes.

MR. FLYNN: Overall we say that the CMA's attempt to fit this case into the round hole marked "pay for delay" is an overreaching. It rests on abstract descriptions that provide no good distinction between proper agreements, improper settlements, good and bad; terms like "inducement" or "buying off", which are not defined and can be applied to any settlement which parties actually agree to reach. It is capable of being applied far beyond any schemes which you could properly describe as a pay for delay agreement to allow the CMA to second guess, long after the event indeed, genuine settlements of complex litigation.

It is essentially a regulatory approach under the guise of finding an infringement.

What has happened in this case, which is not some market sharing artifact of the parties in which the patents played no real part, is that GSK is being penalised for not seeking to pursue the case as to judgment, as it did in other cases. It was always perfectly willing to defend its patent, as you will have seen. Generics are being penalised for seeking to secure some commercial benefit from the arrangement rather than simply capitulating, and GSK is

in effect being penalised for allowing immediate authorised generic entry onto the market when, perhaps with hindsight, it did not need to do so.

That's our fundamental objection to this case.

In terms of what I am going to cover in more detail, as indicated to the Tribunal last week, I was intending to say some words about the patent disputes and their settlement from GSK's perspective, and dealing with the facts on the IVAX case because you have no witness from there. That's not something which the Tribunal will hear about directly.

I am going to look at the agreements themselves briefly and address you on the vertical agreements exclusion order, and then I am going to outline GSK's case on the object infringement, then on the effects aspects of the case before, if time allows, saying a few words on the exemption aspects, if that is convenient for the Tribunal.

THE PRESIDENT: Yes. You say we have no witness on the IVAX case. I thought Dr. Reilly does say something about it?

MR. FLYNN: From the IVAX side of things.

THE PRESIDENT: From the IVAX side.

MR. FLYNN: Yes, indeed.

THE PRESIDENT: We do not have witnesses from GUK or --

MR. FLYNN: You don't have --

THE PRESIDENT: -- or Alpharma either.

MR. FLYNN: Indeed you do not. Firstly, that is why we set out those matters in detail in our skeleton. That is also why you will be addressed by my learned friends on the facts from the perspective of the generic companies.

So it is really an issue of live evidence is what I am saying. You will not have a witness from any generic company. I think I may have been speaking into the wrong microphone. (Pause)

Turning, then, just to the factual matters relating to the patents and the disputes that arose.

We say it is really not clear why the CMA only sets out part of the story in the decision.

The systematic account of the facts is not in there; it is available on the file but it is not discussed in the detail that we say is appropriate for understanding what actually was behind these disputes.

This is not ex-post spinning, as the CMA would suggest. These are accounts of beliefs, facts, discussions and motivations from the relevant time.

We say, for example, that GSK's belief in its strong and legally valid patents was manifest at the time. That is demonstrable on the evidence. It is also clear that each of the generic

companies concerned regarded themselves as on the wrong side of the argument. That, again, is demonstrated. But it is important because the CMA must believe that there is more than a slight chance of independent generic entry, one would hope so; will not quantify that chance, it just calls it a "real chance". That, we say, is not justified on the facts.

Secondly, we say, on the facts, that the evidence does not establish that GSK has some overarching strategy to prevent or delay generic entry, and it certainly did not have a strategy to induce generic companies to accept restrictions on their ability to compete. We also say that the evidence shows that you could not say that the generic companies would have been able to market their proposed generic versions of paroxetine lawfully in the face of GSK's patents.

We say overall that the generic companies were induced to settle their case -- sorry, the CMA's case that the generic companies were induced to settle by the money, the value transferred is not the correct conclusion. They were induced to settle because of their perception of the strength of GSK's patents. They came to believe that a settlement was preferrable to carrying on with litigation that they were basically not going to win, and the CMA does not seriously suggest, we say, that they were overborne, that in some way GSK put pressure on them not to do that but to take the money.

Indeed, at one part in the skeleton, and I think it is in the abuse section, the CMA actually says that these generic companies were prevented from entering the market by GSK. We say that is just not a fair or accurate reading of the evidence. They appreciated the strength of our patents, they saw that a settlement would be desirable. Naturally, when they explored that possibility, they were looking for some advantage to themselves and some protection against their downside costs incurred, and so forth.

They secured terms which enabled them to enter the market, but GSK nevertheless believed, and that is clear, that had it continued to litigate it would probably have prevailed. There is nothing in the agreements to suggest that GSK had any wobbles about their patent. The downside risk is what motivates a company like GSK to enter an agreement like this because, as we have already discussed, litigation is never certain. There is no such thing as a 100% cast iron legal case in relation to patents. You just do not find it. The strongest case is unlikely to be regarded by any sensible company as 100% guaranteed bound to win. It may be thought with hindsight that the view that GSK took was unduly cautious, or that it did not need to enter into settlement agreements that were as beneficial for the Generics as these were.

GSK fought other cases to a conclusion, as you know, and it prevailed in the BASF litigation.

THE PRESIDENT: That was not an infringement case though.

MR. FLYNN: No, that was --

THE PRESIDENT: I thought the only infringement case that went to conclusion was Apotex.

MR. FLYNN: In Apotex it was found that the validity of the process was upheld and Apotex's process was held not to be infringed, and that is a good example, frankly, of the hazards of litigation.

THE PRESIDENT: And if it had infringed the process would have been invalid. That is what the court said.

MR. FLYNN: That is what the Court of Appeal said.

THE PRESIDENT: The one case that did go to conclusion, your client lost. That is a fact.

MR. FLYNN: As a fact, yes, but --

THE PRESIDENT: It does not mean to say that these cases would have gone the same way, I see that.

MR. FLYNN: It does not. It does not.

THE PRESIDENT: I am not quite sure why you say that the later history shows that GSK was unduly cautious, it should have fought all the cases. The one case they did not settle with a generic, they lost.

MR. FLYNN: Sir, the evidence, we say, suggests that these companies knew that they were infringing the patents that we were asserting --

THE PRESIDENT: Yes.

MR. FLYNN: Every reason to fear that.

Shall we have a look at -- I do not say necessarily a look at the patents, but remind ourselves of what they were. They are in the exhibits to the witness statement of Ms. West who, again, is not to be cross-examined.

THE PRESIDENT: Do we need to look at them in detail?

MR. FLYNN: I do not think you do, sir. I was simply going to --

THE PRESIDENT: We know where they are, and Ms. West describes them helpfully in a very clear statement, it seemed to me.

MR. FLYNN: Yes.

THE PRESIDENT: The scientific issues. We can take it from there, we know the patents and we have the judgments, so we know what happened to the product claims in the anhydrate

patent and we know what happened to the process claim, which was the one that survived and which has been found to be valid.

MR. FLYNN: That is in a sense the key, because it is the process claim which is, as it were, the killer because it is the process claim which allows you to work out whether the product that the generic is putting on the market is using the GSK process or not.

THE PRESIDENT: I thought it does not allow you to work out. That is the problem. You cannot just buy the product that the generic has produced, analyse it, as GSK did -- went round the world getting the product -- and work out what was the displacement agent. That is the whole difficulty, as Ms. West explains, with this process claim. That is my understanding. Perhaps I have got it wrong, but that is the way I understood her evidence. Even the experiments on the Delta tablets, they were inconclusive, so she says. The process claim was the valid claim, as it turned out, and obviously if infringed you were able to keep anyone who used that process out.

MR. FLYNN: But for the reasons that are explained by Ms. West in detail, as you say, as far as GSK was aware the process was actually the only possible way of creating the form A, and form A is exactly what the generic companies' products did contain. That is why GSK would have been confident that the generic companies were found to infringe those process claims.

The other area of concern of the Generics was the possibility of conversion or containing traces of the hemihydrate form of the substance, paroxetine hydrochloride, which would, in GSK's view and in the concern of all the generic companies, have infringed the hemihydrate patent as well.

THE PRESIDENT: Yes.

MR. FLYNN: That patent, as you know, was never challenged. It was a matter both regarded as a strong patent and was never the subject of proceedings, but it was a matter of great concern to the generic companies.

Yes, Ms. West explains the strength of the patents and the novelty of the form A production in particular, non-obvious in that it uses water to create a dry product, and the hemihydrate, as I say, was a strong patent that was never challenged.

I should also mention just for completeness the dry tableting patent, which was also a matter of concern for the generic companies because obviously not surprising that you would wish to find a way of producing the tablet that was dry, as it were, to avoid the hemihydrate risk. That was another matter that was of concern to the generic companies and which, as it were,

gets wrapped up in the settlement agreement because they are given a guaranteed non-infringing source of the paroxetine hydrochloride, I should say technically.

THE PRESIDENT: Yes. None of the cases alleged infringement of that, did they?

MR. FLYNN: No, and I think that is probably one reason that speedy trials were possible in that the claims were kept separate. You will remember at one point there was a suggestion of adding a claim of the hemihydrate which Mr Justice Jacobs did not allow, and that was sort of put off for further proceedings. I think one reason it was possible to have speedy trials was --

THE PRESIDENT: It started about three months later, the case. So if you are going to have a six-month speedy trial, start another claim three months into it, it is pretty hard to join it, a quite separate patent.

MR. FLYNN: Yes.

THE PRESIDENT: But what I am saying is when you brought proceedings against Apotex, you did not allege trying to keep them out, infringement of the dry tableting patent, as I understand it.

MR. FLYNN: I do not believe so either. I do not believe the dry tableting or the hemihydrate were the subject of proceedings in this country.

I am told -- in effect it probably does not matter, but in the case of Alpharma one reason they did not disclose their product to us is that they were worried about infringement of the dry tableting patent. I think that is in Ms. West's evidence.

If I move on to the question of strategy, then.

THE PRESIDENT: Just one moment. (Pause)

We do need to take short breaks in the morning for the benefit of the transcribers, and perhaps that is a sensible --

MR. FLYNN: It is as good a time as any.

THE PRESIDENT: We will take 5 minutes.

(11.50 am) (A short break)

(12.00 pm)

THE PRESIDENT: Yes, Mr. Flynn.

MR. FLYNN: Thank you. Thank you, sir. I will move on now, if I may, to the IVAX matters.

THE PRESIDENT: Yes.

MR. FLYNN: As we have already said when we set out these matters in detail in the skeleton, precisely because they are not in the decision and to save the Tribunal fishing around in the various bundles, it seems that task is now made miraculously easier by the Opus system.

THE PRESIDENT: Yes.

MR. FLYNN: We will see how we go with that and call up a few of the documents.

This goes back to May 1999 when IVAX approached GSK to say that it was intending to launch a paroxetine hydrochloride anhydrate product.

THE PRESIDENT: Are we at paragraph 2.70 in your skeleton?

MR. FLYNN: We probably are, sir. I am not following it.

THE PRESIDENT: Just if we are going through that, that sets out the detail.

MR. FLYNN: That is about right, anyway. Yes, it is.

MR. GLYNN: Is it not coming up on the main screen?

MR. FLYNN: I was not going to take the skeleton up on the main screen; I was intending to pull up one or two of the documents that are referred to so that, as I say, sir, you do not have to fish around in the bundles behind you. But, yes, the President has correctly identified where we are in the skeleton.

IVAX tells GSK that it has this intention and that it is intending to -- that it has made, I apologise, an application for a marketing authorisation in Ireland.

You are aware that the point of that was if they get a marketing authorisation in one EU member state, there is the ability to use it to apply for a similar one in other member states.

As we will see, this was essentially being used as a bargaining chip. That is the first call, just planting the seed.

Then, Mr. Blanksby, who is IVAX's managing director, comes back in mid-2000 to say that they have actually developed the product, and this is where Dr. Reilly, who you will be seeing later in the week, comes into the picture.

He was at the time the finance director of GSK's UK business and he is asked by his boss to meet with Norton and find out what they are up to. As you will have seen, there are lots of meetings over 18 months between Dr. Reilly and colleagues of his and Mr. Blanksby, and Mr. Simon Clark of Norton. There is also a Mr. Guy Clark, just to distinguish between the two.

Essentially, as Dr. Reilly says -- it is quoted in the bundle. It is paragraph 24 of Dr. Reilly's witness statement. It is in {E/2/8}.

Paragraph 24:

> "I do not recall the details of the discussions but the meetings followed a similar pattern with each party 'setting out their stall ... IVAX were very aggressive -- they said they would break our patents launch independently and at risk. They said they had a ... product. In one meeting they put a vial on the table but they would not let us

take it away for testing. I recall that in at least one meeting IVAX told us they were in the process of seeking an MA for a paroxetine product in Ireland -- which they eventually obtained in September 2001. We were aware that IVAX intended to use the Irish MA to seek a UK MA under the mutual recognition procedure and although the timing of this was difficult to predict, the grant of an MA gave greater credibility to their claims. They were well aware of the damage to GSK's business to which their actions would lead even if they were subsequently found to have an infringing product. We were equally clear that we would defend our patent position."

As I say, GSK was prepared to go to court, did prepare to go to court, and Dr. Reilly told Norton that. You can see that in file {Z/142/4}.

THE PRESIDENT: What are we looking at?

MR. FLYNN: I beg your pardon, I have given the wrong reference. It is {B4/178/1}. The witness statement is the confirmation that he authored this document. So this is Mr. Blanksby's note.

He says in relation to what GSK was telling them about the patents, there are many types of patent being applied to the molecule. There is a patent on the anhydrous product from Ferrosan (P1). Patent 1, I think:

"GSK claim P1 doesn't work and if you use it you end up with hemihydrate therefore breaking P3.

"Patent on hemihydrate (P3) was introduced by GSK and they referenced a version of anhydrous production (P2).

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

Whatever sense one makes of that it is clear that GSK is telling them that there is a strong patent position.

THE PRESIDENT: This is his report to -- it is a note or it is a report to someone. If we go --

MR. FLYNN: It is a note that Mr. Blanksby made, and whether he says what he did at 4, it is just a file note, I am afraid I cannot immediately say. It is a note from the time of a meeting.

THE PRESIDENT: Yes.

MR. FLYNN: What he is being told by Dr. Reilly and colleagues.

THE PRESIDENT: Yes.

MR. FLYNN: Likewise, in a report -- this is a report then, {Z/313/10}. This is a report from IVAX UK to their US parent, I believe it is. January 2002:

"GSK position: £100 million UK product sales (Seroxat) molecule is off patent."

That is the basic API, the Ferrosan stuff, is off patent:

"... but ... many process and formulation patents claim strong IP position and will sue generic entrants."

THE PRESIDENT: Sorry, the date of this is?

MR. FLYNN: It is January 2002. I believe it is 23rd January 2002.

Perhaps we could see if there is a cover sheet at the beginning of this tab {Z/313/1}:

"IVAX UK In-Licensing.

"Presentation to IVAX US.

"23rd January 2002."

That is what GSK was saying to IVAX. But what IVAX was saying to GSK was that it was prepared to launch risk and that kept the parties talking, one might say. Because, as Ms. West explains in her witness statement at {E/1/17}, paragraph 57 of her witness statement:

"At the time, injunctions in pharmaceutical patent disputes were rare (GSK's subsequent successful injunction against GUK was one of the first against a generics company for a long time). IVAX was the first generics company to threaten to launch a paroxetine product so at the time we could not be sure that GSK would be able to obtain an interim injunction, regardless of our view on the strength of the patent claims and infringement. For these reasons, the risk to GSK of proceeding to litigation would have been very high."

As talks went on, what we see is that the originally highly aggressive stance from Norton begins to be mollified a bit and Norton effectively makes it clear to GSK that it has not made a clear decision that the only way, or its best way to market was the launch of its own generic product at risk.

What it essentially wanted was early access to the market. GSK could not count on an injunction and it had been unable to test Norton's product. Norton had not allowed that. As you have already seen from Ms. West's witness statement, though GSK believed at the time and still believed that form 2 anhydrate could not be produced whatever the earlier disclosures and that an anhydrate in form A had to be produced in accordance with GSK's patented process and would be liable to show traces of the patented hemihydrate.

Norton, by about September 2001, were effectively saying to GSK that they are looking at a number of options -- launch of their own product; sourcing of product from GUK -- and they told Dr. Reilly that GUK were prepared to offer Norton an indemnity in respect of

patent infringement or the sourcing of product from GSK itself, and they said that they were keeping all their options open and they would be deciding at the end of October 2001.

The final decision that it made, and they had kept GSK guessing at the last minute, as Dr. Reilly says, was that they would go with GSK and they signed the agreement on 3rd October 2001 that came into effect on 1st December.

What we now know, because GSK did not know this at the time, but what it knows now is that there was not any truth at all in IVAX's story that it was actually ready to launch a non-infringing paroxetine product. It was desperate to be the first generic company on the market, but it did not have a product to launch. What effectively has happened is that GSK has been strung along and fooled into believing that IVAX would have stood any chance at all in litigation between the parties.

If we look at A5 -- I think this is bundle A5, tab 76, page 17 {A5/76/17} -- we will see Mr. Guy Clark's statement to the OFT.

That is not the right reference. (Pause) I think we have a wrong bundle reference there. I will see if I can find it.

THE PRESIDENT: I think this is Guy Clark's statement.

MR. FLYNN: Because of where the screen is I could not see the bit I was looking for, I beg your pardon. It is paragraph 6.3 in this statement:

> "An MA is a key threshold in bringing a medicinal product to market. Before a company has an MA, it is difficult to know whether it has a viable product or is 'bluffing' about its ability to enter the market. It is therefore a judgment as to how truthful you think a company is being. However, once a company has an MA, it can credibly argue that it has a viable product.
>
> "The grant of the Irish MA in September 2001 was therefore IVAX's bargaining chip to GSK so that it could say, 'Look, we're going to be coming to the market because we have an MA in Ireland'. It gave IVAX's argument credibility and forced GSK to take notice."

6.5:

> "IVAX relied on GSK's slight ignorance of the MRP ..."

The mutual recognition program I think is what the MRP is:

> "... to think that IVAX might be able to make it to the UK market sooner than actually it probably would have done, that is within three months of the Irish MA. In addition ..."

He refers to relationships with Simon Clark and David Blanksby with GSK, because I think one or both of them were formerly of GSK, or maybe it was the other way round. Anyway, they knew people at GSK, so that, presumably, he says, generated trust and integrity to give IVAX a significant advantage with GSK compared with other companies.

THE PRESIDENT: You say MRP is mutual recognition program or process?

MR. FLYNN: I believe that is right, but I will be corrected. Mutual recognition procedure, I am told.

THE PRESIDENT: Procedure?

MR. FLYNN: Procedure.

THE PRESIDENT: It seems a bit surprising that a company like GSK was not familiar with it.

MR. FLYNN: Nobody is saying it was not familiar with it, but he is saying if you have the marketing authorisation, it gives you added credibility because then you have the permission to put it on the market.

THE PRESIDENT: Sorry, can we go back to page {A5/76/17}, please. He does say, I thought:

"IVAX relied on GSK's slight ignorance of the MRP ..."

I just say that -- I do not know, it is rather surprising to me, the thought that a company like your client was not very well familiar with the mutual recognition process. It must be faced with it all the time. That is what he said.

MR. FLYNN: That is what he says, but I think he means that if he waves it around, he may be able to suggest to GSK that IVAX will be on the market sooner than it really could have done. That is within three months of the Irish MA.

I do not know what he is saying about GSK's ignorance, but he is suggesting that this is a valuable or a viable bargaining chip in discussions with them.

THE PRESIDENT: Yes.

MR. FLYNN: No doubt that is a question that can be put to Dr. Reilly.

We say it is clear that actually what IVAX was doing here was trying to position itself so as to be the first entrant on the market and to get supply from GSK, pretending that it had other options available in order to get good terms from GSK, and it did not itself have an intention of coming in by itself.

If we look at {A4/57/10}, under the heading "Paroxetine tablets (In House Development)", this is a monthly report within Norton IVAX.

What it says is, under "Progress":

"The IVAX licence in Ireland was granted on September 7th, giving strong grounds for discussions with 3rd parties in the UK. IVAX have made the decision to launch

paroxetine using a 3rd party source, to minimise exposure on the IVAX product. The in-house development project is to continue in order to support the product in the longer term. The IVAX product will be available for launch when the patent issues are resolved by reasonable testing or if the existing patent is overturned by a 3rd party."

"Plans: Decision to be taken with regard to the preferred partner for IVAX."

THE PRESIDENT: This is dated? This is a note from?

MR. FLYNN: This is September 2001. I don't know if there is a cover page.

THE PRESIDENT: Do we know whose note it is? Someone in Ireland?

MR. FLYNN: It is probably a note -- it is an internal monthly report within the business, and I suspect it has multiple authors depending on the product heading {A4/57/1}.

I do not know if there is anything at the end that suggests who wrote it? {A4/57/12}. I think probably each person with responsibility for -- this is just my guess -- a particular drug feeds into the report.

If we look at B --

THE PRESIDENT: Pausing there.

MR. FLYNN: I beg your pardon. (Pause)

THE PRESIDENT: The third party source he is referring to is what? Who?

MR. FLYNN: He is saying they need to choose their third party. The ones that they mentioned to GSK, as you know, were, as well as GSK itself, GUK. As I think I just mentioned, there was some suggestion that even GUK was offering them an indemnity in relation to the patent issues. Then a company called Tillomed.

THE PRESIDENT: Yes.

MR. FLYNN: If we can move on from that document, sir, and go to --

THE PRESIDENT: Have I got this right? In September of 2001, they were planning to enter not with their own home produced product, but to market in the UK to sell maybe with a product produced by Tillomed, maybe GUK, or the alternative, as it turned out, was getting an agreement with GSK, but at that point they were a potential generic entrant? That is at September 2001 that they were still planning that?

MR. FLYNN: That is September 2001. They are considering their options and the decision that they have taken is to enter with a third party source.

THE PRESIDENT: Yes.

MR. FLYNN: If we look then at the next document, which is from 11th September 2001, and it is at {B4/179/1}, this claims to be a minute meeting of the paroxetine project team prepared by Guy Clark.

What one takes from that is that the GSK supply option is preferrable either to GUK or BASF, as they are talking about it then, because basically of litigation concerns.

THE PRESIDENT: Just a moment. (Pause)

At this point they have not decided to go to GSK, have they? Discussions are on going with two parties. Do you know what "IPI source" stands for?

MR. TURNER: That is IVAX Pharmaceuticals Incorporated.

THE PRESIDENT: I see. Thank you. (Pause)

So they are considering various sources.

MR. FLYNN: They are considering third party sources. They are not considering entering with their own product.

THE PRESIDENT: No, but it would be an independent generic entry who they sourced from Sumika -- that is what GUK later did, I think -- or they considered BASF. They are still planning to enter and they have not decided that the only way in is to take a supply agreement from GSK, clearly.

MR. FLYNN: They are considering the options. That is correct. Then they narrow them down.

THE PRESIDENT: That is the 11th September meeting.

MR. FLYNN: No doubt these things were discussed in different fora at different times. We have done our best to do a chronological sequence.

THE PRESIDENT: Yes.

MR. FLYNN: But if one looks -- well, we say that IVAX told the OFT that it had no appetite for entry at risk. So here, they are evaluating what the risks are, which obviously do not apply to the GSK product. If one looks at {B4/178/1}, we have a note. This is 14th March.

THE PRESIDENT: We are now going back months.

MR. GLYNN: We have already seen this.

THE PRESIDENT: We have seen this. We have just been on 11th September. What happens next?

MR. FLYNN: I beg your pardon?

THE PRESIDENT: What happens next?

MR. FLYNN: The point I am on is whether IVAX had any serious intention of developing an in-house product or serious confidence that it had its own product to bring.

THE PRESIDENT: Does it matter whether it is its own product if it is going to use non-GSK product? It would still be entering as a generic, unrestricted generic, challenging GSK.

MR. FLYNN: That is an option which it rejected because it was not --

THE PRESIDENT: When did it reject it? On 11th September it is still in play. When was it rejected, do you say?

MR. FLYNN: It is rejected -- as they say, a short while ago, they kept GSK guessing right to the last minute.

THE PRESIDENT: Sorry, Mr. Flynn. You are helping us by showing their internal document. Where is their internal document on which you say, before the agreement was negotiated, they had decided "We reject the options of coming in with Sumika's product or Tillomed or BASF"? Because on 11th September those are still in play.

MR. FLYNN: Those are still in play, but if I come to look at those, I will show you that those are not options that IVAX was seriously entertaining. While they are available, they --

THE PRESIDENT: Where do we find that, that they were not seriously entertaining?

MR. FLYNN: I was going to show you first the problems with their in-house supply, and secondly --

THE PRESIDENT: The in-house one you showed us they were not keen on doing. I think you showed us that.

MR. FLYNN: There are other documents relating to that, but I can move on to the non-GSK suppliers.

If one looks, therefore, these come from the witness statements that the IVAX people gave to the OFT about the discussions that they had with GUK.

THE PRESIDENT: Are there any contemporary documents as opposed to witness statements from people who are not giving evidence made years and years later?

MR. FLYNN: I do not think one is going to find a delightful document which says "We reject everything". In our submission, they did not wish to enter risk, they considered the possibilities of getting into bed with GUK, they thought that that was too risky, decided that --

THE PRESIDENT: Sorry, what evidential basis is there for the submission that they did not consider entering at risk, given the document you have just shown us of 11th September 2001 where they are still considering entering with non-GSK third party product, which clearly was a risk therefore? Indeed, they say it.

MR. FLYNN: In that document they explain the risks that those potential options would carry.

THE PRESIDENT: Of course they knew that would be entering at risk, but you say they then rule it out after 11th September -- it is only a couple of weeks later they do the agreement with you. There must have been some internal change of heart to support the submission you are making that they decided entry with these third party options was not something they are prepared anymore to consider.

MR. FLYNN: I think that the evidence as to their views comes from the witness statements to the OFT.

THE PRESIDENT: It is not of great weight, is it?

MR. FLYNN: I do not think we have found an internal document that makes that point.

THE PRESIDENT: So it relies on Mr. Clark's statement?

MR. FLYNN: Mr. Clark and Mr. Blanksby as well, the posture of the company in the market and the fact that ultimately they did want a deal with GSK.

I freely admit that that is what comes from the explanation that they give to the OFT, but in my submission, they are perfectly persuasive and logical.

THE PRESIDENT: They are admissible, but they are not, speaking for myself, of great weight, what someone who does not give evidence here says many years later.

MR. FLYNN: There was no --

THE PRESIDENT: You are not calling them.

MR. FLYNN: No, we are not calling them. We rely on what they said to the OFT.

MR. MALEK: Mr. Flynn, if you served a witness statement from someone from IVAX and you did not call them and the CMA said they wanted to cross-examine them, then we would have excluded that witness statement. So why should you be in a better position in just relying on statements to the OFT from someone you are not going to call as a witness whose evidence cannot be challenged effectively in cross-examination?

MR. FLYNN: Sir, we simply say that those statements are there. It is clear what they say, we can make submissions about it. The proof is in the pudding that they had apparently desultory discussions with GUK, and one can see why, even if GUK were offering them an indemnity, they would be concerned about entering into an agreement with them. They did not find another viable source that was not deep in litigation risk with GSK and they did not fancy it.

That is plainly what happened. It is plainly what their internal discussions at the time say even if they are exploring the options, and obviously they were using those to string GSK along.

THE PRESIDENT: We have your submission, but I have to say I do not attach great weight to statements many years later by people who are not giving evidence. We will look at it, but it is a question of weight.

MR. FLYNN: I understand what you are saying, sir, but one can see how they used these matters to strengthen their negotiation with GSK whilst, if they were being at all sensible about it, would have immense concerns about taking any of the options.

As far as their own in-house product is concerned, which was what kicked this off, it is plain that that was just being used, as it were, as a stalking horse and was half baked and totally inadequate in terms of bringing a product to market, and they knew it.

That, one does see at the time on the contemporary documents. So on the basis of that, for the CMA to conclude that IVAX thought it had a real prospect of placing a generic paroxetine product in the market that would withstand any legal challenge from GSK, which is in the decision, in an early part of the decision, we say is simply untenable. They did not have that product and they did not think they had access to that product, and they really thought that the only source they could identify was GSK itself.

The other point is that it is not a question in this particular case of value transfers overbearing IVAX's otherwise firm desire to enter into the market. The value transfer is precisely what Norton IVAX sought to get for itself. It sought to get supply from GSK. It wanted to be the first into the market and it wanted GSK products. The fact that GSK was prepared to give it is, of itself, no evidence that a good claim was being bought off.

Sir, that is the story in relation to IVAX who wanted supply and took supply. As I already said, the facts in relation to the other two agreements will be set out to you by my learned friends.

We say that whatever enthusiasm they may have had for prospects of independent entry were entirely dissipated when they fully appreciated the exposure that their respective sources had to infringement claims by GSK, and that any lingering enthusiasm they may have had was crushed by the interim injunctions which GSK secured, blocking their ability to place the product on the market.

As you will hear, each of them approached GSK, and not the other way round, to see if there was a settlement available that would ultimately reduce their substantial outlay. Obviously, in those negotiations, as anyone would, they attempt to talk tough and they make their position sound as strong as they can. That is something that you would expect in any settlement with information asymmetry. One thing these proceedings have allowed is,

of course, we can see both sides of the coin and make an appropriate assessment of the position.

THE PRESIDENT: Can I just ask you, one of the third parties they were considering was Tillomed, you said?

MR. FLYNN: Yes.

THE PRESIDENT: They signed heads of agreement with Tillomed, did they not?

MR. FLYNN: They did.

THE PRESIDENT: Have we got that?

MR. FLYNN: Let me see.

THE PRESIDENT: On 4th October it said. They were obviously having discussions with Tillomed in parallel with their discussions with your client.

MR. FLYNN: Yes, they did.

THE PRESIDENT: Have we got the heads of agreement?

MR. FLYNN: I do not know if they are attached to Mr. Blanksby's witness statement, it is possible that they are, which is file {Z/142/1}.

THE PRESIDENT: Perhaps someone can look that up overnight.

MR. TURNER: It is {Z/231/1}.

THE PRESIDENT: Can we scroll down, please, to the next? {Z/231/2} The territory was the UK, was it?

MR. FLYNN: Yes. That is right. It was for supply. It is all a bit mysterious, and obviously this is not something that GSK was --

THE PRESIDENT: Presumably you would not know anything about it.

MR. FLYNN: -- told about it, and in fact what happened was that the arrangement was flipped and IVAX supplied Tillomed, which is a strong indication that Tillomed did not itself have a viable source of supply.

THE PRESIDENT: So it looks as though they were running you in parallel without telling the other, seeing from whom they would get the better deal.

MR. FLYNN: Yes. The suggestion, as far as we can see, is that Tillomed did not actually have a viable source and was happy to talk to IVAX. But eventually it was the other way round and IVAX ended up supplying Tillomed.

THE PRESIDENT: The fact they did not have a viable source, what is the evidence for that? They are saying they are ready to supply here.

MR. FLYNN: This is a murky matter to which obviously GSK cannot speak directly, and one needs to look at Mr. Blanksby's witness statement. He says it is not something that he can remember very much about.

They signed the heads of agreement, and as you say the timing suggests that they were possibly thinking of playing one off against the other and running two horses.

Mr. Blanksby's recollection -- and I think this is in {Z/142/9}, particularly paragraph 5.3 where he says he does not have a clear recollection. He remembers that there may have been a product issue leading to a product recall. He has a vague recollection of feeling Tillomed were less of an option, but just cannot quite remember. That is the best he can do. As far as he can recall, there was some sort of problem. It was all a bit inchoate, as they say. In the event, supply was the other way round.

THE PRESIDENT: Yes.

MR. TURNER: Sir, while we are on that document, for convenience if we go to 5.5 and 5.7 it may save time {Z/142/10}.

THE PRESIDENT: Yes.

MR. FLYNN: Again, he says there he would not have signed it if he thought there were reasons to believe they would not be able to supply. But he does suspect that he had doubts about their product because it is associated company's product at recall, and effectively this was an insurance policy.

MR. GLYNN: He says in 5.7 that he does not recall any issues with the Tillomed product.

MR. FLYNN: Indeed he does say that, sorry. That was what I was referring to, but he says he also thought he was not free from doubt about their product. It is all rather vague and inconclusive, we say, and was entered into as a possible insurance policy, clearly with some doubts about it and, as he says, it was insured in case GSK pulled out:

> "GSK was my preferred option."

That is the Tillomed story, such as it is.

THE PRESIDENT: Yes.

MR. FLYNN: As I say, if we are looking also for the comparison with GUK, I think there we look at Mr. Clark's witness statement {A4/67/10}, paragraph 6.9. That is why GSK was the preferred option and why entering into a deal with a generic competitor such as GUK was not an attractive option for them.

THE PRESIDENT: Yes. So that is IVAX, is it?

MR. FLYNN: That is IVAX. As I said, I am not going to do a similar exercise in relation to GUK and Alpharma. We have done it in our skeleton and in accordance with the division of labour --

THE PRESIDENT: Yes. Presumably Mr. Kon and Ms. Ford will do that.

MR. FLYNN: Exactly. In 5 minutes, would it be worth taking a look at the agreements themselves?

THE PRESIDENT: We might as well look at the IVAX agreement. We have been leading up to that.

MR. FLYNN: To situate them.

THE PRESIDENT: We have a bundle.

MR. FLYNN: We have a bundle. It is bundle L.

THE PRESIDENT: For myself, I like to look at it in hard copy.

MR. FLYNN: The agreements were otherwise dotted around the bundles because of where they had originally been placed, so I hope it is helpful having them all together. Tab 1, then, is the IVAX agreement {L/1/1}.

3rd October 2001, reciting that SmithKline Beecham, as it then was, was the owner of IP rights in respect of the product. It is SmithKline Beecham which is to supply and IVAX which is to purchase product from SmithKline on the terms hereinafter appearing.

It is worth looking at 1.2:

> "Marketing authorisations ..."

Just the definition of marketing authorisations. They were to be obtained by SB on behalf of, registered in the name of IVAX for permitting the marketing and sale of the product by IVAX. In other words, it was SB's responsibility to secure the relevant marketing authorisation to enable this agreement to take place. "Pack" is defined as:

> "... finished patient pack, including patient information leaflet, of thirty (30) tablets of 20mg tablets with paroxetine hydrochloride as its active substance."

THE PRESIDENT: So it does not cover the 30mg; is that right?

MR. FLYNN: That is right. All of these agreements related to the 20mg version, which is the most common.

If one looks at recital 1.5, {L/1/2} definition of "product":

> " ... quantities of those formulations of paroxetine hydrochloride included in Schedule I, from time to time, and which are manufactured by SB for supply to IVAX in PACK form in accordance with the MARKETING AUTHORISATIONS. For the avoidance

of doubt this shall not include paroxetine hydrochloride sold by SB in the TERRITORY (as hereinafter defined) as SEROXAT."

This is an agreement for the generic version, and it is what we used to call a sole distributorship; in other words, the manufacturer is also permitted to carry on distributing. Schedule I on page {L/1/17} lists the product, and as you see it is paroxetine hydrochloride, 20mg tablets in packs of 30.

The supply price is Schedule II, page {L/1/18}, £8.45 a pack. The territory is basically the UK, Channel Islands and the Isle of Man. Then you see supply clause 2.1:

"[SmithKline] to supply IVAX's requirements ... in accordance with the terms ... appoints IVAX ... sole distributor subject to clause 3 ..."

Reserves its right to supply paroxetine hydrochloride to its own customers {L/1/2}, including as Seroxat, but when otherwise give rights to other parties to sell the product as defined in the territory.

Clause 2.2 {L/1/3}, which is important for understanding the links between these agreements:

"IVAX shall have the right to grant subdistribution, marketing and selling rights to third parties in the territory provided that IVAX shall include in all ... applicable terms and conditions ... including ... those applicable to the pharmacovigilance reporting ... confidentiality provisions ... shall enforce ... In the event of termination of this agreement any such subdistribution agreement shall also terminate unless SB" agrees to take on the subdistributor itself.

Clause 3:

"This agreement will become effective on 1st December ..."

So two months' start-up time:

" ... subject to IVAX's right to terminate ... 1 month's notice ..."

Originally entered into for a period of 12 months. Capable of extension. Any extension to be on a sole basis and IVAX to be offered the right of first refusal on the supply of the product for an extended period.

In the event that IVAX cannot sell and distribute a product other than because of its own fault, then SB will make arrangements for IVAX to be supplied with alternative packs at the same price.

Then 3.2:

"At any time during the term of this agreement should 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 ... forthwith."

That is a matter which they have to substantiate. The concern there is obviously what happens if there is a price tumble because others come into the market at risk or GSK is not able to see them off. So that is IVAX's concern there.

I think probably we can turn to clause 4, supply {L/1/6}. Fixed supply price to be reviewed in conjunction with the volume forecast at the end of the initial 12-month period. IVAX sets its own prices. Other things can be added to the list of products.

Clause 5, "Promotional Allowance". 3.2 million in recognition of promotional activities required to support the distribution and marketing of the product, payable in monthly installments, standard formulation there. Quality provisions in clause 6 {L/1/7}. One does not need to read it.

I am conscious of the time, sir, but --

THE PRESIDENT: Just let's finish the agreement. 7 is important, isn't it?

MR. FLYNN: Orders is clause 7. 12 months forecast of its likely sales volume as shown in Schedule III {L/1/9}. You will see Schedule III, page 19 --

THE PRESIDENT: It is just a form, is it not?

MR. FLYNN: It is a form which shows monthly requirements on a quarterly basis. So it requires an estimated monthly requirement and the first month to be firm orders. Requirements to be updated on a monthly basis. It is a rolling forecast.

THE PRESIDENT: Then there is a cap in 7.3?

MR. FLYNN: Yes. {L/1/10}.

THE PRESIDENT: Of 770,000 packs?

MR. FLYNN: In the first 12 months, because GSK had to re-tool the line {L/1/9}.

THE PRESIDENT: It is a 12-month term, isn't it, unless it is extended?

MR. FLYNN: Unless it is extended, that is right.

THE PRESIDENT: They do not specify the technical reasons, do they?

MR. FLYNN: No. I think the reason given -- I think Dr. Reilly may speak to this -- is that GSK had to -- because these were unbranded products that had to be specially made, they had to retool the production line, and so to start up at this notice they required this limit and for production planning purposes. That is, I believe, what is behind that.

MR. MALEK: Mr. Flynn, where do we find what was the actual amount of product which was delivered after this agreement?

MR. FLYNN: I will perhaps find the numbers for you over the adjournment.
MR. MALEK: Thank you very much.
THE PRESIDENT: So we finished with the original agreement. There were various addenda and extensions, quite a number.
MR. FLYNN: Yes.
THE PRESIDENT: In the end, was it eventually terminated or lapsed? How long did it last as extended?
MR. FLYNN: It was terminated. Tab 7 is the termination letter, June 2004 {L/7/1}.
THE PRESIDENT: Yes.
MR. FLYNN: Immediate termination.
THE PRESIDENT: 29th June 2004. Yes. Maybe we will look quickly after lunch at anything in the interim, the extensions and amendments. The side letter is of the same date, is it not?
MR. FLYNN: Yes.
THE PRESIDENT: Shall we just look at that quickly to finish.
MR. FLYNN: Tab 2.
THE PRESIDENT: 3rd October. {L/2/1}
MR. FLYNN: Which is essentially reassurance for IVAX that SmithKline will diligently pursue the action against GUK.
MR. TURNER: Perhaps we can read the full side letter.
THE PRESIDENT: Yes, I think we are. We can read that to ourselves, what they say about the proceedings against GUK.
Very well, we will come back at 2.05 pm.
(1.13 pm) (The short adjournment)
(2.05 pm)
MR. FLYNN: Sir, we were looking at the agreements.
THE PRESIDENT: Yes.
MR. FLYNN: I think you suggested we might just look at the addenda, essentially --
THE PRESIDENT: Yes, we read the side letter.
MR. FLYNN: You have read the side letter, and that is a matter on which Dr. Reilly has given evidence already, so he can be asked about that.
The addenda, the first one is really an extension of the Norton agreement, {L/3/1}. The second one, {L/4/1}, is an addendum by which GUK is added as a subdistributor.
THE PRESIDENT: The first one, again, it is 770,000 a year, yes? The first addendum?
MR. FLYNN: Yes. It is the same amount.

THE PRESIDENT: The second one.
MR. FLYNN: {L/4/1} is the agreement by which GUK is added as a subdistributor. The third --
THE PRESIDENT: Just a minute. Now, it is extended to 13th March; is that right? 13th March 2005? Clause 2.4 on page {L/5/3}. It now runs to 13th March.
MR. FLYNN: Yes.
THE PRESIDENT: The price changes.
MR. FLYNN: I should say in answer --
THE PRESIDENT: Do you know, Mr. Flynn, what the actual -- this is slightly complicated -- formula in 2.9 of the second addendum -- the previous price, remember, was 8.45 per pack of 30. Has anyone worked that out, what the equivalent is? These were partly bulk, I think. It was not in packs anymore.
MR. FLYNN: That is right.
THE PRESIDENT: One can work it out. I wonder if you had.
MR. FLYNN: I have not got that to hand.
THE PRESIDENT: No, okay. If somebody has not done it before, you cannot do it on your feet. I was just wondering whether it went up or down. Maybe it is another way of getting the same price, I do not know.
MR. FLYNN: I am being told from behind that it went down slightly to 8.10.
THE PRESIDENT: It is 8.10 on the first element, the 0.27 per tablet. I think that is easy because it is 30 tablets per pack, but it is the additional price, I think. £252 per 100,000, I do not know what that works out as, but anyway, never mind. It may have gone down slightly. Yes.
Then {L/5/1} is the third addendum, yes?
MR. FLYNN: Adding Alpharma as the subdistributor.
The next tab is adding a further subdistributor, but I think we are not concerned with that one. Tab {L/7/1} is the termination letter, which you have already seen.
THE PRESIDENT: The fourth addendum adds Medis, does it?
MR. FLYNN: Medis.
THE PRESIDENT: Is anything made of Medis anywhere by anyone?
MR. FLYNN: I think not, sir.
MR. TURNER: Sir, before we leave the fourth addendum, clause 2.4 is worth looking at. {L/6/2}
THE PRESIDENT: But this is quite a while, several months after the agreements we are concerned with, is it not, Mr. Turner? We are now in February 2003.

MR. TURNER: Yes, it is an aspect of the promotional allowance which was increased under this addendum.

THE PRESIDENT: Under this, yes, but this agreement as such is not relevant to any of the infringements that we are concerned with?

MR. TURNER: If you are wanting to see how it works. You are quite right that it is not the amount that was offered at the time in cash. This shows how it was developed afterwards.

THE PRESIDENT: Yes.

MR. FLYNN: But nothing is made of it, as I think we are agreed. For the purposes of these proceedings it is not something that you need to be on top of, as it were.

THE PRESIDENT: No.

MR. FLYNN: Those are the agreements between IVAX and GSK.

THE PRESIDENT: Yes.

MR. FLYNN: It may be that the remaining agreements are something that you can explore with the respective parties. I am happy to go through them, I am just rather conscious of time.

THE PRESIDENT: I think we ought to let you go on with your part. This is obviously against you, but if we leave that to the others.

MR. FLYNN: It is just otherwise I think we will be running late on day one, which is not ideal.

THE PRESIDENT: Not a good start. Right.

MR. FLYNN: Sir, the next topic I wanted to address, we will need to look at the agreements, so keep the file to hand, but it is the vertical agreement exclusion order point.

THE PRESIDENT: Yes.

MR. FLYNN: Because as I explained in opening and we set out in our skeleton, it is our contention that not only the IVAX agreement but also the agreements between GSK and, respectively, GUK and Alpharma were covered by the vertical agreements exclusion order, which requires you to put yourself back in the mindset of when the Competition Act came into force in March 2000.

The order itself you will find in authorities bundle {5/75/1}. If you are looking at paper copies, mine is in bundle 20.

THE PRESIDENT: It has not come up on our screens. (Pause)

MR. FLYNN: {A5/75/1}.

THE PRESIDENT: Yes, thank you.

MR. FLYNN: Thank you very much. It is common ground that this statutory instrument, this legal provision was in force throughout the duration of the relevant agreements.

What the order does is to exclude from the scope of the Chapter I prohibition any agreement to the extent that it is a vertical agreement. That is Article 3 of the order. {A5/75/2}

While we have that page in front of us, Article 4 reduces the scope of the exclusion by saying it does not apply when the agreement restricts the buyer's ability to determine its sale price, but we are all in agreement that Article 4 does not play any part here.

So if Article 3 applies, vertical agreement, then the exclusion is given. Vertical agreement is defined in Article 2 {A5/75/1}, back up the page:

> "... 'vertical agreement' means an agreement between undertakings, each of which operates, for the purposes of the agreement, at a different level of the production or distribution chain, and relating to the conditions under which the parties may purchase, sell or resell certain goods or services and includes provisions contained in such agreements which relate to ..." intellectual property rights. But, again, that is not thought by anyone to be relevant for present purposes.

If it is a vertical agreement as defined or to the extent that it is a vertical agreement as defined, the exclusion operates and the agreement concerned falls outside the scope of the Chapter I prohibition.

In the next tab in the authorities bundle, {A5/76/17}, that is flag K14. Sorry, A5 -- maybe there are two different authorities. I have it in authorities bundle 20, tab 14. I understand in the structure you have -- I believe that it is section K in the structure of the authorities. If you have K and then 15 in the authorities bundle, as opposed to the trial bundle, it should come up.

(Pause)

THE PRESIDENT: No, it is K14, I think.

MR. FLYNN: I apologise. Wherever you find the previous document we looked at, it is one after that.

THE PRESIDENT: There seem to be two different indexes of authorities. {Auth-K/14/1}

Here we are. That is it.

MR. FLYNN: That is it. I can tell you that was photocopied from my own personal copy of the Purple Book dating to those years. This is the OFT's guidance on vertical agreements and restraint in the version in force in February 2000. At paragraph 1.4 {Auth-K/14/2} it refers to the exclusion order and gives the reasons why they are excluded, the thinking at the time:

> "Vertical agreements do not generally give rise to competition concerns unless one or more of the undertakings involved possesses market power in the relevant market or the agreement forms part of a network of similar agreements. The purposes of the

exclusion order, therefore, is to provide certainty for business about the scope of the Chapter I prohibition. It avoids an unnecessary burden on business of scrutinising a large number of essentially benign agreements and of making precautionary notifications of such agreements. It also helps to ensure that the Director General," predecessor of the CMA and, before that, the OFT, "is able to concentrate his resources on matters of significant competition concern."

That was the thinking at the time.

The exclusion itself is set out. Some notes on the exclusion are set out in section 2 of this guideline {K/14/4}, the UK exclusion of vertical agreements. It will be remembered that this was one of the aspects where, at the coming into force of the Competition Act, it was intended that the UK would take a substantially different line from that taken in Brussels under the EU rules. This was a distinctly UK feature for the reasons I have just read out in paragraph 1.5.

Now, what we say is that what the CMA is doing here by seeking to say that the exclusion does not apply to the GUK and Alpharma agreements is to bring into its view of how you read this order anachronistic views based on how you would interpret Article 101 or Chapter I.

Those arguments, we say, are wrong. Those arguments should be left out of account when you are seeking to define the scope of a vertical agreement falling within the order.

The procedural history in this particular case is that --

THE PRESIDENT: Sorry to interrupt you. Are we leaving the guidelines?

MR. FLYNN: No. We can look at them now. I was going to come back to them in due course.

Why do we not look now at paragraph 2.3 {Auth-K/14/4}:

"For an agreement to fall within the definition of a 'vertical agreement' in the Exclusion Order and benefit from the exclusion, the economic relationship between the parties must be such that each of the undertakings involved in the agreement operates ' at a different level of the production or distribution chain'. Examples of activities at different levels of the production or distribution chain include supplying raw materials, manufacturing, wholesaling and retailing. An agreement between a wood supplier and a paper manufacturer for the supply of wood to make paper would be an example of a vertical agreement ...

"Different levels of the production or distribution chain may be found within each of the broad categories mentioned above. Within manufacturing, for example, one ... may manufacture a component part of the --

THE PRESIDENT: I do not think you need read it all out.

MR. FLYNN: One can take it as far as it goes. Paragraph 2.5 is probably not relevant because it is just a question of counting heads as long as each undertaking --

THE PRESIDENT: Yes.

MR. FLYNN: 2.6 {Auth-K/14/5}:

> "Undertakings often operate at more than one level of the production or distribution chain. An agreement between undertakings that operate at one or more of the same levels of the production ... may benefit from the exclusion for vertical agreements. This will only be the case, however, where the agreement concerns only respective activities of those undertakings which are at different levels of the production or distribution chain. The agreement can benefit from the exclusion because the undertakings involved each operate at different levels of the production or distribution chain 'for the purposes of the agreement'." Stressed.

{Auth-K/14/5}.

Then they give an example of a manufacturer:

> "... which also distributes ... enters into a supply agreement with a distributor, that supply agreement may benefit from the exclusion even though the manufacturer also has sales activities which operate at the same level of the production or distribution chain as the distributor's activities. The two undertakings are operating at different levels of the production or distribution chain for the purposes of the agreement: the first is acting as a manufacturer and the second as a distributor. A supply agreement between them in these respective capacities (that is, as a manufacturer and as a distributor) may fall within the definition of a vertical agreement and ... may therefore benefit from the exclusion."

I think that is probably what one takes from the guidance.

THE PRESIDENT: Yes.

MR. FLYNN: Under provisions for the benefit of the order to be withdrawn by the Director General, but obviously --

THE PRESIDENT: We are not bothered --

MR. FLYNN: We are not bothered about that, as you have said.

THE PRESIDENT: Yes.

MR. FLYNN: What happened in the procedural history of this case, as you know, is that the CMA, at the same time as taking the decision under appeal, came to the conclusion that the IVAX agreement was excluded by operation of the vertical agreements' order. That was

something which, through two iterations of the statement of objections, it had not accepted, saying that the IVAX agreement could not be properly characterised as a vertical agreement because IVAX was a potential competitor to GSK.

Well, we say that the CMA was right to find that if the IVAX agreement was excluded, it was a vertical agreement, they operate for the purposes of the agreement at the different level of the production or distribution chain and there was nothing to disapply the exclusion.

We say it is just the same with the GUK and Alpharma agreements. In those agreements the two generic companies operate for the purpose of the agreement at a different level of the production or distribution chain. Indeed, they were subdistributors so they were additionally vertical. The basis on which the CMA says that they are different, we say, is wrong.

The no grounds for further action decision, which we could look at if we need to, is in {A3/44/5}. I must say it could become quite addictive calling up documents like this. It is much easier than one has to do back in chambers.

If one looks at paragraph 4.5, you will see the basis for the conclusion:

> "... for the purposes of the agreement ... GSK and IVAX were operating at a different level of the production and distribution chain and ... the agreement did not contain elements (such as an express restriction on entry by a potential competitor) which would deprive the agreement of the benefit of the exclusion."

In the decision -- I do not know how readily we can call that -- the contested decision in bundle V, paragraph 10.40 {V/1/443}, paragraph 10.40, the key distinction is that:

> "... the GUK-GSK and Alpharma-GSK ... agreements specifically related to the settlement (or deferral) of litigation that concerned [the relevant entities'] proposed market entry. GUK and Alpharma (as potential competitors to GSK ..." expressly agreed to restrictions preventing them from entering the paroxetine market independently of GSK.

Therefore, for the purposes of each of those agreements, they were not at a different level of the production or distribution chain:

> "The fact is that they ultimately distributed GSK's product does not alter that conclusion."

We say those legal and factual propositions are not right. Even if we do not query the fact that the purpose of the GUK and Alpharma agreements related to settlement or deferral of litigation, that is not relevant for the purposes of the vertical agreements' exclusion order.

We say it does not matter what the purpose of the agreement was; the relevant question for

the order is whether they operated for the purposes of the agreement at the same level of the production or distribution chain as GSK.

They plainly did not, and in any event they could not. The parties settled the disputes they had about whether GUK and Alpharma could enter by agreements, vertical agreements, providing for supply. Vertical agreements.

The CMA's contention that it is relevant that GUK and Alpharma were potential competitors, we say that is legally wrong. We say in point of fact the generic companies, it became obvious to them that they were not potential competitors and the injunctions prevented them from entering, bearing in mind that the test for a Chapter I purposes of what is a potential competitor is whether there are real concrete possibilities of entry within a short period of time.

THE PRESIDENT: So I understand it, does it come back to the potential competitor's point?

MR. FLYNN: I think that is one of the features. I think there are three features.

THE PRESIDENT: Yes.

MR. FLYNN: That it is a settlement agreement, that they were potential competitors who agreed to restrictions --

THE PRESIDENT: The fact it is a settlement agreement it does not mean that it is only for the purpose of the agreements only in respect of activities at different levels of production.

MR. FLYNN: A settlement agreement could be between people at any level --

THE PRESIDENT: Yes, so the fact that it is a settlement agreement does not take one anywhere.

MR. FLYNN: Does not take one anywhere. These were supply agreements. They were vertical agreements. As I say, the suggestion that it is relevant that they were potential competitors, firstly, we say that is not right anyway and they do not meet the legal test. But that is not a concept that one imports into the vertical agreements' exclusion order, which is only looking at the level at which they operate.

So the three issues I think one can identify as the --

THE PRESIDENT: Just a minute. (Pause) Give me just one moment.

MR. FLYNN: Of course. (Pause)

THE PRESIDENT: If one looks at the GUK settlement agreement, which is at tab 8 of bundle L {L/8/2}, in clause 8 on page 2, it says:

> "During the currency of the IVAX agreement GUK shall not make ..."

So it is referring to the other agreement:

> "... import, supply or offer to supply paroxetine hydrochloride in the United Kingdom save as purchased from IVAX ..."

So it is a restriction on their selling paroxetine hydrochloride in the UK.

Going back to the guideline which you read to us, and paragraph 2.6, which is I think {Auth-K/14/5}, the third sentence:

> "This will only be the case, however, where the agreement concerns only respective activities of those undertakings which are at different levels of the production or distribution chain."

Is that not, clause 8, concerning an activity of GUK at the same level as GSK, is it not? Supplying paroxetine hydrochloride in the UK? Is it not?

MR. FLYNN: The effect of the settlement is that they will not bring in the product that was --

THE PRESIDENT: Yes, so they will not sell in competition with GSK. That is at the same level.

MR. FLYNN: The point, the way the settlement works is that they agree not to supply the product that is the subject of the litigation and instead to take supply under this agreement.

THE PRESIDENT: Yes. So it is not only supply, they take supply, but they also agree they will not sell it themselves other than as a distributor.

MR. FLYNN: That, in my submission, is the settlement boilerplate. As you said, the fact that it is a settlement does not take one much further. The point is that they will take supply, they will supply as purchased from IVAX, or otherwise manufactured or marketed by SB or with SB's consent. That is the establishing of the vertical relationship.

THE PRESIDENT: It does establish a vertical relationship. I see that. My point is that it does not, it seems to me, only do that. It does something else as well.

MR. FLYNN: Well, it settles the litigation.

THE PRESIDENT: Clause 8 is not just settling the litigation {L/8/2}.

MR. FLYNN: It is the provision by which the settlement can take effect.

THE PRESIDENT: It may be that the patents get invalidated by somebody else, but as long as this agreement goes on they will not sell, whether it is a valid patent or not.

MR. FLYNN: The parties were aware of that and that is why of course there was a speedy termination, so they were never locked in.

You have seen that there was termination almost at a moment's notice, particularly where the price fell. So there was never an intention or an expectation that they would be locked in in the event of independent generic entry.

THE PRESIDENT: The litigation did not concern activities at different levels of the distribution chain. It was at the same level.

MR. FLYNN: The litigation concerned their wishing to act as distributors of paroxetine.

THE PRESIDENT: Well, yes, in competition with GSK.

MR. FLYNN: Yes, but it is still -- the way of settling it is by entering into a vertical arrangement for supply.

The matter on which the CMA fastens, which we say is not accurate, is that the terms show that the Generics were tied to GSK. As one can see from the clause, they are to take supply from IVAX and we know that there was no term in the IVAX agreement restricting its ability to purchase from anyone other than GSK. There was no such term.

THE PRESIDENT: There is nothing to stop IVAX making it itself, selling its own product, or purchasing from someone else.

MR. FLYNN: So our point on that is that these parties were no more tied to GSK than was IVAX. The CMA has consistently said that the difference between them, the difference between the agreements, is that IVAX was not restricted from entering the market independently of GSK but these parties were tied to GSK, and in our submission they plainly were not.

We also say that the anti-avoidance provisions in the next subparagraphs, since we are there, do not take matters any further either because these apply to other members of the group, not to the specific Generics who are the beneficiaries of the supply arrangement.

Because the vertical agreements' order was intended to cover the entire range of vertical agreements. There's nothing that says, in fact on the contrary, that exclusive distribution arrangements or exclusive purchasing arrangements are taken outside the scope of the order.

That was really the whole point. Not least as the European block exemption had market share caps and the UK legislator at the time did not want to be notified of agreements that went above those market share caps when they took the view, as I showed you earlier, that vertical agreements are essentially benign unless they include price setting or price inhibiting provisions.

The idea that GUK would not take it from anywhere else is standard wording, we would say, in an exclusive distribution agreement or exclusive purchasing agreement.

MR. MALEK: Mr. Flynn, did IVAX in fact obtain any product other than from GSK during the period of their agreement?

MR. FLYNN: I am not aware that they did, sir. We are looking at the terms of it here. I am not aware that they did. It is possible that they did and we never knew. I have no reason to suggest that they did.

MR. MALEK: Yes.

MR. FLYNN: Incidentally, sir, I might just say, you asked earlier about quantities sold.

MR. MALEK: Yes, I did.

MR. FLYNN: We are not able to just point you to a nice table, but you have seen the quantities --

MR. MALEK: I have seen them in the agreement.

MR. FLYNN: -- as they increased and they were more or less taken to the limit, but not quite to the limit. We are working on a --

MR. MALEK: That is enough for me.

MR. FLYNN: -- schedule.

Those are the reasons, with an eye to the time, why we say these agreements were vertical within the order.

The CMA takes a fallback position that even if the supply elements are vertical, the horizontal elements consisting of the value transfers do not benefit from the exclusion order. That is paragraph 282 of the defence.

We say that is a confusing and wrong argument. The value terms, the use of the term "value transfers", extends to the supply agreements, and the supply agreements were indeed the principal part of the value transferred. We say for the rest, the payments for legal cost or stock purchase, or whatever it might be, do not establish a horizontal or a vertical relationship. They are simply payments made in the context of the agreement which we say is vertical.

At all events, even on that analysis the supply line, the principal element of the agreements, would have been covered by the exclusion, and therefore the Chapter I prohibition has never been applicable to them.

THE PRESIDENT: Did a doctrine of severance apply under this order to an agreement? Is it the whole agreement that has to be a vertical agreement?

MR. FLYNN: No, because the order applies to the extent to which it is a vertical agreement, and I think it suggests in the guidance that it can have bits of both.

THE PRESIDENT: Yes.

MR. FLYNN: I think that is right. As far as I am aware, there has never been any authority on this relatively short-lived but powerful instrument.

May I move on, sir, just conscious of the time, because what I hope to cover in the remainder of the afternoon is the outline of our case on the rather important issues of object and effect.

THE PRESIDENT: Yes.

MR. FLYNN: Which probably I should do. I think I have already outlined this at the beginning.

The Tribunal will be aware that an infringement of the Chapter I prohibition can be designated as one by object or by effect.

THE PRESIDENT: Yes, we are.

MR. FLYNN: Both are alleged here. In both respects, the burden of proof is on the CMA and we are entitled to any benefit of the doubt that there may be.

I also know that the Tribunal does not want to hear and be taken in great detail to the authorities more than once, and Ms. Kreisberger is due tomorrow to develop her submissions on the CMA's theory of harm by reference to the case law.

If I might be permitted to take it quite lightly. I think we are all agreed, I do not think there is any doubt, that the leading authority on what is meant by an object of restriction in Chapter IV, Article 101 purposes, and therefore Chapter I, is the Court of Justice's judgment in *Cartes Bancaires*. Of course the court in *Lundbeck* sought to direct itself by reference to the *Cartes Bancaires* in deciding whether the Commission had been right to find an object infringement.

We say that is the Tribunal's task in these proceedings. You also have to apply *Cartes Bancaires* and its teaching to examine the agreements that are the subject of this appeal.

We set out -- and I am not going to read it all out -- in the early paragraphs of our skeleton, chapter 6, what we have to say on *Cartes Bancaires* and those are agreed, and the case law and object restriction generally. Those paragraphs I think are agreed by all the co-appellants.

Of course one reason why our skeleton was lengthy was that we took the burden of setting out quite a bit of the law for others to build on.

So in the case, as you will be aware, the Court of Justice on appeal from the General Court overturned the General Court for making legal precedent in holding that the notion of an object infringement did not need to be interpreted strictly, error number one, and error number two, that it was sufficient for an agreement to be capable of having a negative effect on competition.

The Court of Justice said, rather, that object categorisation can only be used, must be reserved to agreements which reveal in and of themselves a sufficient degree of harm to competition for it to be permissible, even tolerable, to dispense the Competition Authority from proving the effects of the agreements, and that that particularly depends on having some experience showing that conduct of a certain kind leads to deleterious consequences for consumers being such matters of reduction in output, price increases, and so forth.

As the Tribunal said in one of its earliest cases, the *Institute of Insurance Brokers*, if it is not plain that the object of the agreement is to restrict competition, then the Competition Authority, here the CMA, must go on to prove them. So it is not enough in the case law

that an agreement is capable of or has the potential to harm the competition, there must be a deleterious effect that is plain from the terms. Nothing ambivalent or equivocal -- maybe, maybe not -- that is not just good enough. In order to reach the conclusion, what is required is an examination of the clauses of the agreement, particularly relevant to written agreements, in their actual factual, legal and economic context.

You cannot do that, says the case law, by means of abstract formulas. In my submission, an abstract formula is something like price fixing, market sharing or pay for delay. You have to look at the actual agreement in its actual context.

What you cannot do is to use the examination of the context to suggest that the agreement has the potential for adverse effects and derive from that a conclusion that it has an anti-competitive object. That is what the General Court or what the Commissioner does in *Cartes Bancaires*. It was the approach that the General Court had taken and it is neither one thing nor the other, in my submission. It is neither a demonstration that the agreement in its context had the plain object of restricting competition, and it is obviously not a full blown effects analysis.

We say the CMA here has fallen between those two stools. It has neither demonstrated the inherent propensity of these agreements to harm competition and it has not properly analysed their effects.

A few points just to supplement that. The CMA obviously has no experience of this category of agreements, and we say loud and clear that experience of other authorities is at an early stage, certainly in Europe and also in the US. There is actually not a great deal to go on in understanding how these types of arrangements work.

It is also the case here that because we are talking about things that happened so many years ago, 15 plus years ago, it is not a good start for the CMA, we say, that the actual effects of the agreement can be analysed and can be shown to have been pro-competitive.

THE PRESIDENT: How is that relevant to object?

MR. FLYNN: Because the aim of an object case is to say: these agreements, do not worry, we know they have an inherent propensity --

THE PRESIDENT: Propensity.

MR. FLYNN: I fully accept that that demonstration does not have to be met with. We see examples in the pleadings. You take a price fixing agreement, it does not matter actually, it may or may not in the event have harmful consequences.

We know about those. They are clearly in the object box. When you are dealing with a category of agreements that one is not so sure about, not so familiar with, in my submission

it is relevant to say the CMA would like to say to you that these agreements have an inherent propensity, whereas in fact we say the evidence shows they did not harm competition.

THE PRESIDENT: Would that mean that when the Commission first investigated price fixing cartels, it could not treat them as object infringements. It would have to wait a few years, analyse the effects, discover that actually they did lead to higher prices, they did work, the cartels did not break down, and only then could they say: yes, now we can treat it as an object of infringement because now we have had several years experience and a lot of analysis?

MR. FLYNN: The experience may derive from a number of things. What happened in the first pricing case I would not like to say. But one knows it seems well established in the case of price fixing that unless you can make some demonstration from the context or written agreements with which you will be familiar, those are going to be in the object box. But it is not good enough, we say, to come along with a new category of agreement and say, "We think we can show that the agreement that you are concerned with has an inherent propensity to harm competition" when, in fact, it did not because of the sort of fortuities that the CMA refers to in a price fixing case where they fix the prices, and then there was a shortage of the raw materials, so it did not have any impact on the market.

It is not that sort of thing. These are, we say, the likely effects as well as the actual effects of these agreements. So we just say it is not a particularly good start that in a new area, the first case, the CMA comes along -- I fully accept that it is potentially able to on the case law, but I just make it as an observation that it is something that the Tribunal may wish to be wary about in saying these agreements have an inherent -- these particular agreements in their context -- propensity to harm competition when, in fact, they did not.

When you look at the form of these agreements, neither settlement agreements nor supply agreements themselves are inherently harmful to competition. You get plenty of examples of that is normally beneficial or at least benign. Such agreements fall within large exemptions, get individual exemptions or exclusions, and we would say you can't say that about a price fixing agreement.

MR. GLYNN: Leave aside the facts of these particular agreements, but if it were clear as a matter of concept that an agreement had been made between a patent holder and generic companies to delay entry into the market, or they might have done so, would you agree that that could be viewed as restriction by object?

MR. FLYNN: Yes, and certainly no part of my case that just because you are dealing with a patent or a patent settlement that it cannot be an object infringement. I think it all depends on the circumstances of the particular agreement in its particular context.

Just to say that, it does not mean that we have to say or do say that the General Court was wrong in their *Lundbeck* case. We say these are different agreements, the context is different, and we can show as well their effects on competition. We say it is a big ask for the CMA to come along to the Tribunal and say, "This is our first case that we choose to call a pay for delay case. We are going to equate it with some other things and say that they have an inherent propensity to harm competition".

THE PRESIDENT: Was not *Lundbeck* the first case the Commission did of that nature?

MR. FLYNN: Yes, I daresay it was.

THE PRESIDENT: They found it, despite lack of experience --

MR. FLYNN: Yes.

THE PRESIDENT: It is the experience point that I am struggling with.

MR. FLYNN: I think the experience point, you cannot be an infinite (inaudible), you have to start somewhere, I fully accept. But if in fact you have no experience with handling lots of different forms of, shall we say, patent settlement agreements, it may be leaping to conclusions to put them into a category and say they are harmful to competition, have a look at what they did in Brussels in relation to *Lundbeck*.

I think, as I say, I fully accept you have to start somewhere, but everyone has to do everything for the first time. We say if you read through the decision you will see that the CMA takes the analysis the wrong way round.

You have read through the decision, I know, so I am not going to cause further delay on that. But it does not start by looking at the agreements; it starts by looking at what it says is the context, and we have criticised extensively the breadth and to some extent peripheral nature of the context which the CMA prays in aid before getting onto the specifics of the situation.

It may well be that Ms. Kreisberger will develop these, I do not know. We say these agreements, you have to see them as a whole. It is not just a question of value being transferred in one direction. There are compromise agreements. Both parties get something out of it. There is a balance of benefits going in both directions. But as I have already said, the value even that the CMA discerns, three-quarters of it is taken up with the supply agreements and the rest of the items we say are reasonable and explicable.

The CMA says that, for example, GSK has no benefit from the stock purchase because it destroyed the stock. Well, there is the clear benefit to GSK of ensuring that what it considers to be infringing stock does not make it back into the UK via some other channel.

We have spoken about the so-called restricted volumes. You have seen the agreements. While they set out amounts, there is nothing which says you will not get any more; no basis for suggesting that if some more had been asked for it might not have been supplied. We say the generic companies had good reasons themselves for not building up excess stocks. You see that they are absolutely petrified at the idea at any moment, to coin a phrase, the dam may be burst and they will be stuck with inventory which they have purchased at a particular price.

On the other side, if GSK had not put an allowance in their contracts, they could have taken whatever they wanted. That would have made GSK into a contract manufacturer and eviscerated its business, which is not appropriate in a compromise as opposed to a capitulation.

In any case, as I have already said, the volumes transferred were in fact extremely substantial. As part of the context, the CMA also looks at what it calls the parties' subjective intentions, which a lot of it goes to the bargaining process which will come out no doubt in the facts. But its overall suggestion seems to be that it was GSK had a concern to sort of sweeten the deal and make sure that these people had really as much as they wanted. It is really completely the other way round.

Dr. Reilly can be cross-examined on that. One matter in this part of the context that is referred to several times in the skeleton, just as a point of detail, is the note from Dr. Reilly's successor, Ms. Rachel Parr. Just to be clear, she is presented in the skeleton as the finance director of GSK. It is not quite right. She was the finance director of the UK business of the entity that in these proceedings is called GSK, GSK Plc.

The note that she made is presented in the skeleton as if it were some sort of official record. It says "A note of what had been achieved". In fact, as we know, those notes were manuscript scribbles by Ms. Parr for her own purposes when she came into her new job, not some briefing document on the execution of a master plan.

MR. MALEK: Can we look at that on the screen now, please?

MR. FLYNN: Yes, I am sure we can.

THE PRESIDENT: Do you have the reference for it?

MR. FLYNN: If you look at {B6/225/1}, this, not referred to by the CMA, is her witness statement following a compulsory interview by the OFT. This is where she explains what is in the notes. I think the notes are attached at the end.

So going down the witness statement you can see that she says {B6/225/2} she took over from Dr. Reilly. She was new to the job:

> "This was a more senior, and much broader and more commercial, role than my previous role in R&D."

She says at 2.1:

> "Before being appointed as Finance Director ... I did not have any experience relating to patent settlements, patent litigation or supply agreements ... [was not] involved in the paroxetine project team or 'Project Dyke' ..."

She knew about the agreements and of course she was responsible for making the payments.

If we carry on over to 2.3, {B6/225/3} she had not been involved in the negotiations. She recalls having a brief handover with Dr. Reilly, but does not remember whether the agreements were discussed.

As to the notes themselves, section 4, she confirms they are hers, they are undated, they are intended for personal use:

> "... can't remember anything about them, it is ten years ago."

But what she says about them at 4.3, the subject matter is unfamiliar. She is not a trained lawyer. She had no experience of sort of what happens towards the end of a patent life.

If we go over to {B6/225/4}, she was talking, she says, to a lawyer within GSK, Ms. Robinson although, as she notes, Ms. Robinson had no recollection of making the call and did not agree with the inferences in the notes.

She says the notes were for her own use and they were essentially a recollection, a summary, of a rather verbose legal explanation. A particular phrase might summarise a point made over a period of five minutes or so.

In the previous sentence she says:

> "The ... notes reflected my attempt to try and crystallise, in perhaps slightly rough and ready lay person's terms, a summary of what Ms. Robinson might have explained to me over a long discussion, providing me with more detail than I needed."

They were aide memoires:

> "It was my interpretation of what was said to me ... I describe them as 'impressionistic' ... Given my lack of previous patent experience and the kind of jargon Cynthia may have used, I cannot confirm they are an accurate reflection of the discussion."

Then she attempts to decipher the notes.

If you want to look at them, I believe the notes are attached {B6/225/6}.

The exhibits are not there. I do apologise, then.

MR. TURNER: {Z/301/1}.

MR. FLYNN: These are the transcriptions of her notes. They are actually quite difficult to read in the original.

I do not know if the Tribunal wants the next page? That may be the end of it. {Z/301/2}.

These are the manuscript notes themselves.

THE PRESIDENT: If we go back {Z/301/1}, did she explain in her witness statement what "Bk" is? "Bk. these contracts ..."

MR. FLYNN: I do not know that she does.

THE PRESIDENT: She explains some of the things.

MR. FLYNN: She does. I will just check. (Pause)

THE PRESIDENT: Break? I do not know.

MR. FLYNN: I think what she said {B6/225/4}, I think she says she recognises that she had to make the payments because the termination right was in the Generics' hand rather than in GSK's.

I think possibly that is what that phrase refers to.

MR. GLYNN: She says in the second manuscript note, halfway down, "weak patent" and "stopped entering market". Do you know what she is referring to?

MR. FLYNN: She says, 4.5 in the witness statement:

> "I believe from reading it in context that the reference to ... "wk patent" means 'Weak patent' and that this is likely to have been my own summary language of a lengthy explanation as a lay person ... mechanisms ...
>
> "I assume that the reference 'stopped entering market' would have been my own summary of the conversation rather than the words of Ms. Robinson because it is colloquial and not precise."

MR. GLYNN: But it would have been GSK's patents that were weak and the agreement stopped them entering the market.

MR. FLYNN: I think it can only have meant GSK's patent. Our point on this is that this note, which the author recognises may not be at all accurate and was simply her attempt to summarise something that was being said to her that she was entirely unfamiliar with, that is the only evidence on the file that suggests that the patents are weak. We suggest that you should not put any reliance on it. That is what we have said about this.

We think that Ms. Parr got hold of the wrong end of the stick and her witness statement certainly allows her that possibility.

But you will have seen what the decision makes of it, and as I say, for some reason, having gone a bit quiet on it, suddenly it has appeared a few times in the skeleton. So I thought it right to bring it to your attention.

Generally, except for this which might at one point possibly have been thought to have been the smoking gun, although Ms. Parr's witness statement suggests that really one cannot attach much value to this, there is very little in the decision at all about the confidence that GSK had in its patent position, the deteriorating prospects for the generic companies, the central relevance of the injunctions, and so on. We say these are all relevant contextual matters that you cannot just brush under the carpet.

MR. MALEK: Did Cynthia Robinson, did she give evidence before the OFT?

MR. FLYNN: I cannot recall that. Her evidence about this was that she did not remember having this conversation --

MR. MALEK: I see that in paragraph 4.2 --

MR. FLYNN: I do not think she gave -- no, we do not think she did. I am pretty sure she did not give any separate evidence. She is now a retired in-house lawyer at GSK and she had simply no recollection of having this call and did not understand what the note was meant to be saying.

It sounds as if the two ladies did not get on very well and did not really understand each other.

The way the CMA tries to, as I say, sweep under the carpet all the material about the strength of the patents and the evidence that we have been at pains, possibly too many pains, to draw out in the skeleton, the way they do that is to seek to base themselves on Professor Shapiro's inference, and I am not going to say anything about that in the legal or economic context. I am sure Ms. Kreisberger will wish to do so, not least as she is producing evidence which takes Professor Shapiro on head to head, as it were.

But the point we make, and what has come out in the report and in the joint statement process, is that Professor Shapiro himself takes the view that when there are supply agreements for other non-cash value transfers, as he calls them, his inference is not conclusive as to harm to the competition. He says further analysis is required.

We say that of course is a proposition from an economist. He is not making a legal submission. But the only way to make sense of that is to say that even if the pay for delay inference may be sufficient to identify or begin to identify an object restriction in cases of

pure cash transfers, it does not when there are non-cash transfers and that means they are outside the object box.

I will not say more about the effects and I will not say more in this context about the CMA's failure to address a properly specified counterfactual. We set that out in some detail in our skeleton, 75 to 691, and I imagine Ms. Kreisberger may wish to say something about that.

The bottom line of all this, we say, is that if, in fact, as a matter of likely effect the agreements would lead to price falls at the supply chain level that the CMA has chosen as its focus, the pharmacy level, then the CMA can't demonstrate harm to competition unless it can show as a matter of inherent logic that a better situation would have been expected to emerge if the parties had continued to litigate but, in circumstances where it has taken no view at all on the expected outcome of the litigation, confines itself to saying there is a chance that the Generics might have worked and without saying when that might have happened, bearing in mind that there would have been appeals and so forth, it is just unable to make that demonstration.

Merely talking about litigation is not informative and we say that demonstration would in any case have had to have been made by way of an effects analysis.

Given the time, I will perhaps pause there. There is plenty more that I could say on object, but I perhaps will not now. I do not know if you are intending to take an afternoon break, sir, that would be --

THE PRESIDENT: I think we are being asked to take short breaks morning and afternoon.

Would that be convenient?

MR. FLYNN: That would be.

THE PRESIDENT: We will take a 5-minute break.

(3.25 pm) (A short break)

(3.30 pm)

MR. FLYNN: Sir, if I may turn, then, to the effects side of the case.

As you know, the test is that if an agreement is to be found to be restricted by effect, it must affect actual or potential competition to such an extent that on the relevant market appreciable negative effects on prices, output, innovation or variety of quality of goods and services can be expected with a reasonable degree of probability.

There is plenty of case law on that which has been cited to you, including *Cartes Bancaires* and *Mastercard*, and so forth. Once again this is the CMA's burden to bear. It cannot rely on presumptions and it cannot rely on the appellants to disprove what it says is the

anticipated lack of competitive effect, and it has to make a robust demonstration of the effects.

The CMA has not, in this case, made a positive case that the agreements had actual anti-competitive effects. It does not present anything to suggest that the actual agreement there, the actual effect of these agreements on competition, was negative. It proceeds on the basis that it was likely that there would be negative effects, but that is formulated in exactly the same way as it presents the objects analysis. These are the effects which it expects.

It recycles that object analysis and it is saying, in effect, that the agreements could be expected to improve competition as much as the Generics' continued attempts to enter the market independently. In other words, what it is saying is the benefits of true generic competition are so substantial that an agreement that delays this mere prospect, however small the prospect and however short the time, must restrict competition more than it actually creates it.

You know that there are in fact two counterfactuals, both of which we say insufficiently specified or developed the continuing litigation counterfactual without any attempt to quantify prospects of success or the effects that actual independent entry would have generated at that point, and by way of alternative, the alt-deals counterfactual in which the parties would have settled the litigation on what the CMA calls, not particularly technically, more competitive terms.

These counterfactuals are not developed rigorously or bottomed out. They are merely stated to be possibilities, things that might have occurred absent the agreement. But the CMA says ultimately it does not matter because the agreements themselves were of necessity less competitive than an independent generic entry.

We say this is a reversal of the burden of proof. There is a large volume, and I am not going to try to summarise it. There is a large amount of expert evidence before the Tribunal on effects. This has not come because the CMA has attempted to show that the agreements caused anti-competitive effects in terms of the normal effects that one might expect price increases or lower output or lower quality. That is not what they are seeking to prove. There is no part of their case that those impacts were to be expected.

The reason you have all this evidence is because Dr. Stillman identified that the agreements are, in fact, pro-competitive. He identified that they caused NHS costs to fall and that they caused prices to pharmacies to fall, and that these were the expected effects too. For good measure, Dr. Majumdar has shown that they caused prices to wholesalers to fall as well.

The CMA has responded in great detail to this evidence, but it has not been able to overturn their conclusions. It accepts the fall in NHS costs, at pharmacy level and the wholesale level. The efforts that have been extended, and they are considerable, are designed to challenge the extent of these effects and have involved some creative manipulation of inadequate data which previously the CMA had accepted could not be used for those purposes. Ms. Webster has really added in her evidence large portions of primary material on effects --

MR. MALEK: Mr. Flynn, you said earlier that these pro-competitive effects were, let us say, foreseen by your clients. Will you be showing us any contemporaneous documents where they foresee that those effects will play out?

MR. FLYNN: Sir, no. I think the demonstration has been made through Dr. Stillman, and --

MR. MALEK: At one point I thought you said it was expected, it was anticipated that those pro-competitive effects would occur.

MR. FLYNN: That, of course, is not the legal test, but as a matter of practice GSK -- and you can ask Dr. Reilly about this -- must have fully expected that by introducing these volumes of generic paroxetine to their market, that prices were going to fall and that pressure would have been put on GSK. It hardly expected an easy life having made these compromises on terms that gave the Generics such large amounts of product.

THE PRESIDENT: I think Mr. Malek's question was: are there any contemporaneous documents from GSK indicating them?

MR. FLYNN: I hesitate to say that there are or are not, sir. I do not think -- those have not been at the forefront of the evidence.

THE PRESIDENT: You are not relying on any internal documents from the time to support --

MR. FLYNN: What the internal documents do, of course, is to say, well, compared with what might have happened if we had lost the lie of it, we have achieved a certain degree of stability. There are plenty of documents --

THE PRESIDENT: Clearly --

MR. FLYNN: -- that are made plain.

THE PRESIDENT: But on the point you are making, is there anything you are relying on?

MR. FLYNN: Nobody is suggesting that GSK is a charity, sir. These are compromise agreements.

THE PRESIDENT: We all know that, but it was a more specific question.

MR. FLYNN: In answer to the specific question, I do not think that I am pointing to anything in particular at the time --

THE PRESIDENT: That is what was being asked.

MR. FLYNN: Dr. Reilly has given a lot of evidence on this so I hesitate to say there is not anything. The demonstration in these proceedings has been made in accordance with the tests of the law and to meet the allegations that are in the decision. GSK's own reasons and predictions for entering into the agreements are, as it were, a separate matter.

THE PRESIDENT: You talked about why all this evidence is there, which I still find a little bit -- I am still slightly struggling with that.

Unlike object, effects depends on the counterfactuals, you said. So unlike a cartel is an infringement by object even if in fact there was no rise in prices because members of the cartel started to cheat and keep the agreement, someone from outside came into the market. None of those things would be a good answer to a cartelist.

MR. FLYNN: None of those effects would be an answer to --

THE PRESIDENT: Because it is an object restriction. Looking at it as an effects restriction, they would be if they could say it had no effect. It all depends on the counterfactual.

If the counterfactual were that your client would have lost the patent litigation, then, subject only to a point about time, it seems to me clear prices would have fallen to a much greater extent than they did under the supply agreement. That was the whole basis on which your client got the injunctions.

MR. FLYNN: Yes.

THE PRESIDENT: Clearly, on that counterfactual, if that is the counterfactual, there was a very significant effect. However, the CMA cannot say, "Your client would have lost".

MR. FLYNN: No.

THE PRESIDENT: So what it is saying, as I understand it, is, well, there is the continuing litigation, preserve the possibility, preserve the uncertainty. We will hear from Mr. Turner how he develops that, but if that is given some sort of value approximating to unrestricted generic entry, one can see it would have led to a much more competitive market.

If it is treated as a sort of loss of chance case --

MR. FLYNN: That is not what they have done.

THE PRESIDENT: But if it is not, then the fact that the actual effect of these agreements was the price fell by -- whether it is 10p or 3% or 12% does not seem to me to make much difference, because it is what the CMA has to show is that compared to a realistic counterfactual the result here was significantly worse.

If the counterfactual is that you will get your patents and your monopoly position, then clearly under the supply agreements there was some benefit. But the actual detail of how

much prices fell and whether it was to the pharmacies or to wholesalers and whether it was 3% or 8%, I do not quite see how those distinctions really matter. It all comes back to what is the appropriate counterfactual and how should one view it.

MR. FLYNN: The counterfactuals that have been taken, as you know, are continuing with the litigation without any view being expressed other than there was a chance that the Generics might have won. No attempt to evaluate that or say when they might have won.

THE PRESIDENT: We can get a pretty clear idea of when the litigation might have finished because we know where it got to.

MR. FLYNN: We specified some periods looking at it ex ante, of appeals and so forth, and we know what happened in the actual with the Apotex. Those matters have been looked at by Dr. Stillman.

THE PRESIDENT: One can work out how long the litigation might have taken, is likely to have taken, but not the outcome. That is what I say.

If one puts a certain competitive value on the uncertainty of that in a way that I do not fully understand at the moment, that is what one has to look at in terms of some value of potential generic entry. What I am saying is that the actual detailed discussion, dispute, disagreement between the experts of the actual percentage by which prices fell under the agreements, I do not see quite where it takes one.

MR. FLYNN: We say once you show that there was a fall and you say 10p, 20p, whatever, once you show that there was, then for it to be established that in the counterfactuals something would have been better, there has to be a whole lot more work than the CMA has done. The counterfactual is completely unspecified.

THE PRESIDENT: But that would be true irrespective of the extent of the fall, would it not? If the counterfactual is preserve the monopoly, no kind of entry at all, then clearly there has been no adverse effect.

If the counterfactual is some question about unrestricted generic entry, then somehow one has to get a handle on what that is worth. But again --

MR. FLYNN: We say the CMA has not done that work, it has not got --

THE PRESIDENT: I understand that point completely. I am asking in a sense a narrow point of what is the importance of the degree to which any price fall under the agreement was as suggested by Dr. Stillman, or as suggested by Ms. Webster, or suggested by Dr. Majumdar, and whether it was to pharmacies or to wholesalers, and so on, which we have a huge amount of evidence. That is the point I am struggling with.

MR. FLYNN: I see the point you are making, but I think the debate has been over whether it can be shown that there was the fall at all. That is why there has been the debate. The conclusion is it can.

THE PRESIDENT: But the detail of how much is what I am saying may not matter, unless it is trivial.

MR. FLYNN: We say it is not trivial. Firstly, as you know, we say that the focus should be on the NHS, and those savings are not trivial, and 3 to 4% at the pharmacy level is not trivial either. You are talking about several million pounds there.

So they are not trivial, but ultimately it is the fact that they are established that puts the ball back in CMA's court, we say, and shows that their counterfactual analysis is insufficient. They cannot show that the expected outcome under their counterfactuals would have been worse because their counterfactuals are not precise enough, not realistic, not specified. Carrying on with the litigation with an undeveloped chance Generics might have won or that the parties might have agreed to some other deal, those are not real counterfactuals.

THE PRESIDENT: No, I understand that point.

MR. FLYNN: That is a fundamental point in our case. The counterfactual is not there and we have established, and it is not now in dispute, that the agreements did have these effects. We say that was obvious from the beginning.

If you compare the situation with what happened before they were entering, that is what you would expect and that is what has happened.

Sir, I do not know to what extent you need to be sort of told, at least by way of outline now, how the evidence -- where it sits. We have the material on the NHS prices. You know that the introduction of generic product, once it is widely available, triggers the fall. You have the suggestion by the CMA that it was not foreseeable that that would not be the subject of adjustments, and you have Mr. Horridge's evidence to meet that and say actually it was entirely foreseeable, nobody thought there would be any discount inquiry, the system was completely under review and there was no adjustment.

Dr. Stillman undertook work in what is called, possibly confusingly, his annex 3 report because it had originally been served as an annex to GSK's reply to the statement of objections. But he develops it in his first report on consumer welfare. We set out the details of that, at least the references, if you need to go back to them, at paragraph 7.49 of our skeleton.

What he shows is that not only did the NHS save that amount of money, £15.6 million, but it would not have saved more money if the parties had entered into what the CMA calls an

early entry agreement, which seems to be their preferred alternative under which the parties to this kind of dispute say that the generic could enter on a fully independent basis at a particular point in the future.

We say they are not really earlier. Our agreements were early entry. These are deferred entry agreements. But what Dr. Stillman models is, firstly, to find out if you are going to go for an early entry agreement what would be the crossover date? What would be the earliest date at which an early entry agreement would have saved the NHS the equivalent amount? That month was actually November 2002, so way after these agreements. Then he says: could you agree an early entry deal before that crossover date which would assist the NHS? He shows by a model that the early entry agreement on that basis would have been many months later.

So the crossover date by which the NHS saves the equivalent amount is November 2002, but it would not have been possible for the parties using a standard bargaining theory to enter into an agreement for early entry or deferred entry at that date.

MR. GLYNN: Sorry, could you tell me the paragraph in the skeleton? Is this in the report?

MR. FLYNN: 7.49 is the paragraph in the skeleton which I think itself reports into the report. I will find you the section of Dr. Stillman's first statement. The references are given in 7.49. Section 3 deals with his, as he says, annex 3 report.

The November 2002 date comes in, as a matter of prose, it is paragraph 32. You will see in the tables how he rules that.

So this first section describes his so-called annex 3 report, and the second section, 3.2, responds to the criticisms made of that report in the CMA's decision. That is obviously quite a lengthy section, which it would be unwise to attempt to summarise.

THE PRESIDENT: Yes.

MR. FLYNN: That is where it is, and he still reaches the same conclusion that you cannot find an early entry date, even on the basis the CMA says it should have been done, that would have been in any way better.

That is section 324 of his report. This analysis of Dr. Stillman's is not engaged with by the CMA. It is not taken on.

Their only real point on this is that the bulk of the £15.6 million is attributable to IVAX, and the IVAX agreement which, as we know, is the one that came first rather than the GUK and Alpharma agreements. But we say that is a very artificial way of looking at things, given that the CMA is objecting to all of them, one way or another.

It happens that it has taken the view that the IVAX agreement is excluded by the VAEO. We say those agreements are interlinked.

THE PRESIDENT: Presumably they have to say the IVAX agreement as amended from time to time?

MR. FLYNN: Yes.

THE PRESIDENT: Because that is how they say it is attributable to the IVAX agreement; is that right?

MR. FLYNN: They say the original benefit was secured by bringing in IVAX at all, by entering into the agreement with IVAX.

THE PRESIDENT: But it was only a one-year agreement.

MR. FLYNN: It was only a one-year agreement. You will see the sequence of the way the drug tariff was amended. We say you can't cut them up like that; the agreements have to be seen as a suite, as it were, and you cannot just pretend that IVAX was a pre-existing feature of the landscape and say this benefit had already happened.

In relation to this question of foreseeable and actual effects, I see your musings. We say really the right approach is the one that you indicated in the *Streetmap v Google case*, which we cite in the skeleton argument.

Really if the actual effects are known, the way you put it is that if the test is whether the conduct is reasonably likely in competition, the court will, when determining that question, take into account the actual effects, if known, as, as you said, very relevant consideration. That is Professor Shapiro's view as well, who says the actual effects can tell us a lot about likely events. It probably sounds more profound when he says it than I do. But that is basically the message. We say the Tribunal in this case should be extremely slow, indeed completely reluctant, we would say, to find that there were foreseeable anti-competitive effects if there are actual pro-competitive effects.

We say the CMA makes a reference to the price fixing case that is about paragraph 150 of its skeleton. The price fixing case, I think it's (inaudible) Pharma, that we discussed earlier where price fixing people said, look, the cartel did not have any effect because the market was starved later, so the prices would have gone up. Of course that does not apply in an object case, but that is way off beam for the point that we are on.

I will not go over again the foreseeability of the NHS matters. In relation to prices to the pharmacy, which the CMA insists on focusing on despite the highly regulated nature of this channel, and firstly there is no suggestion that the price to pharmacy of 20mg paroxetine

went up because of the agreements. What the decision says is that broadly prices were the same before and after the agreements.

But that finding, or basis of their analysis, was done on a false premise. They now accept that they made an error in the calculation which understated GSK's prices at the beginning of the period in which they are comparing, that is 2001, because they overlooked the fact that in 2001 nearly three-quarters of GSK's sales were to wholesalers, not to pharmacies. So the prices in 2001 needed to be adjusted for the mark-up that the wholesalers would have applied. So the left-hand side of the comparison was too low, and obviously it goes up.

Really, the evidence that you are saying does not excite you very much, the evidence is really how steep is the slope? That is really what it goes to, and we say our expert's calculation is that the price falls are in the 3 to 4, 3 to 5, 3 to 4.3% range. That is significant and we do not have to show any price fall. Once we have shown a price fall, we say the rest falls away.

THE PRESIDENT: Do GSK reduce its prices as a result of the agreement?

MR. FLYNN: Slightly is the answer. The main competitive pressure felt by GSK is essentially in terms of volume. Sales of Seroxat were considerably reduced.

THE PRESIDENT: You say competitive pressure. I mean, competitive pressure, there is no question of competition on quality here, is there? Competition is only on price.

MR. FLYNN: Largely price.

THE PRESIDENT: Yes. So competitive pressure felt by GSK, if it did not really reduce its price presumably there was not any?

MR. FLYNN: Well, it reduced its volume.

THE PRESIDENT: Yes.

MR. FLYNN: That, in our submission, is a response, if you cannot make as many sales --

THE PRESIDENT: But if it is competitive pressure, you respond to the pressure by using your price; it is pretty basic, is it not?

MR. FLYNN: Not necessarily, sir, and you can take a different view as to what competition demands of you, focussing on different context.

So I do not think that merely price response is appropriate. Bearing in mind the GSK product was a branded, patented drug, and the response when a generic version of the product comes in can be varied and it is not necessarily slashing your prices. It may be taking the hit on volumes but maintaining your quality, reputation and that certainly is what happened when Prozac went generic. Lilly maintained it because of the brand recognition, they maintained their prices despite the full patent expiring full generic entries.

We absolutely do not say the only competitive response is one on price. That is a matter you may wish to explore with the experts, including Dr. Stillman in due course. The end result, however one gets there, and no doubt it is a complicated picture and a somewhat turgid read in the joint report, but nevertheless it is accepted that there were falls in the prices to pharmacies and there were falls in the wholesale level and the CMA, we say, has no basis for coming back -- it just has not done the work to come back and say, "But we would have expected something even more pro-competitive". It just has not done that and we say that is really the big hole in the decision.

The CMA's point maybe hangs ultimately on its view that you would not expect any competition because the volume allocations were fixed in its view. But, again, Dr. Stillman has shown that if you use the standard model on anticipating effects in those circumstances, you can show that there would be price falls even assuming that the allocations were fixed allocations.

We have developed that in our skeleton and Dr. Stillman will, no doubt, say more to it. Once you see what the actual effects were, we can see that the volume allocations being fixed is a matter of irrelevance actually.

We obviously say they are not, but as I think I have said more than once today, the important matter is that they were substantial volumes.

THE PRESIDENT: Yes.

MR. FLYNN: They produced those effects, at least as Dr. Stillman would expect.

Sir, I hope that is, as it were, sufficient introduction to the effects case and the evidence of the claimant.

MR. GLYNN: If I may make one comment, pretty much along the lines of the President's questions to you earlier. I think when one is talking about effects, I think it is very important to distinguish a comparison with prices compared with what they were before with the comparison of the actual prices with what they would have been in the absence of the agreement. I think the term "effect" has been used to mean both those very different concepts.

MR. FLYNN: There is the actual effects and there is the anticipated effects and the anticipated effects is the point --

MR. GLYNN: No, what I mean is the effect is what happened compared with what would otherwise have happened. It is not the post hoc, propter hoc comparison.

MR. FLYNN: Indeed, I fully accept that but the problem is that the comparison that one might expect to see has not been --

MR. GLYNN: I understand that point entirely.

MR. FLYNN: I may well have confused the two concepts in speaking, but I think we understand each other on that.

Sir, it has been a long day already and I am not seeking to weary the Tribunal further than they have already been wearied by reading our skeleton, but I would like to observe, if I may, there are other significant matters in our skeleton argument which I shall not be developing today.

We have a lot to say on the question of potential competition, which is pretty fundamental in this case, and I think it is important to bear in mind there that it is a legal test, a legal concept requiring a demonstration with the burden on the authority of an actual ability to enter. It is not being called potential simply because it might happen; it is being called potential because it did not. The question is whether real concrete possibilities -- two strong adjectives -- built in there expressly by the court, so it is not airy fairy, might be-type possibilities. These are real concrete possibilities that amount to an actual ability, even if not acted on, to enter the market within a short period of time, sufficiently short to act as a constraint. That is the essence of the test, and we develop that through examining the case law in some detail.

That is one point which we say is fundamental, and that this case is, apart from the *E.ON Ruhrgas* case that we cite where there was a legal monopoly preventing entry, this is the only case that I know of where it is said that people are potential competitors who not only had difficulty with their entry strategy, suggesting whether they might have had a real concrete possibility, but were actually blocked at the time of the agreements by the court. I think that at least needs to be taken into account, and we have developed that argument and I won't dwell on it.

THE PRESIDENT: It does not apply to IVAX, though.

MR. FLYNN: The injunction point does not, but you have to take a view on whether IVAX had a real concrete possibility of --

THE PRESIDENT: The injunction point does not apply.

MR. FLYNN: The injunction point does not apply to IVAX, that is absolutely right.

MR. MALEK: Presumably you say that had they gone ahead you would have gone for an injunction?

MR. FLYNN: Yes, they were left in no doubt about that. That is why, I mean, it is described as a settlement agreement. We say it avoided litigation that would undoubtedly otherwise have happened.

On every case, win or lose. The fact that we lose is not an indication of lack of confidence or readiness to litigate, which is a (inaudible) condition here. But IVAX were left in absolutely no doubt that if they put a foot wrong, they would find themselves in court.

Now, it is true, as we have said, that at the time interim injunctions were not to be expected, and it was the GUK case there that was the ground breaker. You will have seen that in all the papers, including the reactions when it came in.

It might seem as if the situation is different now, but what we are assured is that at the time you could not count on an interim injunction and the GUK one is the first for some time. That was a factor in GSK's strategy, as I said.

I am also not going to touch, then, on *Lundbeck* at all because Mr. O'Donoghue will deal with that tomorrow. I do want to remind the Tribunal that as well as saying that *Lundbeck* is really a very different case, we do also make the point that where *Lundbeck* is seeking to apply *Cartes Bancaires* or other Court of Justice case law, then that is what you have to do and you should look to the court's case law.

You may on different facts come to different conclusions, and we do maintain that it is not incumbent on the Tribunal blindly to follow every twist and turn that the General Court's case law may take. They were certainly influential and entitled to respect, but if you have a choice, we say, the Court of Justice is more binding than the General Court, and we have drawn --

THE PRESIDENT: Why is it more binding?

MR. FLYNN: We have drawn to your attention the recent ruling by Mr Justice Popplewell in the *Mastercard* case, where he was persuaded that a particular holding of the General Court was inconsistent with the Court of Justice case law and he said he would not therefore take that approach.

Now, that is right or wrong, but that is, we say --

THE PRESIDENT: You say it is right.

MR. FLYNN: I say it is the right approach. I am not seeking to -- I do not know whether he correctly analysed -- although I noticed that the passage which he said was not consistent with the Court of Justice's case law had also been the subject of some discussion in the *Greyhound* case earlier. The Tribunal said we have difficulty reconciling these approaches; you will perhaps recall that.

But as a matter of approach, I say that is absolutely correct. So we say that, for example, it should be open to us, should it be necessary, to persuade you that a case like *Cartes*

Bancaires at first instance, which was held to be, on appeal, inconsistent with prior case law of the court, if need be it should be open to us to make a similar submission to you.

THE PRESIDENT: Let us see where we get to.

MR. FLYNN: That is essentially --

THE PRESIDENT: We saw that you make that point.

MR. FLYNN: Also we make it against the background of there not being anything specific yet that is identified as a crux point on which, whatever you think about it -- and you may be in perfect agreement with it, but whatever you think about it, the CMA will say you are bound and you have no choice, which is what they will say if it comes to it. What we do not know is whether it will come to it, and that is it.

The other matter that I then will not have time to develop is our case on exemption, which is chapter 8 of our skeleton, which is set out in appropriate detail, we would hope, and refers back as necessary to our notice of appeal.

THE PRESIDENT: Yes.

MR. FLYNN: Which has not been really engaged with by the CMA in their skeleton.

We say most of the points there are made. We say they are powerful. You do not have to ascribe every benefit to a specified head of the categories of exemption. The way to approach the benefits is to see if they are reasons for or justify the exemption. You do not have to tag each one according to which paragraph of Article 101.3 or Section 9 they meet.

We say you are looking for efficiencies, or as Mr Justice Popplewell called them, relevant benefits and we have identified benefits, notably the pricing benefits coming from the introduction of authorised generic competition.

We say they come from the agreements as a whole, and the fact the CMA says, well, that is no good we say is not sufficiently argued. Our case is set out in detail and, we say, with some strength.

Their case on essentiality is tied to their insufficiently specified alt deals, if I can call them that, their counterfactual. They say, well, because there was a possibility of some other deal, you cannot say that anything in these agreements was essential to achieving the benefits. We say that is simply wrong as a counterfactual.

These agreements were entered into because these are the terms which the parties were able to reach and these are the benefits that flow from them, and without the restrictions, such as they were, then it would not have been a workable settlement because GSK was defending its patents.

Anything that did not involve maintaining the integrity of the patents, as GSK called it, would not have been a viable alternative deal. So the terms in these were indispensable and the benefits, we say, incontrovertible, in short.

I am just checking there is not some major point that I failed to make. (Pause)

Sir, unless I can help the Tribunal further, I will call it a day.

THE PRESIDENT: Thank you very much. We are hearing from all the other appellants tomorrow, the four of you, so I think we will start at 10.00 am to give a bit of comfort in terms of timing.

10 o'clock tomorrow morning.