IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

1 March 2017

Before:

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

(Sitting as a Tribunal in England and Wales)

BETWEEN:

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

Appellants

- and -

COMPETITION AND MARKETS AUTHORITY

Respondent

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HEARING

A P P E A R AN C E S

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

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

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

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

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

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

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THE PRESIDENT: Yes, Mr. Turner.

MR. TURNER: May it please the Tribunal, I am going to structure the opening submissions for the CMA in the following way: first, give an overview of the case, setting out main themes and explain the crucial differences between the parties.

I will then take the Tribunal to relevant facts as revealed by a number of the key documents.

Third, I will go to the important judgments of the General Court in the *Lundbeck* case on 8th September last year, with some care. Finally, Ms. Demetriou on my left is dealing, for the CMA, with the abuse of dominance side of the case and with certain other issues, and she may briefly address the appellants' arguments in relation to the vertical agreements exclusion order in opening.

THE PRESIDENT: But the rest of the dominance case --

MR. TURNER: That is going off until later.

THE PRESIDENT: Yes, thank you.

MR. TURNER: So I will begin with the overview.

The CMA's case in the decision is based on a very simple and intuitive proposition. It is that if the owner of a patent protected product agrees to pay a potential competitor to induce it not to launch a rival product for the duration of the agreement, then that agreement is by its nature something which is antithetical to the competitive process.

The European General Court in *Lundbeck* described this as, in essence, a kind of market exclusion agreement or arrangement. The purpose, the object of such an agreement is restricting competition.

If I may, I will start with one facet of the European Commission's reasoning about this at recital 1300 of its decision, which you should find at authorities 10, tab 16, page 436.

THE PRESIDENT: You need to give the other reference, I think, which is {Auth-F/16/436}.

MR. TURNER: If you take the second from bottom paragraph:

> "The Commission considers that as established throughout this decision, Lundbeck was perfectly aware that the examined agreements were aimed at excluding competitors. It was the very purpose of Lundbeck's strategy in concluding those agreements. Similarly, given the nature of the commitments, which they agreed to, the generic companies were fully aware that the aim of the agreements in question was their exclusion, at least temporarily, from the market.
>
> "There may not be any established precedents specifically in relation to reverse payment agreements, however, the notion that such agreements which are aimed at market exclusion in exchange for a payment are likely to constitute a restriction by

object under Article 101 of the Treaty is well established and cannot be seen as novel."

That was the Commission's decision.

Then the General Court in the *Ranbax*y judgment, one of the series, expressly approves that reasoning. If you go to bundle {W/2/39}, you should have paragraph 222. Is the Tribunal following this one in hard copy?

THE PRESIDENT: Some of us are. We are not all acting the same way, so we are doing both. But it is on the screen.

MR. TURNER: This is page 39, 222:

"As the Commission rightly pointed out in recitals [including 1300] of the contested decision, that is, in essence, a market exclusion agreement. Such an agreement proudly equates to two examples of particularly restrictive agreements covered by the non-exhaustive list contained in Article 101(1) TFEU, namely those listed under points (b) and (c) (see paragraph 206 above), since market exclusion is an extreme form of the desire to share a market and limit production."

If you go back to 206 {W/2/36}, you can see the relevant Treaty rules that they are referring to. That is on page 36, just to have it at the forefront of your mind.

(b) and (c) are the:

"Limit or control production, markets, technical development, or investment;

"(c) share markets or sources of supply ..."

Now, it has been well established law, at least since the *Consten v Grundig* case in 1966, that if the object of an agreement is to restrict competition, there is no need to examine its effects.

If we call up *Consten v Grundig* --

THE PRESIDENT: If you give us the reference, I think that is pretty well established.

MR. TURNER: Yes, there is a particular passage I would like to go to. It is {Auth-I/2/42}.

That comes up very quickly. You will see towards the bottom of that page, third paragraph from the bottom, take it further up:

"The principle of freedom of competition concerns the various stages and manifestations of competition. Although competition between producers is generally more noticeable [inter-brand] than that between distributors of products of the same make [intra-brand] it does not thereby follow that an agreement tending to restrict the latter kind of competition should escape the prohibition ... merely because it might increase the former."

Interesting there, in this classic case we have an example of the applicant saying, "Well, if you look at it in terms of competition between brands, there is an increase in competition", and the court is saying, "We are focusing on the reduction of the intra-brand competition":

> "Besides, for the purpose of applying Article 85(1) [which is now Article 101] there is no need to take account of the concrete effects of an agreement once it appears that it has as its object the prevention, restriction or distortion of competition.
>
> "Therefore the absence in the contested decision of any analysis of the effects of the agreement on competition between similar products of different makes does not, of itself, constitute a defect in the decision."

I draw your attention to that passage to show there were two different sorts of competition at issue, and for the purpose of the object analysis they focus on one of those kinds.

Ms. Kreisberger's case for Merck yesterday came close to a submission that an effects case is standard and that an object case is something which can only be found after long experience shows that there are inevitably going to be bad outcomes for consumers and customers from it, that you will inevitably see higher prices or lower output.

That isn't correct. Object and effect are two alternative ways of proving an infringement under Article 101 of the Treaty and under our domestic Chapter I prohibition. There is no standard or default approach of considering effects first.

The reason why payments by originators in the pharmaceutical industry to potential entrants not to pursue independent efforts to enter the market are by their nature anti-competitive and so count as object restrictions, is that such market exclusion agreements involve buying off potential competition using a share of the incumbent's profits, which would otherwise be shared with customers in the ordinary give and take of competitive markets.

If you now go to the main *Lundbeck* judgment, you come to one of the most important paragraphs in it. Paragraph 352, it is at {W/1/74}:

> " ... where a reverse payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry ..."

I dwell on that because you must remember that is also part of the vice:

> "... the Commission rightly took the view that it was possible to consider that such a limitation did not arise exclusively from the parties' assessments of the strength of the patents but rather was obtained by means of that payment ... constituting, therefore, a buying-off of competition."

So two points you gather from that are, first, as I say, the reference to limitation of the incentives as well as an exclusion in direct terms. But also that it is possible, they say, to

infer from the fact of that payment what the assessment of the strength of a patent is. It is not, therefore, something which arises exclusively and independently, the deal, from the parties' assessments. Where you see these features then you can consider that that payment has had a role and has obtained the restriction.

So that is a key aspect of the European Court's approach. The term "pay for delay" is sometimes used to describe how these sorts of agreements are by their very nature injurious to normal competition. Pay for delay, and the vice requires each of those three elements together. Each of those three words does work.

Payment by an incumbent supplier to a potential competitor, four, which causes or contributes. I pause briefly there because Mr. Kon's submissions yesterday for GUK were pitched at a very modest level. He said about Mr. Urwin of GUK, and I quote:

> "Of course he was looking for the best possible deal, but that does not mean the sole inducement for him entering into these arrangements was the value transfer ..."

That is {Day2/34:21}.

We do not say the payments were the sole inducement but they were an inducement, and ultimately they were the deal clincher when the deals were made.

The third way is "delay". Deferral of efforts by the potential competitor towards independent market entry. Where you have this sort of agreement it is restricted behaviour in its own right. It subverts the process of competition, which is a particular feature of this market context in the pharmaceutical sector.

So one asks: what is this context? What is the competitive process in the pharmaceutical industry which is protected by the competition rules?

So I now focus on this sector. There is a dynamic competitive process that typifies the pharmaceutical sector in relation to the supply of commercially valuable patented drugs. If you now go to the *Lundbeck* judgment, the main one, at paragraphs 91 to 94, those are at {W/1/21}.

91:

> "In recitals 615 to 620 of the contested decision, the Commission examined the specific characteristics of the pharmaceutical sector and identified two phases in which potential competition could occur in that sector."

92:

> "The first phase may begin several years before the expiry of the patent on an API, when generic producers that want to launch a generic version of the medicinal product concerned begin developing viable production processes leading to a product that

meets regulatory requirements. Next, in the second phase, in order to prepare for actual market entry, a generic undertaking must apply for marketing authorisations ... pursuant to Directive 2001/83/EC ... of the European Parliament and of the Council ... "[They] order tablets from one or more generic producers or produce them itself and find distributors or set up its own distribution network, that is to say, it must take a series of preliminary steps, without which there would never be any effective competition on the market."

93:

"The impending expiry of the patent on an API therefore generates a dynamic competitive process, during which the various undertakings producing generic medicinal products compete to be the first to enter the market. The first of those undertakings to enter the market can generate significant profits, before competition intensifies and prices fall drastically. That is why those undertakings are willing to make considerable investments and take significant risks in order to be the first to enter the market for the product concerned once the patent on the API concerned expires."

Finally 94:

"In those two phases of potential competition, undertakings which produce generic medicinal products or which intend to sell them are often confronted with issues concerning patent law and intellectual property law. Nevertheless, they generally find a way to avoid infringing existing patents, such as process patents. They have various options in that respect, such as seeking a declaration of non-infringement, or 'clearing the way' by informing the originator undertaking of their intention to enter the market. They may also launch their products 'at risk', defending themselves against any allegations of infringement or bringing a counterclaim calling into question the validity of the patents relied on in support of an infringement action. Lastly, they may also work with their API supplier in order to alter the production process or reduce the risk of infringement, or they may switch to another API producer in order to avoid such risk."

Now, standing back --

THE PRESIDENT: I do not quite understand that. The second phase appears to, as described above, seems to be to get ready for the expiry of the patent and to be ready the moment the patent expires to get onto market because the first generic to enter has a significant advantage.

So you do all your work in advance, get your product prepared, and so on.

That is clear from paragraph 93: The first to enter the market once the patent expires.

MR. TURNER: Yes, sir, I think the confusion here -- I have the same reaction -- is that they are talking there about the compound patent on the API, and after that patent has expired then you have available, as Mr. Flynn has been explaining, the clinical data and you are faced with process patents. You will see --

THE PRESIDENT: Well, processed or there were a series -- it was not just process. It was also derived products here. As we know, they were declared invalid, the claims, but it is not just the original API patent expired, the patent that was used against the Generics was the anhydrate patent initially, not just the process.

MR. TURNER: That is right. The description here though seems to be starting by talking about the patent on the API, the compound patent, and then you will see in 94, if you go to the second sentence:

> "Nevertheless, they generally find a way to avoid infringing existing patents, such as process patents."

It then runs on to talk about the ways in which there can be competition before the expiry of those patents, because it specifically envisages declarations of non-infringement, validity challenges, questioning the validity of the patents, and so forth.

THE PRESIDENT: But they do not always find a way of avoiding infringing patents. That is clear. They may try.

MR. TURNER: They may try.

THE PRESIDENT: They may realise it is too difficult here.

MR. TURNER: They may. That point is well taken.

What one sees, though, is that these are the ways in which they try. It is badly expressed insofar as it suggests that they succeed always, but what it is describing is the competitive process at that time and it specifically is referring to probing, testing validity and infringement in relation to patents at that point.

These are the routes to market and these are the commercial behaviours on the generic side, which are an expression of the competitive process. It also includes the competitive process, the originator's responses to that. But the big point is that the process includes patent challenges.

If you go further down that page to paragraph 96, look at the first sentence:

> " ... the Commission stated that challenging patents is an expression of potential competition in the pharmaceutical sector."

If we turn the page, please, {W/1/23}, we probably do not need to read the rest of 96, but if you go to 97, you will see that:

" ... the Commission identified eight possible routes to the market ..."

If you run your eye down those and look at the third and fourth indent, you will see there that those are specific references to patent litigation challenges in terms of validity and infringement.

If we go forward in this document, please, to page {W/1/39}, you then come to paragraph 171.

I will read that:

"It must also be observed that potential competition [we are now talking about this market sector] includes inter alia the activities of generic undertakings seeking to obtain the necessary MAs, as well as all the administrative and commercial steps required in order to prepare for entry to the market ..."

Then there is a reference back to the paragraphs we have just read. So those are the steps. This is what the European Court says about them:

"That potential competition is protected by Article 101 ... If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product, including obtaining an MA, and which have made significant investments to that end, to cease or merely slow that process, effective competition would never take place, or would suffer significant delays, at the expense of consumers, that is to say, in the present case, patients or national health insurance schemes."

So I am trying to show you now the basic architecture and approach of the *Lundbeck* judgments, and the point is that an incumbent, an originator, is paying to stop or to delay particular steps being taken on the road to entering the market.

Provided that the other company, generic, has real concrete possibilities of navigating those steps, including through contesting patent rights in court, it is enough if you observe the incumbent buying them off.

This basic framework is part of the CMA's decision. If you go to the CMA decision, I will show you one paragraph --

THE PRESIDENT: But I find this, for myself, a bit puzzling. I can see that if you pay a generic to stop them getting an MA or stop them building up stocks or doing all sorts of things that your patent does not give you the right as such to do, that would be anti-competitive. It is going beyond the protection of your patent.

But your patent, if you think it may be a good patent, gives you a right to exclude them. Of course your starting position, that if someone on a market pays somebody else who might be about to enter the market to keep out is an object restriction, I think everyone can understand that. But things are dramatically changed by the fact that the person on the market has a patent which, of its nature, is a right to exclude. That is what patent essentially means, for the duration of the patent.

So it is when one gets to paying them not to challenge validity or, having challenged validity, to settle your case, it comes close to saying you cannot settle patent litigation by paying the other party that is claiming the patent is invalid or that it is not infringing, because the litigation going through is the competitive process and you are stopping it happening.

That is a very extreme proposition, is it not?

MR. TURNER: I say it is not an extreme proposition when you bear in mind the perspective. Perhaps I should develop this a little bit further, but the grant of a patent is not in itself an definitive right to exclude because the system is set up to enable a patent right, which has been obtained through the ex parte process and so forth, to be challenged in court, contested in that way.

THE PRESIDENT: It is not an indefeatable one. It is a right to exclude as long as valid, yes. There are a lot of bad patents around and the granting process is, as you say, is an ex parte process, and all the things that come up in patent litigation are not something the control of patents could be expected to take into account. So it is open to people to challenge it, but until either it has been declared invalid or their product does not infringe -- well, that is perhaps slightly different -- the product doesn't infringe. But insofar as it does infringe, it is a right to exclude, and that is what a patent is. But you can bring a case saying the rights have been improperly granted.

MR. TURNER: Yes. The key is, sir, you said until declared invalid or found infringed. The point made here, the law is laid down, is that the interruption of that process, not per se because, of course, you can settle a case, but when it is bought by a payment either in cash or cash equivalent by the patentee, that is restrictive in its own right because you are buying off potential competition because of the possibility that that patent litigation brought by or resisted by the generic, would succeed for the generic.

THE PRESIDENT: I do not want to take you out of your course, but you can develop it at some point, I do not quite understand how you settle a litigation other than by if one says, "You can only settle it by granting a patent licence with a royalty, or allowing entry before the

end of the patent period". But if the patentee -- which, of course, what they want is to preserve their patent and they have a view of its -- how much it is at risk and the generic challenger has a view of how much it is at risk, then they come to a deal, it is not like a claimant paying money to a defendant, it seems to me, because either could be the claimant. One could be claiming invalidity and the other is claiming infringement. Indeed there is a claim and a counterclaim in all these litigations. It does not really matter who goes first.

MR. TURNER: No.

THE PRESIDENT: There is going to be a payment from the patentee to the generic, otherwise the case will not settle.

MR. TURNER: Sir, that is not the case. I will take you to this, but there are many ways in which you can settle without the patentee making a payment to induce the generic, whether they are the challenger or resisting infringement action, to cease their efforts to enter the market independently.

Where they make a payment, which is part of that inducement, that takes you -- and I will develop this with some further material then -- but that takes you into a situation where you are paying off a potential competitor, somebody who may succeed in that action, and just as with a marketing authorisation, which is another legal requirement before you can market your products, overcoming the litigation hurdle is equally another requirement which must be navigated. Where there is uncertainty in the possibility of doing that, you should not pay in order to achieve that end.

I will say in a moment an important qualification, which I think we should all have in mind, which is that the way in which the Treaty system works, that is an object restriction. That does not mean it is per se illegal under the competition rules. You then go through to Article 101(3) and the point then is that it is for the people who have made the payment to justify it as being a competitive arrangement, according to the likes of that paragraph.

MS. KREISBERGER: Sir, I hesitate to interrupt, but Mr. Turner said there was no need to read the rest of paragraph 96. He took you to the preceding paragraphs. We would just ask that you do direct your attention to paragraph 96 in full.

THE PRESIDENT: Yes.

MR. TURNER: I am happy to go back to that. There was no deliberate exclusion. I do not know if Ms. Kreisberger wants to wait or would like us to go back now.

THE PRESIDENT: We can read that to ourselves now, paragraph 96, if we can go back to that, which is page {W/1/23}, starting:

> "It is for the originator undertaking to prove ..."

(Pause)

MR. TURNER: Yes, I am not sure exactly what point Ms. Kreisberger is making. If you go to the end of that:

" ... the Commission concluded that Lundbeck's process patents were not capable of blocking all possibilities of market entry open to the generic undertakings."

That is the key. Prior to that there is a recital of the facts of that case, and she may be referring to the fact that in that case there is a reference to a 60% chance of being held invalid. In which case I think that she is going to say that they place reliance on that likelihood having been identified in that litigation as crucial to the outcome --

THE PRESIDENT: I think it is the sentence:

"In those circumstances, the Commission considered that the possibility [of entry] ... 'at risk' and ... face infringement actions ... was an expression of potential competition."

MR. TURNER: Yes. The circumstances of that case and at risk is one of the list of things that are then enumerated below. Rather than go further into that now, perhaps it could be developed in closings. I will move on.

If we go back to the CMA decision, just to confirm how it was approached there. I will give you only one reference for the moment, at paragraph 6.33, which is at {V/1/250}:

"In this regard, patent challenges by generic medicine suppliers are part of the overall competitive process both for generic suppliers seeking market entry for their essentially similar medicines and for originator companies that invoke process patents or other patents in an attempt to repel such market entry. In such a situation, patent litigation reflects the independent efforts of generic undertakings trying to enter the market and is also an expression of competition from the side of the originator, which is trying to defend its market position against true generic competition. Agreements that result in patent challenges being 'bought off' may therefore seriously impact the competitive process as they are frequently the very expression of potential competition in this sector."

Now, in view of the comments, it may be sensible to go to two paragraphs of the *Lundbeck* Commission decision as well, at {Auth-F/16/212}.

Sir, do you have that? It should be paragraphs 625 and 626. This is really to help on that point about how the Commission and the European Court were approaching patent litigation in this sector and its role in the competitive process.

625:

"Patent litigation, which is very common when new generic products become available through expiry of exclusivity on originator medicines, is in fact an expression of the independent efforts of generic undertakings to enter the market and therefore a form of competition in the pharmaceutical sector. Likewise, patent litigation is also an expression of competition from the side of the originator undertaking, which in this way is trying to defend its market position against generic competition.

"In the pharmaceutical sector, patent challenges are an essential part of the competitive process between generic companies seeking market entry for compounds that are no longer patent-protected and ..."

Compounds, going back to your question, sir:

" ... originator companies that invoke process patents or other process patents [it says] against such market bring. The Commission's 2009 --

THE PRESIDENT: It looks like a mistake.

MR. TURNER: That is a mistake.

THE PRESIDENT: It may be "or other patents".

MR. TURNER: Yes, it must be a mistake.

"The Commission's 2009 inquiry into the pharmaceutical sector found that 'about half of the medicine subject to in-depth investigation faced generic entry within the first year after loss of patents (including SPC) and data exclusivity ... Delays are important as the price at which generic companies enter the market was, on average, 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after the entry, prices of generic medicines were on average 40% below the former originator price'. In such a situation, competition - actual or potential - from generic undertakings trying to enter the market by inventing around, seeking declarations of non-infringement, or trying to invalidate process patents or formulation patents [there you are] still held by the originator undertaking, or indeed by generic entry at risk, is the essence of competition in this sector. Denying that in such situations potential competition exists would amount to denying the existence and thriving of the generic pharmaceutical industry and of the competitive pressure it exerts on the originator industry when expiry of exclusivity looms. Accepting that merely because of the (threatened) invocation of a patent or even a genuine patent dispute, an originator undertaking can pay money to a generic undertaking in exchange for the latter signing a document stating that it (possibly) infringing a patent and ceasing its efforts to enter

the market, would make the necessary application of competition law to market exclusion agreements in this industry de facto impossible."

Now, I show you this because this is -- and it is important to establish it at the outset -- the European legal framework, its application to object agreements in this sector and how it analyses the process of competition in this particular industry.

THE PRESIDENT: Taking that literally, any settlement of a patent action has the object of restricting competition because they are saying, which I can understand, that it is part of the dynamics of competition not only actually in the pharmaceutical industry, but that is one of the main instances because of the strong generic sector, that there are patent challenges that may take place and that whole process is a way in which, in the form that competition takes place, potential competition, I see that.

But then you say any agreement, go back to the Treaty, which prevents that process of competition is therefore prohibited whether you pay money or not. You settle it, you make an agreement that the challenge is not going to proceed and you have prevented this competitive process as described here from playing out.

MR. TURNER: No. That is one's immediate reaction. It is not in fact the way to look at this.

It is accepted by the Commission and by the European Court that settlements of patent litigation are entirely legitimate. They do not say that you have to continue because it is such a good thing to have these patents tested in court. The settlements themselves are competitive too.

The feature which creates the problem -- and I believe that in this paragraph it also refers to it, but perhaps not prominently -- yes, four lines up -- is the payment by the originator in order to achieve that. Hence we come back to the phrase "pay for delay". If you merely settle patent litigation, if you merely settle it because the appreciation is that there is uncertainty and that if it is a very weak case that is being brought against the patentee, the generic feels that it wishes to extricate itself, then it is one thing.

If the originator says, "We want to get rid of this and we are willing to pay up to our level of the litigation cost that we are going to avoid to get rid of this", which is another thing that you will see in the materials, equally that form of payment to achieve that end is not treated as objectionable.

THE PRESIDENT: You have those two extremes, but take a case where the originator thinks they have got a good patent but maybe 80% chance of success against the generic, and the generic, their view is their chance is actually about 30%, not necessarily identical view. So at that point the generic is not just going to give up the payment of its costs because it has a

good chance, albeit not better than evens, of achieving much more than the originator who believes it is going to win. But it has this concern that it might fail; it is not implausible that it will fail.

The generic's case is not hopeless. So, inevitably, it seems to me there is going to be some sort of payment if they are going to settle. Unless the originator says "Well, I will do it by way of royalty".

That is what I struggle with. It would be the logical, normal way you would settle a case in those circumstances.

Unless one is taking the position -- perhaps that is the position -- that never mind the size of it, it is not saying that there may be such a huge payment that the only explicable inference is that in fact the originator really thought its case was hopeless. I can follow that situation. You can infer that the only way you can rationalise that level of payment is that it meant that it had a very strong sense it is going to lose. But apart from that, the mere fact that there is payment as part of the settlement, it is a very strong conclusion to say that makes it anti-competitive; the payment in excess of litigation costs.

MR. TURNER: We say it is not, sir, because, first of all, we can show you -- we will come to it -- some of the evidence that in fact although you have speculated that it may be normal, it is not normal. There have been surveys, both in America and in Europe, putting in context how frequent this sort of practice is. It is not normal although it does occur.

Where it occurs it is in those circumstances paying to prevent the generic taking these steps towards independent market entry, and you have seen the analysis of the Commission, certain statements so far of the court.

It is perfectly possible to reach other kinds of settlement agreement, and they are present in this industry. For example, we have referred to, and, sir you have referred yourself, to the royalty possibility, early entry possibilities, agreements on those. These are considered, they are features of this industry. So this is not, as it were, a rule saying that settlements are somehow made impossible.

THE PRESIDENT: But it is saying that certain kinds of settlement, a long category of settlements, is impossible.

MR. TURNER: It is saying that a category is an object restriction, and therefore you would need to go into Article 101, paragraph 3.

One way to think about it is that when a generic and an originator enter into this form of contest, say that they enter litigation regardless of which is the claimant. They can take it

through to judgment and the court will adjudicate on whether the patent is valid or infringed, or alternatively they can seek to settle their differences.

When they seek to settle their differences, the result of this rule, subject to Article 1, paragraph 3, is that one way of settling, one option, is not available. That option is viewed as anti-competitive and it is off the table.

MR. GLYNN: If that is right, it would be a very strange situation we would have reached, would it not? Because value can be transferred between two parties in numerous ways.

I mean, it could be royalties were okay and the cash payment was not, then you could tinker with the size of the royalty and achieve exactly the same result. It would be very odd, would it not, if the form of the settlement were to make it per se anti-competitive rather than the substance?

MR. TURNER: Yes. We say it is not a question of form, it is a question of substance. This will be an area that may be explored when the economic experts come to be questioned on this. But we have said that cash or cash equivalent being paid by the originator is different from entering into a kind of arrangement, let us say, under which real competition may occur. Where a generic says to itself: the value that I will derive from this settlement agreement will be derived from a process of competition, I will enter the market, I will compete against the originator company and I may increase my sales, I may win business, and by doing that and engaging in competition, I hope to profit.

That is certainly valuable. It is different in kind and in substance from receiving a cash payment which is not a key to unlocking competition. The analysis in this case is that there were large cash payments, neat, undiluted, supported by certain supply agreements -- I will come on to this directly -- and that these supply agreements were looked at conscientiously by the CMA, as well as the cash payments, to see whether those were value transfers in the bad sense which is being condemned here, or not.

MR. GLYNN: Forgive me, I will not take much longer, I am still struggling with the conceptual framework that you are using.

If it is possible for a patent litigation to be settled and, depending on the strength of the two cases and their perceptions of it, this settlement might involve a transfer of value either way, if that is the situation then that seems reasonable.

If it does not essentially matter whether the form of the payment is cash or a discount or a royalty payment, or whatever, then we are still left needing to know what the acid test is that you are using to distinguish between a payment which has an anti-competitive purpose, such as, for example, might be made if there was no patent in question at all, if somebody

had no patent and he simply paid his potential competitors to go away then nobody would take a second to answer that one.

But in this kind of case, where you have got clearly different views about the strengths of the cases, clearly different assessments of the likely outcome of the litigation and there is an agreement reached, and what we have to do to follow your line of argument, I think, is to distinguish between what would have been an acceptable settlement of a patent litigation and what would be anti-competitive, I do not understand the basis on which you are distinguishing.

MR. TURNER: The anti-competitive basis -- coming back to that tag, "pay for delay" and the references in the European Commission and Court judgments, involves a payment which is not merely an aspect of value because it is creating competition.

Contrast it with an agreement whereby early entry by a generic onto the market several years before the stated date of patent expiry is provided for. So far as the generic is concerned, the value that it is deriving is the ability to come on and compete with an independently sourced product earlier than the stated date of the patent expiry, and it hopes therefore to gain the profits from coming onto the market first and competing first, which will make it worthwhile.

That sort of arrangement is to be contrasted with being paid either in cash or through a vehicle which is set up not to lead to competition in that way between the incumbents and the generics, but merely to transfer the equivalent of cash.

That is the touchstone. Certain payments, you will have seen from our skeleton, I will just add for completeness, may also be made where a generic, let us say, undertakes certain valuable services, something of that kind.

MR. GLYNN: Yes (inaudible).

MR. TURNER: No. What you see from this case though is that in relation to the cash payments in particular, certain attempts were made to say, well, these are to be explained by reference to certain legitimate factors and a large part of section 6 of the decision, which will need to be read in full because that is the object part of the case, is a meticulous examination of the reasons why it was said that these cash payments were not inducements or were to be explained by other factors.

At the end of it the CMA concludes that there are significant payments which cannot be explained in the way that was sought to be advanced.

I just say that for completeness because that is part of this case. You will see that in section 6.

THE PRESIDENT: We do not want to spend too much time on this, although it is very much the heart of the object case.

MR. TURNER: Yes.

THE PRESIDENT: There are a lot of detailed things about the particular payments, and so on. But the most troubling thing is this basic proposition. Of course, if you are right, that is the object case determined; one then goes into details of the payment here. But it is this fundamental point; it makes me think if the CMA have not fined the Generics in this case and had only fined GSK, not only would you be facing only one appellant, but the Generics would be cheering you on because all they have to do is bring a bona fide patent challenge and they are going to get entry. Perhaps with a high royalty, but they will get onto the market with a generic product because there is no other way it can be settled.

MR. TURNER: There may be different reasons and different incentives for companies, depending on whether they have originator and generic arms, or whether in particular litigation they fear follow-on actions for damages, whether they are seeking to preserve an arrangement that works quite well because it enables them without much effort -- without much effort -- to be paid something which means that they do not have to go through the effort and the uncertainty of competition, but instead can receive cash or cash equivalent which leaves them as well or better off.

Also, from the Generics' side, you will appreciate that there can be good reasons for thinking that an arrangement which suits both them and the originator but not the customer --

THE PRESIDENT: Yes, we can understand that.

MR. TURNER: It is opportune, given this exploration, to recall that the case against us is precisely, or includes precisely that patent challenges in this field are not to be considered as an expression of competition.

Patent litigation in the appeals against us are the antechamber of competition. You are in the waiting room. It is only if and when an assertion of a patent can be demonstrated by a competition authority or a claimant to be misconceived that you have for the first time then potential competition.

That is a large part of the appeal. I will show you that, if you go to --

THE PRESIDENT: Is this the potential competitor point?

MR. TURNER: It is the no potential competition. No competitive process even starts until you have got past the patent litigation.

If you go to GSK's skeleton {S/2/108}, you have paragraph 5.43:

"To spell this out, as the CMA seems not to have grasped the argument that GSK is making: in the face of GSK's patents which the CMA has to presume valid, if it wishes to establish that GUK and Alpharma were potential competitors (in order to condemn the litigation settlement agreements as object infringements), the CMA would have to demonstrate that the GUK and Alpharma paroxetine products did not infringe those patents."

We have to do that:

"It could only do that if they were manifestly not infringing because it would be simply beyond the CMA to resolve any doubts over infringement. This is not a demonstration that the CMA has attempted. The CMA does not have (and has disclaimed) the competence enabling it to make direct determination as to either validity or infringement in absolute or probability-weighted terms, and has not engaged with extrinsic evidence concerning the parties' views at the time."

Pause there.

If you then go forward to 6.90 at {S/2/136}:

"The CMA cannot save its case by saying that it is plain or obvious that the settlement of litigation constituted in itself an interference with the competitive process (for example, it cannot sensibly be suggested that they were sham agreements). GSK does not accept that litigation in itself constitutes an aspect of the competitive process ... and the *Lundbeck* judgment finds that the Commission were wrong to take that view. Even if that is wrong, settlements of litigation are in turn an inextricable aspect of litigation and, as the CMA accepts, are generally pro-competitive."

We can pause there.

I do not mind if you read to the end. But GSK is saying here that the European Court in *Lundbeck* agrees with their approach and has disagreed with the Commission and with the CMA.

In fact, I have already shown you one paragraph, we will look at it in a moment. But that is wrong. The General Court plainly endorses the view that patent challenges in the pharmaceutical sector are an expression of competition. GSK here is relying on other parts of *Lundbeck* to argue the contrary.

I will just show you one for the moment from one of their footnotes. If you go to {W/1/30}, that is *Lundbeck*, the judgment.

You have here the first of the paragraphs they rely on, paragraph 128.

The court said:

"It must therefore be found, as the Commission did in recital 635 of the contested decision, that in general the generic undertakings had several routes -- constituting real concrete possibilities -- [we have seen those] to enter the market at the time the agreements at issue were concluded."

Back to paragraph 97, you will recall that was the list of the indents including the patent challenges. Those possible routes included, inter alia, launching the generic product "at risk" with the possibility of having to face proceedings brought by Lundbeck.

Pausing there. Those routes which are approved by the court include the one which was of concern there, the launch at risk.

Then at 129:

"That possibility represents the expression of potential competition, in a situation such as that in the present case where Lundbeck's original patents, concerning both the ... API and the cyanation and alkylation processes, had expired and where there were other processes allowing the production of generic citalopram ..."

We say the natural interpretation of that from paragraph 128 is to set out the general proposition, and 129 is referring to the circumstances in the *Lundbeck* case. But this is not the court disagreeing that patent challenges are an expression of competition in this sector at all. That -- conscious of the time -- is the competitive process in this market sector and how it has been examined by the European Commission, considered by the European Court and considered by the CMA.

THE PRESIDENT: There is nothing in that passage which says the Commission was wrong about anything.

MR. TURNER: No, there is not.

THE PRESIDENT: So it does not support the statement in 6.90. What about 146?

MR. TURNER: We can go to 146. I do not have the page reference.

THE PRESIDENT: Page {W/1/34}.

MR. TURNER: 146:

"... as the Commission rightly submits, at the time the agreements at issue were concluded [this is a furthermore] no interim measure had been obtained by Lundbeck, whether against generic undertakings using the Natco citalopram, such as Merck ... against generic undertakings using the Cipla citalopram or the generic citalopram developed from the API produced by the Indian company Matrix ... such as Arrow and Alpharma, or against generic undertakings using the generic citalopram developed

from the citalopram API produced by Ranbaxy ... and no court in the EEA had found an infringement of the crystallisation, amide or iodo patents."

THE PRESIDENT: I looked at 166. None of these paragraphs say the Commission was wrong in anything.

MR. TURNER: No. It can be addressed in closing.

THE PRESIDENT: Yes, so we need not spend time.

MR. TURNER: It will no doubt be addressed in detail in closing, but I am therefore pointing out at this stage we say the court and the Commission are at one on how to look at this.

Then we do come to the question that you have adumbrated, sir. What can an originator do lawfully when generics threaten to enter, threaten to defeat their market position? What is compatible with the competition rules?

Clearly they can pursue the patent infringement proceedings or resist validity challenges. There is no objection on competition law grounds, as one knows, apart from in exceptional cases of vexatious litigation to a patent holder seeking to enforce its patent claims in court. The patent holder can also settle, and as I say there is evidence, I will give you more subsequently, that settlement can take a number of forms. In this case, for example, GUK did consider the possibility of a settlement based on a royalty arrangement in return for GSK granting them a non-exclusive licence to sell their own product. That would have been more competitive because they can come in, they are not restricted on the amount, they are not given a fixed volume and they can seek to grab business.

If you go to the decision at V/1 --

THE PRESIDENT: I think we understand that, that that is more competitive. You can just go through what you say are the possible forms of settlement. That's one.

MR. TURNER: If I can perhaps do it in this way. I will just give you two references now, one of which is a footnote in the decision listing the US experience, and then I can develop that subsequently in closing, as needed.

If we go first to the decision itself just to show one aspect of what happened in this case. At {V/1/121} at 3.289 on your screens you will see the internal GUK email. That is November 2001, where they were considering suggesting to GSK "How about if you allow us still to sell our independently sourced Sumika product?"

They were under suggestions that they:

"... allow us to sell our anhydrate product from Sumika without any patent litigation fears, where we pay a (small/reasonable) royalty from our profits in Europe (to include Israel) for non-exclusive patent rights/licence."

That was one of the things they were considering.

If you go to page {V/1/354}, in this document you will see footnote 1169, which is a long footnote giving examples from the US experience:

> "... the evidence on settlement agreements concluded in the US indicates that branded and generic companies can settle their patent disputes without using value transfers in return for entry restrictions. For example: 'A third agreement provided for payment of a royalty by the generic to the brand based on the generic company's in the exchange for royalties and a share of the generic's profits from marketing the product' ..." and so forth.

I need not read this now, but the parties can as necessary show you how this has been considered in the US and, indeed, by the EC too.

THE PRESIDENT: But it is any form of settlement that prevents generic entry, unrestricted generic entry, with their own product would fall foul of the prohibition as you have outlined it.

MR. TURNER: When it has been purchased by cash or cash equivalent.

THE PRESIDENT: Well, if they throw their hand in or just get their costs, which is almost saying that is all right, you say, but if they get anything beyond that it is not?

MR. TURNER: If they are being paid sums which are above that level in return for ceasing their efforts to enter with an independent product.

THE PRESIDENT: Settling the litigation. So that means they are not going to, yes, enter.

MR. TURNER: Yes. If we go to the *Lundbeck* judgment also, I will complete, sir, the answer to your question.

The court in *Lundbeck* specifically does point out that settlements in this field do not need to contain reverse payments, or where they do, that the reverse payment does not have to be accompanied by restriction on entry, because there was a real life example in that case of the latter situation, a company called Neolab.

I will give the reference. If you go to {W/1/87}, this is *Lundbeck*. Paragraph 412 you should have on your screens. That is page 87 of the judgment. You can read it to yourselves, but I will go to the fourth line from the bottom:

> " ... there is no obligation on the originator undertaking to initiate litigation in every EEA jurisdiction in order to protect its patents, since it is still possible, for example, to conclude settlements which do not contain any reverse payment or to conclude settlements which, although they provide for such payments, are not accompanied by

any restriction on the market entry of generics (see the example of Neolab, cited in paragraph 350 ...)

MR. O'DONOGHUE: Sir, I hesitate to interrupt. Can we also read paragraph 164 of the Commission decision because the *Neolab* case is the case where the patentee had lost.

MR. TURNER: I am sure Mr. O'Donoghue will come to that, but I will make progress.

THE PRESIDENT: We will not jump to it now because we are in a different document, but --

MR. TURNER: To help Mr. O'Donoghue, let us go back to paragraph 350, and maybe he will be happy with that, because that refers to the recital that he is worried about.

350 is on page {W/1/73}:

"The contested decision nevertheless acknowledges that the existence of a reverse payment in the context of a patent settlement is not always problematic, particularly when --."

Now look at these three conditions:

"... (i) that payment is linked to the strength of the patent, as perceived by each of the parties, (ii) it is necessary in order to find an acceptable and legitimate solution in the eyes of the two parties, and ..."

Now I emphasise this:

"... (iii) it is not accompanied by restrictions intended to delay the market entry of generics."

Pause there and underline that for a moment:

"It thus took as an example the company Neolab, with which Lundbeck had also concluded a settlement agreement, which was not considered to be problematic -- even though it involved a reverse payment -- since that payment to Neolab had been made in exchange for a commitment to Neolab's part not to seek damages before the competent courts and Lundbeck had agreed not to bring any claims under its patents during a certain period."

There is the recital Mr. O'Donoghue mentioned:

"In that case, the actual object of the reverse payment was to settle a dispute between the parties, without, however, delaying the market entry ..."

That means the independent market entry:

"... of the generics."

MR. O'DONOGHUE: Sir, I am not very happy with that. We do need to read 164.

MR. TURNER: If I may, I think Mr. O'Donoghue will have to wait.

THE PRESIDENT: I think we can do that later, but we will make a note that we should look at recital 164 of the Commission decision.

MR. TURNER: That is completely fine. We can perhaps do it over the lunch adjournment, but there is quite a lot to get through.

THE PRESIDENT: You have to get through a lot and we have been interrupting you a lot. We are just trying to understand, because it is crucial for this case, the scope of this core submission on object.

MR. TURNER: It is. That is why I am taking such care to ensure that everybody is aware of how the case has been developed and how it fits with the European Court's exigencies of the principles.

Before leaving this, at 351 you will see in the last sentence -- you can read this as well in relation to Mr. O'Donoghue's recital:

> "That latter commitment is therefore crucial, since, contrary to the agreements at issue in the present case, the payment made by Lundbeck was not made in exchange for an exclusion from the market, but was accompanied, on the contrary, by an acceptance of non-infringement and a commitment not to hinder the market entry of Neolab with its generics."

I mentioned in 350 that there were three conditions that the court and the Commission referred to.

If you go to GSK's skeleton, it is instructive to see how they approached that paragraph in the court's judgment. Go to {S/2/150}.

You have paragraph 6.137:

> "The General Court also identified potential features of the factual, legal and economic context which might suggest that an agreement was not restrictive by object ..."

Yes:

> " ... including:
>
> "(1) If the reverse payment is 'linked to the strength of the patent, as perceived by each of the parties' ..."

Yes:

> "(2) If the reverse payment was 'necessary in order to find an acceptable and legitimate solution in the eyes of the two parties'."

Yes, and the third condition, the crucial one, is not there.

If, instead of having the validity and infringement of a patent tested in court or settling on other commercial terms only, the originator decides to make a substantial transfer of value to the generic, and in my submission that is either cash or cash equivalent in the way I have described, to induce the generic to abandon its patent challenge, that is the feature, that is the feature, which is blatantly anti-competitive and which has the object of restricting competition.

It is a very harmful practice in the interests of customers and consumers, particularly because of the general public interest that patents granted in error should be open to challenge. That is the point emphasised by the Court of Justice in the *Windsurfing* case, which is repeated both by the General Court in *Lundbeck* -- I will merely give you the reference -- paragraph 119, and by the CMA in this case, paragraphs 6.19 and --

THE PRESIDENT: You have to say more than that. It is not patents granted in error should be subject to challenge, but patents should be subject to challenge to establish whether or not they were granted in error. That is what you are saying?

MR. TURNER: Yes, that is right.

I am reminded by Mr. O'Donoghue that I have carried on for quite a while without a break, and I do not know if it is convenient. I am happy to stop whenever it is felt by the shorthand writers to be needed.

THE PRESIDENT: I think it would be appreciated, yes. We will take 5 minutes.

(11.50 am) (A short break)

(12.00 pm)

THE PRESIDENT: Yes.

MR. TURNER: May it please the Tribunal. I will move on to differences in the fundamental approach taken by the appellants on the one side and the CMA on the other side about how competition law should grapple with the problems in this case, these contested agreements and how they should be characterised.

The CMA's approach in the decision was meticulous, extremely thorough, but also firmly anchored in the case law of the European Courts under Article 101 of the Treaty.

There are 11 core facts, building blocks, which we say are essentially not in dispute. The first is that GSK was aware of the competitive threat from generic undertakings seeking to launch generic versions of paroxetine, and it sought to defend itself against the potential competition.

The second is that IVAX, GUK and Alpharma all made significant investments to launch independent paroxetine products, and that GUK's and Alpharma's competitive efforts to

enter included engaging in these challenges to GSK's patents which were close to or on the point of trial at the date of these settlements.

The third point is that there was -- a factor that we rely on on our case -- uncertainty on all sides as to whether GSK's patent rights would be held valid and infringed. By way of example, GSK gave a very clear indication of its recognition of the situation in its response to the statement of objections at paragraph 4.26. I will give you the reference now. It is bundle {A3/46/156}.

This is a very important paragraph which we do not wish to be lost. If you go halfway down you see this, these are important words:

> "For GSK, the rationale for settlement of the patent disputes was in each instance essentially the defence of its valid patent rights and their commercial value (the status quo), and for this it was prepared to compromise based on its assessment of an uncertain litigation outcome. Each generic company sought early entry to the UK market for a paroxetine product and each had its own particular conditions for compromise which had to be accommodated to resolve the patent disputes."

You will be aware also that GSK accepts in its notice of appeal that, as a matter of ordinary language, GUK and Alpharma were potential competitors and a threat to it.

If we go to bundle {A/2/132}, 6.38:

> "As noted above, it is of course true as a matter of ordinary language (rather than as a matter of the legal principles applying to Chapter I infringements) that the generic companies were potential competitors of GSK, and that GSK considered them as such and perceived them as a threat."

So that is the third essentially uncontroversial situation, how GSK perceived the Generics and what GSK sought to derive from the deal.

Fourth, the litigation came to an end on the basis of the contested agreements, although both sides reserve their right to resurrect the dispute in the future. So the patent position was not resolved.

If you go to bundle {B1/21/1}, you have an email from Mr. Rosenberg of GUK to the Merck parent company, and you will see how he describes the settlement that he had reached to the parent:

> "We settled in the UK for commercial reasons with no decision on patents. BASF continued with invalidation attempt to the anhydrate patent and the result is expected in about a month. (We would have done a better job!!)

"The settlement was not really satisfactory from the legal point of view because it did not settle anything. We will have to continue litigation in 3 years time (I expect). It also did not take into account our 'responsibilities' towards the supplier of the active in the medium and long term.

"You may be approached by GSK with an offer to sell their product. If the offer is of interest to you, before you commit to anything, please can we have a discussion ... We may have to insist on extra terms (which GSK might not like)."

So there you see it was not a settlement in terms of resolving the patent positions.

Fifth point, pursuant to these agreements, GSK transferred substantial value in the form of hard cash and a portion of its profit margins on supply to each of GUK and Alpharma.

Now, on Day 1, Mr. Flynn for GSK said it was beyond dispute that 75% of the value secured by the Generics lay in the supply agreements. That is {TR/1/5}. That is not correct. The only way in which he arrives at that figure, which was puzzling to us, was by lumping in the cash, the so-called promotional allowances, with the supply agreements.

You see this if you go to {A2/117}, which is GSK's notice of appeal, at paragraph 5.41(e)(ii). It is at the top of the page:

"Given the direct linkage between the supply agreements [they say] and the promotional allowances which supported them cited above, on the CMA's own numbers a full 75% of that £50 million should not properly be regarded as part of any such 'payments and other value transfers' at all."

Then you see the associated footnote.

In our skeleton, we set out the relative size of the different transfers. To refresh your memory that is at {S/6/11}, paragraph 24. You will see there that we have identified for convenience the size of the straight cash payments and compared those with the sacrifices of profit margins through transferring allocated limited product volumes to the others. I do not need to run through those, but for your note you will see the figures there.

Point 6 is that the payments which were made could not be explained as remuneration for services provided to GSK by the Generics or on any other legitimate basis which was advanced to the CMA.

It was about transferring enough value in cash or cash equivalent terms to lead them to say, "We are better off doing this than by pursuing with our efforts".

That was, as I say, the whole point of the Section 6 decision, which is a consideration of the value transfers that were made and whether they stood to be explained away in the various ways that the appellants are contending for.

In the end, our case is that it is tolerably clear from the contemporaneous evidence that these payments were in each case part of a deal to give the Generics enough to allow them to discontinue their efforts at independent entry because finally, and I quote, "the numbers were right".

I will go to one document here at {E2/26/1}. Here you have an internal Alpharma email dated 24th October 2002, therefore less than a month before the reverse payment settlement deal is accepted. You will see a reference to having concluded yesterday the UK settlement for paroxetine with Mark Reilly and Cynthia Robinson, who were the responsible people at GSK.

The reference in 2:

> "They will be ready to offer 500,000 packs of the 20mg ... at a transfer price of £8.45. The value of this offer is app £2.5 million on a 12 month basis. We will receive profit compensation for any delays after 1st December ...
>
> "£0.1 million promotional allowances per month, ie £1.2 million on an 12 month basis.
>
> "£3.5 million 'other'. For this amount we need input from Finance on ideal timing, so we can try to phrase the contract accordingly.
>
> "Exclusivity period ... for a range of GSK products ..."

Then:

> "Andrew and his team will work on the value proposition for this when we receive the details. Linked to this we will get £0.5 million which Brendan cleverly suggests to name 'promotional allowance' in the contract to make it hard money."

So, really, and this adds to documents which the appellants have already taken you to, what is happening is that this is money being treated as essentially cash and whether it is a good enough deal, and there are discussions about the way in which to present it.

The seventh point is that the value transferred by GSK was expressly conditional on GUK and Alpharma committing not to launch an independently sourced product for the duration of the agreements. That is clear.

Eighth point, GUK and Alpharma enter into agreements with IVAX to resell a fixed quantity of GSK's generic paroxetine. Mr. Malek asked about the amounts that were actually sold by the Generics on {TR/1/30}. If I may give some assistance on that.

Start with IVAX. If you go to {V/1/526}, please. That is paragraph B.74 at the bottom. Please turn the page, I apologise, to {V/1/527}.

If we look at the second indent down and then the third, the second says:

"GSK has not denied that the limit of 770,000 packs was a contractual restriction. In particular, in response to a question from the CMA regarding the reasons for the inclusion of the volume restrictions in the Agreements ... GSK stated that 'it had no obligation to provide unlimited volumes to the generic suppliers - and we remain of that view today. If a patent holder settles a dispute on a basis that includes a supply agreement, it does not have to subsidise unlimited competition to itself. The volumes were negotiated and agreed'."

The volumes, third bullet point:

"The volume restriction was, in fact, binding on IVAX in the sense that during the ... agreement and prior to generic entry IVAX ordered the maximum volume of packs available to it. Teva has provided data that demonstrates [that is the associated company] that IVAX received 98% of its volume allowance in the first contract year ... and 101% of the allowance in the second contract year. IVAX itself ... recognised that the values it could obtain from GSK were 'limited'."

Perhaps if you go on to {V/1/558}, here at paragraph B.147 at the bottom -- now we need to turn the page, I am sorry -- you will see that the actual numbers, for your reference, at the top two bullets:

"... during the IVAX-GSK agreement, IVAX received 755,261 packs in the first contract year and 776,800 packs in the second contract year. These ... 98% and 101% of the restricted volume in each year respectively.

"In 2003 Moss Pharmacy was seeking additional supply from IVAX. In a note of its discussion with Moss Pharmacy, IVAX recorded that its response to Moss Pharmacy's request had been: 'at this stage there [sic] it was not possible for us to offer reduced prices on this line as all the limited values we were getting were being sold immediately at our market price."

For completeness, if we look at Alpharma, that is at {V/1/370}. I will merely flash this up. We might need to read this. 7.80 we see there, again from Alpharma, the figures about what they received and what that equated to in terms of the restricted volumes. Do you have that? There is an equivalent one for the third generic, GUK, at {V/1/339}, paragraph 7.29. This is GUK. You will need to go over the page here as well {V/1/340}. You will see what the volumes are, what they equate to again.

At 7.30:

"Consistent with this, when planning its own independent entry, GUK had been planning to supply a greater volume of paroxetine than it could supply pursuant to the ... Agreement:

"When considering its volume requirements in order to launch its paroxetine product in the UK, GUK was aiming to supply '50-55% of the generic market'," and so forth."

These were binding constraints.

If you look at footnote 1115 at the bottom of that page, you will also see the note there, right at the bottom of the page:

"The CMA also notes that during the negotiation of the ... agreement, GUK requested a higher allocation of packs ... than the 750,000 packs eventually included in the agreement, but this was rejected by GSK ... 'As you know, one of the ... sticking points has been that GlaxoSmithKline, through yourselves, has been unwilling to meet our required demand of 1 million packs per year'."

Hence this eighth point, that they enter into agreements to resell a fixed amount and it was limited and binding on them.

Neither generic had incentives to cut their prices. They would not increase the volume of sales if they cut prices because that was their limit. If they did that, they would sell out quickly and they would end up losing.

The Generics worked out what the supply agreements were worth to them, this is why I come on to the cash equivalent approach, by factoring in a definite profit margin based on what they knew to be the buy-in price from GSK and the intended stable selling price.

If we go, for example, to GUK, go to {Z/415/1}, here we have an internal email to GUK of 22nd December 2001. You will see Richard Saynor writing to Mike Urwin, describing a summary of what was on offer, and you see the way that he approaches it. He works out what the packs are coming in at, the cost of goods, and this will give gross sales of 6.2 million, net profit of 1.63 million.

Then, halfway down:

"In summary over a 3 year term they are 'guaranteeing'.

"Gross sales ...

"Profit ...

"Net less active costs."

This is the guarantee, as it were. Because the assumption is stable market conditions.

Now, I think you will recall that we saw a document relevant to this from Alpharma already, but just to give it to you for your note again {E2/26/1}.

A similar sort of approach. Now, the appellants are characterising the supply agreement in these proceedings as competition, as a competitive deal under which you would expect competition to break out between them, the authorised Generics and GSK as they vie with each other for custom and try to sell more product.

Mr. Flynn concentrated on Day 1 on the large amounts, the absolute number, of product transferred for resale. He said that the fixed volumes amounted "ultimately to around 60% of what GSK had been supplying as Seroxat", 60% of that pre-existing amount, when it was the only domestic supply.

It is a very large amount. It is a misleading submission for a reason that is convenient to touch on now. The fixed volumes that were given to the Generics, allocated to them, effectively replaced all the parallel imports coming into pharmacies, which reduced rapidly to almost zero from quite substantial levels within a very short timeframe.

I will illustrate this if you go to {V/1/173}. This is the decision. If you look at figure 3.4, that is volume, value is the figure below. Either is all right, but if you look at volume, figure 3.4, and look at the dotted line at the bottom, that dotted line is the parallel imports. You will see the vertical line showing the dates when the authorised Generics come on. You will see that prior to IVAX coming in, that dotted line, if anything, is very, very gently increasing, and then as soon as the generic entry takes place, it dives down dramatically by the time of GUK's entry. By the time Alpharma comes in in February 2003, you will see it is effectively eliminated.

Do you see that?

THE PRESIDENT: Yes.

MR. TURNER: So the surplus for the Generics above that displacing Seroxat in pharmacies, GSK's domestic branded product, and where GSK UK made a profit sacrifice with its eyes open, was much smaller. It was not 60%. It was only around 14% of what GSK had been supplying of Seroxat.

THE PRESIDENT: This is by volume?

MR. TURNER: That is by volume. Yes. GSK's perspective on the supply agreements was clearly that these are not going to unlock competition. The common assumption is that these are, the business assumption, a mechanism for stability, not a concession to competition which would undermine stability. There is lots of evidence of that.

If you go to one document, {Z/294/1}, this is a GSK operating plan in the UK 2003. The date is December 2002, although I cannot immediately see where that comes. If you turn to the second page, please, {Z/294/2} and you look at the top:

"Generic paroxetine."

Do you see that at the top of the page?

"Generic paroxetine - Settlement has been reached with IVAX and GUK (Merck Generics) ..."

This is obviously prior to Alpharma:

" ... and a supply agreement has been established with IVAX. This is a key strategy to maintain market stability for Seroxat across the Plan period. In the plan it is assumed that one further party joins the supply agreement. The plan assumes that growth of the Seroxat molecule will achieve £4.3 million, while the lost margin as a result of the supply agreement will be £14 million."

That is the eighth point.

THE PRESIDENT: Sorry, what do they mean by "growth of the Seroxat molecule"?

MR. TURNER: As far as we can see that means the growth of it in the market. It is a way of expressing that, commercial sales of this Seroxat molecule.

THE PRESIDENT: Seroxat.

MR. TURNER: I believe when they refer to molecule, they refer to the active ingredient in that line of anti-depressants.

THE PRESIDENT: But growth, do they mean the market will expand?

MR. TURNER: It appears to mean that, yes.

Now, if we go to the ninth point. Events in the market which transpired support the CMA's case. The appellants' case against us is that they undermine it and conflict with it, and we say they do not.

There is unequivocal evidence before the Tribunal that GSK did not reduce the price of 20mg Seroxat at all in 2002 or 2003 in response to the authorised supplies. You will recall that 30mg is not included in the deal anyway.

If you go to {S/6/27}, you have our skeleton and a figure in it, which is derived from the decision and included in one of the expert reports. There you see the movement of Seroxat prices from January 2002 forwards, marking on it the entry that took place by GUK and then Alpharma at the relevant times.

There is no upset, no disturbance at all, no constraint whatsoever, and from January 2002 there is no doubt about the data. You will hear from the economists, and any attempt that is made to question the movement in the Seroxat price comes by looking at data in 2001 which is less clear than the data in 2002 and 2003, which is unequivocal and accepted.

THE PRESIDENT: That is because of the mark-up on the wholesale; is that right?

MR. TURNER: It is, because from 2002 we have good reliable solid data showing you the actual prices. Prior to that there is less clarity about how one deals with it, and so the economists had different approaches to estimation.

That is the ninth point. Tenth, there is also very solid evidence that the Generics did not respond to one another's entry either. So IVAX did not lower its prices in response when GUK came in, and neither IVAX nor GUK cut their prices at all when Alpharma came in. If you go to {S/6/28} you see there movement of IVAX prices with lines showing GUK and Alpharma. No response. Then GUK, once Alpharma comes in. This is not competition. You will see that in relation to IVAX not only do you not see a reduction, but you will see, if anything, after GUK's entry, an increase.

That is the data. Now, if you go to the contemporaneous statement by Mr. Reilly of GSK, in October 2002, and you will find that at {E2/28/1}. This is his evidence in October 2002 in the patent proceedings.

If you go in it to page {E2/28/6} and read paragraph 6.6, take it from four lines down:

> "However, GSK concluded, since IVAX's selling price to its subdistributors is likely to be above the price which IVAX pays to GSK, any subdistributors' prices to their customers are unlikely greatly to undercut IVAX's own and, therefore, the financial impact on GSK would, again, be minimised."

6.7:

> "I believe the current situation, therefore, is that the price at which both IVAX and its subdistributors sell Distributed Paroxetine has remained stable since the coming into effect of the IVAX Agreement. In reality, the price of Distributed Paroxetine is probably slightly higher than parallel imported paroxetine. This is because purchasers of Distributed Paroxetine are willing to pay a slight premium to avoid perceived customer resistance to parallel imported products."

So one sees, therefore, in these different ways the evidence of the main witness and the evidence of what happened. No competition.

MR. GLYNN: There had been competition between the parallel importers and the Generics people; there had clearly been a major change in the market.

MR. TURNER: Yes, the Generics come in, as we have seen, you are quite right, sir. They replaced the parallel importers and they took their sales all the way down.

MR. MALEK: He confirms that in paragraph 6.8.

MR. TURNER: Yes, that is right. So far as the sales of GSK's Seroxat is concerned, though, you do not see impact.

Now, 11, the final point is that the average prices in the market remain available all the way to December 2003, and that is the time when, if I may use the expression, the dyke is breached by Apotex. Independent entry materialises. At that point you get the sharp drop in prices.

If you go to our skeleton at {S/6/74}, please. That is the movement in prices if you take the figures from our expert economist Ms. Webster to see what happens.

You see Seroxat in the average overall price of paroxetine and you see the figure for what happens. If you then turn the page, please, {S/6/75}, you then have the build-in of Dr. Stillman, the expert for GSK, how he says prices moved. We will see that really you do not find any material change in the picture. Before independent generic entry, you have a very small drop in average prices, which is due to what has been called by the experts a mix effect, which is essentially the mechanistic consequence of GSK having allocated controlled amounts of paroxetine to GUK and Alpharma, which they sell at a price which is slightly above the parallel import price, as far as the evidence of Mr. Reilly is concerned, but to a small extent have replaced some Seroxat sales.

THE PRESIDENT: That is the 14%.

MR. TURNER: Yes. Now, I stand back and say that it is clear from these essential facts that the contested agreements were designed, they had the purpose of avoiding the risks of what has been called in this case a true generic competition through making reverse payments to the Generics.

If you go to our skeleton at {S/6/61} and paragraph 141 at the bottom. I just ask you to run your eye over these. These are a list from the evidential record showing that the parties' expectations were not that there would be genuine competition at all. You will see (a), the skeleton argument supporting the application for an interim injunction where GSK submitted -- you will need to turn the page, I am sorry.

It will enable GUK to sell at the parallel import prices. That is what it is envisaged there. It will not enable it to undercut the price and destabilise the market.

Then I think for the rest if I could just ask you in your own time to read paragraph 141 to save time.

THE PRESIDENT: Yes.

MR. TURNER: I just say that true generic competition is not the CMA's phrase. A number of the business people have used that phrase, including Mr. Eddie Hart of GUK and Andrew Collier of Alpharma.

If I could go to {B1/13/1}, here you have an email from Mr. Hart of October 2002(sic) which is the day after the interim injunction.

I would ask you to look at that and look at the second paragraph:

> "Going forward you may also be aware that Norton [which is IVAX] have signed an agreement with GSK to launch the GSK 'generic' version of this product. We are not fully informed as to the nature of this agreement but it is very likely that Norton will be heavily controlled by GSK in the amount of product they can sell and the price they will sell it at -- probably a penny or two under the PI [parallel import price, I suppose]. Also, Norton are free to sublicence the product to other generic players. We have been offered this deal but frankly the terms are not interesting to us. In fact they could well play into our hands. Assuming Norton launch limited quantities into the market in December [the earliest date we have heard] we will only have to wait a further three months to launch our own product which we know will be much more competitive than Norton.
>
> "Additionally, it will be patently clear to our customers that Norton again are the generic spoilers in this regard in aiding and abetting a multinational company by preventing true generic competition and artificially managing the situation which can only harm the short-liners."

It is a type of wholesaler:

> "This point should be clearly stressed."

So that is the use of the phrase "true generic competition" in the perspective of GUK at that time.

If you go to {A6/108/13}, please, this is an extract from a witness statement, you can read the entire document, of Andrew Collier who is a witness for the CMA in this case, in the Alpharma litigation in 2002.

It is dated 24th July 2002. If you take it from about eight lines down, in paragraph 37 he says:

> "Although Generics UK and IVAX are already on the market, everyone is aware that their product is in fact sourced from GSK and is therefore not a true developed generic product. Our proposed product is and that is important to market perception. The market will be aware that there are constraints imposed by GSK on IVAX and Generics UK relating to their supply of paroxetine. Being truly independent will mean that Alpharma's product will be viewed to be a true alternative to Seroxat, which will help us not only enter the market but also maintain our usual market share. The same

rule as to the reluctance of directors and patients to move brands applies to us. If we are able to establish Alpharma's paroxetine as a true alternative before others come on to the market, we will have built up a position that is difficult to assail."

You see there a recognition by both GUK first and Alpharma second that this is a form of ability to compete, if they come on with an independent product, which is different from the state of affairs that prevails under what they have called "generic product from GSK".

THE PRESIDENT: This is his witness for Alpharma in the Alpharma litigation; is that right?

MR. TURNER: That is right. We can go to the first page {A6/108/1}. You will see there it is dated 24th July 2002. He says in paragraph 2 what he is making the statement in connection with.

Sir, that is before the hearing which takes place a week later.

THE PRESIDENT: Yes. He was the sales and marketing director, I think, at Alpharma.

MR. TURNER: That is right.

At this point it is convenient to make a general comment about the appellants' approach to facts in this judicial appeal.

If the appellants had wanted to make a root and branch attack on our understandings, the authority, the public authority's understanding of the documents and evidence in our administrative decision, for their judicial appeals to you, they could have called the protagonists.

We do have, it is true, Mr. Reilly of GSK who is coming to court, and he was a major figure. But they have not offered up any witness who would otherwise come, because they were involved in the negotiations of these deals or were privy to the thinking.

Mr. Kon said on behalf of GUK yesterday, and I quote {Day2/11:1}:

"Without giving evidence myself, I know Mr. Rosenberg well enough to know he believes all patent challenges will ultimately win."

That was close to giving evidence himself.

THE PRESIDENT: Yes, well, we disregard it.

MR. TURNER: Ms. Ford indicated that Actavis had not made efforts to bring the witnesses on whom they want to rely to court. They were not employed by the company anymore.

Well, Mr. Collier, who is one of the key players is available to come to court. He is a witness, and GSK and the two Alpharma appellants could have sought to cross-examine him. They have not done that. Their approach to the presentation of evidence to this Tribunal is not sufficient when the appellants are all relying heavily as part of their case on their subjective confidence in the strength of GSK's assertions of patent rights.

MR. MALEK: Just one thing here. How was LPP dealt with during the inquiry? Because if you are someone, let us say, at GSK and you are forming a view as to the strength of the patent, your likelihood of winning this litigation, surely that view would be informed on the basis of legal advice, would it not?

MR. TURNER: Yes. We did not ask for, and we had no right to ask for, professionally privileged advice. It is their prerogative if they want to say this is what our view was to waive that privilege.

MR. MALEK: Yes. So we neither have the underlying witnesses at the time, apart from Mr. Reilly, but we do not really know what advice they were getting at the time so it is difficult to get into their minds as to what they thought the true merits were.

MR. TURNER: That is so. The problem is that their case is now relying on their subjective assessments at the time.

MR. MALEK: Yes.

MR. FLYNN: I beg your pardon, sir, I was just going to point out that of course we have got a witness statement from Ms. West who is a patent attorney, and that is of course in the file and not being questioned.

THE PRESIDENT: I think this criticism is not being directed at your client. I was going to clarify that.

MR. FLYNN: Thank you.

THE PRESIDENT: Because not only that, but the witness who is going to be cross-examined is very much the negotiator from GSK. Am I right, the points you are making are really directed at GUK and Alpharma?

MR. TURNER: Mainly, that is so.

THE PRESIDENT: Because you have two witnesses from GSK.

MR. TURNER: Yes. In relation to Ms. West there is a slightly different point we have made in our skeleton.

THE PRESIDENT: But I mean --

MR. TURNER: She now says --

THE PRESIDENT: Let us park her for a moment. But is there anyone else you say GSK, as it were, ought to have called and have failed to call and adduce evidence from?

MR. TURNER: Well, there were a number of people at their end involved in the deal. In one of the documents, you have seen a lady called Cynthia Robinson was attending the meetings with Mr. Reilly. Cynthia Robinson is a lady who communicated the information to Rachel Parr, who is Mr. Reilly's successor.

THE PRESIDENT: There is Rachel Parr, I see that because of what she says in her note that you rely on.

MR. TURNER: Cynthia Robinson was another possibility as well. She was at the meetings.

MR. FLYNN: Ms. Robinson was the lawyer, as I pointed out when discussing Ms. Parr's note.

THE PRESIDENT: I thought she was a patent attorney. Is she a lawyer?

MR. FLYNN: She is an in-house lawyer --

MR. TURNER: She is a lawyer.

MR. FLYNN: -- at GSK.

MR. TURNER: She was there at the meetings as well.

THE PRESIDENT: Yes. At some point I would like to know are you asking us to draw an adverse inference from the failure to call, for which you know there is established authority, of (inaudible) inference. You will not deal with that now.

MR. TURNER: I will not deal with that now. What I do say now is that it is not a sufficient approach for them to prove the case that they are advancing vehemently before you.

Whether I go further and say you can draw an adverse inference, I will reflect on.

THE PRESIDENT: That is a further stage.

MR. TURNER: Yes. All openings of three of the appellants, excluding Mr. O'Donoghue and Ms. Kreisberger, were devoted to a granular consideration of what was meant by particular individuals who have not been called as witnesses, in documents which were shown to you and which were relied on in the decision.

I will turn to examine specific aspects of the facts a little bit later and I will be as brief as I can be on that. But for now, I would say this is an important deficiency, this is a judicial appeal and it is not a sufficient approach.

THE PRESIDENT: We made our view fairly clear about what weight we attach to interviews ten years later from people who were not prepared to come here and give evidence, or have not been called to give evidence. I do not say they are not prepared to come, but they have not been asked to come.

MR. TURNER: The CMA applied the European and the parallel UK competition rules to the facts that I have outlined in skeletal form and found that the agreements had as their object restriction of competition. They saw what the agreements were doing, what the restrictions were. They looked at the context. They looked at the objectives and they found that the very nature of this sort of agreement was antithetical to the competitive process.

If I may, just before leaving object, I will just take you to one further authority for perhaps a basic proposition, but it is an ancient authority. {Auth-I/4/32}

This was referred to in our skeleton. It is a 1969 case about the Quinine Cartel. It is therefore in the pharmaceutical industry.

THE PRESIDENT: Just to be awkward could you give me the bundle number in the hard copy?

MR. TURNER: One thing I can say about that is that our skeleton argument was very diligently updated overnight to a hyperlink, so if you go to our skeleton argument --

THE PRESIDENT: I am very grateful for that, and we are all very grateful for that and that it was done so quickly. I am still working off the old one because I have annotated it quite heavily, but I will replace it and that will solve that problem.

MR. MALEK: So what paragraph are you in in your skeleton?

MR. TURNER: I will have to find it. Chemiefarma.

Volume 16, tab I, subtab 4 {Auth-I/4/33}.

This is a case, it is a classic case, but you get two points of relevance from it. At paragraph 117 there is a reference to the problem. There was a gentlemen's agreement between companies which guaranteed protection from each domestic market from producers of various member states.

125:

> "The applicant maintains that owing in particular to the shortage of raw materials the sharing out of domestic markets, as emerges from the exchange of letters of October and November 1963, had no effect on competition in the Common Market."

They say it had no effects.

127:

> "On the other hand such a situation cannot render lawful an agreement the object of which is to restrict competition in the Common Market and which affects trade between the Member States."

128:

> "The sharing out of domestic markets has as its object the restriction of competition and trade within the Common Market."

This is an illustration that where you are talking about an object restriction, what actually happens with effects is not relevant, and secondly, that there is no need for long experience to be gained before you see that a kind of agreement antithetical to the competitive process itself can be characterised as having the object of restricting competition.

Mr. Flynn said on Day 1 that our effects case recycled the object case. It is {TR/1/51]. That is not correct. If you go to {S/6/64}.

THE PRESIDENT: Sorry, are you moving on? Have you finished object?

MR. TURNER: I have finished object.
THE PRESIDENT: You are starting effect.
MR. TURNER: I am explaining what we found which was object and why, and I am now going to briefly talk about effects and what we actually found because this relates, sir, to a question that you raised with Ms. Kreisberger yesterday.
THE PRESIDENT: Yes. I am just thinking if you are starting the effects section --
MR. TURNER: Not yet. This will take a few minutes.
THE PRESIDENT: Yes, fine.
MR. TURNER: If you go to -- yes, we have it on screen now -- paragraph 146 and 45. At 145 we point out what the object case is about. It focuses on the anti-competitive nature of the agreements, it looks at what their purpose was, what they were by their very nature.
Effects is different because it looks at elements beyond the purpose of the agreement. It looks in particular at whether restricted generic entry was likely to increase competitive constraints in this case and it relies in particular on what was to be expected to happen given the market conditions and the nature of these agreements, what was expected to occur.
It was borne out by events because we saw that GUK's and Alpharma's entry had no discernible impact on Seroxat prices, GSK's prices whatsoever. That is CMA decision paragraph 7.2.
To the extent there was any impact on average prices in the market, that was trivial and essentially due to a product mix effect, not due to any competitive interactions between GSK and the authorised companies.
Now, sir, finally I come on to a point that you raised yesterday. The counterfactual, that recognises that it is not possible, it is simply not possible to reconstruct exactly what would have happened if this chance of independent generic competition had been closed down at an early stage.
THE PRESIDENT: You are moving to effects now?
MR. TURNER: I am happy to stop. This will take only a minute or two. I only wanted to raise one point on the counterfactual and the approach. I am happy to --
THE PRESIDENT: We might want to raise some points, Mr. Turner, on the counterfactual.
MR. TURNER: In that case I am happy to wait.
THE PRESIDENT: We will come back at 2 o'clock.
(1.00 pm) (The short adjournment)
(2.00 pm)
THE PRESIDENT: Yes, Mr. Turner.

MR. TURNER: Sir, what I am doing now is not a detailed investigation of the effects case, but I am explaining the analytical approach that was taken. I have talked about the object case and been through that and explained the approach.

THE PRESIDENT: Yes.

MR. TURNER: To introduce the effects case, it is sensible to start with an element of the *Lundbeck* judgment.

If you can go, please, to {W/1/99}, we know that the *Lundbeck* cases were decided on the basis of object alone.

Here, this is page 99 of the main *Lundbeck* judgment. If you go to paragraph 472 at the bottom of the page and read from there:

> " ... inasmuch as the applicants submit that the Commission should have examined the counterfactual scenario in the present case, it must be recalled that, as regards restrictions on competition by object, the Commission was only required to demonstrate that the agreements at issue revealed a sufficient degree of harm to competition, [it includes the competitive process] in view of the content of their provisions, the objectives that they are intended to achieve and the economic and legal context of which they formed part, without being required, however, to examine their effects."

Then 473:

> "The examination of a hypothetical counterfactual scenario -- beside being impractical since it requires the Commission to reconstruct the events that would have occurred in the absence of the agreements at issue, whereas the very purpose of those agreements was to delay the market entry of the generic undertakings ... -- is more an examination of the effects of agreements at issue on the market than an objective examination of whether they are sufficiently harmful to competition. Such an examination of effects is not required in the context of an analysis based on the existence of a restriction of competition by object."

So that is the legal context in which we find ourselves.

THE PRESIDENT: Yes.

MR. TURNER: Our counterfactual in the CMA decision --

THE PRESIDENT: What you take from that is no need for a counterfactual as regards the objects case?

MR. TURNER: Yes.

Also, though we take the point, because it is entirely correct, that in a case such as the present where what has been done is payments in order to stop early steps being taken on the road to entering the market, that it is impracticable for a competition authority to say what would have ultimately happened had those steps been followed through. Patent litigation and what the outcome would have been being one such uncertainty.

You have seen the way that the European Court therefore approaches this question. It is simply wrong to stop these steps from taking place by means of a reverse payment.

Those steps are themselves protected by Article 101.

THE PRESIDENT: That is why they say it is an object case.

MR. TURNER: Yes. The counterfactual that the CMA has adopted here recognises that it is not possible to reconstruct exactly what would have happened in the market if the chance of independent competition had not been adjusted out at an early stage.

In this context, our counterfactual is that there would have been a more competitive market situation in place at the time of the agreement but for the making of these contested agreements. That could only logically have taken one of two forms. Either you would have had a real concrete possibility of true generic competition if either GUK or Alpharma had continued the litigation to judgment, the patents had been tested in court, or else the generics would have struck a settlement with different terms making the numbers right for the generics, allowing them to compete more effectively than on the basis of the deals which were made.

THE PRESIDENT: Those are two possibilities.

MR. TURNER: Those are the only two possibilities. You are in litigation, you either press ahead, or if the anti-competitive option is taken off the table, accepting a payment in return for the entry restriction, then if you are going to reach a settlement at that point the settlement will have terms which, in order to ensure that, again to quote the GUK executive, the numbers are right, would need to involve giving them value without the payment in cash or the cash equivalent.

THE PRESIDENT: The thing I struggle with is when you say a real concrete possibility of true generic competition, that is another way of saying a real concrete possibility of no generic competition.

Those are the two, depending on how the litigation is resolved. If one can say a counterfactual is a possibility and that is enough to say there are effects, well, yes, of course it is a possibility. But is that really enough? Not even a probability, just a possibility; not a fanciful possibility, but a real possibility. Is that really enough to say it has anti-competitive

effects when there is equally a likely possibility that there would have been no generic competition at all?

MR. TURNER: Yes.

THE PRESIDENT: It may be because it is, in practice. I do not know what went through the Commission's mind precisely because if the court says the Competition Authority cannot reconstruct it, that they did not feel they could bring an effects case, that is speculation. Just to do it and say a counterfactual can be one possibility when there is another equally likely possibility, that is a striking proposition.

I do not know if it has ever been held anywhere that that is enough when there is an equal and opposite and wholly uncompetitive possibility.

MR. TURNER: Can I respond to that in a number of ways. The first is to point out, although it is not currently before the Tribunal and I was not going to take you to it, in the *Servier* name Commission decision, which was also a pay for delay case, they have produced an effects case and it does follow this approach.

Second --

THE PRESIDENT: If that is relied on, we would need to look at it.

MR. TURNER: Yes, and we can come to that.

Second, though, we do not put it in terms of there was a possibility of an outcome occurring, had that outcome occurred prices would have formed as such. The way we put this case is that were these agreements not struck, at that time there would have been a competitive process left to continue.

You will recall the way that I opened, which was to show that in this industry that phase including the patent challenge itself is regarded as an expression of competition itself.

The reasoning is that by taking these steps to pay for stabilisation, what you avoid is a competitive situation from continuing. One may say, well, why have you chosen that particular point, why do you not choose a year in the future? The time at which you choose for the counterfactual scenario is apt if you choose the time when the agreement was made and at that time what would have happened is that in either of the two respects that I have outlined a more competitive process would have been there.

THE PRESIDENT: I do not think the way I understood those passages you took me to to say that the litigation is a competitive process. It is part of how generics and patentees/originators compete in one sense, but it is not a --

MR. TURNER: They do say, and it is part of the case, that even the litigation itself, it is as with applying for an administrative marketing authorisation, viewed in this way is itself part of

the competitive process. It was particularly clear in one of the passages from the Commission decision that I took you to earlier, and I will get that reference. I will have the page reference and the recital in a moment.

That is the way that the case is put. That is the way that it is expressed in the decision, and at 7.2 in the overview the effects section --

THE PRESIDENT: This is in 7.2 of?

MR. TURNER: This is of the decision itself.

THE PRESIDENT: Our decision or rather your clients' decision, the one we are concerned with, yes.

MR. TURNER: 7.3. 7.2 I was covering earlier which was that the starting point, and I will come back to it in a moment, is that there is no change, there are no benefits to consumers, there is no discernible impact at all.

Therefore, if one is conducting a form of weighing exercise to say, well, you are in the position of needing to weigh benefits from these agreements against benefits from not having entered into them, the case is that any benefits look at the completely flat profile of Seroxat prices and only a trivial change in relation to overall average paroxetine prices, there is nothing to weigh in the balance.

Then when you get to 7.3 --

MR. GLYNN: Sorry, this is not yet on the screen.

THE PRESIDENT: You need to give a bundle number.

MR. TURNER: It is V/1 ...

MR. MALEK: 326.

MR. TURNER: {V/1/326}, thank you.

THE PRESIDENT: It is 7.3.

MR. TURNER: "In the absence of the infringing agreements, it is likely that the relevant litigation would have continued and the validity ... Would have been tested [which is part of the competitive process] ... or else the parties would have entered into settlements on terms that reflected the real uncertainty that GSK faced about the strength of its patent claims. Had GUK and/or Alpharma pursued their strategy of independent entry by progressing litigation, there would have been the real possibility of a victory for GUK and Alpharma ... Alternatively, if the parties had settled their differences, the agreed terms would not have involved the transfer of value by the incumbent to delay independent entry by the challengers."

THE PRESIDENT: As I say, it is taking a more than fanciful possibility as an applicable counterfactual, which is unusual.

Suppose we said yes, that is right, so there is restriction by effect and then subsequently the purchasers, whether it is the NHS or pharmacists, never mind, there is a group of purchasers, they bring a damages claim, it is an effects case so we have been damaged. We would have had all the benefit of the lower prices through what you called earlier true generic competition. The court would say, well, you have to show that on a balance of probabilities. You might not. It all depends on -- it is a loss of a chance, it is no more than that.

One would have to look at what might have happened in the patent litigation. We would be avoiding all that by just saying, well, it is still an effects case even though it is not necessarily a balance of probabilities that that would have happened; it is just a possibility. That is what I find perplexing, speaking for myself. It is unlike any other effects case that I can think of.

MR. TURNER: I will return to it in greater detail, but just to reiterate, although that paragraph does end by referring to the outcomes that might have occurred, the gist of this is to say that at the time when the agreement was struck, the likely effect, indeed certainly the effect, is to prevent competitive processes from continuing which might have taken one or two forks in the road.

MR. GLYNN: Forgive me, is that different from simply saying that the effect would have been the end of litigation; in other words, the settlement itself?

MR. TURNER: Yes. It is saying the point in time chosen for the counterfactual is the date when the agreement was struck, and observing that at that time the litigation is going forward. But there is a process to test the validity or whether the patent is infringed which is interrupted by the payment made by the incumbent.

MR. GLYNN: Interrupted by the settlement of the case, is it not?

MR. TURNER: It is interrupted by the payment producing the settlement or as part of the settlement, yes.

THE PRESIDENT: The whole of the agreement. Everything in it is what stops it.

MR. TURNER: Yes.

THE PRESIDENT: Looking at it as a whole.

MR. TURNER: Yes. The payment for the entry restrictions which include, if you are in the litigation, discontinuing the litigation, stopping the litigation.

MR. GLYNN: The trouble I have with that is that it is very, very close to saying that settlement, because it stops this part of the competitive process, is itself anti-competitive, which I do not think is where you want --

MR. TURNER: It is absolutely not. It is the reverse payment which is a key facet of the vice. So you have to put the two together, both in the object side of the case and in the effects analysis. I am certainly not saying that merely to prevent the stopping of litigation is itself a problem, but where the incumbent is paying a challenger in order to achieve that effect.

THE PRESIDENT: But litigation is the competitive process.

MR. TURNER: Is a part of it.

THE PRESIDENT: The agreement, whatever is in it, whoever is paying who, is preventing that from going ahead. Unless the agreement is one that also has true generic competition as a result, it is stopping the competitive process.

On an effects approach, it is quite different from object, it seems to me. Why does the payment make a difference?

MR. TURNER: Although patent litigation is itself part of the competitive process, that is not to say that settlement outside of it is not equally part of the competitive process. It is. The only feature that makes it anti-competitive is when you have the two together and you have the incumbent making a payment in order to achieve the discontinuance of these steps towards independent market entry.

Two more points and perhaps I will move on, and I will come back later or in closing to the question of effects.

The first, sir, is to return to your point about the *Lundbeck* decision and my response. I have been helpfully reminded of the reference. It is the recitals I took you to before {Auth-F/16/212}, recitals 625 and 626.

It is expressed in very clear terms:

> "Patent litigation, which is very common when new generic products become available through expiry of exclusivity on originator medicines, is in fact an expression of the independent efforts of generic undertakings to enter the market ..."

I have taken to you this before.

THE PRESIDENT: Yes.

MR. MALEK: Yes.

MR. TURNER: The other point to conclude, and I will come back to this in a few moments, is that when a settlement is concluded without a reverse payment being made by the incumbent, there the terms of the settlement are competitive because they do accurately

reflect the strength and weaknesses of the patent position in a competitive fashion and not in the way that merely means that the parties to the agreement are better off.

So that is the analytical approach to the effects case. The CMA contends that for either or both of those reasons, object or effect, these agreements infringed Article 101.

MR. GLYNN: Forgive me yet again, the term "reverse payment", does it simply mean a payment from one side to the other, from the --

MR. TURNER: No.

MR. GLYNN: How do you define it?

MR. TURNER: It has a narrower meaning. If you have our skeleton, it is defined in various places, but we quote an extract from the Supreme Court in the US in the *Actavis* case.

There the justice opens by referring to a reverse payment.

THE PRESIDENT: It is bundle {S/6/5}.

MR. TURNER: Yes, in paragraph 11, thank you, halfway down the quotation:

> "Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a 'reverse payment' settlement agreement."

THE PRESIDENT: That makes sense when the infringer has gone onto the market, but when the infringer has not gone onto the market, whether because it has refrained of itself because it wanted to wait for the outcome of the litigation and see what happened on the challenge to validity before it -- it did not want to enter at risk, in other words -- or there is an injunction, it seems to me it makes no difference, you would not expect it the other way round because the "infringer" has not actually infringed it so it has not suffered any loss. So the originator has not suffered any loss.

MR. TURNER: Yes.

THE PRESIDENT: So the infringer would not be paying it.

MR. TURNER: Let me put it another way and just leave it here for the moment.

If the direction of the settlement suggests that the patent rights are maintained, as GSK says their integrity is maintained, and no longer challenged, then in those circumstances the patentee has won effectively. Yet you see a payment being made by the incumbent to the challenger in those circumstances.

There is a tension between the outcome as the parties arrive at it and the direction of the payment which is made. That is the feature that causes the puzzlement. You ask yourself in these circumstances: what is GSK getting for its payment? What is it paying for? The answer was given in candid terms by GSK in paragraph 4.26 in its response to the statement

of objections: to maintain the status quo, to maintain stability and commercial certainty. That is the puzzle.

Now, whether this case is, under Article 101, won by object or by effect, once that paragraph is engaged it is then for the parties to the agreement to show that the agreement can still be justified under paragraph 3 of Article 101. It is not a per se wrong.

If we go to *Lundbeck* {W/1/105}, you will have paragraph 498.

Reading five lines down:

> "The anti-competitive object of those agreements being sufficiently established -- since they amount to agreements excluding potential competitors from the market in exchange for payment ..."

There, by the way, is a very succinct description of what gets you through Article 101(1):

> " ... even if they might also have benefited competition and consumers ..."

If they might also have done so. Recall *Consten v Grundig* in the argument there:

> " ... those effects must be demonstrated by the applicants and examined in the light of Article 101(3) ... and not evaluated by the Commission in the context of the first paragraph of that article ..."

So the show is not over, but you now move to the applicants to do this.

If we go to page {W/1/142} in this judgment please. At 709, to remind the members of the Tribunal, at the foot of the page, you see the four conditions that then have to be met by the parties to the agreement:

> "... [contributing] to improving production or distribution or ... technical or economic progress."

Number one.

No restrictions which are indispensable to the attainment of those objectives. That is progress. Number two.

Consumers get a fair share of the benefits. Number three.

And fourthly, importantly:

> "... must not allow undertakings to eliminate all competition or a substantial part of that competition in respect of the products in question."

The fourth condition is obviously very important in this context, although we say the contested agreement fails to meet any of them because it is clear from the evidence before the Tribunal that these agreements were designed precisely to eliminate all competition to Seroxat in a substantial part of the products in question. It was the explicit aim.

If you go to bundle {A9/172/17}, you have the European Commission's guidelines on how to approach Article 101(3).

They say at paragraph 105 -- take it from the second sentence:

> "Ultimately the protection of rivalry and the competitive process is given priority over potentially pro-competitive efficiency gains which could result from restrictive agreements. The last condition of Article 81(3) [now 101(3)] recognises the fact that rivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the shape of innovation. In other words, the ultimate aim of Article [101] is to protect the competitive process. When competition is eliminated the competitive process is brought to an end and short-term efficiency gains are outweighed by longer-term losses stemming inter alia from expenditures incurred by the incumbent to maintain its position (rent seeking), misallocation of resources, reduced innovation and higher prices."

As I say, this is a case where you have seen the documents.

The aim was precisely to achieve stabilisation and to protect Seroxat from competition.

Having said that, I now turn to certain further conceptual points which will be important for the Tribunal's judgment.

There are a number of profound differences in the approach to the substantive question of infringing competition law taken by the appellants compared to the CMA.

I dealt with the first of those, the proposition that patent litigation is prior to and separate from the competitive process. They say it is the antechamber before any form of potential competition can exist, but another aspect you can find in paragraph 6.93 of GSK's skeleton at {S/2/136}.

Could we go over the page to {S/2/137}. This is their reference to what they have termed the IP bargain:

> "An important aspect of the context in which the agreements were struck derives from the IP bargain, which the CMA purports to recognise but in fact seeks to undermine at every turn in the present case. It is a feature (justified in the public interest) of the research-based pharmaceutical sector that the grant of a patent enables the holder (if, but only if, the product or process is successful) [but which I think they mean commercially successful] to earn profits which offset its upfront investments in research."

That is not what we understand to be the IP bargain.

The IP bargain does not involve paying potential competitors not to challenge a granted patent. IP bargain only protects patents that have not been granted in error or which are genuinely infringed.

In the same paragraph GSK goes on then to say:

> "A necessary corollary of such a system is that the patent holder will always stand to lose more by the removal of patent protection than any single generic company stands to gain by removing it (asymmetry of risk). Inherent, therefore, within the true context of the litigation of the type at issue in this case is the possibility that, for reasons having nothing at all to do with the strength of the holder's patent (which might be overwhelmingly strong), any settlement of litigation with a generic company -- even one whose case against the holder is hopeless -- risks over-compensating the generic company."

Now, this account misses, from a competition and consumer perspective, one very important point. A private settlement between two pharmaceutical companies where the incumbent buys off a potential competitor may well be satisfactory to both of them, but it comes at the expense of the customer. If the situation is that an incumbent typically has a very strong incentive to pay off potential rivals to preserve its profits, which Glaxo rightly recognises there, then there is a particular urgency in competition law protection applying to protect the consumer interest for that very reason.

This is the first area of substantive debate between the parties. The settlement deals under which large cash and other transfers were made by GSK do, in a sense, reflect the parties' mutual assessment of the strength of GSK's patent assertions.

The fact of GSK's unexplained large payments reveals the risk that the patent assertion may fail in court, and that is precisely the problem. If a settlement deal is going to be reached, the risk should be reflected in competitive terms which do not cut out the consumer interest.

The second substantive conceptual area is the intense focus --

THE PRESIDENT: Just one moment.

MR. TURNER: Yes. (Pause)

THE PRESIDENT: Yes.

MR. TURNER: The second area is this. It is the intense focus which has been given on the appellants' side for the supposed need for you, the Tribunal, in this hearing to inquire in a different way into what was the strength of these patent rights asserted by GSK, or at least into what GSK and the others now say that they genuinely thought about them at the time.

If you go to GSK's notice of appeal at {A/2/28}, please, you have paragraph 1.51. What they said there was, in introducing their appeal -- this is the notice not the skeleton:

> "Whether any of the generic companies could have entered with a paroxetine product was the issue in the avoided litigation. That precise question is now moot and cannot be determined in this appeal, and certainly could never have been determined by the CMA. The important point for present purposes is that, in GSK's submission, the CMA has no ability to establish that any of the generic companies could have entered independently of GSK. In other words, it cannot say whether any of the agreements actually restricted competition."

So GSK recognised at that point, at the beginning of its appeal, that it is impossible for this Tribunal and for the CMA to consider the details of the outcome of that litigation over the patents, despite, if I may say, the very intricate account which was subsequently given in chapter 2 of GSK's skeleton.

Not only is it an impossible task, it is also, in our submission, unnecessary. It is unnecessary because, as the *Lundbeck* judgments show, the concern is with agreements that transform the uncertainty of the litigation and whether you have a 40% chance or a 50% chance, or any degree, it transforms the uncertainty of the litigation result into a certainty of no independent market entry in return for a payment.

If you please go to {W/1/85} you have an important paragraph in the *Lundbeck* judgments, paragraph 401.

Sir, are you --

THE PRESIDENT: Yes, we have it.

MR. TURNER: It is page 85, paragraph 401. You can take it from halfway down:

> "Replacing that uncertainty in relation [the litigation] to whether or not the generic undertakings were infringing and to the validity of the applicants' patents with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue constitutes, as such, a restriction on competition by object in the present case, since that result was obtained through a reverse payment ..."

What the Competition Authority has to show is the level of uncertainty at the time of the agreement, and there is overwhelming evidence of it in this case.

THE PRESIDENT: I can understand that in terms of an object restriction. But I struggle with it in terms of an effects restriction.

MR. TURNER: Sir, I understand that. I will need to come back to that.

GSK also seems to be claiming that the ultimate question in infringement in competition law has to depend on the subjective assessment of whether in the minds of the parties in the litigation there was a belief that one side was going to win in court.

That explains the way in which the opening submissions of several of the appellants were presented to you. GSK relies on *Lundbeck* for that idea, and if you would please go to {S/2/138}, you have internal page 137 of GSK's skeleton, and at page 584 at the bottom of the page they say:

> "The General Court recognised in the *Lundbeck* judgment at [352], that an entry restriction which 'arise[s] exclusively from the parties' assessment of the strength of the patents' does not amount to a 'buying off' of competition."

So they take that from the *Lundbeck* judgment.

Then if you go to 6.94, the end of that page:

> "The presence of direct evidence as to the parties' views of their patent position must trump the information gleaned through making this indirect inference."

THE PRESIDENT: Sorry, you are where?

MR. TURNER: It is the same page. It is the end of paragraph 6.94, just above the number "6.95" in the middle of the page.

The last sentence concludes their reasoning process there, that although one might infer from the fact of a payment that there is a perception of risk, in fact, the presence of direct evidence, last sentence:

> "... as to the parties' views of their patent position must trump the information gleaned through making this indirect inference."

At 6.95 they continue:

> "That evidence shows that GSK was confident in the strength of its patent position (whilst wisely not regarding it as 'impregnable'). The CMA has not engaged at all with GSK's evidence as to its confidence in its patents (and notably the defence contains no discussion at all of the witness statement of Ms. West, whom the CMA does not propose to cross-examine). Similarly, by the time of the agreements, the generic companies had no confidence that they would be likely to succeed; rather they were fairly certain that they would lose. Moreover, even to the extent that GUK did consider that it was able to produce a non-infringing product ... this view was based on a belief that GSK firmly believed to be incorrect ..." and so forth.

GSK have mischaracterised the General Court in *Lundbeck* in footnote 584 for a very important proposition by using a truncated quotation.

If you would please go to {W/1/74}, this is the first paragraph I took you to in opening, but you will see that that is not what that paragraph says.

It says:

> "... where a reverse payment is combined with an exclusion of competitors from the market or a limitation of the incentives to seek market entry, the Commission rightly took the view that it was possible to consider that such a limitation did not arise exclusively from the parties' assessments of the strength of the patents but rather was obtained by means of that payment ... constituting, therefore, a buying-off of competition."

So the General Court there says that where two elements are present, the reverse payment combined with the exclusion of competitors or the limitation of incentives, then one can consider that such a limitation does not arise exclusively from the assessment of the strength of the patents. To put it another way round, the fact that the originator makes a reverse payment to the generic to achieve the settlement, itself reflects the weakness in the originator's assessment in the strength of their patent.

The appellants argue that the economic expert on behalf of the CMA, Professor Carl Shapiro, and his "pay for delay" inference, is inconsistent with our legal analysis. You heard that over the first couple of days. GSK says Professor Shapiro just puts forward a rebuttable inference that a pay for delay agreement is anti-competitive.

If you go to {S/2/145} and you look at paragraph 6.121, you see they say that there:

> "It is ... the very essence of [his] theory that it only permits ... [an] inference to be drawn ... even where an originator makes a cash value transfer, all that is established by his theory is an 'inference' which can be 'support[ed]' or 'undermine[d]' by the contemporaneous evidence. A large cash value transfer is; inherently suspicious' -- but that does not make it an infringement, still less an infringement by object."

That is wrong. It is a mischaracterisation, as you will read when you read Professor Shapiro's evidence in full, hear from him as to what his position is.

His evidence on the pay for delay inference is in his main report. I will take you to one extract now at {H/1/15}.

Within his report -- this is his main report -- you go to section D, which starts at paragraph 57 on page 12. There we are. Under the heading "Pay-for-Delay Inference", at 57 to 59, which are very important paragraphs in his report:

> "The net result of this analysis is that one must ask just what the branded drug company received in change for a Reverse Payment it made to the potential generic

> entrant, to see if this is a deal that disrupts the competitive process. If the Reverse Payment is otherwise unexplained, then given the features of the pharmaceutical industry described above ... this points to the conclusion that the payment was made in exchange for delayed generic entry or some other anti-competitive restriction that weakness the ability of the generic firm to compete. I call this the 'Pay-for-Delay Inference'."

His opinion matches the CMA's case that an unexplained reverse payment in a patent settlement agreement allows you to infer that this is a deal that disrupts the competitive process. Similar to paragraph 352 of the *Lundbeck* judgment.

If cash is handed over by the originator as part of securing an entry restriction, the inference applies then and there. In the framework of the European competition rules, there is an agreement with the object of restricting competition. Pay for delay agreements can still be justified, but under our legal system that then happens in the context of Article 101(3).

The appellants point out that Professor Shapiro has said that if the value which is transferred to a potential entrant under the settlement deal is not cash, then further analysis is required. They treat that as though Professor Shapiro is saying that even when you do not have a large cash payment as well, you cannot conclude as an economist that there is behaviour which is inherently disruptive of the competitive process until further analysis happens. Again, that is not what he has said. He is clear in the report that an agreement involving paying a potential rival not to compete independently is disruptive of competition; paragraph 57, in fact 57 to 59 as a whole. The inference falls to be drawn straightaway when you observe that behaviour.

What he means by the need for further analysis, picked up by my learned friends, in the non-cash case is that where you have got a supply agreement or something like that in the mix, it is not cash, you do need to check to see if that also is simply another part of the value transfer from the incumbent. I was debating earlier with Mr. Glynn it is equivalent to the passing of cash. Or if it is an arrangement which merely provokes competition between the entrant and the incumbent which may lead to customer benefits.

In this case, Professor Shapiro reviewed the CMA's analysis. He saw that the supply agreements here involved allocating a fixed volume of product to the generic companies, and his conclusions in his main report are at {H/1/26}, paragraphs 110 and 111.

111, we can focus on:

> "The CMA's economic analysis does not conclude that the settlement agreements are anti-competitive based solely on the presence of value transfers ... The CMA

examined how the supply agreement operate in context. The CMA found that the supply agreements work to prevent competition between the generic entrant and the patent holder, which would have led to lower prices to customers. Therefore, the transfer of a restricted volume of product was economically equivalent to a cash transfer of a portion of GSK's monopoly profits from Seroxat. Since the supply agreements did not give rise to an increase in competition, it is clear as a matter of economics that the value transfers observed in this case were not designed to bring about an increase in the competitive constraints faced by GSK."

So to conclude, the reference to the further analysis that Professor Shapiro refers to as being somehow undermining of our case is not right.

A third main area of difference between us, which leads directly on from that, is this. The appellants fasten on the fact that the settlements in this case were not only characterised by cash payments, they were involved in making what we are terming authorised agreements with the generics' fixed volume products.

Their case is that the making of these supply agreements meant an increment in competition compared with the status quo ante. It is better than it was. They say it worsened GSK's position, therefore it must have been competitive. It worsened GSK's position, therefore it must have been competitive.

If you go to {S/2/142}, you have GSK's skeleton. Look at paragraph 6.111. GSK says, if you go six lines up from the bottom or so:

"If the agreements are instead evaluated against the prevailing position, [status quo] given that the generic companies had established no independent right of entry," established, "the agreements inevitably and predictably did worsen GSK's position. That is in the nature of a compromise. This particular point is another reflection of one of the central oddities of the CMA's position, namely that generally when pursuing restrictive agreements, the competition authority does so on the basis that the impugned agreement did, or could be expected to, lead to higher prices, lower output, poorer quality and so on than prevailed before the agreement was entered into. It is no part of the CMA's case that these effects were to be expected here."

Now, as per the title just above 6.111, this is used to support the proposition that the supply agreements were "inherently pro-competitive". That claim is incorrect. Yes, GSK's position did worsen because in order to induce the Generics to drop the patent challenges and to counter the risk of true generic competition, it paid them off with cash and by

sacrificing a margin on the product allocated to the Generics as well. That is not inherently pro-competitive.

In line with the CMA's analysis, there was no observable impact at all on the price of Seroxat. There was no competitive process of rivalry at all to supply pharmacies. All that they have is a very small product mix effect, which reflects the fact that although the supply agreements were designed to have limited financial impact on GSK, inevitably the authorised generics would not only displace all the parallel imports, which they did, they would also take some business, previously supplied from Seroxat at slightly lower prices, at the parallel import price or perhaps slightly above.

GSK sacrificed that business intentionally. It was equivalent to a cash payment. It was not a competitive arrangement.

Now, on the other side, Dr. Stillman for GSK produced originally a report called the "consumer welfare effects report". He argued in it that there were theoretical circumstances that it can be better for customers than a simply early entry settlement agreement, better for them, if an incumbent pays value to a generic to enter a supply agreement.

This, you will have seen from the skeletons, is the so-called annex 4. But all that Dr. Stillman's annex 4 does is emphasise that our own case does not fit his model. Professor Shapiro has pointed out in his responsive report that Dr. Stillman's model is based on an assumption that the generic entrant is free to choose its own output levels. It has the scope to get more in and to compete with it.

If you go to {H/1/26}, back in Professor Shapiro's report, that is paragraph 113:

> "Another critical mismatch is that Dr. Stillman's annex 4 model assumes that the generic entrant is free to choose its own output levels. As a factual matter, the settlement agreements at issue in this case do not involve the generic companies paying per unit royalty to GSK and choosing their own output levels. Instead, they involve the originator supplying a fixed quantity to each generic ... at an agreed price. If agreements of this type are studied in Dr. Stillman's annex 4 ... his conclusion that 'a value transfer may be necessary to provide the generic supplier with an incentive to enter into this kind of welfare enhancing agreement' is reversed. In his model, no such lump sum cash value transfer is then necessary: a low enough transfer price will always provide a sufficient incentive for the generic ... to enter into the agreement. I prove this formally in appendix D."

So that is the response to one of the major points ahead of the hot tub that you will be conducting with Professor Shapiro and Dr. Stillman.

There is then Dr. Majumdar, who is an economic consultant acting on behalf of GUK who has put forward a new argument. He says that even though the supply agreements allocated fixed volumes, they still often gave wholesalers the possibility of buying paroxetine at cheaper wholesale prices than they were getting for parallel import products. The wholesalers have then got extra cash available to them, extra cash that they can use for competitive purposes. So, he says, that is a competitive benefit.

In fact, the evidence in this case is that the wholesalers demanded traditional, conventional terms from suppliers for different kinds of product. There was a certain mark-up applied to branded goods, to generic goods and to parallel imports. If you want to get parallel import products to market through a wholesaler, the wholesalers conventionally charge 3.5% mark-up, 3-5% mark-up. I will just give you the reference rather than taking you there: footnote 611 of the decision.

If you want to get generic products to market through full line wholesalers, the conventional mark-up that will be taken by the wholesaler then is 20% of the price paid by the pharmacy. This was covered in the responsive expert evidence of Ms. Webster. But the fact that wholesalers may, as a windfall in some cases, have had extra cash available does not exclude a naked anti-competitive agreement being struck between GSK and the generic suppliers, because these supply agreements effectively led to market sharing that was akin to GSK giving sales in a particular region to an entrant. Because GSK had no intention of competing for the allocated sales. It had no incentive to do so. It sacrificed its profit margin, it did not react.

These supply agreements were part of a wider arrangement to keep up the high prices of Seroxat across most of the market, to immunise most of the market from any competitive constraints.

If GUK wants to argue that this pay for delay arrangement could be justified because it gave some wholesalers extra cash simply as a function of applying their conventional terms, then GUK would need to put forward a case to that effect under paragraph (3) of Article 101. It would be difficult because there is no indication in any evidence that extra cash for some wholesalers in 2002 was a benefit that reached pharmacies at all or put any pressure on GSK.

It is also implausible that in the long run such a temporary cash benefit in 2002 for one drug in the wholesaler portfolio, presumably hundreds, would have led to wholesalers improving services generally, and there is no suggestion of that.

Essentially, just as in *Lundbeck*, where you had cash payments coupled with supply agreements in two of the cases, the supply agreements here were just a vehicle for giving supplemental consideration to GUK and Alpharma.

So that is my introduction to the economic evidence ahead of the hot tub. It is 3 o'clock and it may be sensible to take a short break.

THE PRESIDENT: Yes. We will come back just after 3.05 pm.

(3.00 pm) (A short break)

(3.10 pm)

MR. TURNER: Sir, in terms of timing, I am not going to finish today but I am not going to have a very long opening tomorrow. I am going to make efforts overnight to try to compress this as much as I can with, if I can, a view to finishing in the morning tomorrow.

There is a witness, Mr. Reilly, who is coming on next and there will be a question about whether he comes on Friday or on Thursday afternoon. It could be convenient for him to come on Friday rather than Thursday afternoon, but shall we see how we go?

THE PRESIDENT: Yes. Well, liaise with Mr. Flynn and his team.

MR. TURNER: Yes.

MR. FLYNN: Dr. Reilly will be here tomorrow, so if Mr. Turner finishes in the morning then we could make a start.

THE PRESIDENT: In the afternoon.

MR. FLYNN: And Mr. Sellick, who is following, will be available on Friday afternoon.

MR. TURNER: We will see. In relation to Dr. Reilly, with a little bit more time I might be able to cut that down a little as well.

THE PRESIDENT: Can you help me on one thing. When you were criticising the way the appellants, as it were, mischaracterised the case, you say, or Professor Shapiro's argument, and the perception of the parties' chances of success in the patent litigation therefore is not relevant, but at the same time you do rely on those internal documents, or the decision relies on those internal documents as indicating how internal views were taken, it is said, by some people in GSK of weak patents, and so on. How do those fit together? What, then, is the relevance of the internal documents about the parties' views at the time?

MR. TURNER: The law, sir, as you know, under restrictions by object is that you adopt an objective approach but that you are permitted to take into account subjective intentions as well.

Here, what happened in the administrative procedure is that the appellants did put the case and they had put it in the appeal on the basis of subjective intentions, and this is responding

to their case in relation to that without in any way upsetting our primary case, which is that you can find a restriction by object directly by observing the factors that the European General Court says are necessary and sufficient, constitute as such a restriction of competition by object.

THE PRESIDENT: So what you say is you do not need the internal documents to look at the nature of the agreement against the propositions in *Lundbeck*, and you say that establishes restriction by object. But if you do look at the internal documents, contemporaneous documents, that supports that conclusion because it shows the subjective intent of the parties.

MR. TURNER: Yes.

THE PRESIDENT: Do I have it right?

MR. TURNER: Yes, you have.

Now, I am very shortly going to turn to the facts, but one or two final conceptual points.

THE PRESIDENT: Just before we leave that, on the internal views of the parties, we then have the patent attorney from GSK, Ms. West, who gives her view of the patent's strength.

MR. TURNER: Yes.

THE PRESIDENT: Which has not been challenged.

MR. TURNER: Yes.

THE PRESIDENT: Do we not have to accept that view as therefore the view?

MR. TURNER: No.

THE PRESIDENT: How does that fit? If you are not going challenging --

MR. TURNER: No, you do not. It is the position that we have set out in our skeleton, which is that where -- shall we go to *Lundbeck*, paragraph 139 at {W/1/32}.

Essentially, while that is coming up on screen, in this sort of case contemporaneous evidence, where you are looking at parties' views and intentions at the time, is of value.

Where parties put forward witness statements much later in time, this is paragraph 139, in order to say, "Well, back then I can tell you it was a very strong position", that is to be given limited weight.

It is certainly admissible, but it is your judgment on the weight to be given to it. Where contemporaneous documents show that the position reveals real uncertainty, then that is the best evidence for the Tribunal on which to act.

If you go over the page to paragraph 141 {W/1/33}, the last sentence of the General Court's ruling there:

"In any event, that subsequent evidence cannot be decisive in the examination of the potential competition between the parties to the agreements at issue."

Which was the issue they were considering.

We have pointed out in our skeleton that this Tribunal took a similar sort of view to the approach to weighing evidence as long ago as the *JJB* case in 2003. We can find the reference if needs be. But there, the Tribunal very clearly said that we may have witnesses giving evidence before the Tribunal now many years later, but if the documents at the time tell a particular story, we give that more weight.

MR. MALEK: I can understand the weight point, but in this case you do have the possibility of cross-examining Ms. West, do you not? It is your choice. You can say, well, look, her evidence may be exaggerated, it may not be credible because of the incentive referred to at paragraph 139, or you may say that is it not better to look at the underlying documents created at the time as in 141. But does that allow you to effectively have a free kick by saying you have got the statement, you can discount it, without us actually having seen Ms. West and you putting the general points that you want to put, which is, surely your views are coloured by the passage of time, inconsistent with the contemporaneous documents etc?

MR. TURNER: My primary answer is yes, you are entitled yourselves as the Tribunal without cross-examination to take that view and without the need for us to do that.

Secondly, I point out that in that particular case of Ms. West, you do not find anything there that is so sufficiently clear and strong as to undermine the case that we are putting in any event.

THE PRESIDENT: We will look at it, of course, but as I recall she does say that I thought these patents were strong patents.

MR. TURNER: Yes, she may say now that those patents were strong patents. She does not say that these were patents that they were going to win and she could not possibly --

THE PRESIDENT: She says there is a risk. One can see that. But if on subjective intent you want to rely on the internal documents and she was saying, well, actually, I had a different view and I was involved at the time, and I was involved in the decision-making, normally you would put them to her and you would cross-examine her on them and suggest either her memory is faulty or her view was not shared or whatever. But in some way, because otherwise we are left with a witness in this case, not someone making a statement elsewhere many years later that cannot be challenged. There I can well see one can say, "Well, you cannot put much weight on that", but this is a bit different.

MR. TURNER: Yes, sir. I cannot take it further other than to say that we have taken the view that when you add that unchallenged evidence to the totality of the evidence before the Tribunal, it does not upset the fundamental part of the CMA's case, which is that there was uncertainty of outcome.

THE PRESIDENT: Yes, I think --

MR. TURNER: That is a feature, moreover, that is consistent with her evidence. The precise degree of belief in the strength of the patent, we say, is neither here nor there, and that is why, for example, when you read what is chapter 2 of GSK's skeleton argument, you see a very, very close analysis, blow by blow, of what they thought at every individual stage. That sort of material is not helpful, even if a witness were to come forward with that sort of approach. Our approach to the case is that what matters is uncertainty, which is then removed by a reverse payment.

THE PRESIDENT: And the fact that it may be that GSK thought it had an 80% chance of success, say, whatever strong patent means, not certain, but strong, one might think 80%, much, much stronger than *Lundbeck*, that does not matter.

MR. TURNER: No, it does not, and the fact of uncertainty matters. You see that in return for removing the uncertainty, payments are made --

THE PRESIDENT: Yes, at the high level point it is the subjective, it is the next stage of what does the subjective intention -- what part does it play and how do we assess subjective intention given Ms. West's evidence as regards GSK.

It does not obviously help regarding Alpharma and GUK, but it seems to us quite material for GSK. It is certainly, it seems to me, somewhat different from the view that Rachel Parr expressed in that note, which everyone seemed at some point to get excited about. CMA make quite a bit of it in the decision and GSK has gone to some length to try to play it down, and so on.

MR. TURNER: It is a good contemporaneous note.

THE PRESIDENT: But on this view that is not really very relevant anyway because we have someone else saying it is strong and you say it is just the fact that it was not quite certain or not. A degree of uncertainty is what matters.

MR. TURNER: We say that you are entitled to place in context paragraph 139 of *Lundbeck* and the *JJB* authority, the fact that this is what one might expect when witness evidence is put forward for the company many years later, and that you need to bear that in mind when you are assessing the weight to give to it.

THE PRESIDENT: Just a moment. (Pause)

It may be something that you can explore with Mr. Reilly.

MR. TURNER: There is that point as well, that where -- and this goes back to *Yarn Spinners* and the Restrictive Practices Court -- but where you have more than one --

THE PRESIDENT: You do not have to put it to each one.

MR. TURNER: Yes.

THE PRESIDENT: But I am not sure you can just, as it were, leave it and say we can just discount it because it is many years later when it has not been challenged with a witness.

MR. TURNER: Yes.

MR. FLYNN: Sir, if I might point out also, sir, Ms. West is the patent attorney. You can put questions to Dr. Reilly, but he is not the patent attorney.

THE PRESIDENT: He took the decision.

MR. FLYNN: Of course.

THE PRESIDENT: He would have had the advice.

MR. FLYNN: Of course he would, but I also make the point Ms. West made her statement being prepared to, and fully expecting to, be cross-examined on it and that does change, in my submission, the inferences that Mr. Turner is able to draw, even those fairly weak ones that he is now making for the first time.

THE PRESIDENT: Yes.

MR. TURNER: Sir, I think we will leave this for the moment on the basis that, as I say, Ms. West refers to and accepts the uncertainty which is the basis of our case.

THE PRESIDENT: Yes.

MR. TURNER: A fourth main difference between the appellants and the CMA is this. That GSK in particular argues that it is a wrong approach to consider whether the contested agreements harmed customers. The focus should be on whether the NHS reimbursement rules were triggered, because generic paroxetine, manufactured by GSK, became available from different sources, triggering a category change and an administrative cost saving. Four points only that I will make about that at this early stage --

THE PRESIDENT: Can I ask you, and I am sure it is in the evidence, but if you could, it would help me -- maybe my colleagues are ahead of me. Could you just give a short potted summary of -- I do not think it is controversial -- how the reimbursement rule works and the category point?

MR. TURNER: Yes.

THE PRESIDENT: Just to get the context.

MR. TURNER: It is explained in the decision. I do not have the decision immediately to hand. It is something like 3.106 and following, if I remember correctly.

THE PRESIDENT: It is a while since I read that. Maybe I should --

MR. TURNER: We can go to it. It is 3.106 and following.

THE PRESIDENT: I will go back to that and read Mr. Horridge and not trouble you.

MR. TURNER: I will take one or two minutes then just to explain it: that while there was only the branded drug being supplied domestically, the reimbursement rules of the NHS meant that the list price given to the drug by that manufacturer formed the basis for reimbursing pharmacists who paid for it and dispensed it.

When there is not only that one manufacturer but other suppliers and wholesalers also providing a version of the drug --

THE PRESIDENT: It is still one manufacturer.

MR. TURNER: There is one manufacturer, but now you have also --

MR. FLYNN: No.

MR. TURNER: You have the other suppliers and you have wholesalers as well, in particular AAH and Unicare being supplied through this new route, and when you have that in the mix too, then there is a change in the category of reimbursement applied under this system of rules there was at the time from category C to category A.

Because of that change in the category, the reimbursement price from the NHS to pharmacists who dispensed the medicine went down. This was the reference to the £15 million-odd that Mr. Flynn was talking about. That happened, it was prompted by the first of the agreements with IVAX. When IVAX enters into the supply agreement, then you had IVAX, AAH and Unicare, and then there was the category change.

On that side of the room they say that this change and the change in the rules that it led to is a competition benefit which must be taken into account in the case, and it is a way in which they say these agreements were competitive because they led to benefits to the final consumer, the National Health Service.

There are various mechanisms by which periodically the NHS recalibrates and checks whether the amounts it is reimbursing to the pharmacists is right. This is called the clawback system. In the long term it is accepted on all sides that the aim of the NHS is to reflect the amount that pharmacists have to pay in the amount that they reimburse, and it is done periodically by way of these recalibrations.

There was some argument about whether the clawback would have caught up with or recognised any competitive benefits because pharmacists would have received lower prices or not. So that is essentially the case.

If you go to our skeleton at {S/6/40}. I will now see if the hyperlink works. You should have at paragraph 85 at the bottom our case on this, and it goes from paragraphs 85 to 94, which we encourage you to read.

Our first response to it is that it is very clearly wrong in law. If you go over the page to {S/6/41}, you see a reference to an earlier case, a GlaxoSmithKline case indeed, in the Court of Justice.

Reading from 86:

> "There, the General Court had found that it was not appropriate to hold that certain agreements limiting parallel trade had the object of restricting competition in the pharmaceutical sector."

This was the General Court:

> "That was because the regulatory framework of the relevant member states at the time ... meant that it could not be presumed that parallel trade would have an impact on the prices charged to the final consumers of medicines reimbursed by the national sickness insurance schemes, and thus would confer advantages on them. The General Court noted that the prices of the medicine concerned were to a large extent shielded from the free play of supply and demand owing to regulations, and were set or controlled by the public authorities ... could not be taken for granted that parallel trade tended to reduce those prices, and thus to increase the welfare of final consumers ..."

Then you had the appeal.

87:

> "The CJEU, on appeal, overturned that finding ... paragraphs 62-64 ... stated in particular: 'there is nothing in [Article 101(1)] to indicate that only those agreements which deprive consumers of certain advantages may have an anti-competitive object. Secondly, it must borne in mind that the court has held that, like other competition rules laid down by the Treaty, Article 81 EC aims to protect not only the interests of competitors or of consumers, but also the structure of the market and, in so doing, competition as such'."

If you click on the link at the bottom of paragraph 87 it should take you through to the relevant parts of the judgments. So it works. {Auth-I/36/13}

This, it is simply wrong. The second point, though, is this: that even to the extent it is right to treat the NHS as completely co-extensive with final consumers and just say, well, we ignore people paying for the drug on private prescriptions which has not been looked at, the focus in competition law is on the competitive process. As a matter of basic principle it is about how restrictive agreements and behaviour might impact on the competitive process. The fact that you get a change from category C to category A of the drug tariff, reimbursement price, when the first of these agreements, IVAX, is made, before the GUK, before the Alpharma agreement, that was a consequence of an administrative mechanism. It was not the outcome of competition.

I will give you a reference in our decision. It is {V/1/452}, 10.73. That is the point I have just made. It is in the decision. Do you want to read that and over the page? But I shall not take you to that now.

Fourth, you have clear evidence, and I foreshadowed it, that it was IVAX's entry in 2001. It was not GUK in 2002. It was not Alpharma's entry, February 2003, after an agreement in November 2002 that caused the change in the drug tariff category in June 2002. I can say more about it, but for present purposes for opening that is probably sufficient.

Finally, then, before turning to the facts, I want to highlight just one further curiosity that emerged from the appellants' oral openings yesterday.

In response to Mr. Glynn's question, page 56 in the Day 2 transcript, Ms. Kreisberger accepted that if it was clear that the purpose of the agreement was to exclude competitors, that would be a satisfactory basis for calling it an object restriction {TR/2/56}. But she emphasised that has to be clear on the facts, and we agree.

Now, the Tribunal has heard over two days the appellants' openings and in particular the very strong emphasis of GUK and Alpharma on how lacking in confidence they were by the time of these settlements, their submission, and how any settlement with GSK would be welcome. That was very strongly the gist of their submission.

They took you to some of the documents to show the assessment by the Generics of the advantages for them of these authorised supply agreements, which would give them value. Then later at page {TR/2/74} of the transcript, Mr. Glynn points out to Ms. Kreisberger that presumably the generic firms would have entered without the cash payments. He said:

> "There would be access to the market in itself, which was part of the agreements they reached. It would have had some value to them ...

"... If the agreements had not included any payment but had simply been: we will let you into the market under whatever controls were there in the different cases. They would have entered, would they not?"

Ms. Kreisberger answered:

"We do not know. That is what our economics evidence goes to, that the payment would have been a necessary means to bridge the gap to achieve a settlement involving early entry."

so at that point, having urged the Tribunal that the facts of the case are key and have been ignored, Ms. Kreisberger departs from the appellants' own account of the facts to rely on the expert evidence.

It is not clear to us that Ms. Jenkins, who is the expert for Merck, does say on the facts of this case that the cash payments were needed to persuade the Generics to accept a settlement. But, in any case, the contemporaneous evidence not the ex post facto opinions of consultants is what matters.

With that, I conclude an opening introduction to the general themes and issues in the case and apologies that it has taken quite so long. I am now going to deal with the facts, but will deal with them in a more abbreviated way assisted by the ground that has already been covered.

Before I do that, I will make two overarching comments. The first comment is that the appellants want to make the key question in this case for you to decide: did that part of the settlement agreements which provided for the allocation of product to the Generics cause a small decrease in average market prices? That is for them the key question for you to decide.

In our view, the key question for the Tribunal is a simpler factual one. Once you see that GSK made large cash payments as well as non-cash transfers to the Generics, then the real question to be asked is the one that Professor Shapiro has highlighted in paragraph 57 of his report which we looked at: what were these payments for?

The Tribunal should approach that factual enquiry against that broader question. What benefit would GSK hope to get out of making large payments to companies that were trying to break into the market to compete against it?

One should also ask, by way of background: what benefit would GSK expect to get out of the fixed volume supply agreements that it made with its potential competitors, contributing to improvement in distribution and technical progress, and so on?

It is the first point. The second is that as a matter of judicial process, another dimension not yet touched on, it is important to take stock and ask: what are the findings of fact in the decision under appeal which are challenged?

Section 3 of the CMA decision sets out the facts relied on. In paragraph 6.18, for example, of the decision, the CMA makes clear it relies on those facts and matters for its conclusions on the object aspect of the case. Under the rules of this Tribunal, the notices of appeal must identify to what extent the appellant contends a decision was based on an error of fact.

Merck has clearly indicated in paragraph 5 of its notice, if you go to {A/5/11}, paragraph 5, you see at the top, they do not dispute the primary facts found by the CMA, which are set out in detail in Part 3 of the decision.

The other appellants are less clear, although GSK says -- I will not take you to this, but it is note of appeal 1.9: "there are not many substantial factual disputes on important factual matters".

I am sorry, I do not have the reference to call this up, but they do identify three factual points in paragraphs 1.10 and 1,11. The three factual points are --

THE PRESIDENT: Sorry, this is GSK's Notice of Appeal?

MR. TURNER: Yes. {A/2/15}. Thank you. So at 1.9 you see them saying this is not a case where there are many substantial disputes on important factual matters.

Then they elaborate in 1.10 and 1.11 exceptions to that proposition. There are three of them.

{A/2/16}. The first is, you see this from 1.10, the alleged erroneous calculation by the CMA on the impact of the agreements on prices to pharmacies. They say there, at the top of the page, that prices to pharmacies, the overall average prices, dropped by at least 4%.

That is the first. Then the second is at 1.11 (a), the alleged errors in the CMA's treatment of similarities and differences in the therapeutic qualities of paroxetine and other anti-depressants in the SSRI class.

THE PRESIDENT: That is the market definition for it?

MR. TURNER: Yes, it is. So that is the second factual dispute. That is going to be considered in the abuse of dominance part of this hearing.

The third, at 1.11 (b), is the CMA's description of the administrative clawback aspect of the reimbursement system for pharmacies which purchase and then dispense medicine on the NHS.

Beyond those three things, the complaints by the appellants seem to be either that the CMA has missed out certain material facts, which were needed to give proper context, or that the

CMA has misinterpreted primary facts and failed to draw the correct inferences from them. So that is the area of factual dispute.

MR. MALEK: Just for my own purposes, have they stuck with that in their skeleton argument? Because it seems the skeleton argument does seem to challenge a bit more than that.

MR. TURNER: The skeleton argument is a new departure and we have complained about it because in chapter 2 of the skeleton argument, GSK -- it is extremely long, that is about 80 pages by itself -- but it relies on large numbers of new facts and matters and contains new allegations, including some of primary fact that we have not seen before.

We made a point that this is inconsistent with the Tribunal's guide, paragraph 4.5 (i) and authorities about how things should be done, and, yes, we do say that in the skeleton argument they have gone further.

I can elaborate non-exhaustively, sir, if you would like?

MR. MALEK: What I would like, just for my own purposes, is a piece of paper identifying, from GSK's point of view, and your point of view where they are contesting findings of fact in the decision in their skeleton argument. I can see from the Notice of Appeal, it seemed to me it was going to be fairly narrow and there was not a huge amount of fact, but when I read the skeleton I had a different impression.

So I would like to know what paragraphs and what factual findings in the decision they are challenging over and above what specifically is identified in the notes of appeal and that is probably for Mr. Flynn rather than you. You just happen to be the one standing up.

MR. TURNER: Sir, I agree. We received that as well and we are also in the same position, sir, as you are. We had the same impression.

I will mention now perhaps just one particular matter because as well as a large number of primary facts, they advance an argument that had not been pursued by GSK in its notice, that GSK strongly believed in the validity and infringements of its patents and the generic companies knew that they were on the wrong side of the argument, knew that they would lose, and they were bluffing, not just IVAX but the others, about being in a position to enter the market.

I will leave it therefore, if I may.

MR. MALEK: The impression I got reading the papers before was that this is a case where it seemed that everyone accepted this litigation could go either way and your complaint was that they were buying certainty in place of uncertainty in litigation which could have gone either way. Whereas, when I read their skeleton argument, the impression I get now is that

they are saying, no, this litigation almost certainly would have gone one way and that is in our favour.

MR. TURNER: Yes, that is precisely the point. I think perhaps I will give you the reference to that because that is precisely the case. In their notices of appeal this is one paragraph in which they actually say that there was real uncertainty --

MR. MALEK: I know the bit, I have that.

MR. TURNER: Then when you get to the skeleton --

MR. MALEK: They had moved.

MR. TURNER: -- it is a different account. It is largely all based on seeking to establish something different therefore.

MR. MALEK: Yes, okay.

MR. TURNER: So I now turn to the specific facts and if I can begin with paroxetine and the importance of Seroxat, I will take this very quickly. If you go to {V/1/71} we have paragraph 3.140 of the decision describing the importance of Seroxat. It is a blockbuster drug at the time of the agreements. In 2001, GSK sold £91 million worth of Seroxat in the UK. That is at {V/1/9} paragraph 1.4. There you see the size of the market.£91 million of sales.

Now Mr. Reilly's evidence during GSK's litigation with GUK back in 2001 was that paroxetine was one of the best selling medicines in the UK and the world and was therefore a very attractive target for all UK/European and generic pharmaceutical companies.

Go to {V/1/71}. It is the quote just under 3.140.

THE PRESIDENT: It was their top seller, I think.

MR. TURNER: It was at that time. Then if you go to {S/2/20}.

At 2.56 of GSK's skeleton argument, they say that:

> "In or around the time when [the compound patent] was due to expire," which is January 1999, "GSK understood that it might well face attempts by generic companies to launch generic versions of GSK's paroxetine products in different jurisdictions."

This is now giving flesh to the theory about how the market works in terms of dynamic competitive processes by reference to the facts of this case.

Next, not only did GSK understand that it might face Generics trying to enter, they were very conscious of the threat that that would pose to their sales of their best selling product Seroxat, the prices, and thus their profits. To see the scale of what they had to lose, you go to what their experts said during the litigation with GUK. You can take that from the summary in the decision at {V/1/252}.

Halfway down 6.37 at the top:

> "In an expert report for GSK in the GUK litigation in September 2001, Heinz Redwood (an independent pharmaceutical consultant) put forward the opinion that the impact of generic entry on Seroxat would be 'serious', leading to significant declines in paroxetine prices and a sharp decline in GSK's market share."

Then you see at 6.38 his reference to the extent of the expected falls in price. He quantifies. Then the questions is: Glaxo sees the threat, how does it respond to it? That brings us to Project Dyke.

GSK sets up an internal project team. It is called Project Dyke and it considers ways of defending Seroxat from independent generic entry. Its strategy is outlined in our decision at 3.144 {V/1/72}. It is from this paragraph forward. For your note it is 3.144 to 3.154, ten paragraphs.

We will look at a few documents, but there are three points that are going to come out of this. The first is that Dyke was the defence strategy designed to protect the price, among other things, of Seroxat and GSK's market position and its profits.

The second is that the defence strategy explicitly includes not only seeking to enforce the patents in court, but also entering into what are called co-marketing supply agreements with challengers.

The third is that while Dyke has a pan-European dimension, the UK is not sealed off and separate, it is not irrelevant to the European consideration. The UK market was one of the most valuable of the national markets and it was part of the Europe-wide defensive strategy. Those points are made in the decision. I will just give you the reference without going there because I have it readily to hand: 6.40 to 6.46, as part of the relevant context at the time of these contested agreements. They help to understand the purpose of the agreements and what GSK was seeking to achieve when it made them.

Now, GSK addresses Project Dyke in some detail in its skeleton. Forgive me, again I have not referenced this fully, but I will give you the paragraph numbers: paragraphs 2.56 to 2.69. It basically is making three points. It says that the decision does no more than hint at wrongdoing and is willing to wound but afraid to strike. Second, that Project Dyke is a red herring because no properly run originator would stand idly by without discussing internally how to defend patents against attack. That is 2.61.

2.65, they said care must be exercised when considering documents generated by Project Dyke meetings because it is not always possible to ascertain whether they relate to

European meetings or meetings of the UK IP -- intellectual property -- and regulatory monitoring group. That is 2.65.

They say the net position is that the CMA makes no positive case about Project Dyke. Paragraph 2.64. That is a misunderstanding of the point which is being made in the decision. This is an important part of the specific context that helps you understand the purpose of these agreements.

The best way to appreciate that and see what they were seeking to achieve at the time is to turn up a small number of the contemporaneous documents.

The first is at {B2/31/4}. This is an extract from a document cited in footnote 216 of the decision called "CNS central nervous system -- Psychiatry -- Depression and Anxiety". If you go to fourth page of this document -- you are on it -- this refers at the bottom, three lines up from the bottom under the heading "Anhydrate":

> "Strong co-marketing strategies have continued to sustain Seroxat volume both in these markets and others where anhydrate has approval."

The picture is unclear, but it includes the UK:

> "However there are increasing pressures on pricing where anhydrate has been launched which will challenge the current European floor price for Seroxat in 2003."

If you turn to the next page, please, {B2/31/5} under the map there:

> "With a combination of heightened market awareness to all new registrations for either anhydrate or mesylate, legal and regulatory actions implemented immediately to defend our patent, and co-marketing strategies [so it is two pronged] all orchestrated through the Dyke project, Seroxat has successfully maintained sales in 2002 with only a 2% decline on 2001 performance."

You see the reference to orchestrating all of that through Project Dyke and how successful it has been for Seroxat.

Then at the bottom of that page under the next figure:

> "The levers of anxiety and brand fragmentation as outlined above have yet to significantly impact giving clear indication of the value of Project Dyke [it puts the two together] (patent defence and co-marketing) in maintaining the value of Seroxat in 2002."

What one sees from that is a two-pronged strategy. It has been applied, it has been successful in maintaining profit levels and the two prongs involve not just patent defence but also co-marketing.

Then if you go to {B2/38/5} of this document, you see here one of the next steps. I cannot immediately locate the date for this document, but it says:

"Explore agreement with third parties."

Among them is GB:

"... to draft agreements for internal approval asap. All countries to identify third party players."

I am told it is 11th May 2001, this document.

The next document is at {H3/19/1}, a document cited in the decision. It is December 2002. It is entitled "Seroxat Brand Planning Europe". It is cited at 3.146 to 3.148 of the decision, and 6.42.

There are three points from this presentation. The first is on page {H3/19/4}, point 2:

"Generic defence strategy."

If you look at the defence strategy and what it comprises, the fourth bullet is:

"3rd Party supply agreements."

The second point is a brief reference to how things were going after the IVAX agreement. If you go to page 25, please, {H3/19/25}, the second bullet under the UK:

"Early indications are that total Seroxat revenues are holding up well."

The first bullet says:

"Generic Seroxat launched in mid 2001 -- GSK-Norton co-marketed version of Seroxat available with a price of approx 70% of branded version."

The third point is at page {H3/19/34}, appendix H because this provides an insight into GSK's thinking on the pricing strategy. You see the heading "Price Defence Strategy":

"Defences undertaken to date are crucial to protect Seroxat prices."

The first is the legal challenges; the second is the co-marketing strategies, and a reference to it covering the UK. I mention this because of the point that the European documents are supposedly different, and:

"... allow participation in generic market," important words now, "without undermining Seroxat price."

Finally, just above the heading "2003 Price policy" at the bottom of the page:

"Experience shows that GSK should not drop prices pre-emptively. This only forces a price war. Optimal strategy for branded products generally is to follow price reduction rather than lead."

There, taking stock, one does have a description of what clearly seems to be a wider strategy. We are not saying that that strategy in itself was a breach of the Treaty, but it does

help you in understanding the basis and purpose of the agreements which are before you, which we do say amount to a breach of the Treaty.

So in terms of timing I am planning to run to about, let us say, 4.15 pm.

THE PRESIDENT: That is fine.

MR. TURNER: I turn then to the parties' contemporaneous views on the process patents. As I have outlined, our submission is that the legally relevant question for you is whether at the time these settlement deals were struck you have genuine uncertainty about whether the patents would be held by the court to be valid and infringed.

In their respective opening submissions we have heard from GSK, from Actavis, from GUK and they have each given a different narrative and a gloss on the events leading up to the dates of the settlement. I return to our fundamental point, which is that at the time of the agreements it is clear that the outcome of the patent litigation was uncertain.

If I go back to the important paragraph of 4.26 of the GSK's response to the SO at {A3/46/156} just to remind you, they say:

> "For GSK, the rationale for settlement of the patent disputes was in each instance essentially the defence of its valid patent rights and their commercial value (the status quo) and for this it was prepared to compromise based on its assessment of an uncertain litigation outcome."

Then there are two documents from 2003 which support this view, and I will take them very quickly because the first is one, you have already seen it, is the note from Rachel Parr, who is the finance director succeeding Mr. Reilly, at {B1/6/1}.

At the bottom of the page under:

> "[Weak] patent and stop entering market.
>
> ""Rest of Europe, hands not tied, cos were asking to supply our products and not threatening litigation.
>
> "... payment the agreement were mechanisms for paying a certain amt they settled on. We then devised mechanisms."

That is important because the reference to the terms of being mechanisms for paying a particular amount, in other words, that the payments were not themselves fulfilling specific functions, is important and you have already seen that from some of the documents, that the purpose of these payments was to reach an acceptable level to persuade the Generics to settle.

If you go to {Z/131/9}, this is a response by GSK to the then Office of Fair Trading, describing this.

I am sorry, at 12.5 it is a reference to what the typed notes say:

> "The typed note on the transcript 'to herself as she got up to speed on the historic patent disputes, litigation, settlements and supply agreements' was added in 2006 during the European Commission investigation ..."

When she was asked about that by the Commission. I am not going to make any further submissions about the Rachel Parr note at the moment. You see what it says about the strength of the patent, but also the purpose of the payments. We will be making submissions about the weight that is to be attributed to this document in context.

The final observation on GSK's argument that it had great confidence throughout about the strength of its patents is that their protestations now about the belief in the strength of the patents is to some extent undercut by what happened with Apotex.

Apotex did manage to break the dyke in 2003 in December. In that month the Patent Court finds that the anhydrate patent is invalid in its entirety and is in any case not infringed by the paroxetine product supplied by Apotex, Neolab and Waymade.

If you go to {V/1/66}, you have paragraph 3.135 explaining what happened. Then at 3.136, an important point given, an exchange with Mr. Kon, you see that on 18th December, three lines down:

> "... the interim injunction against the Apotex parties was removed, after GSK indicated to the High Court that it would not seek to maintain the injunction pending an appeal against the first instance judgment."

So at that point, GSK does not automatically say I am going to continue this injunction, it accepts it for its own reasons.

Then the appeal is brought on, if you turn the page {V/1/67}.

THE PRESIDENT: Of course Mr Justice Pumfrey had invalidated the whole patent.

MR. TURNER: He had. At that point he had invalidated the whole patent. He reached conclusions on non-infringement as well. But GSK does not ask, pending a swift appeal, "Can we have the interim injunction maintained" for its own reasons.

That point, it was suggested by Mr. Kon yesterday that if GUK had won at first instance, you can assume that GSK would certainly have maintained --

THE PRESIDENT: Ms. West says that. She explains why the situation was different at the time of Apotex from the position at the time of GUK.

MR. TURNER: All right, sir. I will leave that point. Nor did GSK even try to rely on the hemihydrate or the dry tableting patents.

As, sir, you remarked yesterday when Ms. Ford was opening, neither of those two patents was being relied on against Alpharma at the time of their agreement either, suggesting that with Alpharma the critical one was the anhydrate patent.

Then after December 2003, without the interim injunction being maintained, true generic competition does begin. Apotex enters with a competing non-GSK product and then the other Generics closely follow, including those subject to these supply agreements, GUK and Alpharma.

If you go in the decision to {V/1/165}, there is a table 3.3 and you will see the list there, and you can see the sequence of who comes in when and with what products, 20mg or 30mg paroxetine.

You will see the non-GSK generic paroxetine, halfway down, Neolab and Waymade, firstly 20mg only and then Alpharma with a 30mg dose and non-GSK paroxetine coming through very quickly in rapid succession.

Sir, I am going to move on now to deal with the three Generics as briskly as possible, but if it is convenient to the Tribunal, I can leave that there.

THE PRESIDENT: Just one moment. (Pause)

Mr. Turner, you took the decision that you did not want to cross-examine Ms. West. When was that that you notified us?

MR. TURNER: I will have to check. It was before the PTR.

THE PRESIDENT: That is what we thought.

MR. TURNER: Yes.

THE PRESIDENT: At that point you had the notice of appeal from GSK. You did not have the skeleton.

MR. TURNER: Yes.

THE PRESIDENT: There are a lot more factual issues, as you pointed out, raised in the skeleton on this area than in the notice of appeal.

MR. TURNER: Yes.

THE PRESIDENT: Which very limited the factual challenges.

Now, many more factual disputes have, you say impermissibly, but they have been raised, so it seems to us that it is open to you to reconsider that decision, if you wish, given what GSK has only very recently raised.

MR. TURNER: Yes.

THE PRESIDENT: Which was not in its notice of appeal.

MR. TURNER: Sir, I am grateful. We will do that.

THE PRESIDENT: It obviously would not be tomorrow, but she can be interposed at some point if you wanted to.

MR. TURNER: I am obliged.

THE PRESIDENT: 10.30 tomorrow morning.