**IN THE COMPETITION APPEAL TRIBUNAL**

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

30 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

THE PRESIDENT: Yes, Mr. Turner.

MR. TURNER: May it please the Tribunal, I turn from the specific arguments raised about Alpharma's position, that I was touching on yesterday, to GUK.

Mr. Kon argues first that the interim injunction against GUK, pending trial, should be viewed as meaning that the paroxetine market was not open to competition from GUK. If you go on Magnum to {M/1/5} in Mr. Kon's closing, you have the heading halfway down the page:

> "GUK was injuncted and the market was therefore not open to competition".

At paragraph 2.5, he explains four lines down that:

> "The CMA argues that the injunction was 'temporary'. By contrast, GUK's case is that such a characterisation is misconceived since the injunction would only avoid becoming permanent in the event that GUK was successful in the patent litigation. By describing the injunction as 'temporary' the CMA therefore prejudges the outcome of the litigation and replaces facts with fiction."

What the submission does is to suggest that unless the interim injunction is conceived of as effectively permanent, that we are prejudging the outcome of the litigation and that is, in our submission, the wrong way round. It is precisely if the interim injunction is described as permanent that the outcome of the litigation is prejudged.

THE PRESIDENT: Yes.

MR. TURNER: A key point which is admitted by GSK in its notice is that GSK did view the threat of independent entry by GUK as a real threat to its business.

It therefore made the patent settlement agreements interim injunction or not. That was in express terms, the reference is at paragraph 6.38, we need not go there.

THE PRESIDENT: Of the?

MR. TURNER: Of GSK's Notice of Appeal.

THE PRESIDENT: Of the Notice of Appeal, thank you. 6.38.

MR. TURNER: 6.38. Dr. Reilly expressly confirmed this in his testimony. He was specifically questioned about the reality of GUK as a perceived threat, applying the test that he laid out for assessing when a generic was a threat to the business. If we look at that briefly, that is at {TR/5/63} at lines 10 to 15. That is the conclusion of an extended piece of the cross-examination, looking at the various factors which led GSK to believe that these particular generic companies, well-established companies, were particular threats.

GUK certainly did have real concrete possibilities to break into the market. The evidence is very strong. It was a formidable generic company, it had a marketing authorisation, it was

advanced in its preparations for market entry, and if it succeeded in the litigation, it certainly had the ability to come in quickly, and all of that undoubtedly put pressure on GSK.

In fact, GSK regarded GUK as such a threat at the date of the settlement that it was prepared to pay it to cease its efforts to enter independently, £13.7 million in cash, and at least £7.5 million through the supply of GSK's product, with a guaranteed profit in that case, in a three-year supply deal.

We have seen yesterday that that was an amount which would give GUK a sufficient return on the investment, compared with the more risky, more uncertain efforts to enter independently.

Given what the Tribunal has seen, and given the evidence it has received, one struggles to see how GUK can argue that it did not have real concrete opportunities to get into the paroxetine market because of the interim injunction.

Now, here, following Mr. O'Donoghue, Mr. Kon said that its argument was supported by the European Court case of *E.ON* and *Ruhrgas,* both of them joined in that point. So I will deal with that quickly. There is absolutely nothing in the *E.ON* case to support their argument. It is at {Auth-G/27/1}.

THE PRESIDENT: Can we have the bundle reference.

MR. TURNER: Volume 15, I apologise.

If we go in *E.ON* to page {Auth-G/27/11} you have under the second part, towards the bottom, the submission that the undertakings were not potential competitors at relevant times.

At paragraph 84 the court explains that the competition rules only apply to sectors opened to competition. So if competition is not possible at all, then an agreement which, on its face, prohibits competition cannot meaningfully be said to do it.

The test, the classic test is laid out at paragraph 86 {Auth-G/27/12}, at the top of the page:

> "In order to determine whether an undertaking is a potential competitor in a market, the Commission is required to determine whether, if the agreement at issue had not applied, there would have been real concrete possibilities for it to enter that market and to compete with established undertakings. Such a demonstration must not be based on a mere hypothesis, but must be supported by evidence or an analysis of the structures of the relevant market."

The European Court's application of that test in *E.ON* was completely consistent with the way the CMA has applied it here. On page 12 at paragraph 89, the court found that in a

period from 1946 through to August 2000, there was not a possibility of competition at all in France. Paragraphs 90 to 93, the court found that from August 2000, when a directive for liberalisation should have been transposed, competition in France became possible and although Ruhrgas was in practice only able to serve a limited group of customers, that was still enough for a real concrete possibility of entering the market.

Over the page {Auth-G/27/13} paragraph 98 through to 103, the court explains why in Germany, in the period from 1980 to 1998, you see that from paragraph 98, competition was in practice impossible there, even though it was in theory permissible under German law. That was because public service companies had made demarcation agreements between themselves on a territorial basis and also local authorities had given such companies exclusive concessions.

That was the de facto monopoly that Mr. O'Donoghue talked of. On page 13, paragraph 104 -- I am sorry. {Auth-G/27/14} paragraph 106 the court is concluding that the Commission has not established a real concrete possibility for GDF to enter the German gas market and compete.

It does not matter whether the barrier to entry is legal or factual in nature, it does not matter to the analysis. The basic question remains always whether the standard of real concrete possibilities is satisfied.

That is simply what the CMA has done in our case. It has not tried to show that these generics would definitely have entered the paroxetine market themselves. What it has done is to show that these well-known companies, GUK and Alpharma, did have more than a theoretical chance of breaking into this market with an independent product.

They had the marketing authorisations, they were geared up, they were regarded by the incumbent as a concrete threat as it scanned the horizon. There were real concrete possibilities of entry and the interim injunction obviously does not change that; and moreover it was open to GSK at the date it made the settlement agreement, in March 2002, to have struck a different kind of deal with GUK then. For example, one providing for GUK's immediate entry at that time, subject to the payment of royalties. If such a deal had been struck, there would have been actual competition quickly.

We know that GUK internally considered just such a deal in November 2001. If we go in the decision, please, to {V/1/121} at paragraph 3.289. There you see the quotation from an internal GUK email concerning the draft agreement which GSK had sent at that time and GUK was considering what it might do.

You see under "Suggestions":

"'GSK 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. […] If we win in the USA then all our royalty payments cease […]

"'Advantage is that Sumika is happy and we can control (to some extent) our base costs.'"

{V/1/122}:

"'Disadvantage to GSK, they lose volume and control. (I suppose we could agree to maximum volumes, if needed, to assist a settlement?)'"

Now, on Tuesday, Mr. Kon argued that this route was out of the question for two reasons. The first was that GSK was not prepared to grant that sort of deal and the second was that GSK was legally committed not to grant GUK any different sort of deal.

If we go in the transcript of Day 15, please, to {TR/15/36}. You see at lines 18 down to 22 --

THE PRESIDENT: I think it is enough if you give us those references, when we are just talking about what happened yesterday. I think we can just about remember that, if you give us the references.

MR. TURNER: I will do that.

THE PRESIDENT: You will recall, Mr. Kon made those two points.

MR. TURNER: On the first point, the fact that Dr. Reilly was not prepared to grant GUK a different sort of deal in a world where he saw it as the better commercial option for his company does not tell you anything, because if pay for delay deals are prohibited, it alters the equation. On the second point, it is wrong to say that GSK was bound not to offer GUK a royalty agreement, because it was obliged to mirror the pre-existing IVAX agreement. Reliance was placed on clause 2.2 of the IVAX-GSK agreement, and we can go to that directly so you can see it. It is at {L/1/3}. It is at the top of the page:

"IVAX shall have the right to grant sub-distribution ... rights to third parties ... provided that IVAX shall include in all such sub-distribution agreements all applicable terms and conditions ..."

So forth. That is what the clause says. It imposes an obligation on IVAX, not GSK, and it imposes an obligation where IVAX grants subdistribution agreements. It does not constrain GSK from making separate agreements of a different kind with other companies at all.

THE PRESIDENT: Are there any constraints on GSK --

MR. TURNER: If you go back to clause 2.1 on the previous page {L/1/2}:

"SB shall supply IVAX's requirements of the PRODUCT in accordance with the terms of this Agreement and hereby appoints IVAX as its sole distributor for the PRODUCT ..."

THE PRESIDENT: It is just the sole distributor of the GSK product.

MR. TURNER: Yes.

MR. GLYNN: "... nor grant rights to any other party ..."

MR. TURNER: That is in relation to Glaxo's product.

THE PRESIDENT: Because the product is --

MR. TURNER: It is on 1.5, on the same page.

THE PRESIDENT: 1.5.

MR. TURNER: Yes, just above --

THE PRESIDENT: Yes. But is that not paroxetine hydrochloride as opposed to Seroxat?

MR. TURNER: It says:

"For the avoidance of doubt this shall not include paroxetine hydrochloride sold by SB in the TERRITORY ... as Seroxat."

THE PRESIDENT: Not include, but the product, the definition of the "product" is in schedule 1 on page {L/1/17}.

MR. TURNER: At 1.5, product is the paroxetine hydrochloride included in schedule 1, and which are manufactured by SB. So the obligation relates to product manufactured by SB.

THE PRESIDENT: Yes, I see. It is a rather cumbersome way of defining it but I see what it has done, yes.

MR. TURNER: Finally, on this note, it is worth addressing a point made by Mr. Flynn from Monday about the commercial impracticability of alternative types of settlement like early entry or royalty agreements.

Mr. Flynn's argument was that those sorts of agreements were impracticable because unlike the deals which were done, the supply agreements, those would have sent the wrong signals and shown lack of confidence in GSK's patent.

The transcript reference is {TR/14/22} lines 9 to 15. Mr. Flynn invoked Mark Reilly and, sir, you will recall that Dr. Reilly accepted at the outset in cross-examination the general point that originators certainly do make these sorts of royalty deals with generics for their patented drugs and he was aware too that his own company, GSK, did that.

You put to Mr. Reilly the proposition that a high royalty would not be a sign of weakness, it would be consistent with a strong patent and he accepted that proposition. That is

{TR/6/55} lines 18 to 30. Please do tell me if there are any parts of this that you would wish to look at.

Once that is accepted, GSK's assertion is obviously unsustainable and not least because of the reasons that were given by Professor Shapiro too when he was asked about this topic. He pointed out that other players would generally not be able to observe the royalty level, and they would not know whether it was high or low, and there would be no necessary signal of weakness at all. It is also very difficult to see how GSK can contend that any royalty-based deal would have been impracticable as a sign of weakness, but the actual supply agreements which were made in this case were not equally signs of weakness.

In fact we do know without a shadow of a doubt that what GSK did was perceived, in the marketplace, as a sign of weakness. That was spoken to graphically in the witness statement that you saw from Richard Saynor for GUK itself. Perhaps we should look at the quote there. That is in the decision at {V/1/259} at 6.59. You will recall -- you have seen this already:

> "'In my experience [Mr. Saynor said] of the generics market, no pharmaceutical company has ever attempted to join forces with a generics company to supply a version of its product 5 years prior to the patent on the branded product expiring. Yet that is precisely the position here, which begs the question why is SB doing this? There are only two possible reasons that I can think of. The first and most likely is that it is a reflection of SB's views on the strength of its anhydrate patent, which was granted as recent as 1997. That is to say, the reason that SB is going to start selling generic paroxetine is that it can see that generic competitors will shortly be entering the market in any event, either because the anhydrate patent is invalid or because the competitors have a non-infringing product ...'"

MR. MALEK: Just one question, I fully understand the point that royalty agreements were relatively common, but at the time in 2000 and 2003, the types of agreements we are seeing in this case, were they relatively common or not or we just do not know?

MR. TURNER: Mr. Saynor says no. That is exactly what he is saying here.

THE PRESIDENT: He is talking about the supply agreement, is he not?

MR. TURNER: Yes, Mr. Malek says: the type of agreements in this case, were they relatively common? If we read what Saynor says at the top, that is his evidence.

MR. GLYNN: But the question, I suppose, is also about whether the value transfer element was common in the market?

MR. TURNER: That I cannot -- one thing I can say about it, I will come in a moment to that point more generally, because a number of the appellants have said that this was a large and commonplace category of settlement agreements, so I will need to touch on it.

THE PRESIDENT: We have not really had any evidence one way or the other on that.

MR. TURNER: You have had the assertion there is evidence in the decision which you have not yet focused on.

THE PRESIDENT: Yes, there has been some reference to that, but the point you are making now, about the supply agreement, I think there was a bit of reference to that in Mr. Justice Jacob's judgment as well?

MR. TURNER: Yes.

THE PRESIDENT: Commenting on -- it was GUK's counsel who made a similar sort of submission.

MR. TURNER: Yes.

THE PRESIDENT: Based on this evidence.

MR. TURNER: This is the view in the marketplace. You might also suppose that if generics do observe -- let me turn to the payment aspect and Mr. Malek's point -- suppose that generics do observe an originator paying multimillion pounds to other generics to induce them to cease their efforts at independent entry; that might be viewed as a sign of lack of confidence in the patents too.

THE PRESIDENT: Well, the amount of the payment, that was confidential. Well, the whole agreement was said to be confidential. Obviously the fact that the generic is supplying the product cannot be kept confidential because you can see it in the market. But the actual full deal that was done was kept private.

MR. TURNER: I fully accept that in the same way as one would not expect royalty terms necessarily to be public either. However, to the extent that it was known that a sort of arrangement involving a payment had been made, that would itself very clearly in my submission indicate, if it were the case, a lack of confidence and perhaps encourage "me too" behaviour by others seeking to get a piece of the same action.

MR. MALEK: What you may say is Mr. Saynor's views may be even stronger, had he been told about the reverse payments?

MR. TURNER: Yes. When it was put to Dr. Reilly that the deals done in this very case would be a sign of weakness in no lesser way than a royalty deal, he was, you will recall in cross-examination, unable to give any coherent response. In the interests of time, I will simply

give you the reference again. It is {TR/6/56}. He was asked about that between lines 5 and 33.

That takes me on directly to the related point, which was urged particularly by Actavis in its written closing. Because at two places in their written closing, they say that pay for delay settlements are a large category of entirely commonplace settlement agreements. It is asserted twice in counsel's submission. The implication is that if this sort of agreement, pay for delay, is prohibited, the impact on the good functioning of the industry will be far reaching, and we do not accept for one moment that prohibiting pay for delay settlements will have adverse effects, nor that this Tribunal should proceed on the basis that what Ms. Ford has asserted is right.

MR. MALEK: These are all big players in the market. If GSK has been doing this all the time, they could have given evidence and said: yes, this is just one of many such agreements we have entered into; but we have not seen anything.

MR. TURNER: You have not.

THE PRESIDENT: They might be a bit reluctant --

MR. MALEK: They may be, but they have not given any evidence in support of this proposition. They said there is nothing wrong with these agreements.

MR. TURNER: That is their case, but moreover they do deal with this in their Notice of Appeal at {A/2/135} I think. If we can go there. Paragraph 6.49. This is all that they did say in the appeal, I will take you to the decision part in just a moment but they say:

> "... at Decision 6.23-6.26 the CMA sets out some thinking on '[t]he overall pattern of litigation and settlement in the context of challenges by generic companies in the pharmaceutical sector'. Decision 6.23 gives some statistics from the EPO about percentages of patents revoked, amended and upheld, and success rates for generic companies in patent action. The CMA does not expressly rely in the Decision on any theory of probabilistic patents. GSK simply notes that such statistics can of course provide absolutely no guide to the likely outcome in an individual case and the CMA is wise not to suggest that they might."

If we can go to what the decision says here, it covers more than that. It is at {V/1/247}. The heading is indeed:

> "The overall pattern of litigation and settlement in the context of challenges by generic companies in the pharmaceutical sector".

6.23 is the paragraph that gives the statistics about challenges and the percentage of challenges that were successful in that period, including that only 25% of challenged patents remained intact.

But 6.24 and 6.25 are particularly relevant to the questions the Tribunal has just asked.

6.24:

> "The CMA notes that settlement agreements that do not involve cash payments or other value transfers are common in the pharmaceutical sector. For example, in its Sector Inquiry, the Commission found that over 78% of the settlement agreements in its sample either included no restrictions on generic market entry or included some restrictions on generic entry with no value transfer being made from the originator to the generic."

But 6.25 is also important:

> "Empirical evidence from the United States supports the proposition that branded and generic companies can often settle patent litigation without using value transfers in return for entry restrictions. Although there are legal and regulatory differences between the pharmaceutical sectors in the UK and the US, the fundamental way in which competition in the sector works is sufficiently similar that this evidence is relevant."

THE PRESIDENT: I am rather sceptical about that sentence, Mr. Turner. I think there are very major differences, both in the -- within the Hatch-Waxman protection for first generic to come on and because of the parallel import rules in the EU. It really is a very different situation. I just say that is my own view on that.

MR. TURNER: I understand and take that point on board. Let us finish the sentence, if we can turn the page please, just to see the FTC's statement. {V/1/248}. Because there, although the regulatory environment is different, we nonetheless do see parties finding other ways to settle cases, and what was of interest was that during the period of successful commission enforcement, pay for delay settlements essentially stopped.

So a point of relevance despite the observation, sir, that you have made, is that where pay for delay settlements were previously taking place, when the Commission enforcement began, they stopped. So there was a change even under the constant of that regulatory environment.

THE PRESIDENT: This is in the -- this is set out, sorry -- I have lost you. That is said where?

MR. TURNER: This is the top of page {V/1/248} in italics.

THE PRESIDENT: Yes. It is the FTC commission, yes.

MR. TURNER: Yes. The point I am making is that you can take on board the regulatory environment being different, but in that regulatory environment it appears to have been the case that there were pay for delay arrangements which then stop during the period of successful commission enforcement.

THE PRESIDENT: If you are successful in this case on the broad proposition and if *Lundbeck* is upheld in its broader sense, no doubt it will stop here and across the EU, because it has been found to be unlawful. If the prohibition on them is being enforced, no doubt there will be other forms of settlement, whether to the same extent or whether settlement rates will go down, it is very hard to tell, but that is a bit of a statement of the obvious, that if it had been prohibited and the authority is enforcing that prohibition, it will stop.

MR. TURNER: It cuts out one particular implication. I again take on board, sir, what you say. But if it is being suggested more strongly that if this sort of agreement is prohibited, it is going to lead to a much greater incidence of patent litigation and the courts being clogged up, and parties being less able to reach settlements, this evidence tends to suggest that that proposition would not be right.

If you read on to the end:

> "In less than five years, there were at least as many settlement as there were in the seven years in which [pharma] companies were settling litigation ..."

On the pay for delay basis."

THE PRESIDENT: Yes, I mean --

MR. TURNER: I do not take it further than that, but as a matter of context and in view of the assertions that have been made on the other side, it is relevant to see those findings, and to observe that both the FTC and the European Commission, indeed, have continued to monitor patent settlements regularly now for a number of years and still do.

MR. GLYNN: If we could just, from the same quotation, take the direct answer to Mr. Malek's question, would it be right that about 20% of the settlements before this new period of enforcement came into play might well have included value transfer?

Because 78% do not. I am looking at the end of paragraph 6.24.

MR. TURNER: If we go back please {V/1/247}. That may be so. That appears to be.

MR. GLYNN: It is not entirely clear but it could be obviously -- yes.

THE PRESIDENT: Could I also just check, 6.23, those figures, it suggests that it is referring to pharmaceutical patents. It does not -- it is not quite clear. The last part of 6.23, the third sentence on clearly is because that is the pharmaceutical sector. I was just wondering whether the first sentence and the second sentence ... it does not actually say

"pharmaceutical patents" but I assume it is because it is generic companies, which is the pharmaceutical market.

MR. TURNER: The source is the pharmaceutical sector enquiry.

THE PRESIDENT: If someone could kindly check, but I would assume otherwise, that those statistics are talking about pharmaceutical patents and they are not all patents.

MR. TURNER: We understand that to be the case and we will confirm it.

Sir, I move then to Mr. Kon's next point, which is that a reason for the large payments that it received, GUK, as the price for staying off the market independently, was that GSK was paying it under the cross-undertaking, recognising GSK's exposure to pay damages to GUK for wrongfully having kept GUK out of the market to date.

The argument is not coherent for the reasons I outlined yesterday. It is also not supported by contemporaneous documents. The documents are overwhelmingly clear that GUK was looking for a sufficient sum to remunerate its investment in a general way.

The relevant paragraphs again are 6.136 to 6.139 of the decision. There was a document on which Mr. Kon relied, it is a letter from Mr. Saynor from GUK to IVAX and that is at {B1/18/1} please. So you have that now on the screen.

It is a letter to Mr. Clark of IVAX in January 2002 and in it Mr. Saynor wrote:

> "Whilst there may still be an opportunity to resolve this matter before trial, I wanted to put on record that we have made strenuous efforts to reach an agreement with you but without success."

He wanted to put that on the record.

> "Please note that this letter should be considered without prejudice except in relation to any question that may arise in the litigation relating to costs or Generics UK's claim for damages on SKB's cross-understanding (should we win at trial)."

This does not show that the payment from GSK to GUK was explained by a cross-undertaking. This is a without prejudice as to costs letter written to IVAX which makes a formal reservation from the without prejudice statement that GUK would be free to refer to it in the context of any call on the cross-undertaking.

GUK's next argument is that the payments and allocations of product by GSK, the value transfers, were not sufficiently important as a consideration to allow this Tribunal to conclude that they induced the decision to accept the deal.

This is a variant on Alpharma's argument that Alpharma had already decided it would settle. GUK argues that the Competition Authority has got to show something extreme, that the value transfers from GSK eclipsed other considerations in the mind of GUK.

Now, that is at face value a difficult submission, given all of the contemporaneous documents which I have taken the Tribunal to, and the way in which this submission was supported was explained by Mr. Kon in his oral closing submissions, and I would like to look at these for clarity, please. It is at {TR/15/23}. From lines 5 to 14 he made the point which was not clear from the written closing that he relied on the French language word "eclipse" at a point in the *Lundbeck* judgment and his submission is that:

> "What the court is saying in this paragraph, using the English word 'overshadowed' ... is that the payment overshadowed, it basically wiped out all other considerations. No such case is made here by the CMA."

If we go forward to page {TR/15/25} from line 19, this is where he develops this submission in his oral closing through to the following page, page 26 at line 5.

So the submission was clear in the oral closing and it is plainly not right for three reasons. First, it is plain from a reading of *Lundbeck* that it is not what it says. Take that word and magnify it in that fashion. Second, there is no cogent policy reason that could justify such a test and, third, it is very difficult to understand how one could sensibly assess a case if that were the hurdle that had to be cleared, the benchmark being that this is a consideration that in the minds of the generic eclipsed all other considerations.

On the first point, what *Lundbeck* says, the General Court's reasoning is perfectly clear. If I may here just give a very few references. At {W/4/58}, paragraph 296 --

THE PRESIDENT: This is the generic --

MR. TURNER: This is in the *GUK* judgment. I will not take you back to various references which I am sure you already know in the main *Lundbeck* judgment.

THE PRESIDENT: Yes.

MR. TURNER: Perhaps it is worth spending a moment on the Generic judgment for a couple of other reasons too but at 296:

> "... the Commission cannot be required to show that the reverse payments exceeded the profits expected by Merck (GUK) if it marketed its generics in order to show the existence of a restriction by object. The mere existence of a reverse payment could therefore be taken into account by the Commission [the mere existence] as a relevant contextual element, in order to establish the existence of such a restriction in the present case. In the absence of any alternative explanation that payment may be regarded as consideration for the restrictions ... since it is not certain that Merck (GUK) would have accepted those restrictions in the absence of that payment ..."

It is very clearly put as a "but for" test:

"... and it can be seen from the evidence referred to in the contested decision that it accepted those restrictions provided that the numbers 'stacked up' ..."

Which is language that very closely mirrors the language relating to GSK -- GUK in the present case.

Now, the paragraph we have just read refers back to a number of paragraphs which it is worth showing to the Tribunal, given the submissions that have been made, 262 to 268. If we can go first to page {W/4/51}. It is important because this adds to the reasoning you have already seen in the main judgment and I have noticed that not all of these paragraphs are included on the reading list that you have been given in relation to *Lundbeck*.

262 -- I perhaps should begin at page {W/4/50}:

"The assessment of the reverse payments in the contested decision".

So you can see the topic halfway down the page. At 255, the generic was maintaining that the Commission had reversed the burden of proof by saying:

"... that it was for Merck (GUK) to rebut the Commission's conclusions as regards the value transfer by providing alternative, legitimate reasons."

At 257, at the bottom of the page, five lines down, the complaint is made that the Commission did not address the economic theory they put forward:

"... which clearly showed that the mere existence of a reverse payment does not demonstrate a restriction of competition and depends on the timetable of past and ... future events. In addition, the asymmetry of the risks between the parties as to the outcome of the litigation and its likelihood, and also the risk aversion of one or other of the parties, may explain ... [the] payment ..."

So forth. This is even clearer than we have seen in the main judgment.

THE PRESIDENT: That is the Dr. Jenkins' point?

MR. TURNER: Yes. It brings to the fore some of the arguments you have particularly heard on the Merck side. It is the way that the court deals with it here which is in a sense clearer than you find in the other judgment.

At 262, the first of the paragraphs referred to in 296, the one I first went to, the court finds that:

"Contrary to [Merck's] assertion, the very existence of a reverse payment may constitute an indication of the weakness of a patent and of the fact that the holder of that patent is not entirely convinced of its chances of succeeding ..."

So similar again to the US Supreme Court in *Actavis* {W/4/51}.

If we go forward -- they quote *Actavis* at 263. At 264:

"In a situation where the parties to a settlement agree that there is a genuine risk of patent infringement, it is rather surprising to see the holder of the patent at issue paying the generic undertaking to withdraw its generic product from the market."

{W/4/52}

That is the Commission's explanation we saw for reverse payment in the decision picked up.

THE PRESIDENT: That is not relevant to this case, it is the reverse point, is it, to our case? Because nobody had entered the market.

MR. TURNER: This is -- that was a payment to withdraw. The reverse point is relevant because it was a payment not to enter independently.

THE PRESIDENT: But what they are saying is you would expect the payment the other way round, because -- to compensate the unlawful entry. In the present case you would not expect a payment the other way round. It would make no sense at all.

MR. TURNER: That I understand. However, the point that was made by the Commission more broadly, of which this is an instance, is that if a payment is made to a generic in circumstances where the integrity of the patent is completely maintained, that is the puzzle.

THE PRESIDENT: I do not think it is a puzzle. As you said earlier, it is commercially entirely rational for the payment to go in that direction. It is not a puzzle. It may be anti-competitive but it is not a puzzle.

MR. TURNER: Well, it is a puzzle in the sense that if the criterion is taken to be the legitimate criterion, the prospects in the litigation, if that is the criterion, which is meant to be internalised in the terms of a settlement, then to see someone being paid entirely to stay out when they receive the payment is surprising on that basis.

But you see this developed now, I will quickly --

THE PRESIDENT: But why, I am sorry I do not follow that. Sorry, Mr. Turner, I just do not follow that.

If they have come in and, therefore, have taken some business from the originator, then, depending on strength of patent, you can see it would be odd -- it might be said to be odd that they get paid as opposed to the other way round. It might be. But if they have not come on at all and agreed to stay out, then, unless the patent is 100% inviable, they have potentially suffered some loss because there has been an injunction against them and they are agreeing now to stay out.

So they are the people who are giving something up.

MR. TURNER: Yes. The theory is, we can go back to the original Commission statement, but it is developed a bit further on here, is that if you are agreeing to stay out of the market completely, then this is because there is an implicit acceptance that the patent is valid and infringed.

THE PRESIDENT: We all know that -- no -- the position is that the patent may be to some extent uncertain.

MR. TURNER: No, we do know that.

THE PRESIDENT: Which direction -- it is only about which direction would you expect the payment to go. That is all I am saying, and the size of the payment may reflect the strength -- the parties' perception of the strength of the patent.

MR. TURNER: The direction too -- and perhaps we should go back to see how the Commission explained it, but it is explained a little bit further on here. The direction as well as the size is important, and the reason for that is that if the originator is paying in the litigation settlement the generic which is trying to enter, but the outcome of the deal is something which in its effect means that the patent has been completely validated, then the -- if, leaving aside the commercial considerations we debated yesterday, the focus is on purely the strength of the patent and what would have happened in the case, that is -- the direction is seen as a surprise.

THE PRESIDENT: But why would the generic, if it is agreeing to stay out and has not come on, be expected to pay the originator?

MR. TURNER: The surprise is about the payment to the generic, and that is what I am focusing on in the context of someone who has not yet entered the market.

THE PRESIDENT: But the point they are making is that the payment ought to be going the other way -- and I am saying that is because --

MR. TURNER: I do see that for this case, yes.

THE PRESIDENT: That is all I am saying.

MR. TURNER: Yes.

THE PRESIDENT: Hence this whole concept of reverse payment, or reverse settlement, it does not seem to me that applies in this case, but I do not know if it matters.

MR. TURNER: Let us very quickly come through to the end and I will return to that if need be. At 265:

> "It is true that, as the applicant submits, the asymmetry of risks between the generic undertaking and the patent holder may lead the latter to make a reverse payment in order to avoid all risk, even minimal, that the generic undertakings may enter the

market, especially when the patented product, like Cipramil in the present case, is its flagship product ..."

Pause there. That is the commercial rationality being recognised that we debated yesterday.

THE PRESIDENT: Yes.

MR. TURNER: 266:

"It must be recalled, however, that the fact that the adoption of anti-competitive behaviour may be the most cost-effective or least risky course of action for an undertaking in no way excludes the application of Article 101 ... particularly if that behaviour consists in paying actual or potential competitors not to enter the market and sharing with those competitors the profits resulting from the monopoly rent, to the detriment of consumers, as in the present case."

So there, again, sir, that neatly encapsulates the debate we were having yesterday and it is the perspective. 267:

"From the applicant's perspective, while it is true that the Commission cannot require that a undertaking take commercial risks that it does not wish to take ..."

Pause there. They mean, we are the generic, we are being told we cannot settle in the way we would like to settle:

"... the steps taken and the investments made by Merck (GUK) in order to enter the market in the present case show that it was ready to run the risks that such market entry entailed (paragraphs 66 and 67 above). Accordingly, although Merck (GUK) was not required to enter the market if, having regard solely to Lundbeck's process patents, it considered that that entry was too risky, it could not, however conclude agreements such as the agreements at issue, by which it undertook not to enter the market with its generics in exchange for considerable reverse payments especially where those payments correspond to the profits that it expected to make by entering the market."

268:

"Lastly, it must be found, as the Commission submits, that the existence of a reverse payment may constitute an indication that there is a restriction of competition by object, where it is apparent that that payment induced the generic undertaking not to pursue its efforts to enter the market, as in the present case."

Perhaps a couple more on the next page {W/4/53}. 269:

"Moreover, the applicant wrongly submits that the Commission reversed burden of proof in that respect."

They say at the end of that paragraph:

> "... the applicant has provided no plausible explanation as to why Lundbeck paid it EUR 19.4 million under the UK Agreement ..."

So the no other explanation point is an evidential burden point which they approve as being placed on the company.

270:

> "It must be held, therefore, that the Commission fulfilled its obligations as regards the burden of proof in the present case, in accordance with the case-law ...."

272:

> "It is true that, unlike the circumstances in the case that gave rise to the BIDS judgment cited in paragraph 135 above (EU:C:2008:643), the agreements at issue were concluded in a context in which Lundbeck possessed patents allowing it to prevent the market entry of infringing products."

That is the key point:

> "It must be recalled, nevertheless, that, in the present case the existence of new Lundbeck process patents did not preclude the generic undertakings from being considered potential competitors of Lundbeck, as can be seen from the assessment of the fourth plea ..."

Now we have a sentence that I will be returning to on effects:

> "Article 101 ... protects potential competition as well as actual competition ..."

Finally, if we go to page {W/4/56}. 287. After the survey of the evidence, the last sentence:

> "In the absence of any other convincing explanation as regards the nature and amount of those payments, the Commission could rightly conclude that they had served as compensation that led Merck ... to accept limits on its commercial autonomy."

That shows you the role of the no alternative explanation factor, which was one of the major points arising after the appellants' oral closing submissions. It also bears to some extent on Mr. Kon's point about how these cases are only concerned with factors that eclipse all other considerations, which is not what has been said.

That takes me on to another argument raised by Mr. Kon. This is the claim that the real reason that GUK accepted the settlement did not have anything to do with the value transfers; it was in fact a complete loss of confidence on the part of GUK that it would be successful in the patent litigation.

This was again put more strongly in oral opening than it had been in writing, if we can go to that please. It is at transcript {TR/2/4}.

THE PRESIDENT: Was that really pursued in closing?

MR. TURNER: Mr. Kon may wish to clarify that because if not, I am happy to leave it.

THE PRESIDENT: You said in opening, Mr. Kon, that GUK have reached a point where it had to settle, as it were, settle at any price. It could not contemplate going ahead because it knew it was going to lose. That was the way you opened it.

MR. KON: I am not convinced, sir. I would need to go back and look at the transcript --

MR. TURNER: It is in front of you.

THE PRESIDENT: It does not really matter, if you just clarify what the case is. We are not holding you to that.

MR. KON: I think the case is that we had a decreasing level of confidence in our ability to succeed in the litigation. I do not think we have said that we were bound to lose. I think we equally said the reverse payment, as characterised by Mr. Turner, was a consideration, I think in response to a question from Mr. Malek. I think it would be disingenuous not to accept that the payment had a role to play in our decision, but it was a combination of factors. The point I made on the eclipsing point was that there was a balance to be struck and there were a variety of factors, and my submission was that the payment -- the CMA would need to demonstrate that the payment eclipsed all of the other factors, which we think explained, as I put it, the unexplainable. But I do not think I submitted that the payment was the fundamental sole consideration because we were going to lose the patent litigation. I do not think I put it that way.

THE PRESIDENT: Anyway, as I say, one uses words in oral submissions that cannot be held to you precisely, so whatever you said at the outset, we understand that is the position that you are putting forward, decreasing level of confidence in the outcome of the litigation.

MR. KON: Certainly.

THE PRESIDENT: That is helpful. Thank you.

MR. MALEK: I think Mr. Kon accepted this is not one of those scenarios where the client is saying: we do not care what the terms of the settlement are, that is the end of it, we are not going to fight. It is somewhere -- his case is that whatever the merits -- whatever we perceived the merits to be before, we felt we were a lot more vulnerable by that stage and that was a factor in the settlement process.

MR. KON: That is precisely it.

MR. MALEK: That is how I understood it.

MR. KON: Thank you, sir.

MR. TURNER: In that case, I will leave to one side the question of the legal relevance of the position we have arrived at, because it was easier to understand a submission that there was no inducement on the basis that I had apprehended from the opening submissions, that there was a complete loss of confidence.

If the position now is: I recognise that this was a consideration and indeed an important consideration, however my confidence level had decreased from the level it had previously been at; then the question of the legal relevance of the submission is questionable.

But nonetheless, taking that as a legally relevant point, that there had been a diminution in the degree of confidence compared to what it had been before, reliance was placed very heavily again in oral submissions, but again more recently in the written closing, on the evidence of Mr. Mike Urwin, the key decision-maker on the question of loss of confidence, who had given evidence before the Office of Fair Trading.

So, again, perhaps I should just clarify whether there is still reliance on the evidence of Mr. Urwin for that proposition or not.

THE PRESIDENT: Perhaps if you point -- bring up the passage.

MR. TURNER: It is on the page in front of you now {TR/2/4}. You will see from lines 7:

> "Our submission in that regard is GUK was not induced as a result of a value transfer to re-enter the market. The evidence, we believe, is very clear, that it was not a value transfer that induced GUK to do so, it was a loss in any confidence on the part of GUK that it was going to be successful ... The key decision-maker in that regard for GUK was Mike Urwin, who has given evidence, was called by the OFT ..."

THE PRESIDENT: I suppose line 7 should say: was not induced as a result of value transfer, not to enter the market.

MR. TURNER: That is right but you see the linkage there. The proposition is put forward, the key decision-maker was Mr. Urwin and then there was the exchange, you will recall, about the importance of having had him or not to support that proposition. At lines 22 to 23, the proposition is put in bold terms. The evidence is consistent and strong that GUK settled because it was going to lose the proceedings.

THE PRESIDENT: Well, I think it is not as --

MR. TURNER: Now it is not that.

THE PRESIDENT: It is not quite as strongly as that. It is that it felt more vulnerable, was less confident, that is my understanding and therefore keener to settle, but not that it had to settle.

MR. TURNER: You see, on that issue, there is not much of a factual debate.

THE PRESIDENT: No, because you say uncertain.

MR. TURNER: We say uncertain. To the extent -- I suppose I should pursue this simply to finish the point then. To the extent that it is said that there had been a severe loss in confidence, if you go in the decision {V/1/127}; remind you of the things said by the company's representatives the day before and the day of the settlement itself.

So at 3.302:

> "Although negotiations with GSK were ongoing, an internal GUK email sent by Steve Self on the same day (12 March 2002) referred to its continued view that it had a 'good case' in the patent litigation with GSK in which it was arguing that (i) the relevant patent claims were invalid; and (ii) that its product was non-infringing ..."

The quote is given there. At 3.303:

> "In another email on the following day ..."

That is the day on which they settled the litigation, Mr. Self says:

> "'the first [stage] of the case is no issue ... ie anhydrate ... think we can win this part … hemihydrate is a bit more tricky because we know that under certain circumstances or [sic] product can contain hemihydrate ... think it is winnable but it is a bit more uncertain'."

So that is actually on the eve and on the day of the settlement. Then there is the question of how, to the extent that reliance is placed forensically on Mr. Urwin as being the right person to consult on the question of confidence, the documents bear that out and the procedure that we are engaged in should have required him to step forward as a witness.

The transcripts of the interviews with Mr. Urwin do not bear out what Mr. Kon says either about Mr. Urwin's role, the key decision-maker on this particular matter, nor his perceptions.

Indeed, Mr. Kon's attitude to the closeness of Mr. Urwin to this case has developed since the time of the interview of Mr. Urwin. The transcript of the interview is at {A2/62/1}.

(Pause)

I am sorry it is my mistake {A4/62/1}. I beg your pardon. Here is the transcript of the interview, supported by the statement of truth. If we go to page {A4/62/47} which is at the end of the interview, Mr. Kon at the end, bottom of the page says:

> "I think I'd just make one observation, which is that Mr. Urwin in fairness has made it clear from the outset of this interview that he had no direct involvement in negotiating or indeed in assessing agreements of this nature. That he was advised by those who

reported to him and in particular Eddie Hart, and Richard Saynor and you're asking him questions which I think by his own admission he has no insight into, from his professional work at GUK or elsewhere."

So that was the description of his role at that time. If we go back to page {A4/62/4}. Mr. Moore from the Office asked Mr. Urwin, towards the top:

"Can you tell me something about your role in relation to Paroxetine specifically?"

Urwin:

"The role I had, again, was a very indirect role. The day to day discussions and negotiations, calculations and so on, were performed by the company itself. My role was, as I said, as the chief executive officer of the group and this was one of a multitude of agreements that I would be reviewing at a macro level, at that time."

He says in relation to the next question:

"I would have been the decider sort of last resort if you would like to see it in that way. As I said, we had many agreements in many companies over that period of time and I would ultimately sign off many of them."

Towards the bottom of the page, Mr. Moore asked him:

"Just in terms of other individuals or the individuals within Generics itself who were most involved in this process, who were the actual key decision-makers from your perspective?"

Urwin:

"The person that would have had the most involvement in terms of day to day would have been Richard Saynor who was the General Manager, I recall of GUK at that point."

Then {A4/62/5}:

"Eddie Hart probably would have also been quite closely involved given he was head of the region, that he was head of Europe as opposed of specifically head of GUK. He had previously been head of GUK though before he took the broader role."

At page {A4/62/38}, halfway down. Moore:

"Would you have been involved in any sort of aspect of this particular agreement in the sense of saying I want this in, I do not want this in, that sort of issue?"

Answer:

"I had nothing to do with this agreement."

Nor does Mr. Urwin say that he had lost all confidence in the litigation or had suffered a serious diminution of confidence by the time of the settlement, in the interview or in the

subsequent statement, although, in view of the way the case has now been qualified, it is fair to me to show you the statement because it does go some way down that track.

The statement is at {A2/6B/1}. If we go in that to page {A2/6B/4}. I have not shown you the front page --

THE PRESIDENT: What is this statement?

MR. TURNER: We need to go back to page {A2/6B/2}. It is the witness statement that was put in of Mr. Mike Urwin after the Statement of Objections and which Mr. Kon says should itself stand in these proceedings because of its contents.

THE PRESIDENT: Because it is verified by a statement of truth.

MR. TURNER: Yes, it is.

THE PRESIDENT: So it is the witness statement to the CMA?

MR. TURNER: Yes. The date is at the top --

THE PRESIDENT: After the SO.

MR. TURNER: -- 25th July 2013. It is fair to go to page {A2/6B/4}. It is here that one sees the closest that one comes to the submission as it is now made at paragraphs 9 and 10.

Paragraph 9 quotes the email, "provided the numbers are right".

There at paragraph 10, Mr. Urwin responds to the final part of paragraph 9, concerning a mere risk "which, according to the OFT, may have been no more than a 25 per cent risk". He says that is incorrect. He says he had a real concern that GUK would not prevail. He does go on to say:

> "As I explained during the Interview, the risks of losing the litigation with GSK were too significant to play around with probabilities. I also noted that the litigation process could have gone on for years and that if there was any hemihydrate in our product we would have found it difficult to have prevailed. Therefore at that point my objective would have been to settle on the best possible terms with GSK. This is effectively what I said in my [interview with] John Montgomery."

MR. MALEK: Email.

MR. TURNER: I am sorry.

> "I can also see that I said more or less the same to Richard Saynor to whom I wrote on 12 March 2002 that 'the only reason we are contemplating a distribution agreement with GSK is because there is a real chance we may not prevail in the court'. I also said to Richard Saynor in the same email that '(t)his one (i.e. Paroxetine) I would not launch at risk'."

MR. KON: Could you read on to 11 and 12?

MR. TURNER: Of course:

> "Shortly after the Settlement, I reiterated my position to Cecil Taitz on 12 April 2002 in an email in which i wrote that [we] were injuncted - and may never have prevailed i.e. there was a risk that we might never have launched in the UK [hence the settlement.] I also reiterated in the same email that 'we would not have launched at risk.'"

12:

> "I am advised that the OFT believes that in my email to Cecil Taitz I would have wanted to overemphasise the risk that GUK would not have won in order to present to Sumika a position that best benefitted GUK for the purpose of upcoming negotiations regarding how much GUK should pay Sumika to compensate it for no longer requiring API from it. I do not understand how the OFT could have reached such a conclusion. I do not recall having suggested at the time that we needed to over-emphasise the risk position to Sumika. Rather insofar as we were going to have any negotiations with Sumika, I would simply have wanted to make sure that they understood the position we were in and why we had decided to settle."

{A2/6B/5}.

Are there any other parts?

MR. KON: No.

MR. TURNER: Now, if GUK wanted to interpret that section as meaning that the company had decided not to go to court, whatever the deal offered by GSK, that would be inconsistent with the documentary evidence that you have seen. It would, in our submission, need to have called Mr. Urwin as a witness.

This Tribunal has consistently emphasised that in this form of judicial appeal, parties who rely on the evidence of witnesses, which are intention with clear statements in contemporaneous documents, should normally call them, because then the evidence can be tested by cross-examination if the opposing party considers that appropriate.

So, Mr. Malek asked me to pull out some authorities on this. If I give you a limited number, I should begin by saying that we have looked in the field of directors' disqualification and insolvency first. We have not found anything specifically on the point. We have found one case of some relevance that I will take you to briefly of Mr Justice Newey. To begin with this jurisdiction, the first case is *Durkan Holdings* which is at {Auth-Q/3/1} or volume 27 of the hard copy.

The relevant part starts on page {Auth-Q/3/36} at paragraph 104. This is part of the construction litigation. There, the Tribunal records that:

> "Mansell also made their employees available to be interviewed by the OFT. On 17 April 2007 two investigators from the OFT interviewed Peter Goodbun in the presence of Mansell's solicitor. Mr Goodbun was the Estimating Manager of the Mansell office which handled the Claremont Close tender."

So the bid rigging case:

> "The transcript of that interview was one of the principal pieces of evidence relied on by the OFT to establish the involvement of Durkan Limited in Infringement 220 and we will need to examine what was said in more detail later. The transcript records that Mr Goodbun was reminded at the start of the interview that it would be a criminal offence (under section 44 of the 1998 Act) for him knowingly to give false information in the course of the interview."

So a similar sort of situation to what was read to here Dr. Reilly and Mr. Urwin.

If we go forward to page {Auth-Q/3/38}. You have paragraphs 109 and 110. We should pick it up from the top of the page in paragraph 108, where the Tribunal records that this is now the Office being criticised. That:

> "The OFT's decision not to lodge witness statements in support of its case caused us some concern, as we made clear at the outset of the hearing in this appeal. The OFT was asking us to uphold a finding of infringement -- for which it had imposed a fine of over £3 million -- on the basis of a transcript of an interview with a person who was apparently not the person who had written the notes on the key contemporaneous document. Mr Beard argued that criticism of the OFT's approach to proving its case would be 'a complete triumph of form over substance' and that there was no real difference between the transcript we were shown and a witness statement setting out the same facts supported by a statement of truth."

109:

> "... after the hearings in all 25 appeals against the Decision had been completed, the OFT wrote to the Tribunal summarising its position and explaining how the transcripts had been prepared and checked for accuracy. This letter, however misses the point. No one is suggesting that Mr Goodbun was lying in his interview or that the transcript does not fully and properly record what he said. The significance of the failure to produce a witness statement is two-fold. First, Mr Goodbun has not been pressed about any of his answers -- his comments in the interview in 2007 appear to

have been simply taken at face value throughout the investigation and this appeal. If, once the appeal had been lodged, the OFT had gone back to Mr Goodbun to take a witness statement they may well have filled in many of the gaps that currently exist in the account of what happened. Faced with only the transcript of the interview, we do not know, for example, whether Mr Goodbun's evidence was based on what Mr Hart had told him had actually happened or whether he was simply inferring from the marks on the document the same 'facts' as any person familiar with what went on generally in the industry could infer. We do not know what Mr Goodbun's reaction would have been had he been told that Mr Sharpe vehemently denied that he had given a cover price. Mr Goodbun was not asked whether there might be an alternative explanation for the marks on the Report."

110:

"The second disadvantage of relying on an interview transcript is that Mr Goodbun's evidence has not been tested by cross-examination, a process which might also have generated a better understanding of the strength of the case against Durkan Limited. We reject the OFT's suggestion, made both at the hearing and in their letter of 6 August 2010, that because it was open to Durkan Limited to call Mr Goodbun [the other side] as a witness for the purposes of cross-examining him and they decided not to do so, that Durkan is somehow restricted in the extent to which it can challenge what is recorded in the transcript of his interview. It is not the task of the Appellant to supplement the evidence relied on by the OFT. Similarly, we reject the suggestion that because the Tribunal did not exercise its powers on its own initiative to call Mr Goodbun, his 'evidence' is somehow immune from criticism."

So pausing there. We saw the point, it is not appropriate to require the opposing party, which here is the CMA, to call a witness for an appellant in this context for the purpose of cross-examining him. So that was a case where it was the Office being criticised for not having called a witness and relying only on the transcript of an interview.

If we turn to the *Tesco* case, which is at {Auth-Q/5/1} and should still be, I think, in volume 27 of the hard copy bundle. Go to page {Auth-Q/5/58}. This is a December 2012 decision. Lord Carlile presiding:

"Reliance on notes of interview" is the section. Section D. At 137 the Tribunal records that:

"The OFT (in the Decision) and Tesco (in its Notice of Appeal) relied on notes and/or transcripts of interviews (together, the 'notes of interview') that had been conducted

with individuals who were employed by one or other of the companies under investigation at the time of the Infringements. Those interviews were conducted either by the OFT during the investigation or by solicitors acting for one or other of four ERA [that stands for early resolution agreement] parties, namely Asda, Dairy Crest, Glanbia and Wiseman. None of the individuals who were interviewed have been called to give evidence except for Mr Arthur Reeves of Dairy Crest. No one from Tesco was interviewed."

Then you had the Office submitting that no substantial weight should be placed on the notes of interview, because the individuals in question had not been called to give evidence, and their evidence would not be tested by cross-examination, which is the *Durkan* point. *Tesco* then goes further and submits that the Office could not rely on the notes of interview at all.

Then if we turn over, {Auth-Q/5/59} 139, we have a point of principle:

"We share the doubts of other Tribunal panels as to whether material contained in a note of an interview (especially one conducted by lawyers acting for an admitting party, rather than by the OFT) -- even if reviewed and confirmed by the individual concerned -- can constitute a proper means of evidencing alleged infringements in a case of this kind (see, for example, Willis at paragraph 67). We agree with the OFT therefore, that the Tribunal should place no substantial weight upon the notes of interview, some of which were not in any event contemporaneous. We note the OFT's position that its case does not depend on those transcripts/notes and would observe that, to the extent that Tesco considered one or more of the interviewees to have made statements pertinent to the disposal of this appeal [they are the appellant] it was open to Tesco to seek to call that individual as a witness. Our approach to the various notes of interview, whichever party sought to rely on them, has been a cautious one, and we have looked for corroboration, whether from contemporaneous documents, surrounding circumstances or witnesses who did give evidence before us, wherever possible."

They take it into account. It is not inadmissible but they do say that even when it is the appellant which is relying on these, it should be the case that if it is an important point for you, that you should bring forward a witness in support of your proposition; he who asserts must prove.

Finally, perhaps before a short break if that is convenient, in terms of directors' disqualification, at {Auth-A/6/1} still in bundle 27 of the hard copy, we have the decision in

the Secretary of State for Business, Innovation and Skills v Doffman and Isaacs, a decision of Mr Justice Newey.

THE PRESIDENT: Forgive me just a moment. It is not in 27.

MR. TURNER: I apologise. I am sorry, I am told the reference was wrong {Auth-Q/6/1}. I apologise, it does not appear to be in the hard copy bundle.

THE PRESIDENT: No, it is not. We will get it later. Yes.

MR. TURNER: So in this case, if we go to page {Auth-Q/6/4}. You see here from paragraph 15, the role of Grant Thornton being appointed as administrators of three companies, in respect of which allegations were made in these insolvency proceedings.

At paragraph 21, the judge records that only hearsay evidence was available from certain witnesses; consisting primarily of notes or transcripts of interviews or other meetings with representatives of Grant Thornton or Simmons & Simmons:

> "... (acting either for the administrators or Barclays). The relevant individuals not having been called, I think I should be slow to place substantial weight on this material when considering factual disputes, especially in the context of allegations of serious impropriety. That is particularly so since there are, on the face of it certain inconsistencies within the material."

If we go through to page {Auth-Q/6/27} finally. The final references are 153 to 157. 153 refers to the fact that there was:

> "... hearsay evidence that Mr. Bradshaw was not told the purchase price."

154, Mr Justice Newey remarks that:

> "... Mr Bradshaw has not given evidence in these proceedings, and no explanation for that has been proffered by the Secretary of State. Moreover, while I am certainly in no position to make any adverse findings against Mr Bradshaw (and am not to be taken as doing so anywhere in this judgment), it can be seen that there are matters which the defendants might have wished to explore in cross-examination had he given evidence. Mr Adair pointed out that, to judge from the meeting notes, Mr Bradshaw himself accepted, for example, that deals had been "'dressed up' as something else ..."

So forth. At 155:

> "It is true, as Mr Davis-White submitted, that judges often have to make decisions without evidence from someone who might have been a relevant witness. Even so, I do not consider that, in the present case, the Secretary of State has proved that Barclays was not informed of Wellington Farm's purchase price, especially as the Secretary of State's allegation potentially has a connotation of fraud. Further, I have

not been persuaded that there is scope for an independent complaint that DTZ was not told the price. If Barclays was told, I cannot see how failure to tell DTZ can provide evidence of unfitness."

Essentially, the judge is saying, again, I take at least into account at least as a factor, I do the best I can, but I attribute some importance to the fact that a witness has not been called who might have been expected.

THE PRESIDENT: Yes. That is a sensible moment, is it? Is there anything else in this judgment?

MR. TURNER: There is nothing in that. There is one final point perhaps which is that Mr. Kon rightly drew my attention to an additional paragraph in the witness statement. You will recall that one of the points that he has made is not just this broader point about loss of confidence, it is that a particular email relating to the reason for telling Sumika, the supplier, that there would not be the possibility of entry until a certain date, had been accurate and had not been spun in any way.

That is considered in the decision, I will simply give you the reference, at 3.300. It is true that the CMA found in that paragraph of the decision, perhaps you can call it up, it is at {V/1/126}, that, on any view, Mr. Urwin did not say that the GUK case would have been hopeless, or that GUK would have abandoned the litigation in the absence of the lucrative deal GSK was offering, because that was our case. But the email in question, to the extent that that is an issue in this case, goes, in my submission, to a very minor point, whether that statement about the date when independent entry could have been expected was exaggerated or not. It does not affect materially the outcome in any way, but, again, if GUK had wanted to say the decision was wrong in that regard, it could and should have called Mr. Urwin.

Sir, that is all I will say on that topic.

MR. MALEK: They do dispute your sentence which says:

"The CMA finds that Mike Urwin's characterisation of the risks of litigation in these emails was affected by his desire to put GUK's actions in a favourable light."

Because he has effectively responded to that in that witness statement we saw, and he was saying: look, I am not in the business of misleading anyone, I said it as it is.

MR. TURNER: I agree, I accept that. The points are twofold. First, that in the overall context of the issues, that is a small point.

MR. MALEK: It is a small point.

MR. TURNER: Secondly, that even in relation to that point, if that is part of the contention that they were making about the perception of Mr. Urwin, it would have been appropriate for him to have been called.

MR. MALEK: If the case turned on it, obviously, Mr. Urwin should have come and given evidence. But it is such a minor issue, I think you are right in taking a realistic view that this is really, in the scheme of things, a bit of a nonissue.

MR. TURNER: Yes, sir.

Sir, if that is a convenient moment.

THE PRESIDENT: Yes.

(11.31 am) (A short break)

(11.45 am)

MR. TURNER: Sir, I think I have covered most of the -- I hope all of the main factual points that have been raised on the other side. I turn to the arguments which bring us back to some of the more fundamental legal points, whether the *Lundbeck* judgments are not wrong on that fundamental point, but fall to be distinguished, because there are relevant differences between that case and our case.

The appellants have tried to distinguish *Lundbeck* in four main ways. The first is the notion that in *Lundbeck* there were routes to market that did not infringe the crystallisation patent, one of the three patents, and that the settlement deals precluded the generics from using such non-existing -- non-infringing routes.

According to GSK and Xellia, that is different from our case. You will recall that GSK says that our case involves restrictions narrowly tailored to the scope of the patents.

The second point is the assertion that the payments by *Lundbeck* were shown on evidence to match or exceed the profits which the generic companies expected to get if they had entered independently. Xellia says that at paragraph 70 of its closing.

Whereas we have no evidence of that in this case. GSK even suggests the fact that the payments in *Lundbeck* exceeded the profits the generic would have paid is the point that led to the conclusion that the generics had been induced to accept limitations on their behaviour. But that was the key factor allowing the finding of inducement to be made. Paragraph 46.2 of GSK's closing, at least comes close to that point.

The third area of purported distinction is that they say that there was overwhelming evidence that Lundbeck knew its patents were weak ones, but by contrast, GSK was always confident in its patents and GUK and Alpharma thought that they were going to lose. That is Xellia, paragraphs 73 and 74.

So the payments by GSK again did not induce the settlement.

Fourth, the supply agreements in *Lundbeck* only allowed the generics to resell Lundbeck's product as Lundbeck's product and they did not affect the drug tariff. But GUK and Alpharma were selling GSK's product using their own livery, their own brand, and the generic supply did trigger from IVAX the change in the drug tariff.

Those are the main ways in which they say that *Lundbeck* -- where they -- some of them say it is wrong, apart from Actavis, but they all seem to rely on these distinctions.

THE PRESIDENT: In fact, in your closing you identify five distinctions, the other being the injunction.

MR. TURNER: Yes. The injunction. I apologise, you are quite right. I am not going to cover the injunction point further unless the Tribunal wants me to.

THE PRESIDENT: You have addressed that.

MR. TURNER: I have addressed that sufficiently now.

THE PRESIDENT: That is one of the main distinctions that is emphasised.

MR. TURNER: It has not only been addressed in writing, I addressed that particular point fully in my opening and unless you have anything further on that, I do not propose to add to that one now.

The first area then is the submission that in *Lundbeck* you had settlements which go beyond the scope of what could have been achieved in the patent litigation as relief granted by the Patents Court beyond the scope of the patents.

That point, in our submission, does not affect the application of the treaty prohibition. The vice which the court in *Lundbeck* makes very clear is that an agreement which excludes potential competitors in exchange for payment is as such a problem, irrespective of whether that goes beyond what is called the scope of the patent. I will give you only a few references on this.

Paragraph 401 in the judgment, which is at {W/1/85}.

THE PRESIDENT: This is the *Lundbeck*.

MR. TURNER: This is the main *Lundbeck* judgment.

The court actually says:

> "In any event, even if the restrictions contained in the agreements at issue potentially fell within the scope of Lundbeck's patents, in that they could also have been obtained through litigation, the contested decision rightly finds that this was merely a possibility at the time the agreements at issue were concluded [as the court had not yet pronounced]. Replacing that uncertainty in relation 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 (see paragraphs 336 and 363 above)."

Accordingly that paragraph crystallises the basis of what the *Lundbeck* court finds to be an agreement which has, as its object, to restrict competition and it makes clear in explicit terms that whether or not the restriction falls within the scope of the patent is not the point. The point is that a possibility, what the court would have decided, is closed off by a settlement induced by a reverse payment.

At paragraph 495 {W/1/104} the same topic is revisited. You will see at the top of that page, the court referring to the Supreme Court of the United States at paragraph 492:

... concluding an intense debate on that issue, adopted the same approach by rejecting the 'scope of the patent' test applied by some lower courts in its Actavis judgment ..."

The culmination of the reasoning is in 495:

" ... the fact that some restrictions contained in the agreements at issue were considered by the Commission as potentially falling within the scope of Lundbeck's patents means only that the applicants could have obtained comparable restrictions through court rulings enforcing their patents, assuming that they succeeded in actions brought before the competent national courts."

Again, the conceptual framework is that that is something that has not yet happened:

"In that respect, even if the agreements at issue also contained restrictions potentially falling within the scope of the applicants' patents, those agreements went beyond the specific subject matter of their intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or potential competitors were paid not to enter the market ..."

So pausing there again. The approach taken by the court is that the right granted by the patent is the right to oppose the infringements, to go to court to validate these rights. It is something therefore which should not be assumed, and you do not have a right to conclude agreements by which you pay the potential competitors not to enter.

That goes beyond the specific subject matter of an IP right.

THE PRESIDENT: You are saying it includes the right to but does one not get that clearly if one goes back, Mr. Turner, to page {W/1/101} and sees what was the plea at the top of page 101?

The appellant there, Lundbeck, was saying the Commission was wrong because it did not accept the scope of the patent test as the key standard. That was the grounds that Lundbeck was arguing that that should be the key standard, that if it is in the scope of a patent, it is not an infringement, and that plea, which was split in two parts, is rejected.

MR. TURNER: I agree.

THE PRESIDENT: That is the key point, is it not? There are a whole lot of arguments why.

MR. TURNER: It is the basis for the reasoning that you have seen being expressed. However, the reasoning that you see there and in the other paragraph that I took you to which is even more stark, paragraph 401, not in that section, is a very clear statement that the basis for the court's decision does not rely on this form of reasoning.

THE PRESIDENT: Yes, well, it says it is not --

MR. TURNER: Therefore, for the applicants here to -- the appellants here to say, indeed the applicants before the General Court too, that a material difference between this case and *Lundbeck*, assuming that it was correctly decided, even on that basis, is the scope of the patents test is wrong, all it does is take you back to the fundamental question that we debated at the outset, which is whether the fundamental reasoning of the General Court is right in what they say, which is expressed in stark terms in paragraph 495.

THE PRESIDENT: There are a number of places. The other one seemed to me, with all the paragraphs you asked us to read was 572, which sums it up.

MR. TURNER: Yes.

THE PRESIDENT: I mean, that crystallises the General Court's Holdings {W/1/119}:

> "As the Commission submits, such commitments are, in any event, anti-competitive by their very object, whether or not they went beyond the scope of Lundbeck's patents ..."

It says it all. That is what the General Court held. It goes on to express the short reasoning which is your case.

MR. O'DONOGHUE: Sir, if it assists, to speed things up, I am certainly not making that scope of the patent argument. I never have.

THE PRESIDENT: It may be -- no doubt it will be pursued on appeal in *Lundbeck* and we do not know what will happen, but it seems to me that the General Court has made it clear that that is not the -- the fact that it is within the scope of patents is not an objection to the infringement. It is not an argument defeating infringement. I think Mr. O'Donoghue accepts that.

MR. TURNER: At least Mr. O'Donoghue does. I am grateful for that clarification.

THE PRESIDENT: He is Mr. Lundbeck for this appeal, I think because he is --

MR. TURNER: In these proceedings, it perhaps would be a good idea if the others would make it clear that that is their position too.

THE PRESIDENT: It does seem to me very clear.

MR. O'DONOGHUE: Sir, to be clear, I am making a scope of the patent point about the settlement which Mr. Turner has not addressed.

MR. TURNER: Do we understand what Mr. O'Donoghue has just said?

THE PRESIDENT: Well, I don't quite follow.

MR. O'DONOGHUE: To clarify. In *Lundbeck* there were non-Lundbeck routes to market, which were under active use in the market and they were snuffed out by the settlement.

THE PRESIDENT: That is saying the settlement went beyond the scope of the patent.

MR. O'DONOGHUE: Sir, there is a difference in that they were in active use in Lundbeck.

THE PRESIDENT: Yes. I thought that is why it was said in *Lundbeck* it was beyond the scope of the patent, that was the -- was it not, that was the scope of the patent argument in *Lundbeck*. That is precisely why they said it was beyond the scope of the patent. That was Lundbeck's argument. Is that not right, Mr. O'Donoghue?

MR. O'DONOGHUE: Sir, yes, I am only making a factual point, in that case, there were other routes to market which were actively being used.

THE PRESIDENT: Yes, but the court says it does not matter whether -- even if the settlement was confined to the scope of Lundbeck's patents, it is still an infringement. I do not quite understand your point. We have a separate scope of patent point here in terms of -- as regards to UK, in terms of duration, which does not affect Mr. O'Donoghue's client, which I raised -- which is not in the decision, but which I raised with both Mr. Kon and Ms. Kreisberger.

MR. TURNER: At all events, the reasoning of the General Court then, it is clear, shows that scope of patent is not something on which it relied, because it relies on the feature that the patent right is not something that one can validate by making a consensual agreement supported by a payment to the generic to drop the litigation.

Here I shall not add to what I have said yesterday in relation to the finding in the decision. Paragraph 6.88 and 6.89.

The second area is the claim that this may be a different case, because in *Lundbeck* the payments were shown to exceed the generics' expected profits. As I say, in paragraph 46.2 of GSK's closing at least, it appears to be suggested that that is a factor which may support a

finding of an inducement, if it is pitched at that level of the payment, whereas otherwise you would be either unable or less able to make a finding of inducement.

On that issue, first, I should make clear that our findings of inducement were based on the very specific elements of evidence that I have now taken the Tribunal through, regardless of this point.

But in any event, the judgment itself at the General Court does not require a showing that the amount of the payments made should approximate expected profits from generic entry, and for this to be shown by concrete evidence relating to the particular weighing-up carried out internally by the companies concerned.

In the main *Lundbeck* judgment at {W/1/84} on the Magnum system, you see that if you go to paragraph 399 at the bottom of the page, and over the page {W/1/85}, three lines down, the express statement that:

> "Even if the payments were less than the expected profits, they nevertheless constituted a certain and immediate profit, without necessitating the risks that market entry would have entailed."

That is similar to the language that you have now seen used by the representatives of both the generic companies in this case, about the reasons why they chose to settle was that they achieved the certainty of money now instead of uncertain money later.

Similarly, one example of that was Mr. Torben Laursen, who is quoted at paragraph 6.202, just for your recollection, of the decision.

Then, on page {W/1/88} paragraph 414, the way that the court approaches the issue of the vice in the payments here is put in this way:

> "Thirdly, the Commission explained, in the contested decision, that the reverse payments were particularly problematic, in the present case, since the amounts provided for in the agreements at issue broadly corresponded to the profits expected by the generic undertakings if they had entered the market or to the damages that they would have obtained if they had succeeded in litigation against Lundbeck (paragraph 388 above). In such a case, any incentive for the generic undertakings to enter the market is considerably reduced, if not eliminated. What is important, therefore, is that in the present case the amounts of the reverse payments provided for in each of the agreements at issue were sufficiently high to allow the generic undertakings to accept the limitations on their autonomy and to reduce their incentives to enter the market with their generic products ..."

Again, you have all the references in our case, for example, to GUK specifically saying that they would only settle provided the numbers were right, to show that if the importance of this fact is to be sure that it amounted to an inducement, we have the evidence in this case to show it.

It is not a point of distinction in itself.

MR. GLYNN: May I ask, Mr. Turner, does this paragraph give us the essential reason why in *Lundbeck* they pay so much attention to this question of the expected profits of the entrants?

MR. TURNER: It explains that it was a particular factual feature of the case, which gave assurance that there had been inducement because they had reached the levels required for the generics to be sure that this was a good deal, and gives them a reasonable return, compared to what they would otherwise receive.

MR. GLYNN: That was the reason why they included it in their checklist almost as factors that they were most keenly interested in?

MR. TURNER: Yes, that is right. I took you earlier, I think now on more than one occasion to the clear statement of principle at paragraph 296 in the Merck GUK judgment at {W/4/58} which again nails down the point, perhaps if we just go back to it just to have it on screen. {W/4/58}.

Making clear that this is not a necessary element of what must be shown and precisely why the payment can be regarded as an inducement, that, in the absence of an alternative explanation, the authority is allowed to regard it as having been the inducement because it is not certain that Merck would have accepted the restrictions in the absence of the payment, and you can see from the evidence there that it accepted it provided the numbers stacked up. That was the same sort of evidence -- in almost the same language -- as we have in our case.

The third area, I will touch on quite briefly, because again, I covered it quite exhaustively in my opening oral submissions, which is the submission by the appellants, their third distinction between this case and *Lundbeck*, concerns the patent position.

They say that unlike our case, in *Lundbeck* you have a company which thought its patents were extremely weak. Because you had the evidence that they thought that their chances of success in litigation were small, there was some contemporaneous documents saying that, that showed it was the sort of case where a competition objection could be taken to the agreements.

Their case on that point is wrong. It is wrong both in law and in fact. It is wrong in law because that was not the basis of the finding in *Lundbeck*, as is very clear. I will simply go to two references. Paragraph 369 first {W/1/78}. The court says there:

"In any event, the Commission was not required to demonstrate irrefutably that the applicants doubted the validity of their patents in order to establish the existence of an infringement by object in the present case, since the evidence set out in the contested decision shows that the generic undertakings were confident of their chances of being able to enter the market within a sufficiently short period, either by overcoming the applicants' infringement allegations, or by challenging the validity of their patents, in the event of a dispute ..."

Then this:

"What matters, therefore, is that there was uncertainty, at the time the agreements at issue were concluded, as to the possibility, for the generic undertakings, of entering the market without being subject to injunctions or infringement actions or of successfully challenging the validity of the applicants' patents, and that those agreements had replaced that uncertainty, by means of significant reverse payments, with the certainty that the generic undertakings would not enter the market during the term of the agreements at issue ..."

Finally, page {W/1/83} paragraph 390. Halfway down under the reference to the *Windsurfing* case:

"Although the applicants were entitled to enter into settlements with the generic undertakings in order to avoid the costs of potential litigation, they could not, on that ground, substitute their own assessment of the validity of their patents and the infringing nature of the generic undertakings' products for that of an independent judge while paying the generic undertakings to comply with that assessment and refrain from entering the market for a certain period."

The basis of their reasoning is that it is the payment that makes the difference. The settlement without the payment, the reverse payment, does not suffer from this objection.

MR. GLYNN: The objection applies even if it is a reverse payment in respect of the litigation costs for some reason?

MR. TURNER: If it is more than the litigation costs --

MR. GLYNN: But if it were simply the litigation costs, that is not regarded as offensive?

MR. TURNER: It is not.

MR. GLYNN: The reason why not is what?

MR. TURNER: The reason why not is that if you are simply paying in order to cut through costs of litigation that would otherwise be incurred to achieve a particular result, then that is not regarded as paying to induce the other party not to enter the market, but merely to obtain a

shortcut by getting rid of the litigation costs that would otherwise tediously be incurred. That is the idea anyway.

MR. GLYNN: Yes, okay.

MR. TURNER: That is what the General Court says on the law, and so one can see, in my submission, quite clearly that their reasoning does not depend upon some element of likelihood of victory, having been unearthed through a trawl of the documents of the companies before the Competition Authority.

The key is the replacement of the uncertainty about what the court will decide when the patent holder exercises their right to oppose the market behaviour of the generic with a certain outcome achieved through a cash payment.

It is also clear, however, that the appellants are wrong on the facts, because you have now received evidence showing that GSK had a much more measured view of the strength of its patents. So, to the extent that you will hear or have heard on the other side that you should assume that this is a case where likelihood of victory for GSK is part of the factual matrix, that is not borne out by the evidence you have heard. It is also, as we understood Mr. Flynn when questioned on this in his opening on Monday, not quite a way in which they are putting the case. They are not saying that.

THE PRESIDENT: In his closing.

MR. TURNER: I am sorry, in his closing. He does not say that. He does not say: we have shown you that we were likely to win or you must find that on the evidence before you. He puts it the other way and says the authority has not proved the reverse.

That links to what I apprehended when I began this closing address is the way that they put their wider case, which is that we can only succeed by showing that the patent is indefensible or a sham or hopeless.

THE PRESIDENT: I do not think they are putting it that high, because they are likely to lose (inaudible).

MR. TURNER: The case in the Notice of Appeal appears to be that it is necessary for a competition case to get off the ground and even to enter the arena of potential competition to show that an asserted patent right is indefensible.

MR. MALEK: They may have just exaggerated the point there, to make your burden much higher but their argument --

MR. FLYNN: I think if one reads the Notice of Appeal, one will see that we do not actually say that. We gave that as examples of cases that a Competition Authority might be able to bring home, not that it is the only test.

MR. MALEK: The more difficult argument is, particularly in relation to the effects case, is where they say, you know, you have not shown on the balance of probabilities that we would have lost the litigation, but no doubt you will come to that later.

MR. TURNER: So far as the way that they put the case is concerned, I am not sure that Mr. Flynn is correct. I can take you to those paragraphs myself. That is exactly how they put the case.

THE PRESIDENT: Well, we can look at it, but in any event the way it is put now is that they accept there was uncertainty.

MR. TURNER: They say they have always accepted there was uncertainty. The question is whether they say either that we have to establish before a competition case can get off the ground hopelessness, or the lower test, that we have to establish that it is likely that they would have lost.

THE PRESIDENT: Yes. In any event you are not accepting either test.

MR. TURNER: We are not accepting either test, and we are not accepting that this Tribunal is in a position to have found on the evidence, even that they are likely to have won the litigation.

THE PRESIDENT: Yes.

MR. MALEK: But they say your problem is that -- they say your test of uncertainty does not get you home. They are saying that that is not the right target.

MR. TURNER: They are saying that. We say that that is the wrong target, supported by the General Court and the reasoning there. There are certain practical reasons too, particularly in circumstances where the parties concerned are withholding their legal advice, if that were the test, how it could ever be said to be a sensible hurdle to have to cross, and where parties, as in this case, simply put forward two witnesses whose evidence eventually boils down to some very measured and prosaic propositions.

Ms. West said, eventually, that GSK were cautiously optimistic. Dr. Reilly stood by what he had told the CMA in a previous interview, which is that the external legal advice we have not seen was that the patents were reasonable and we had a fair shot at it.

THE PRESIDENT: In any event, Mr. Turner, the issue is what is the test. If you say that the test is genuine real uncertainty, Mr. Flynn accepts there was real uncertainty; he is not saying no, this is a case -- whatever Mr. Reilly may have said in his witness statement, GSK was confident it was going to win, it is certainly not now, if it ever was, but certainly not now their position. He says the test must be at least that you must establish that GSK was likely to lose, and if that is the test, you accept that you cannot fulfil it.

MR. TURNER: That is correct.

THE PRESIDENT: So the issue is what is the test?

MR. TURNER: That is correct. If that is the test, I have nothing further to add to what I have just said, which is simply that it proceeds from no obvious principle and in practice, particularly in circumstances where you cannot investigate that sort of issue with any certainty, it is not a sensible test.

THE PRESIDENT: We understand that.

MR. TURNER: Sir, the fourth point concerns the distinction relating to the supply agreements, where it said -- in *Lundbeck* there was mere resale of Lundbeck's product. Here you have resale of GSK's product, but using the generics' own livery. For example, Xellia's closing submissions at paragraph 75.

THE PRESIDENT: Yes.

MR. TURNER: That is correct, but it is not a relevant point, because what matters in both cases is that the supply agreements were an integral part of the value transfer from the originator to the generic.

The way that it was presented was not an important case and did not mean that there was somehow the introduction of new competition, which entirely changes the analysis.

You see that most clearly from the *Ranbaxy* judgment in the General Court, which is at {W/2/43}.

Towards the bottom, at paragraph 246, under the heading:

> "The allegedly pro-competitive nature of the agreement at issue", *Ranbaxy* submitted that the agreement had a pro-competitive character because it provided that they would distribute Cipramil as a finished product, which allowed the applicants to develop relationships with wholesalers and allowed Lundbeck to increase the sales of its product.

That was the way that the argument was put there and addressed. At 247:

> "In that respect, it must be borne in mind that the applicants became distributors of Cipramil and enjoyed a discount of 40% on the purchase of Cipramil under Article 1.3 of the agreement at issue, that is to say the same provision which provided for the payments which constituted the consideration for the ..." entry restrictions.

248:

> "Accordingly, as the Commission rightly submits, it is not a separate distribution agreement, with a pro-competitive character. The provisions concerning distribution were an integral part of the agreement at issue and served to supplement the

consideration granted to the applicants for refraining from the production and sale of their own citalopram during the relevant period, as Lundbeck admitted, according to the documents cited in ... the contested decision."

Stopping there. The situation that is described is exactly the same as in our case. The agreements here involving the entry restrictions were an integral part of the overall settlement and the agreements for supply too.

The provisions concerning authorised supply supplemented the consideration that was given to both GUK and Alpharma through the transfer of the profit margins associated with the limited volumes of product. Although Xellia suggests that the generics were able to get an early mover advantage by selling GSK's product in their own livery, one should go back to what Alpharma said at the time of the litigation and that is in the decision at {V/1/134} at paragraph 3.320. Four lines down:

"Although Generics UK and IVAX are already on market, everyone is aware that their product is in fact sourced from GSK ..."

So the market knew that:

" ... 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 GUK 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 to enter the market but also to maintain our usual market share..."

This was a witness statement made in the patent litigation for Alpharma by Mr. Collier in 2002. One sees from that very clearly that the market did know about the way in which the authorised product had come about and that this was not an expression of strong competition by the generic.

MR. GLYNN: If I may again ask you a further question on that. If you take a longer term view about the way in which competition in these kind of markets would develop, the establishment by a powerful generic company of its own livery and get-up, as they call it, would be, I imagine, quite an important part of the way in which longer term competition between generics will develop.

So changing slightly the focus, perhaps this is too broad a question really for this case, or perhaps it is not; changing focus slightly from the immediate question of the market for this product and the price of this product to the way in which the competition in the market between generics and patented products will develop, the reinforcement of the position of a

powerful generic company, with an important product sold and promoted in its own livery, would be potentially quite a significant competitive development, would it not?

MR. TURNER: Yes, let me respond to that briefly. Firstly, it was not a material point in the *Lundbeck* case, as you have seen.

MR. GLYNN: Yes, forgive me, I was moving outside the Lundbeck --

MR. TURNER: No, no. It is not a material point that was taken here either. What was said here was, to the extent that there were competitive advantages, they rely on the fact that they could establish the relationships with the wholesaler customers anyway.

MR. GLYNN: Indeed.

MR. TURNER: So that point was there in any event.

MR. GLYNN: Yes.

MR. TURNER: The third point is that, to the extent that that was going to be taken further as a basis for why these agreements should be treated as pro-competitive and, sir, developing the supposition that you have fairly made, one would expect that to have been brought out in evidence again before this Tribunal, more than it has.

MR. GLYNN: More than it has, yes.

MR. TURNER: I go from there -- I am not proposing to cover the injunction point because I did cover that in the opening fully. So I move to a particular point that GSK says it finds support in the *Lundbeck* judgments for what it did because the arrangements in our case are not materially different from the *Neolab* settlement in the *Lundbeck* case and that was not objected to. That is paragraph 51.3 of GSK's written closing submissions.

The Neolab case --

THE PRESIDENT: I think Mr. O'Donoghue interprets it quite differently in his closing; Neolab.

MR. TURNER: He may interpret it differently, but I am addressing the close reasoning in GSK's written closing. Perhaps we can bring that up, at {M/2/18} paragraph 51(3). We have a very long subparagraph talking about the settlement with Neolab by Lundbeck. You will see about six lines down, the only difference between the present case and the Neolab example is that the value transfers were made in advance in our case and the generic companies were thereby permitted to enter on an authorised basis much earlier than they would otherwise have been able to, leading in particular to substantial savings to the NHS and a fall in prices to pharmacy. Nothing in the *Lundbeck* judgment suggests that such an agreement is worthy of condemnation.

So they make a very clear and specific point, perhaps alone, that they are on all fours materially with a settlement that was approved as pro-competitive in the *Lundbeck* case.

So I should deal with that. The *Neolab* case was outlined in the Commission decision at recital 164 and that is at {Auth-F/16/70}. Volume 10 of the hard copy, if, sir, you are looking at this in hard copy.

Perhaps it is quickest, if you not seen this before, if the Tribunal reads it to yourself, because it is quite a long paragraph.

(Pause).

THE PRESIDENT: I may be misremembering but I thought Mr. O'Donoghue had described the distinction of the Neolab position in his closing?

MR. O'DONOGHUE: Sir, yes. It was a case where Neolab had effectively won because of the gap and Lundbeck was paying out for damages rather than delaying the inevitable. That is all.

MR. TURNER: That is our case --

THE PRESIDENT: That is your point I think.

MR. TURNER: We and Mr. O'Donoghue are as one.

THE PRESIDENT: It is set out somewhere in Mr. O'Donoghue's closing, I cannot find it.

MR. O'DONOGHUE: It is the only thing we agree on.

THE PRESIDENT: I think he summarised --

MR. FLYNN: Perhaps I should add to the harmony and say we agree with that too. What we are saying in this paragraph is that economically you can see our agreements in a very similar way.

MR. TURNER: That is very helpful, so perhaps we should just deal with that. If the Tribunal wishes to read recital (164).

(Pause).

Sir, if we go back to the previous page on the screen {Auth-F/16/70}. This is something that is totally different economically from GSK's case, where the originator has made payments to induce the generics to cease taking steps towards independent market entry. There was a contractual settlement on 22nd December 2003. In that contractual settlement, Neolab did not accept any entry restrictions. It had already entered the market in October 2003 and it was and remained active on the market. Previously Neolab had given undertakings in the same way as Alpharma. It had received in return a cross-undertaking in damages from Lundbeck and then, in December 2003, GSK -- I am sorry, not GSK -- Lundbeck paid Neolab under the cross-undertaking, not a payment to induce Neolab not to enter.

In effect, GSK's submission is that the combination of an interim injunction or an undertaking and a cross-undertaking in damages amounts to a form of legitimate arrangement of a pay for delay kind or perhaps they say it is economically the same. It is not economically the same. They seem to ignore the December 2003 contractual settlement, which is what the Commission and the court were focusing on, and the claim that there is economic similarity ignores that, in our case, the originator is making payments precisely with the object of delaying independent market entry of the generic in question, concerning its future behaviour.

So I do not --

THE PRESIDENT: Just one moment. (Pause). Sorry.

MR. TURNER: The only additional point is that here, with *Neolab* , the cross-undertaking and the interim injunction arrangement was part of the litigation process and the cross-undertaking explained the payment that was then made to the generic and the agreements in our case do not have those features. The payments were not ancillary to the litigation process, which is going to reach the definitive determination on validity or infringement and the payments could not be explained in our case by the cross-undertakings.

Sir, I turn to the case on effects. In terms of timing, once I have covered this area, which I hope will not take too long, Ms. Demetriou has about an hour and a half or possibly up to two hours, but maybe an hour and a half on the other part of the case. So we will finish in good time.

THE PRESIDENT: Yes. That is Chapter II and penalties?

MR. TURNER: Yes.

So I turn to effects. The crucial point dividing the parties is whether Article 101 prohibits agreements that have got the effect of restricting potential competition, irrespective of whether they have the likely effect of restricting actual competition, and where an agreement shuts out the real concrete possibility of a potential competitor entering a market, we are submitting that it is not necessary to show that that potential competitor would have entered the market but for the agreement.

It is good enough to show that the elimination of an important potential competitor has happened by blocking a route to market and so harming the competitive process. That eliminates the real concrete possibility of actual competition. The point of the real concrete possibilities test, which you have now seen in the *E.ON* case, for potential competition, is to demarcate the sort of competition that Article 101 is there to protect.

If we may recall the important statement in *Lundbeck*, the main judgment, at {W/1/39} paragraph 171. This is key to this argument:

" ... potential competition includes [all] the activities of the 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 ... that potential competition is protected by Article 101 ..."

THE PRESIDENT: But there are two distinct points. One is: are these parties potential competitors? If they are not, there is no Article 101 case on object or effect. *Lundbeck* was an object case; you have to start finding potential competitors as you do in your case. But that does not tell you whether it is object or effect.

If you are running an effects case, then you have got to look, as I think you accepted, at the counterfactual. You have to say: what was the counterfactual?

MR. TURNER: Yes.

THE PRESIDENT: Then, one gets to the question: do you have to show for an effects case as opposed to an object case that, without the agreement, the counterfactual was more likely than not?

MR. TURNER: Our counterfactual here is that it is certainly more likely than not because you have to focus on what the counterfactual is.

THE PRESIDENT: What is your counterfactual?

MR. TURNER: Our counterfactual is that the potential competition would have continued to exist.

THE PRESIDENT: But that is not a counterfactual.

MR. TURNER: Yes, it is. I will explain. I am sorry I think Ms. Kreisberger is laughing so she may want to say something.

THE PRESIDENT: No, I think for you to say something. Potential competition would have continued to exist.

MR. TURNER: I will return to the metaphor of the bridge that Mr. Malek gave. Imagine that the paroxetine market lies ahead of you and if I, the generic, can get over the bridge I will compete and prices will fall. There will be potential effects which have not yet happened. I am not yet at the bridge. The incumbent in the market is putting hurdles in my way to stop me reaching the bridge, for example, in this case, by preventing the patent hurdle from being overcome. This now, you will see, links to the reasoning in paragraph 171.

You see the difference therefore between potential effects, the effects that would occur in the actual market if I get over the bridge and compete, and potential competition which if you have paragraph 171 open, relates to the preparatory steps before I get to the bridge. The proposition is that, as part of the effects case, it is wrong for a restrictive agreement to prevent the reaching of the bridge by preventing the potential competitor to get into the market. That is a disruption of the process which can also sound in an effects case. It is supported by principle and authority.

THE PRESIDENT: When you say prevent the competitor getting to the market; if the counterfactual is, it is more likely than not it would have been on the market, I can understand that. But if the counterfactual is, it is more likely than not it might have been on the market --

MR. TURNER: No, the counterfactual is that a party that was preparing to enter by taking steps towards that aim would have continued to be able to take those steps with a real prospect, real concrete possibility of achieving the aim.

THE PRESIDENT: A real possibility but not a probability.

MR. TURNER: Not a probability, no.

THE PRESIDENT: So therefore the counterfactual may not have resulted in actual competition.

MR. TURNER: That is right, but what you have done is you have snuffed out the prospect of it by a restrictive agreement. You have certainly, as opposed to only likely, snuffed out the possibility of the generic reaching the bridge, crossing it and competing.

THE PRESIDENT: But this is true of almost any object case. If you take, say, an information exchange agreement, that is a restriction by object. A restriction by object because, if the parties had not exchanged information, it may be that the prices that they would have charged or the way they would have marketed their product would have been different from the way they were as a result of the information exchange. The way in which they competed was changed. But that does not make it a restriction by effect. You would have to show, to achieve an effects case, that actually the prices or market conduct was materially different.

MR. TURNER: The confusion there is between potential effects and potential competition again because to go back to my metaphor, where there is the information exchange, you have two parties already in the green pastures of the market competing against each other and they exchange information; and has the object of restricting of competition, it may be used in a way which reduces the extent of competition, keeps prices up. But they are already actual competitors with each other.

In my example, the potential competition comes from somebody who is not yet in the market and, in that case, the right category of object restriction to have in mind is a market exclusion agreement and we have here a species of market exclusion agreement, and I am concerned with a case specifically where an incumbent monopolist is paying to stop people not yet on the market from entering it.

THE PRESIDENT: I understand that, but if you cannot show that, on balance of probabilities, they would have entered it, where is the effect? It is only a conceptual effect that there is no longer a potential, but that is a less than 50% effect.

MR. TURNER: It is true it is a less than 50% effect if you are looking at potential effects on competition in the market. It is a 100% chance, or effect, or counterfactual, if you are focusing on the removal of the prospect of that competitor, the potential competitor, getting to the bridge. It is a certain outcome. Therefore, the debate that we have just had has teased out an important point.

THE PRESIDENT: So every market exclusion agreement, as well as being an object infringement, is an effects infringement even if the person being excluded in the absence of the agreement might not in fact have come on the market.

MR. TURNER: That is right, provided that it is shown that it is not merely a form of agreement that had no application whatsoever.

THE PRESIDENT: Well, yes, but if it is a realistic agreement, that is basically what you are saying?

MR. TURNER: Yes.

THE PRESIDENT: It is a fairly startling proposition.

MR. TURNER: It is not a startling proposition -- well, it accords with principle in that the starting point I will take as paragraph 171 of *Lundbeck* --

THE PRESIDENT: As I say, *Lundbeck* was not an effects case. On your submission, the Commission could just as easily have run an effects case.

MR. TURNER: I am going to turn in a moment to show you how this has been approached by the Commission in a very similar case, *Servier*.

I start with paragraph 171 because it makes a general statement that potential competition is protected by Article 101 {W/1/39}. At this point it is making a more general claim about the nature of the prohibition. It is saying that potential competition is equally protected.

It is a point, therefore, which comes down to -- I am very glad we have raised that at the outset because it comes down to a difference that needs to be appreciated between potential

effects, which do have to be proved on the balance of probabilities in the market, and, if we are right, certainly stopping potential competition from occurring.

MR. MALEK: What happens if you take the view that the prospect of GSK winning is 90%, would you still have an effects case?

MR. TURNER: Yes. In this sort of case, I approach it in this way, *Lundbeck* took the case as an object case and said that --

MR. MALEK: I understand why they did.

MR. TURNER: -- to achieve it had the object of restricting competition. Equally, and on the same basis, given what happened, it could have been presented in that way. The reasoning relies on stopping a real prospect. Sir, so when you say 90%, in terms of litigation prospects, to me at any rate that is almost effectively a certainty, which makes it a difficult case.

MR. MALEK: Yes. That is why I am trying to test it, by looking at the extreme.

MR. TURNER: Yes, I understand that. I would say though that if one focuses on a case which is not at the absolute extreme of effective certainty, but where there is a real possibility which you pay to exclude, that can be expressed also as a restriction, when you pay to achieve that end, which has the effect of restricting the potential competition.

THE PRESIDENT: 90%, you say may be close to "sure to get home". But if you take a 70% chance. In other words, on the balance of probability, GSK was likely to win, but there was some real uncertainty.

MR. TURNER: Yes.

THE PRESIDENT: It may be that if it was over one year it was 90%, even the object case would have problems. But that is not this case, or indeed *Lundbeck* on the percentage one finds in the judgment. Say it is a 75% chance of winning. If the counterfactual is: there had been no agreement, there had been continuing litigation, on the balance of probabilities GSK would have won. That is what it means to say -- that follows, does it not?

MR. TURNER: Yes, of course.

THE PRESIDENT: Yes. So the counterfactual is one where GSK succeeds in keeping out the generics?

MR. TURNER: No because, in my submission, I think -- I am going to illustrate this by taking --

THE PRESIDENT: On the balance of probabilities the counterfactual --

MR. TURNER: No. So my submission again on the principle is that one is looking in the wrong place, because if you are looking to see what would have been the likely effect in the actual market, you are looking at the potential effects in the market. If you are looking, however,

at the restriction of potential competition before it reaches the market, there there is a likelihood or certainty that you will achieve the snuffing out of that.

The reason why it accords with principle is because the prohibition is concerned not just with showing that certain parameters, prices, output, innovation, have been affected and proving that, but with protecting competition as such as a process. Therefore, an agreement which interrupts or disrupts the process is equally a concern for Article 101, both by object and by effect.

THE PRESIDENT: That is why the information sharing would be an effects because it is disrupting the process of competition, is it not?

MR. TURNER: Of course it is.

THE PRESIDENT: But it would not be an effects case. You would need to show -- I mean it might be -- but you would then need to show that it actually translated into higher prices.

MR. TURNER: Yes, in that case. As I say, that is a different matter from ours because here we have --

THE PRESIDENT: Why is disrupting the process of competition between someone on the market and someone not on the market yet conceptually is different from disrupting the process of competition between people who are on the market?

MR. TURNER: Because in this case one is simply stopping a process of competition from taking place that would otherwise occur and, in that way, you are stopping the process from developing to a point where effects on the market can be felt. Perhaps I should illustrate this, if I should move forward, by showing you the way in which the reasoning has been developed in the case law.

I am going to begin with the *Servier* case. This is going to take us over the short adjournment, perhaps if I start it now. It is in {Auth-F/17/1}. If we go to page {Auth-F/17/273} you have paragraph recital (1197).

I am sorry. I am told it is volume 11 of the hard copy.

THE PRESIDENT: Yes, I have it.

MR. TURNER: So, here, they say:

> "If the patents had been enforced, quod non, the courts may or may not have sided with Servier. The relevant counterfactual 1689, to eliminating a potential competitor by a settlement akin to the investigated ones, is not that the patent would be invalidated but that the competitive process consisting also in genuine patent challenges by potential competitors (as well as their legitimate interest in settling) would remain undistorted by inducements affecting the generic companies' incentives

to compete paying potential competitors not to try to enter the market with their product is not based on any rights granted by patent law ... Nor is it one of the legitimate means society has provided for the defence of patent rights."

You see there how they frame the counterfactual and it is on all fours with the way in which the authorities in this case is doing the same. If we go forward to section 5.1.7 on page {Auth-F/17/279}. It is towards the bottom of the page, entitled:

"Assessment of patent settlement agreements with reverse payments as restrictions by effect pursuant to Article 101(1) of the Treaty."

This section perhaps over the short adjournment the Tribunal might wish to read for itself.

THE PRESIDENT: Yes, I think that would be sensible.

MR. TURNER: I will draw your attention just to two paragraphs.

THE PRESIDENT: Just tell us what also you would like us to read from possibly the whole section.

MR. TURNER: That section.

THE PRESIDENT: It goes up to where?

MR. TURNER: (1227). If I invite you to look at two recitals in it. If you go forward to (1217) {Auth-F/17/280}. Here there is the reference to one of the classic cases in the court, Tierce *Ladbroke*:

" ... the General Court recalled that 'the prohibition set out in Article 85(1) of the Treaty covers all agreements, decisions by associations of undertakings or concerted practices whose object or effect is to restrict not only actual or possible competition between the parties concerned but also any possible competition between them or one of them and third parties'. In this case,Commission rejected a complaint on the ground that the alleged agreement not to grant a licence to third parties did not restrict competition as it was a 'normal consequence of the fact that neither [of the third parties] were currently present on the betting market'. However, the General Court disagreed with this view and concluded such an agreement would "be liable to impede the entry of each of [third parties] on to the Belgian market […] in general and thereby restrict such potential competition as might exist on that market, to the detriment of the interests of bookmakers and ultimate consumers. Moreover, the effect of such an agreement might be to `limit or control ... markets' and/or to `share markets.'" The Court thus clarified that the Commission should look at the effects of the agreement on potential competition. Such analysis is directly relevant for the investigated settlement agreements, where value transfers constituted a significant

inducement affecting the generic competitor's incentives to prepare for generic entry in one or more EU markets."

{Auth-F/17/281}

THE PRESIDENT: I think one would have to look at Tierce Ladbroke because "liable to impede", I do not know what that means, whether it means more likely than not. Clearly, even if one were to reverse the example, if we knew that GSK's chance of winning was only 20% or 30%, then, one could understand an effects case but it still would be potential competition. It would still be because the generics are still only potential competitors because they are outside the market, but the more probable than not situation in the counterfactual is they would then have succeeded in getting in. So you are still impeding potential competition.

MR. TURNER: Yes. But there it is used in the narrower sense that you are impeding a likelihood or preventing a likelihood that someone outside the market will get in, leading to certain consequences.

THE PRESIDENT: But it is not clear to me what *Tierce Ladbroke* is doing when it says "would be liable to impede the entry". Whether that means they are likely to have entered if not for the agreement?

MR. TURNER: Yes I am afraid --

THE PRESIDENT: It is not clear.

MR. TURNER: -- we will have to look at that. But the way it is used in *Servier*, the other recital very quickly, perhaps you want to read this one particularly over the short adjournment, is (1219) where there is reliance placed on the *Visa* case, which is the case that we had taken you to on this point as well.

THE PRESIDENT: We will read (1212) to (1227).

MR. TURNER: I am obliged.

THE PRESIDENT: We will return at 2 o'clock.

(1.00 pm) (The short adjournment)

(2.00 pm)

THE PRESIDENT: Yes, we have read those passages.

MR. TURNER: Sir, to help Ms. Demetriou and myself, at the moment I am assuming that you will not want to sit much after 4.30 pm. I do not know if you do have any time in hand as you had done on the first two days or not but I am going to take this at an brisk pace anyway.

THE PRESIDENT: Yes.

MR. MALEK: We are still on *Servier* are we is this.

MR. TURNER: We are on *Servier*. So in *Servier*, I am only going to take you to a very few references. In the section that I asked you to look at, recital (1219) that is the one which refers to the *Visa* case on page 281.

{Auth-F/17/1} hard copy volume 11.

THE PRESIDENT: You want Servier or Visa?

MR. TURNER: I am going to leave Servier in a moment but I am going to show you --

THE PRESIDENT: (1219).

MR. TURNER: Yes, {Auth-F/17/281}. You have read this but you will see that the way they approach the issue of the counterfactual and potential competition; their methodology is explained at the end of (1219) at the bottom of that page:

> "The Commission will first establish the concrete effects of the settlement agreements on potential competition: the removal of the generic company as a potential competitor (which is also analysed under the rules for ... object)."

Step one. Then they say {Auth-F/17/282}:

> "In the second step, the Commission will then examine whether the elimination of a single potential competitor was likely to have effects on the competitive structure ..."

So that is the way that they approached it. They looked to see whether the competitive structure of the market in question was going to be affected. They had in mind there that this was a single competitor. In our case, I will briefly remind you, but we do not need to go to it, of what Mr. Torben Laursen said, which is at paragraph 3.359 of the decision, it is quoted on page {V/1/153}, that he records GSK regard us as the only serious threat at this point.

It has come up on screen anyway, towards the bottom of that page:

> "GSK consider us the only serious threat right now, but will be ready to consider similar deals if others make a similar threat."

So they were seeking essentially to keep the structure of the market stable, albeit that they would not necessarily succeed, there is a 45% chance that these supply agreements will not hold. That is what they are trying to achieve.

Only two other places in *Servier* and then we leave it. At page {Auth-F/17/487} recital (2032), foot of the page they said:

> "In the reply to the Statement of Objections, Lupin tries to show that the Lupin Settlement Agreement had no actual effect on competition; however, the Commission

does not make any inferences that Lupin would be an actual competitor absent the agreement."

Likely to have become one:

"The counterfactual is that Lupin would remain a potential competitor to Servier."

THE PRESIDENT: Yes.

MR. TURNER: That is how they do it. Finally -- I am sorry I am asked to read also (2033):

"Therefore, in the absence of the restrictions in the agreement, Lupin would have remained a prominent potential competitor to Servier through its challenge to patent validity ..."

So forth. Finally, you see this consistent approach also in relation to the Servier/Niche settlement agreement which is at page {Auth-F/17/319}. At the bottom of that page, the heading of the section 5.2.2.4 is:

"Competition that would have existed in the absence of the restrictive agreement and the importance of Niche/Unichem in view of the remaining competition".

(1384):

"This section will examine the competition that would have existed in the absence of the restrictive provisions of the Niche/Unichem Settlement Agreement. The section will focus on the competitive behaviour that Niche/Unichem would have been likely to engage in, absent the agreement, and on the other relevant sources of competition to Servier thereby demonstrating the importance of Niche/Unichem as a competitive threat to Servier."

(1385):

"In the absence of the restrictive provisions of the Niche/Unichem Settlement Agreement, Niche/Unichem which considered itself to have a 'limited lead over other generic competition' ..."

Again similar to Alpharma in the part that we have just seen:

"... and which was the first undertaking involved in infringement proceedings with Servier would have remained a competitive threat as a potential generic entrant with perindopril in the UK and in other EU markets. Niche/Unichem would have retained significantly more ability and incentive to compete and challenge Servier's significant market power if it had not settled or if it had settled on less restrictive terms in the absence of the reverse payment ..."

{Auth-F/17/320}

Over the page --

THE PRESIDENT: Well, Perhaps the next paragraph.

MR. TURNER: (1386)? Yes, I have no objection. One can read that page and the following page. I was going to go to the conclusion. Sir, (1386) that they would have remained the only undertaking involved in litigation with Servier before a national court, and the litigation concerned the perindopril process patents:

> "With respect to the process patents, Niche considered that it had a realistic chance to win the case on non-infringement. Given that litigation, Niche constituted a significant competitive threat for Servier and this may explain why Servier settled the litigation on the day of the hearing before the High Court. In the absence of the settlement agreement ..."

So this is how they are thinking of a counterfactual, something which is not yet there:

> "... this threat would have been maintained and Niche may have been able to establish Matrix's API technology as an enabling technology ..."

This is the philosophy. Over the page at {Auth-F/17/321} of the Magnum version, 320 of the internal, at (1391) is the conclusion of the recital:

> "Therefore, absent the agreement and its restrictive provisions, Niche/Unichem would have remained a prominent potential competitor ..."

This is how they conceive the counterfactual to Servier:

> "... through its opposition before the EPO, its challenge before the High court and its advanced product development. In its reply to the Statement of Objections, Servier claims that the Commission refers to different actions that Niche could have undertaken but which would not have had the expected effects. In particular, Servier argues that (i) the outcome of the process patent litigation could not be anticipated, (i) it was unlikely that Niche enters at risk, (iii) Niche would not launch a revocation action on the '947 (iv) withdrawal from the EPO opposition had no appreciable effect on competition and (v) Niche had no interest or financial resources to oppose the beta patent). However, the counterfactual described by the Commission refers to a number of possibilities which were likely since Niche was well advanced in its development project with Matrix -- had it not been for the settlement with Servier, Niche would have remained a competitive threat (through litigation and potential entry)."

So that is how they are approaching this.

MR. MALEK: Can you look at (2052) on page {Auth-F/17/491}.

MR. TURNER: Yes. Shall I read this, sir?

"On the basis of the foregoing considerations, the Commission finds that the Lupin Agreement was such as appreciably to restrict potential competition among Servier and the generic companies and barred 'real concrete possibilities' for Servier and lupin to compete between each other or 'for a new competitor to penetrate the relevant market and compete with the undertakings already established'."

MR. MALEK: Yes, carry on.

MR. TURNER: "By discontinuing Lupin's patent challenge, removing the possibility of launch at risk with Lupin's product or transfer of Lupin's technology to other generic companies the Lupin Settlement Agreement appreciably increased the likelihood that Servier's significant market power would remain uncontested for a longer period of time and that consumers would forego a significant reduction of prices that would ensue from timely and effective generic entry."

Yes. This is consistent with the same analysis. It says that because that risk was removed of entry and therefore of Lupin competing, it was likely that -- it increases the likelihood, it does not create the likelihood, it increases the likelihood -- that Servier's significant market power remains uncontested and therefore of these effects eventually --

MR. MALEK: When I read that, I thought it goes quite far, on one view too far, but it is quite a -- it is consistent with your case anyway.

MR. TURNER: No, I do understand that. The case -- we have now debated it -- but you see how I put it.

THE PRESIDENT: Yes, I see that is consistent with *Servier*. Is this one where they found all this leads up to, that there was an infringement by effect as well as by object?

MR. TURNER: Yes.

THE PRESIDENT: Is that one of the issues under appeal?

MR. TURNER: Yes, it is. It is.

THE PRESIDENT: Yes, and we are not bound by that, of course.

MR. TURNER: No.

THE PRESIDENT: We have to take it into account.

MR. TURNER: That is right, you have regard. However, it is also consistent with the court's judgment which operates under section 60(2) of the Act and that takes us to the *Visa* case. The *Visa Europe* case is in {Auth-G/24/1} volume 15 of the hard copy.

THE PRESIDENT: We can put away Servier, can we?

MR. TURNER: Put Servier away. Yes.

If we begin on page {Auth-G/24/3} paragraph 5. There was a complaint. The conduct at issue that was complained about was Visa's refusal to let Morgan Stanley become a member of the Visa Europe system. If we go forward to page {Auth-G/24/7}. At the top you have paragraph 17. The court notes that there were three potential relevant economic markets that should be considered for issuing cards, for acquiring, where the banks compete to have contracts with the shops, the merchants, for card processing and a network services market. At paragraph 18 the court notes that although Morgan Stanley is refused admission, it could have had effects in both issuing and acquiring, the Commission's finding relates exclusively to the acquiring market.

The third part of Visa's third plea in law is to be found on page {Auth-G/24/43}. This is the relevant part of the judgment. The heading above paragraph 153 is "Insufficient and erroneous analysis of the effects of ... non-admission on competition".

That therefore is the issue.

It concerns the link between admitting Morgan Stanley to the scheme and the effects on competition in that market for providing acquiring services which the Commission had found in the decision.

The critical question which is addressed by Visa's submissions is recorded beginning at 153 and going through to 157, and it is whether the Commission has established that if Morgan Stanley had come in, it would have entered the acquiring market at all; had it been shown to be a likelihood or better.

At paragraph 153 to 156, Visa are complaining that the Commission did not do an analysis to compare the situation on the market, if Morgan Stanley had joined the scheme, with the situation where they had stayed outside.

At 157, at the bottom of page {Auth-G/24/44} the complaint is that the:

> "... the Commission based the assumption that Morgan Stanley, once it became a Visa member, would have entered the acquiring market [got into the relevant market] on nothing other than a ... professed 'continued intention' ..."

That was the complaint. At 158 Visa challenges other evidence relied on by the Commission and it also points out that when Morgan Stanley does come into the Visa scheme as a Visa member bank, it chooses not to go into the acquiring market at all, it just focuses on the issuing market.

They say you have not made out the effect on competition. The court then rejects the Visa submissions, beginning at 162 at the top of page {Auth-G/24/46}. Throughout the

reasoning that follows the court is making clear that all the Commission has to show is that Morgan Stanley had been a potential competitor within the meaning of the case law. There is no need for the Commission to show that Morgan Stanley would have likely got into the acquiring market had it been admitted.

At paragraph 162, the court characterises the complaint, the argument, as a claim that the Commission failed to establish Morgan Stanley was a potential competitor.

Then, over the page at {Auth-G/24/47} paragraph 166, they say one of the issues raised was the legal tests:

> "In the second place, as regards the legal tests which should be applied in order to determine whether Morgan Stanley was a potential competitor in the market in question, it follows from the case-law cited in paragraphs 68 and 69 above that the Commission was required to determine whether, if the Rule had not been applied to Morgan Stanley, there would have been real concrete possibilities for it to enter ..."

It is after considering that evidence in some detail that the court gives its conclusions on page {Auth-G/24/52} at paragraph 187:

> "Since it follows from the foregoing that (i) the Commission's assessments of Morgan Stanley's ability to enter the market ... are ... challenged ..."

Ability to enter the market are not challenged:

> "... the hypothesis that Morgan Stanley might enter the market in question is not merely theoretical it must be concluded that the Commission did not err in law by describing Morgan Stanley as a potential competitor."

Therefore the complaint must be rejected. So they are not saying that it was necessary for the Commission to show that it would have been likely, had this restriction not operated, that they would have entered the market, only that the real concrete possibility had gone. That analysis is consistent with *Servier* and supports the approach of the CMA.

THE PRESIDENT: Would there be a difference if, suppose after patent expiry, GSK knew that there were these two generics who might enter the market, although they have not yet got their marketing authorisations, so they are clearly potential entrants, potential competitors and then paid them not to proceed to get market authorisation, or enter, so even though the patent had expired, there is no generic entry which of course keeps the price up; you see then one could say that it is potential competition, they have not come in and maybe it is not clear that they would have come in, but it is a plausible assumption that they would.

Is there not a difference where there might be a legal prohibition on them coming into the market, because there is a potentially valid patent right? That seems to me rather different from the situation discussed in paragraph 186 here.

MR. TURNER: This takes us back to the analysis in *Servier*.

THE PRESIDENT: I see --

MR. TURNER: -- paragraphs 91 and following. Sorry, not Servier --

THE PRESIDENT: Servier is on your --

MR. TURNER: I apologise. What I meant was the *Lundbeck* General Court judgment, because they point out that following the Commission in the *Lundbeck* case, the attempts by generics to get into the market require them to overcome a number of hurdles before they reach that bridge. Those hurdles include getting the marketing authorisation. They include also in many cases, in this sector, the pharmaceutical sector, overcoming the patent hurdles and taking part either in challenges to validity or resisting infringement challenges.

In the section from paragraphs 91 to 97 of the *Lundbeck* General Court judgment, the main section, a list of the routes to market is laid out, of the steps that must be taken before you get in, and they conceptualise the patent challenge as part of that. They say it is a mistake to conceive of the grant of the right, the assertion of the right by the incumbent as itself a legal prohibition equivalent to that in the E.ON Ruhrgas case, for example, where you will recall that so far as the French market is concerned, there is law that says you cannot compete until a certain date.

That is one thing where there is a law which says you cannot compete until a certain date. But where there is a patent right in the hands of the private party, and you have the ability to challenge it and thereby overcome -- to come in, that is something different. It is different from legislation.

THE PRESIDENT: But you see in 187 they say:

> "... the Commission's assessments of Morgan Stanley's ability to enter the market ... are not challenged ..."

They were able, there was no bar to them entering the market. It is a question of did they intend to and have they got the relevant skills and so on --

MR. TURNER: We agree.

THE PRESIDENT: -- and experience.

MR. TURNER: But that is an immaterial -- it is true that they in this case picked up on a question of the intention of the potential competitor to enter the market, and there were not doubts about the ability of it to do so.

But that is immaterial to the proposition on which the court rested its conclusions, because the only reason why Morgan Stanley, why the complaint is upheld is not because there is a finding that because of that ability, they would have entered the market or likely have done so; it is because the ability test is the litmus test for potential competition rather than intention.

Therefore, it was the reason for finding that there was real concrete possibility in this case. That is why the point is an irrelevance. Either way, the Commission did not have to prove on the balance of probabilities that in the absence of this restrictive agreement, Morgan Stanley would have come on to and have been active on the acquiring market.

So that is the first point that was made on the other side. Actavis make a related point, paragraph 74 of their closing, where Ms. Ford says the *Visa Europe* case did not concern a scenario in which a potential competitor could, on one potentially likely counterfactual, lawfully be excluded from entering on to the market by assertion of a valid patent.

That is true. But the *Visa* case did concern a scenario where the only affected potential competitor may well have chosen not to enter the market at all on a potentially likely counterfactual. The result is the same, the Commission could not prove it was likely that Morgan Stanley would have entered, but the finding of infringement is endorsed by the court.

Finally, Xellia deals with *Visa* in detail in its closing in paragraphs 59 to 60. Their account of the judgment is, in my submission incorrect. They say the issue in that case was a purely factual question to do with Morgan Stanley's entry. The case gives no hint of a suggestion that it was proposing a radical new legal test for counterfactual analysis along the lines --

THE PRESIDENT: What paragraph of the closing?

MR. TURNER: That is paragraph 59 of Xellia.

The claim that the issue in *Visa* was purely factual and not a legal one is not right because the complaint in this third part of the third plea was legal in nature, and I stressed those words when I took you to the relevant part of the judgment in paragraph 154.

It concerned the alleged failure by the Commission to apply the tests drawn from the *European Night Services* case to Morgan Stanley's entry prospects.

At 166 of the judgment, the General Court answers that, not only by summarising the evidence on which the Commission relied, but by identifying the right legal tests which should be applied.

So, in summary, with an eye on the clock, the appellants' criticisms of the reliance on *Visa* are not right. It was correctly relied on by the Commission in the *Servier* decision, and it supports the approach that I have outlined and which the CMA has adopted as well.

MR. MALEK: Can I just put a scenario to you. You have got a patent dispute and the position is uncertain as in the present case. You settle on terms like the present, but three months later you get a judgment in a related case which upholds the patent. Are you saying you still have an effects case?

MR. TURNER: I do. I will come to that because one of the points that has been raised, going the other way actually, is *Apotex* and the outcome of the *Apotex* case as a relevant benchmark for effects. Could they have come in before the *Apotex* judgment comes out? Because then we know the market opens up at the end of December 2003, early 2004.

But that is not the correct approach in my submission. You look at the agreement and its validity or illegality at the time it was made. At the time it is made you do not know what may or may not happen with extraneous events. Apotex may or may not have succeeded, or, if one takes the strategy being adopted by GSK in this case, you find competitive threats when they arise, and you speak to the relevant generic and settle with those, it may have been that they would have made agreements later with Apotex. They might have done. But the legality of the agreement cannot depend on those subsequent extraneous events.

THE PRESIDENT: That has the consequence, Mr. Malek's example, that if three years later someone, the NHS, sues, saying: we want damages because this had the effect of restricting the competition; then, GSK could say: no, you did not suffer any loss because there was subsequently someone else who did take it to trial, the patent was held to be valid, and that would follow, would it not, subject to the non-infringing point, which is a complication.

MR. TURNER: That is right.

THE PRESIDENT: So you would have, on the one hand, a finding of restriction by effect, and then you would have the person who would suffer from such effects being unable to recover compensation because the court would say no, it did not have any effect.

MR. TURNER: Again that comes back to the distinction one must be careful to draw analytically between restricting potential competition from moving forwards and the effects, as you have seen those are articulated by the Commission very clearly, recital (1219) and, on the other hand, a damages claim in court which by its nature is dealing with the question whether the claimant has suffered financial loss, which is a separate question and should not drive the analysis of the restriction in the first place in public law.

MR. GLYNN: If I may, sorry, does the approach you are taking mean that every settlement of a patent litigation case would be anti-competitive in its effect?

MR. TURNER: No it does not because the settlement process, I come back to my submissions on the first day, is equally a part of the competitive process. What makes it anti-competitive is where there is an inducement to achieve a result which closes off a route forwards to a generic to entering the market. It is essential to the analysis that that should be present as well.

I turn then to the question of increases in competitive constraints, because having shown that there was a restriction of potential competition by knocking out one after the other, each of the major generic threats, in the decision the CMA goes on to examine whether there had been any increase in competitive constraints and observes that there were not. It observes the flat line in Seroxat prices. It observes the complete absence of competitive responses.

THE PRESIDENT: Sorry, you are addressing now something quite different from effects, are you?

MR. TURNER: It is part of the effects analysis in chapter 7 of the decision.

THE PRESIDENT: What is the point this is going to?

MR. TURNER: This is that there is a restriction on potential competition, which is shown, and then it is reinforced in the section 7 analysis by the examination of whether there was any increase in actual competitive constraints.

THE PRESIDENT: This is to do with the supply agreements?

MR. TURNER: Yes.

THE PRESIDENT: It is a slightly separate point, is it not?

MR. TURNER: Well, the supply agreements were part of the settlement arrangements. What is said by the appellants is that the arrangements as a whole have to be taken as a package. They rely on that for a different proposition from the authority, because the authority takes the same approach as *Lundbeck* which says it is a supplemental consideration, or as Professor Shapiro, who points out that where you have a hybrid case of cash and non-cash, then the mischief done by the cash cannot be ignored.

They say, on the other side, that because the supply agreements were part of the overall settlement package, it is necessary when you are assessing effects, at least to weigh up any reduction in potential competition relied on by the CMA, against a benefit in actual competition resulting from the agreement, which they say comes from the supply agreement side.

THE PRESIDENT: But this is not something in the section on effect in the decision. It is an argument now put up --

MR. TURNER: I am sorry, it is, because the section in the decision, section 7, has quite an extended part on no material increase to actual competitive constraints. For example if you look on {V/1/334} above paragraph 7.25, you see the heading which then introduces the discussion of whether competitive constraints were increased or not.

It extends for a significant part of the section. That was the way in which the decision examined it, having pointed out the restriction on potential competition, by returning to the question that there was not an increase in competitive constraints to reinforce that.

THE PRESIDENT: Before you move on to that, there is a long section on the counterfactual in the decision, I think, starting on -- probably separately for the two agreements -- but the Alpharma one starts on page {V/1/381}. I imagine there is a parallel one for GUK.

MR. TURNER: Yes. Let us take that then.

THE PRESIDENT: It says -- that looks at the counterfactual --

MR. TURNER: Yes.

THE PRESIDENT: -- in 7.100, which says at the bottom of that page:

> "The realistic and likely outcomes are that Alpharma would have pursued its challenge to GSK's patent claims or, alternatively, that Alpharma would have entered into a settlement on terms that were not 'bought' ..."

MR. TURNER: That is right.

THE PRESIDENT: Then it looks at each of those two alternatives. At (a):

> "Alpharma seeks to enter the UK paroxetine market independently of GSK".

In other words, the litigation would have continued as it is explained in 7.102. Then 7.104 {V/1/383}:

> "It is therefore likely that, had the litigation progressed and had Alpharma successfully defended its product launch before the Courts, other generic suppliers would have entered soon after."

MR. TURNER: Yes.

THE PRESIDENT: But does one not need both parts of that sentence? That this is taking an approach of likelihood and following it through to Alpharma being successful.

MR. TURNER: That is not what was happening, no. That is not the right reading of this. If you go back to 7.100, the reasoning actually tracks quite closely the approach taken by the Commission in *Servier*. So 7.99 says it is examining the competitive landscape. 7.100 points out that they would have continued to be a competitive threat and remained a

potential competitor that was pursuing the efforts to enter the market independently, because their behaviour would not have been distorted.

The following part, sir, that you read, relates to the possible things that might have happened, and there were in fact only two things, given that they are in litigation: either it goes forward or they get out through some form of agreement, either capitulation or a settlement agreement.

We then have, beginning at 7.101, the expression of how these are possibilities that might have occurred. What this entire section is there to show is that these possibilities could well have led to outcomes. Could have led to outcomes, not would have led to outcomes that may have increased competition in the actual market. It is concluded after those two sections at page {V/1/388} with a similar parallel to *Servier* that:

> "The absence of other relevant sources of competition ... meant that ... [this] Agreement assisted GSK in preserving its market power", similar to the Servier finding.

All of this, though, is not seeking to make any finding about what would actually have happened, but pointing out that these are possibilities that could have gone forward to something that would have led to consumer benefits.

It is therefore a close parallel to the paragraph in the *Servier* decision that Mr. Malek identified before we went away from it.

MR. GLYNN: But it is a racing certainty, is it not, that a decision would have been made within the relevant timescale one way or the other.

So that if you are thinking about the counterfactual of continued litigation, to imagine that as continued litigation just going on as continued litigation, and therefore a continued uncertainty which could be removed, is unreal, is it not?

MR. TURNER: You were right, sir, when you -- I cannot remember with which of my colleagues you debated this point -- but you were right to observe that the CMA is not talking about a process of endless litigation, which is akin to a form of hell for some people. They were thinking about a process that will come to some conclusion.

MR. GLYNN: Come to an end one way or the other. Just so.

MR. TURNER: Yes, one way or the other. The point that is being made is that one of those possibilities, although not the likelihood, which has been shut off, is that the generics could have won. In the paragraph that the President has identified, they are pointing out that, had those possibilities crystallised, had the litigation progressed and had Alpharma successfully

defended its product, had that outcome eventuated, that would have led to the benefits eventually which competition law is seeking to protect.

MR. GLYNN: But I think it is common ground, is it not, between everybody, that if you are thinking about an effect of an agreement, you have to compare what actually happened with what would otherwise have happened in the counterfactual.

MR. TURNER: Yes.

MR. GLYNN: If the counterfactual, if we thought about it -- I am now going beyond what has been fully discussed -- but the counterfactual has to be over a reasonable or realistic timescale. It would be artificial to say that the counterfactual is just for a fortnight or something like that. You would have to take it over the relevant period.

MR. TURNER: Yes.

MR. GLYNN: If the relevant period includes the litigation coming to a settlement, then -- to a judgment, forgive me, I am so sorry, to a judgment, then the state of the world with which we have to compare what actually happened is with intended litigation up to a point in time, then, either (a) or (b). In that case we are inevitably into the world of uncertainty and what happens in the real market, as opposed to what happens in the market before the settlement -- I understand entirely the point you are making.

MR. TURNER: Yes. The conceptual head set is that, at the time the agreement is struck, it prevents a process of competition going forward. At that point the litigation is continuing or a settlement deal might be struck.

MR. GLYNN: Yes, and the potential --

MR. TURNER: But it does look forward in time and it identifies here in paragraph 7.104, a potential future outcome which might have occurred, and the difference between this approach and what is understood to be a possible difficulty is that it is not saying: you have to show that that would likely have happened.

MR. GLYNN: No, no. But in your world of where we are, uncertain, we do not know. This Tribunal cannot form a view on what the probabilities were. So we are dealing in a world in which there is uncertainty, except that we can be certain that there will be either (a) or (b). In -- we are thinking about the effects of these agreements, we have therefore to compare it, surely, with, if you like, two possible counterfactual scenarios which would be a completely conventional way of doing the economics of an issue like this, two alternative counterfactuals, and you would be weighting the probabilities of either of them when you are reaching your balanced view about the effects of the issue you are analysing. You are

departing from that, it seems to me, if I may say so with respect, by just limiting the counterfactual discussion to the period before there is a judgment.

MR. TURNER: We do not seek to do that, sir. I do understand your point. If there is, let us say, a 30% chance that the generic will succeed in the litigation, the complaint is that through a restrictive term or restrictive agreement, that possibility, which would have gone forward to something then transpiring has been shut off, and so looking at it also in economic terms, one is suppressing a possibility. Going back to the debate that was held with Dr. Jenkins over the Ford and Apple driverless car, for example, one leaves aside the fact for the moment that this is patent litigation; as she says, as expert economist for Merck, from her perspective, to prevent a possible outcome, even if it was only 45%, from transpiring, was anti-competitive in nature.

That is alleged, but nonetheless it is restrictive. Here what is in effect being prevented is the possibility, the potential for that to exist.

This is why in the *Lundbeck* case, the distinction that I am drawing is referred to by the General Court by saying that if it were otherwise, and you always had to show that it would be likely that somebody would have come on to the market with certain price effects taking place, the distinction between actual and potential competition would be eliminated.

MR. GLYNN: But here what we have is a situation in which what actually happened, compared with the status quo ante, was some developments which could reasonably be described as having some pro-competitive elements in them, without evaluating that, there is some competitive benefit from the settlements, arguably and if we are thinking about an effects case, we have to have something with which to compare them over the relevant timescale. Therefore you have to go beyond the point which you make about striking out the uncertainty to do an effects analysis.

MR. TURNER: That takes us back to the way in which the appellants are putting their case, which is to say even if we are right that there is a restriction on potential competition which engages the legal prohibition, you have to weigh against it the benefits that they urge occurred under the supply agreements, before you can reach a conclusion that there was overall a competitive harm.

THE PRESIDENT: They say that for object as well.

MR. TURNER: They say it for object --

THE PRESIDENT: They say that precludes the inference to the agreement.

MR. TURNER: Yes.

THE PRESIDENT: That is a separate point from --

MR. TURNER: Here in effects they say that it defeats the effects analysis as well.

THE PRESIDENT: You say that the balance of probabilities requirement is satisfied, is that right, because it is more likely than not that there would have been an unlikely possibility of entry?

MR. TURNER: It is --

THE PRESIDENT: It is more likely than not that in the absence of the settlement, and the litigation continued, there may have been an unlikely possibility of entry?

MR. TURNER: Not an unlikely possibility of entry, but a real concrete possibility of entry occurring.

THE PRESIDENT: Which may be unlikely?

MR. TURNER: It may be unlikely yes.

THE PRESIDENT: That is good enough?

MR. TURNER: It is. If you take the *Visa* case and return to the court's finding, which is very clear, there is no finding that Morgan Stanley would have entered or likely have entered the relevant market, for providing acquiring services.

The court did not say that the Commission needed to find that Morgan Stanley would or would not have entered. The court was satisfied that infringement by effect was shown because of the real concrete possibility.

Sir, I am going to deal with this last area as quickly as I can. Can I take it that we may be able to sit a little bit beyond 4.30 pm or is that not -- because Ms. Demetriou will need to know, and it will affect the way in which I proceed.

THE PRESIDENT: We need to understand your effects case, which we have been struggling with, to be frank.

MR. TURNER: Yes. So I will proceed. The other area covered by the decision, and which the appellants refer to on the front foot for their case, is whether, because of supply agreements, you do or you do not see increases in competitive constraints.

Our case is that even were you to see pro-competitive effects from these agreements, as with the object case, you should be analysing those in any event under paragraph 3, where the weighing between pro and anti-competitive effects takes place.

We also come back to Dr. Stillman's very powerful evidence that in this sort of agreement, you can expect with a fixed welfare pie that if the parties to the settlement agreement are benefiting from this sort of arrangement, that in aggregate, collectively, the customers are suffering.

Now, the CMA did look and find that there was no increase in actual competitive constraints. The contrary case is: yes, there were. GSK began the debate by submitting Dr. Stillman's appendix E, predicting, using the model called dominant firm competitive fringe, that GSK could be expected to lower its price eventually because of pressure.

THE PRESIDENT: I think he went off that on the basis that they did not and nobody expected them to.

MR. TURNER: That is right. In their closing submissions, GSK is therefore silent for that reason on the question of effects which Dr. Stillman has been -- had put forward. I will simply give you a couple of references without going to it in relation to Dr. Stillman's evidence. I will give you one to take for the note, which is {TR/9/79} line 31 to page {TR/9/80} line 31. If I may go to one shortly on the screen {TR/10/28} at lines 10 to 15.

You will recall this exchange at line 10:

"So far as Seroxat is concerned, the evidence that we have considered is consistent with these agreements having been designed to maintain stability of the Seroxat prices in market and achieving that aim?

"Answer: Relative to what?

"Question: Relative to the status quo ante --

"Answer: Okay. Yes, it is consistent with that."

Here, not comparing it with what would have happened, but seeing whether there has been an increase in the status quo ante in competitive constraints, the expert for GSK agrees that the market evidence is consistent with that.

There is a part of GSK's closing submissions beginning at paragraph 61, where they address the actual observed effects of the agreements. They merely conclude in paragraph 81 that the final position is that the agreements before the Tribunal viewed ex post led to increased competition, suggesting their likely effects were similar.

But essentially you have seen the pricing data, you have seen all the graphs and the documents, and the views of the experts in the hot tub, and one can see from that that these agreements did not lead and were not meant to lead to increased competition.

Finally, one comes to two areas of dispute which are the focus of the appellants' arguments, the mix effect and the wholesaler benefits.

The mix effect is this: GSK submits that although its own original submissions from the expert, Dr. Stillman, were not borne out, there was a product mix effect which meant that on average there were lower prices for paroxetine over the period from January 2001 to November 2003.

But that, in our submission, is a consequence of the allocation of product and the sale of that product at slightly lower prices by the generics.

The tiny decrease in average prices which is observed, whatever the range precisely may be, fails to take into account the shifts in the product quality.

So far as wholesalers are concerned, this argument, you asked Mr. Kon when it first came in, it was not in the response to the SO as an argument. It came in in a developed form with the reply, which is when Dr. Majumdar first filed an expert report.

THE PRESIDENT: The reply on the appeal?

MR. TURNER: On the appeal. That is when the expert report with this comes in. Dr. Majumdar pointed to the gains that the wholesaler made, and we therefore need to ask: what does the wholesaler gain tell us about competition in a market where the wholesalers are taking a cut of the price to the pharmacies?

We know that Alpharma operated on the basis that there would be a 25% wholesale mark-up across its portfolio. We know that they focused on the price at which their product would be sold in the pharmacies, and they set the price to the wholesalers, knowing the price that they wanted to achieve in the pharmacies.

Once you get competition, the full generic competition, wholesalers still take the same cut, but the prices in the pharmacies have then radically come down. So if the price to pharmacies drops, plummets from £13 to £6, the wholesalers take £1.20, 25%.

In short Dr. Majumdar has identified something that he says shows competition, which ironically means wholesaler gains are at their highest when competition at the pharmacy level is at its lowest.

THE PRESIDENT: We know that they still take the same margin, do we?

MR. TURNER: Yes, I will need to get you the reference after this, I apologise.

It is important to emphasise also that these Alpharma selling prices to pharmacies were understood between GSK and Alpharma. If you go to the decision at {V/1/368}, at the foot of the page:

> "In an internal email, dated 29 October 2002 [this is one of the Alpharma operatives] Ketil Sverdrup appears to confirm that GSK and Alpharma shared an understanding that the volume restriction would have the effect of maintaining prices at the prevailing level.
>
> '"The Sales price of £13,7 reflects what the negotiation ended up with -- a sales price which GSK and Andrew [Collier], I believe, agreed on would be the correct one to be able to sell 500 packs."'

{V/1/369}.

If we go to -- the reference in the documents for that, if you want to see it separately is at {H3/11/2}. Perhaps if we can open that up. There is the email and if you go to the previous page you see the reply and the reply is at the bottom of that page from Mr. Russell Howard. He writes back:

> "Thanks Ketil this all makes sense -- but we need to review the Paroxetine position. In discussions with Helen [that is Helen Toogood of Alpharma] the now model is based on an ASP of £10.50 and holding for the year."

So they assume that there is going to be stability in what they are able to sell this through the pharmacy at.

To draw the strands together, the evidence that you have heard does nothing to undermine the authority's case that these agreements were not likely to increase the competitive constraints faced by GSK.

As Dr. Stillman fairly put it, at the end of his cross-examination, when I asked him about paroxetine prices and whether those might have been designed to be affected, he said: well, why would GSK be concerned about that, they are only concerned with Seroxat; which is right. The effect on Seroxat is quite clear and unequivocal. There was none.

The other flaw in Dr. Majumdar's theory is that it is inconsistent with the evidence about the way in which wholesale prices developed, because if the addition of new sources of supplies, each of these generics comes on stream with their allocation, was going to give greater bargaining power to the wholesalers, then the addition of every new generic should have had some impact on the price that the incumbent generics were charging to wholesalers but it did not.

You see that in the evidence. I will not go to that now at {TR/9/11} lines 10 to 19. Sir, unless there are any further questions from the bench, those are our closing submissions.

THE PRESIDENT: Those are your closing submissions.

MR. TURNER: My closing submissions. My bit of it.

MR. GLYNN: Mr. Turner, the way you developed the argument focuses very much on the Seroxat price; it is one of the cases that you make that these arrangements were not expected to have much effect on that. But you have also said in other places that we should be concerned with the process of competition, which is a broader concept than a single price. We have heard with different degrees of emphasis from different parties during the hearings, reference to -- obviously, as you just mentioned, the pharmacists and the wholesale markets and the developments that took place at that level in the supply chain.

They can be characterised differently, but it was not altogether unfair to regard them as a competitive process in themselves.

I mentioned, and I think I picked up from some of the submissions the point about the livery and get up of the generics' companies, which was something they clearly attached importance to for presumably -- clearly for pro-competitive, longer-term reasons.

There are other dimensions of competition too which have not, frankly, been discussed very much. No, let me modify that. You have spoken quite a lot about the effects on the part of the competitive process which is the process of litigation around contested patents. You are seeing the patent litigation and the settlement of those litigations as part of the competitive process, which is completely right, I am sure.

But we have not had much discussion about what the effect of such settlements would be on that process taking it as a process which would continue over a long time and through other cases.

Another point as well, but this point in question, is are you not being too narrow in focusing on the Seroxat prices, and the absence of an expected and substantial effect on the Seroxat price, in trying to lead to the conclusion that there was not an effect on the competitive process, taken more broadly?

MR. TURNER: We say not. May I make as a preliminary comment a response to, sir, you saying that there is not much evidence that these agreements were expected to have effects on Seroxat; they were indeed fully expected to have an effect on Seroxat, namely, to stabilise it.

The question of the other competitive effects in relation to paroxetine was also a part of what was considered in the decision at the pharmacy level, and I hope I do not do a disservice there to the arguments on the other side, but it has come down to, by agreement between the experts in the hot tub, a question of the mix effect. The original approach --

MR. GLYNN: Certainly, and to interject, many people I think would see a mix effect as being just as much a competitive outcome as a price effect. It is a different way in which the competitive process may work.

MR. TURNER: Yes, the experts debated this point. There was the discussion about the quality adjustments that needed to be made, and also the question whether that mix effect was in itself little more than the outcome of what amounted to a form of market sharing agreement, in which a former monopolist says: from now on, you can have a piece of the fixed pie and you will be able to supply it and you will be able to supply it at slightly lower prices.

In those circumstances, for the parties concerned when challenged to come forward and say, well, this is competition, rings rather hollow.

The additional point is a technical or legal one, that once we have identified an important restriction of competition as we say we have of this kind, and the maintenance of the price of Seroxat to pharmacies being achieved as an important anti-competitive end, we then move to the different legal world of paragraph 3, Article 101 to conduct any form of weighing exercise.

In that context, the burden is then, the legal burden on evidential moves to them to say: these are important.

Therefore, sir, the things you have picked up as possibilities, the livery point and how this establishes further relationships, are things which, if they are going to be put forward as good explanations to defeat the overall infringement, need to come from them in evidence, not from the authority.

MR. GLYNN: One final question, if I may. There was the concept of the welfare pie that you touched on a few minutes ago.

MR. TURNER: Yes.

MR. GLYNN: I think we have also had, with argument, about its cause, how one should really interpret it but the agreement that the NHS save 15% or £15 million odd, whatever it was, in its purchase of this drug.

Where do you think that money came from?

MR. TURNER: The pharmacists are squeezed because they are paying out, and now they are not receiving the same level of reimbursement, even though the prices that they pay remain stable.

MR. GLYNN: So it is the pharmacies are squeezed is your -- that is your --

MR. TURNER: Absolutely, but I come back to the point I was making yesterday, I have given you some references, we focus on the position of the pharmacies, not because we say that they are the final consumer or their interests need to be consulted, but because that is, as Professor Shapiro put it, the right locus of competition to see the way in which the competitive process is affected by these agreements. Not in itself. Sorry, a final point is that effects on livery, I have made the point that it is for them to develop that sort of case.

MR. GLYNN: Indeed, yes.

MR. TURNER: We do say that none of those sorts of effects that have been put forward in the course of this hearing, together with the other elements, are material, but even if they were, in our closing, if you look at paragraph 115 which I shall not go to now, explains why these

agreements harm the competition relevant to the continuation of the litigation, in the sense that I have explained.

THE PRESIDENT: Would that be a sensible moment then to take a five-minute break?

MR. TURNER: Yes.

(3.12 pm) (A short break)

(3.25 pm)

Closing submissions by MS. DEMETRIOU

THE PRESIDENT: Ms. Demetriou, we can sit a bit later but we will then need to take another break at 4.30 pm.

MS. DEMETRIOU: Thank you. May it please the Tribunal, I am going to address you on the abuse of dominance case and then penalty.

In relation to the abuse of dominance case, I am going to focus on the market definition and then I will say a few words about IVAX and Tillomed, which is the one subject in relation to abuse on which Mr. Flynn addressed you in his oral closings.

So starting with market definition. I wish first of all to start with GSK's position as it was explained by Mr. Flynn in his closing submissions. Secondly, I am going to move on to the expert evidence given in the hot tub, and identify the narrow area of dispute between Professor Shapiro and Dr. Stillman. Finally, I am going to explain why we say the Tribunal should resolve that narrow question in the authority's favour.

Starting with GSK's position, can we go to the transcript, {TR/14/40}. These are Mr. Flynn's closing submissions and it is convenient just to take it from lines 18 to 33. So what Mr. Flynn said there is he said:

> "A particular point that I think it is perhaps worth stressing is that there was quite a discussion in the hot tub particularly about the possibility of two markets and facing two ways on the bridge.
>
> "In our submission, and we have said in our closing submissions that the experts may have muddied the water somewhat by talking in terms of merger cases, when you are necessarily doing a prospective analysis and considering whether it is a branded generic merger or branded branded, considering what would happen if a particular product, the same molecule, came under single hands.
>
> "We say, in fact, in this case the relevant market is the SSRI market, and that remains so even after genericisation of a particular originator's SSRI. Because at the time that we were talking about, for example, one of the players in the SSRI market was Eli Lilly despite the fact that its fluoxetine molecule had been genericised."

Then he goes on to say obviously in a merger case it is different.

So GSK's position is as follows, they say that the relevant market is the SSRI market.

Secondly, they say, in any abuse of dominance case, the Competition Authority should take into account solely the competition on marketing and advertising and such between the SSRIs.

They say critically that that is true after independent generic entry as well as before --

THE PRESIDENT: I did not understand that, Mr. Flynn will correct me if I am wrong, as meaning after genericisation of the paroxetine market, which would be contrary to Dr. Stillman's view. I understood it to mean that even after another of the SSRIs was genericised, then that did not change the market definition as regards paroxetine before it was genericised.

MS. DEMETRIOU: We understood the former because we understood -- and it is notable --

THE PRESIDENT: Perhaps Mr. Flynn can clarify.

MR. FLYNN: I do say that just as Eli Lilly is competing in the SSRI market, despite the fact that fluoxetine is genericised, so when it comes to it, GSK is competing in the SSRI market, once paroxetine is genericised.

That is what Dr. Stillman says in his market definition report.

THE PRESIDENT: So you say even after full generic entry here --

MR. FLYNN: Despite the fact that the nature of the competition changes, as we all accept, the focus changes from essentially detailing to the prescribers to --

THE PRESIDENT: I see. Well, then Ms. Demetriou is right.

MR. FLYNN: That is what we say and that is what Dr. Stillman --

THE PRESIDENT: I do not think it is what he said in the hot tub.

MR. FLYNN: I accepted that in discussion with Mr. Malek, and I do say that -- I maintain that the discussion got a bit confused because of the merger issue, frankly.

THE PRESIDENT: The merger point, yes, I see.

MR. FLYNN: So our evidence remains, of course, he is talking about a time pre-genericisation obviously, but he is saying the relevant market in which we were competing at the time is the SSRI one, and within that you will find both branded originators, some of whom whose drugs are on patent and some of whom were not.

THE PRESIDENT: You were right, I am sorry, Ms. Demetriou.

MS. DEMETRIOU: I will come on to look at what Dr. Stillman says, because we say that it is different to the case as Mr. Flynn put it and as he has just explained.

THE PRESIDENT: I think Mr. Flynn accepts, in the hot tub --

MS. DEMETRIOU: He accepts that.

MR. FLYNN: I do accept that.

THE PRESIDENT: -- he said, but we need to look at whether he was talking about mergers or whether --

MS. DEMETRIOU: Yes, and we say it was a more general point and I will come on to that, but before I do that, can I just dwell for a second on what GSK's position would mean in practice. Their position is that even when there are suppliers of paroxetine on the market, already on the market, such as generic companies, who are imposing a competitive price constraint on a patent holder, that competitive price constraint must be ignored in favour of the marketing competition going on between the SSRIs. That is essentially the position, and we say that in terms of what that would mean in practice, I want to take the example of parallel importers, which was an example that the President put to Mr. Flynn during the course of his closing submissions.

As the President pointed out, there was a competitive constraint on GSK in its pricing, imposed by the parallel importers who were on the market. Now, what if GSK took action designed to exclude those parallel importers from the market, because it wanted to keep the price of Seroxat higher? The hypothetical monopolist test, we say would seek to establish whether the hypothetical monopolist of paroxetine could profitably raise prices by 5% to 10% above the prevailing open price, so above the price at which GSK was competing with the parallel importers.

We know that GSK could sustain a SSNIP above that price, because they were charging the closed price as well. In other words, the other SSRIs did not constrain, they could not constrain GSK from charging that higher price, but on GSK's approach, the market should nonetheless be defined by reference to the non-price competition of the other SSRIs, and that is so, even though those constraints would be entirely irrelevant to the issue at hand, which is namely whether the exclusion of parallel importers would be a problem in terms of meaningful loss competition.

As the President said during the course of debate with Mr. Flynn, the parallel importers were, at the time, the biggest price constraint on GSK, really the only price constraint, and they reduced, as you put it, sir, their price to Boots not because of Cipramil but because of parallel importers.

We say that is the impact -- that would be the practical effect of GSK's position. Now turning --

THE PRESIDENT: This was not really discussed in the hot tub, perhaps I had not thought of it at that point, about whether -- what is the significance of the parallel import constraint.

MS. DEMETRIOU: That particular point was not discussed but we say in terms of the issue of principle, it is the same thing, because if you are going to ignore a price constraint which is already there on the market, which is what Mr. Flynn's case is, then you have got to do that in respect of parallel importers, just as you do with generics.

We say that that would be a consequence of GSK's position. Now, turning to the hot tub, as Mr. Flynn accepts, the proposition that he advances was not the position adopted by GSK's own expert, Dr. Stillman. He very clearly accepted that after genericisation, the market should be defined at the molecule level. Can we turn to the transcript {TR/13/24}. If you go to lines 13 and following. Mr. Malek said:

> "That is what I understood. Because look, once you have got independent generic entry, as I understand it, you fully accept that is the -- paroxetine is the relevant market."

That was the point being put to him and he says:

> "That is correct."

Mr. Malek:

> "Because you have GSK branded product competing with the generics and you can see all the price changes. But what you are saying is prior to that, that is not the relevant market."

Then Dr. Stillman goes on to say:

> "Yes, that is right. Then we do get to what Professor Shapiro described as the nub of the issue: what about at the border? You know what about when we are moving from one to the other?"

So that is the narrow issue as between the two experts as it emerged from the hot tub. We see this too if you go to {TR/13/38} lines 1 to 5. Perhaps we can go to the previous page just to see the proposition {TR/13/37}. Mr. Malek:

> "Before you do that. Can you tell me whether you agree or do not agree that there can be a different market definition depending on what you are looking at?"

Dr. Stillman:

> "Yes, I think that is correct. I mean again most obviously, as I say in my papers, if I am talking about the period prior to independent generic entry and I am thinking about the tying example or I think about a merger in that setting, the market that would exist

in that setting would be across molecules as I believe it is in this case. Whereas if I had a situation after the generic competition, the market would be narrower."

He said that clearly and it is not limited, it is not limited and that was the point that Mr. Malek was clear to elicit, it is not limited to mergers. He is talking much more generally. What we have --

MR. FLYNN: I do not wish to interrupt my friend, but if you carry on in the discussion it says:

"Yes, I am not so sure I agree with that because I am thinking about the merger ..."

MS. DEMETRIOU: I am limited in time, and Mr. Flynn does have a remark in reply; perhaps he could limit his remarks to reply unless I am saying something which is inaccurate. Here he goes on to talk about merger, but on both occasions he has accepted in general terms, and perhaps it emerges more clearly from the first reference that I gave you on page {TR/13/24} --

THE PRESIDENT: Yes, I think he is saying, as I understood it, can you have different market definitions at the same point in time? Yes, you probably can, for a merger as opposed to an abuse.

MS. DEMETRIOU: That is right.

THE PRESIDENT: For an abuse case, you cannot at the same time have two different market definitions, but when you move from the stage of patent protection to the stage of genericisation, which is a different point in time, then the market definition can change.

MS. DEMETRIOU: Yes, but my point is, it is most clear from page {TR/13/24} that he is not just talking about mergers --

THE PRESIDENT: I understand that.

MS. DEMETRIOU: That was the point I wanted to elicit.

What we have is a position where both experts have agreed, so there was a large measure of agreement between the experts. Both experts agreed that before there is any suggestion of generic entry, the relevant competitive constraints on a patented drug such as Seroxat are typically non-price competitive constraints. So here the marketing activities of the other SSRIs, and you heard Professor Shapiro accept that in the hot tub.

They both agreed that post-genericisation, then the market would generally be defined at the molecule level. You have seen the section where Dr. Stillman identified what he said was the nub of the issue between the two experts, which is what happens on the bridge when you are moving from one to the other. In other words, what is the correct approach to take in a case like this where generic entry was looming and the very issue under consideration was action taken by the patent holder to stave off that looming generic entry.

That is the nub of the issue. It is a narrow point. Professor Shapiro explained very clearly in our submission why the authority's approach is to be preferred. You may recall him saying that, ignoring the competitive constraints imposed by the looming generic entry, would be to miss the main show.

The action being examined is action to stave off generic entry and so the issue which arises under Chapter II is whether that matters in competition terms.

Does it matter that the patent holder is taking action to stave off generic entry? It only matters if those generic entrants are capable of imposing a competitive constraint on GSK. So that is the question that must be addressed. Are they capable of imposing a competitive constraint on GSK?

The authority's point that we advance to the Tribunal is that that question cannot be addressed by focusing on the non-price competition between Seroxat and the other SSRIs. It is important to identify what Dr. Stillman's objection was to the CMA's approach. The important point here is that he very fairly did not express his objection as one being about the fundamental economics. His objection was a concern about business certainty, and we see this from the transcript {TR/13/33}. We see at the bottom of the page, line 33:

> "I understand that approach ..."

That is Professor Shapiro's approach:

> "... and it has a certain logic to it, certainly under some circumstances. The problem that I have with that approach, however, is that while one might -- maybe there is a way to articulate the definition of dominance so that it is specific to conduct, but that is not the way it is normally done and that is not the way, at least in my understanding and experience."

He is saying it is not the way that it is normally done. Then if you go down the page {TR/13/34} to line 9 he says that:

That is certainly a risk of that interpretation that firms would face when deciding what kind of business policies and practices that they feel comfortable engaging in.

> "I think what we have to recognise is that with rules there are -- no rule is perfect. We have costs. In the one case, if we do not take the conduct into account, maybe there is a case we miss. But, on the other hand, if we do take the conduct into account and use that as the way in which we are trying to define the approach of dominance and we do it in the way that has been suggested by the CMA and Professor Shapiro, there are other costs, very broad costs that I think very much need to be taken into account when considering the appropriateness of that approach."

What he was talking about, you will recall, was the chilling effect on business through the absence of business certainty.

Having made those points, he went on to accept that the market might well be defined differently at the same point in time. That is the second of the passages I took you to at the outset, depending on the question in hand, and he gave there, as an example, a merger.

He says when you define the market at a time when generic entry is on the horizon, he says that if you are looking at a merger, then it may well be right to take into account the constraint imposed by the impending generic entry.

THE PRESIDENT: I think he was saying you could only define it -- the only acceptance he had that you can have different definitions at the same point in time was in the merger.

MS. DEMETRIOU: Yes, that is right. That was exactly his point. But what we say about that is that once you accept, as he does, both that in an abuse of dominance case, the definition of the market appropriately changes at different points in time, so before and after genericisation, and you accept that for any one point in time, depending on the question in hand, so whether you have a merger or not, the market definition might be different, then the business certainty objection that he raises starts to crumble.

THE PRESIDENT: It is quite well established that you can have a different market definition for mergers.

MS. DEMETRIOU: Yes.

THE PRESIDENT: I think it is even in the guideline.

MS. DEMETRIOU: So we say -- that is why we say that limited weight is to be given to the business certainty objection.

THE PRESIDENT: But it is a rather different consideration from running a business and deciding whether a merger will escape regulatory scrutiny.

MS. DEMETRIOU: Sir, that may be different, but even on Dr. Stillman's own approach, he accepts that post genericisation, the definition of market will take into account those constraints. Actually the business certainty issue starts to disappear, because if the only question is when do you take those constraints into account, the CMA's approach is modest. It does not require an incursion or a demolition of business certainty, because all the CMA is saying is that when you have got impending generic entry, and the very point at issue in the case is staving off that very generic entry, at that point in time, the market should be defined in the same way that Dr. Stillman says it should be defined post generic entry.

MR. GLYNN: The point he was making about business certainty was not -- it was a little bit broader I think then you have said. It was really that if you follow the logic of saying that if

you have an effective patent, in other words, a patent which allows you to charge substantially more than the generic alternative, call that a worthwhile patent, then if that is almost by definition or by definition becomes a dominant position, then on every action that a patent holder might take, they would have to be -- see themselves as subject to the added constraints of being regarded as dominant, rather than the normal business constraints. It is not just an uncertainty point, is it?

MS. DEMETRIOU: I entirely accept that point, Mr. Glynn, and what we say about that is that that is quite right because the fact -- this comes back to the one of the main points of principle in the case -- that one holds a patent does not mean necessarily that the patent is valid, or that somebody else might not be able to produce a non-infringing product.

So, the fact that one has a patent does not somehow immune the patent holder from treading carefully when it comes to taking steps to save off independent generic entry.

MR. GLYNN: No, but the question is whether -- it is almost a policy issue rather than a case issue, it is whether the patent holder should be subject to greater constraints on its competitive behaviour than a potential business in some other work.

MS. DEMETRIOU: We say that for this precise question, which is when the issue is action taken by the patent holder to stave off, to prevent or delay independent generic entry, then it is quite right that they should operate under those constraints.

What that does not mean is that -- it means that they will almost certainly be dominant in this kind of market, but what it does not mean is that they will have abused their dominant position, because that comes down to what they actually do.

When they settle the patent litigation, is the settlement an anti-competitive one or not.

MR. GLYNN: If they were to, let us say, put forward rather dubious attempts to extend the patent, a sort of patent thicket problem, that presumably would also be regarded as an abuse of dominance on your --

MS. DEMETRIOU: It would, which is exactly one of the abuses identified in *Servier*.

That is right. So any action that is taken to -- with the purpose of staving off generic entry, you have to look at whether that matters in competition terms and so you have to look at the constraint that those generics are imposing, whether they are imposing a constraint or not.

THE PRESIDENT: Given that patents of highly successful drugs, blockbuster drugs as they are often called, do attract the attention of the generics for over quite a long period, we are looking here just at two years, but in general, once a pharmaceutical company has established a very successful patented branded product, the generic companies get interested

in that market; it means that the patentees of the blockbuster drugs, in all action they take vis-a-vis a generic threat will be dominant.

MS. DEMETRIOU: That is right. But that does not mean to say that they are abusing their dominant position.

THE PRESIDENT: No, of course not.

MS. DEMETRIOU: They just have to be careful about what they do.

What I want to look at is what the consequence of GSK's position would be. Because GSK's position is that this type of forward-looking analysis, that Dr. Stillman accepts you can have in mergers cases, applies only in mergers cases and not in abuse of dominance cases, and we say that that would yield arbitrary results.

Firstly, of course, an abuse of dominance case might concern action that has not yet happened or which is continuing to happen. I am not going to turn it up but the *Purple Parking* case is an example of that.

Any case where you are seeking an injunction to prevent imminent behaviour that might be abusive is necessarily forward looking, and it would not make sense in that case to define the market in ignorance of the future competitive constraints that might operate.

Secondly, we say the question whether or not a patent holder could take action to stave off independent generic entry, would depend on precisely when it took that action. We say that that is undesirable. So if it took the action, for example, taking the facts of this case, the day after the *Apotex* judgment, then in Dr. Stillman's opinion, GSK would be dominant, and any action that was abusive taken to stave off generic entry would be subject to the Chapter II prohibition.

But if GSK took the same action the day before the *Apotex* judgment, then in that case the market would, on Dr. Stillman's analysis and on GSK's analysis, be defined by reference only to the set of more distant competitors who operate in the sector, and GSK would not be dominant, and it would be lawful for it to take action to stave off generic competition.

So we say that result would be arbitrary and that was a point that Professor Shapiro made.

If we go to the transcript {TR/13/23}. It is lines 10 through to 28. So he says:

> "... [just] before generic entry took place. Let us say it is two months and the branded firm -- let us say it still has a patent. Let us say the patent is about to expire. Suppose maybe it is six months and it enters into some conduct which is designed to stop effective generic entry. Maybe they purchase key inputs that the generics would need. Maybe they withdraw marketing authorisation. There are a whole range of different

types of conduct that we might consider. At that moment there is still no generic entry. There is no price competition yet.

"I would say at that point the relevant market will still be the molecule, just as it will be in six months from now, because the critical competitive constraints that are at issue are the generic competition. I think Dr. Stillman would agree, if a year goes by and now they are saying -- suppose the branded firm still had -- let us say after a month or two of generic entry, still had a large share and they engage in this conduct, it could be abusive. Anyhow there would be a relevant market, we should worry about loss of competition in that realm and the same is true slightly earlier.

"So it does not make economic sense to me to define the market prior to generic entry in a radically different way than you would immediately after generic entry. That is the problem with Dr. Stillman's approach of saying: no, just look at the current market conditions, no generic entry, compete with other drugs, not -- you know the relevant market is very broad and then it is suddenly going to shrink to a molecule if generic entry comes in.

"There is a problem with that approach. That does not work."

We endorse that, we say that as Professor Shapiro says, defining the market just before generic entry in a manner which ignores the competitive constraint imposed by the generic companies does not make any sense, because quite simply, the extent of competition with other SSRIs on marketing does not shed any light on whether there would be a competition concern if GSK were to snuff out the much greater competitive constraint that would be imposed by generic entry.

Just going back to the question about business uncertainty. I have made the point that the CMA's case is not a radical one. It is a modest case because it simply requires that where the issue being considered is this one, whether or not it is problematic in competition terms to take steps to stave off independent generic entry which is looming, then the market should be defined by reference to the constraints imposed by that entry.

We say that that is an easy exercise. It is an easy exercise to predict, and it is simpler than the kind of multifactorial analysis of qualitative material that GSK calls for.

Secondly, we say that any concerns about business uncertainty are dwarfed by the disadvantages of GSK's approach which we say involves -- leads to arbitrary results, illustrated by the extreme example I have given of action the day before and the day after the Apotex judgment.

Now, what are the other objections raised by GSK? There are really three other main points that we have identified. The first point is, well, that is not how it is done. The second point is that they rely on paragraph 24 of the Commission guidelines, which talk about not taking account of potential competition. The third point they have made is that the CMA's approach would lead to all patented drugs being dominant in cases concerning generic entry.

I think I have dealt with that third point in the course of the submissions I have just made; but taking the first two points, in terms of as to that is not how it is done, well, of course, we rely on the Commission's decision in *Servier* which is on all fours with the approach the authority has taken in this case.

GSK makes some attempt in its written closing submissions to distinguish that case, but we say that those attempts are misplaced, and it is easy to see that when you go back to the recital that we read out in our opening on the Chapter II case, recital (2546) which is at {Auth-F/17/648}.

Recital (2546) at the top of the page:

> "The generic constraint must be regarded as critical for the assessment" --

THE PRESIDENT: Yes.

MS. DEMETRIOU: You have seen that before. The second point is paragraph 24 of the Commission guidelines and we see how it is relied upon in GSK's closing submissions at {M/2/45}. It is paragraph 116 of GSK's closing submissions.

You see what is said there. They have set out their paragraph 24 of the Commission's guidelines which says that:

> "'[P]otential competition is not taken into account when defining relevant markets ..."

We say that on proper analysis that is not what the CMA was doing in this case and that when read in context, paragraph 24 has nothing to do with this case, and indeed, that is not a surprising conclusion to reach, given that the Commission in *Servier* did not consider itself constrained by paragraph 24, and as far as I can see, did not even discuss it.

Turning the guidelines up, they are at {A5/73/1}. If we go on to page {A5/73/2} we can see the context of paragraph 24, so starting at paragraph 13 at the bottom of page 2, this points out that:

> "Firms are subject to three main sources or competitive constraints: demand substitutability [in other words, customers switching from one product to another] ... supply substitutability [in other words, firms that currently supply one product

switching to supply another] ... and potential competition [in other words, firms that are not currently supplying any relevant product entering a market to supply one]."

Over the page, paragraph 14 explains that for obvious reasons, supply substitution and potential competition are generally less immediate than demand substitution. So they are generally dealt with as part of the analysis of dominance or effects on competition, rather than as part of the definition of the relevant market.

What that means is that when we are considering whether a price increase above competitive levels for our candidate set of products, for our focal product, would be profitable or not, we focus on the question of whether consumers would switch to other products outside the candidate market, and not on whether other firms would enter the candidate market in response to the price increase. You can see how that works following through the later paragraphs. So paragraph 17 sets out how the question for demand substitution is posed, in terms of the 5% to 10% price increase for candidate products. Would that result in sufficient customer switching to render it unprofitable? Paragraph 20 explains that contrary to the general position in paragraph 14, supply side switching in response to a price increase in the candidate market can also be taken into account where it is likely to be as immediate and effective as customer switching.

In other words, if a price increase in the candidate market would cause firms outside that market to switch to supplying in the relevant market very quickly, so as to render the price unprofitable, then those firms should be included in the relevant market too.

Then moving to paragraph 24 which is the paragraph relied on by GSK over the page:

"The third source of competitive constraint, potential competition, is not taken into account when defining markets, since the conditions under which potential competition will actually represent an effective competitive constraint depend on the analysis of specific factors and circumstances related to the conditions of entry. If required, this analysis is only carried out at a subsequent stage, in general once the position of the companies involved in the relevant market has already been ascertained, and when such position gives rise to concerns from a competition point of view."

Now, that is confirming what paragraph 14 said, so, in other words, when considering what would happen, if prices increased 5% to 10% above the competitive level in the candidate market, what you do not say is: well, if that were a permanent price increase, all of these firms currently outside the market might develop their own products and come in and take

away market share, so you do not include those potential competitors alongside the other SSRIs. That is what that is getting at.

That has nothing to do with our case, because we are not relying on potential competitors in our market definition exercise at all. We are saying that a monopolist of our candidate market, paroxetine, would have -- we are not saying that a monopolist of our candidate market paroxetine would have been constrained by anyone at all. We are not saying they would have been constrained by potential competitors.

On the contrary, what we are saying is that a hypothetical monopolist of paroxetine would be able to increase prices many times more than 5% to 10% above the competitive level, because there is very little demand substitution, and nothing else that would prevent a hypothetical monopolist from increasing prices. It is a different exercise. That is why the Commission did not feel constrained by paragraph 24 in *Servier*.

Our point --

THE PRESIDENT: Is it discussed in *Servier*?

MS. DEMETRIOU: Not that I could find. I am sure I will be corrected if that is wrong. The point in our case has nothing to do with that section of the guidance, as it did not in Servier, because our point is that when you are considering the competitive benchmark for the application of the hypothetical monopolist test, then you take the price as being the competitive price, the generic price. That is the correct benchmark, we say, in this case. But that is nothing to do with taking account of potential competitors that might come in with other products, once you have applied the SSNIP test to that focal product.

THE PRESIDENT: I am not quite following this. If you just take it as applying the SSNIP test, you do not need generics at all. You just look at the market as it is and say, it is not price sensitive, subject only to a cellophane fallacy, they could increase their price by 10%, people will not switch because of that price increase. But that is because the SSNIP test, it seems to me, does not really work when you have price regulated markets in this way --

MS. DEMETRIOU: We say it does fall to be applied in this case, because what you are looking at here is whether or not it is a problem in competition terms to snuff out price competition. So you have to look at the constraints on GSK in terms of that price competition. It is a bit like the point you made, sir, about parallel importers. So you do apply the SSNIP case. The question in this case is what is the level from which you apply the SSNIP test when you are deciding whether paroxetine is a market, or whether you need to add further products in.

THE PRESIDENT: There are markets where you cannot apply the SSNIP test --

MS. DEMETRIOU: There may well be markets where you can't --

THE PRESIDENT: -- and that is well recognised. Speaking for myself, a price regulated market is one where it does not work very well. But you can still ask about competitive constraints.

MS. DEMETRIOU: Sir, the broad point that we make is that the issue about potential competition in paragraph 24 is a red herring because it is not looking at that question, and that is why the Commission was not diverted from its course in *Servier* by paragraph 24, so it is a different point.

Sir, those were my submissions on market definition, unless the Tribunal has --

THE PRESIDENT: Yes, and you have dealt with (c) in answer to my question, the third objection --

MS. DEMETRIOU: Yes, I think I dealt with that in answer to your question.

So on abuse. Now, we established that the abuse case in factual terms overlaps considerably with the Chapter I case. Nobody on either side has made separate submissions on the facts on abuse.

You do have submissions on the law in the respective skeleton arguments.

THE PRESIDENT: It is accepted, is it, from the CMA if there is no Chapter I violation, neither by object nor by effect, subject only to this vertical agreements' exemption point, apart from that, the conduct here cannot be abusive?

MS. DEMETRIOU: Subject also to various legal arguments, which I am not sure to what extent they are pursued. For example it is said that unless you can slot -- I think one of the appellants did persist with this in closing -- the object case into a particular legal category, you have to give up. So we do not accept -- if we are defeated on that point, that we would be defeated in Chapter II terms.

Certainly as far as the factual case is concerned, if we fail on a factual case, then, yes, it overlaps considerably with the Chapter II case. We cannot eke out an independent victory under Chapter II if we fail on the facts under Chapter I.

The only issue that Mr. Flynn dealt with in his oral closings in relation to the facts and in relation to abuse was the question of IVAX and the Tillomed supply.

I just briefly want to respond to that. So what Mr. Flynn said in closing was that he said it was quite clear that at October 2001, when the IVAX agreement was signed, IVAX did not have a genuine source of supply, because he said that Tillomed did not have a product, and he relied on the fact that Tillomed's product was withdrawn from the Danish market, and Mr. Flynn's point is that that was due to some kind of technical problem with the product.

THE PRESIDENT: This is the point set out in their note.

MS. DEMETRIOU: In their note, precisely. It is just that point that I want to respond to you briefly. The fact is that there is no clear piece of evidence in this case that we have been able to discern, certainly none that has been pointed to by GSK, establishing that the reason for the withdrawal of the product from the Danish market was certainly to do with a problem with the product.

We say that in fact the evidence indicates the contrary. So there is no clear piece of evidence establishing one way or the other. We say the weight of the evidence tends to establish the contrary.

First of all, we say that GSK's position is inconsistent, first of all, with IVAX having entered into the heads of agreement with Tillomed in October 2001, which demonstrates that IVAX was sufficiently sure of the value of Tillomed's product.

We know that IVAX was aware of the withdrawal of the Hexal product from the Danish market at the time that it signed that heads of agreement, in fact, by 14 August 2001 and we can see that from the document at {Z/151/1}.

So you see, if you see the date at the top, which is August 29th 2001 and these are minutes -- delayed minutes you see at the first line from the meeting of 14th August.

Down the page:

> "... It was noted that Gea have recently withdrawn [GEA is essentially Hexal] their product from sale to the Denmark market. AJW suggested that there may be impurity issues with their product."

Then you see:

> "Actions arising from meeting".

Down the page:

> "GC to ask DB if he knows why Gea product was withdrawn from Danish market."

IVAX were aware of the issue from August 2001 and yet they still entered into the heads of agreement with Tillomed in October.

Then we have the --

THE PRESIDENT: Sorry to interrupt you, this is from? Who is this from, this email? Guy Clark is where?

MS. DEMETRIOU: Guy Clark is at IVAX, and this is an internal IVAX -- so he was head of new business development, and later director of new business development IVAX, so he was in some capacity a head of business development --

THE PRESIDENT: It is an internal IVAX email?

MS. DEMETRIOU: Yes, it is an internal IVAX email, and they are talking about an internal IVAX meeting.

You see paroxetine project team. That was the meeting. Then you have the list of participants. They have noted, at this stage, the only point I wish to draw from this, that the product has been withdrawn from the Danish market, and they are then going to carry out enquiries to work out why that was. So that is what they are saying in August.

Our point is that they did indeed, in the knowledge of the withdrawal from the Danish market, enter into the heads of agreement with Tillomed in October 2001.

Then, pursuant to the heads of agreement, they entered into the IVAX/Tillomed supply agreement which implemented the heads of agreement. That is at {B4/181/1}. It may be in fact, given the time, easier to take it from the decision. You have in your note where that is in the bundle but the decision describes the course of events at {V/1/89}. It is 3.207 and 3.208 of the decision.

> "To implement the IVAX-Tillomed Heads of Agreement, on 11 December 2001 IVAX and Tillomed entered into an agreement (the 'IVAX-Tillomed Supply agreement') which provided that IVAX would acquire the exclusive rights to the Tillomed MA for paroxetine. In consideration, IVAX agreed to pay Tillomed a royalty of 50% of the net profit IVAX made from the sale of paroxetine in the UK (including from the sale of GSK's paroxetine)."

{V/1/90}

So what we take from that is that they paid very significant sums to Tillomed in order to acquire the exclusive right to the MA and we know -- this is a further document at {Z/19/3} -- that Hexal subsidiary GEA succeeded in obtaining a UK MA on 8 January 2002. That is {Z/19/3}.

You see that at the top of the page, were eventually approved by the authority on 8 January 2002, showing that the UK authority considered the Hexal product was safe for use.

The idea, we say, that the product had a problem is inconsistent with these pieces of evidence and, in fact, we note in passing that Richard Saynor's view -- we see this from his witness statement in the GUK proceedings -- that is at {A5/77/8}. His view, and this is paragraph 25, he says:

> "Tillomed's parent company, Hexal, had launched its own paroxetine product in Denmark but it has now apparently concluded an arrangement with SB to obtain a supply of paroxetine from SB (at least in Germany), and it has therefore withdrawn its own product in Denmark."

So his view was that the reason for the withdrawal was because of the supply agreement between GSK and Hexal and you see that at document {DHU/1B/1}. Then over the page {DHU/1B/2}. So this is an agreement between GSK and Hexal. Once Hexal -- Richard Saynor's view is that this agreement, which provides for a fixed -- similar, there is no value transfer, but it is similar to the agreements in this case -- volume supply from GSK to Hexal of GSK's products, that this is why Hexal withdrew from the market.

THE PRESIDENT: We do not know which comes first -- chicken and egg.

MS. DEMETRIOU: We do not know which comes first, but we do ask rhetorically the question: why GSK would have entered into this agreement if there were a problem with Hexal's product? Why not just enter the market itself and exploit it? So if Hexal had to withdraw from the market because it could not make a product, then, presumably, the most commercially sensible course for GSK would have just been to have entered the Danish market with its own product, rather than entering into this kind of supply agreement.

To conclude, and drawing those threads together, we say that the evidence tends to support a conclusion that there was no problem with the product.

THE PRESIDENT: Wait a minute, there was no patent protection in Denmark.

MS. DEMETRIOU: There was no patent protection in Denmark.

THE PRESIDENT: So if GSK had gone into Denmark with its own products --

MS. DEMETRIOU: It was in Denmark -- it was already supplying its own products in Denmark.

MR. FLYNN: It had withdrawn from the Danish market.

THE PRESIDENT: Yes.

MS. DEMETRIOU: No, that is not correct. There is a graph which is at -- if you look at -- this may be helpful to go to {Z/1590/5}. That shows the graph.

This shows over time, do you see the purple is Seroxat. Then you have got sales by value on the left-hand side, and you see that -- sorry, the blue is Seroxat.

They are constantly in the market. Then the yellow is Hexal's product which came in and was then withdrawn. You then have the supply agreement after that between Hexal and GSK. So there is no sign on this graph, we do not have any evidence to suggest that GSK withdrew from the Danish market.

That is all I wanted to say about Tillomed and IVAX. The final section of my submissions in closing relates to penalty. Would it be convenient to turn to that?

THE PRESIDENT: Yes. I think perhaps if we have finished that and we are moving to penalty, which is the last part of your submission.

MS. DEMETRIOU: Yes it is.

THE PRESIDENT: Perhaps it is sensible then to have a break now.

MS. DEMETRIOU: Of course.

THE PRESIDENT: Then we will sit until 5 o'clock.

MS. DEMETRIOU: I am very grateful.

THE PRESIDENT: I cannot sit longer.

MS. DEMETRIOU: I think I will be finished by 5 o'clock.

(4.15 pm) (A short break)

(4.25 pm)

THE PRESIDENT: Yes, penalties.

MS. DEMETRIOU: There is much common ground about the proper approach to penalties, we see that in the various written submissions, in terms of the framework and the approach that the Tribunal should apply, but I would like at the outset briefly to draw the Tribunal's attention to certain features of the statutory framework.

Secondly, I am going to look at the approach adopted by the CMA in the decision, and why it reached the view that these penalties are appropriate and proportionate. Finally, I would address the principal arguments made against the authority in relation to penalty.

So in terms of the statutory framework, could I just remind the Tribunal of paragraph 502 of *Napp* which is at {Auth-B/3/138}. That is volume 5 of the hard copy.

Paragraph 502 deals with the need for deterrents. If you go down about a third of the way:

The policy objectives of the Act will not be achieved unless this Tribunal is prepared to uphold severe penalties for serious infringements. As the Guidance makes clear, the achievement of the necessary deterrent may well involve penalties above, often well above, 10 per cent of turnover in the products directly concerned by the infringement, subject only to the overall 'cap' ..."

Since Napp and indeed since the construction appeals that also feature in the appellants' notices of appeals, there have been two material changes to the statutory framework. The first is the addition of section 36(7A) of the Act, and this is at {Auth-K/12/34}, volume 20 of the hard copy. It is at the bottom of that page in square brackets. So:

"In fixing a penalty under this section the CMA must have regard to --

"(a) the seriousness of the infringement concerned, and.

"(b) the desirability of deterring both the undertaking on whom the penalty is imposed and others from ..."

Essentially engaging in anti-competitive conduct.

THE PRESIDENT: Sorry, what was it -- I should know this, what was it before?

MS. DEMETRIOU: That is a addition. It was added in 2014, that came into force on 1st April 2014.

THE PRESIDENT: So there was nothing about what the CMA should have regard to before?

MS. DEMETRIOU: So Mr. Bailey points out that that used to be in the policy guidance, but now it has been elevated into a statutory requirement on the CMA.

THE PRESIDENT: But the policy guidance was to similar effect, was it?

MS. DEMETRIOU: Was to similar effect.

THE PRESIDENT: There is something somewhere saying that the CMA or previously OFT should have regard to its guidance?

MS. DEMETRIOU: That is correct.

THE PRESIDENT: So it is a tidying up rather than --

MS. DEMETRIOU: Nonetheless, the legislature thought it was important enough to elevate into the statute. Then the second change is at page {K/12/36} under the same tab. That is section 38(8). That now provides that the Tribunal must have regard to the penalty guidance. So that was not there before either.

We say that the effect of these changes is that the Tribunal's analysis should be closely tied to the guidance, and also that the Tribunal, like the CMA, must be guided by the need for the penalty to reflect both the seriousness of the infringements, and also to operate as a deterrent, both to the infringing undertaking and to others.

THE PRESIDENT: The requirement for the Tribunal to have regard is new, I think.

MS. DEMETRIOU: That is new as well.

THE PRESIDENT: Because there was this disconnect between how the CMA had to do it, and then what the Tribunal --

MS. DEMETRIOU: That is right.

THE PRESIDENT: -- would do on appeal.

MS. DEMETRIOU: That is quite right. That was also introduced, as I understand it, in 2014, so that is the same legislative -- at the same time. That is all I wanted to say about the framework. As I say, there is much common ground.

But turning now to the CMA's approach to penalty in the decision, in setting these penalties, the CMA of course followed the six steps in its penalty guidance, and had regard both to the need for them to offer the penalties to operate as a deterrent, and to their overall proportionality. The GSK penalty was set at just over £37.5 million, and it is important to bear in mind the context of that sum.

So, if you turn to the decision at paragraph 11.56, which is at {V/1/474} what is said there is that the agreements allowed GSK and the generics to sustain far higher prices than they were able to sustain following independent generic entry, and we see there that GSK, for example, made profits on its sales of Seroxat in 2001 of 46.3 million, and that these had fallen to 5.8 million by 2005 after the emergence of true generic entry.

Then moving on in the decision to paragraph 11.65, which is at page {V/1/476}, we have there a comparison between the penalty imposed -- this is in fact the higher -- the aggregate penalty which was then reduced. We see at the top nearly 51 million which was then reduced. But there is a comparison between that figure and various measures of GSK's size and financial position, such as GSK's worldwide turnover.

You see under the first bullet that that higher aggregate penalty was just 0.2% of GSK's average annual worldwide turnover in its last three financial years, which is obviously a very small proportion indeed. We say it needs to be borne in mind, given the emphasis placed by the Act on the needs for deterrents.

Then, at paragraph 11.69 of the decision, over the page {V/1/477} there is a comparison between the Chapter II penalty and GSK's worldwide turnover and the other relevant indicia.

THE PRESIDENT: Well, similar.

MS. DEMETRIOU: Similar, exactly. Then in relation to the generics, the GUK/Merck penalty was for just over £5.8 million, and the Alpharma penalty was set at just over £1.5 million and we see --

THE PRESIDENT: We have seen this.

MS. DEMETRIOU: You have seen similar comparisons.

THE PRESIDENT: You can move on.

MS. DEMETRIOU: It is important to consider as well the adjustments made by the CMA at step 4. We see this if you go to page {V/1/474} paragraph 11.57. Given the high prices that the agreements enabled them to sustain, the CMA considered, we see this at 11.57, whether, in fact, to increase the penalty, in order to ensure that they would act as a deterrent.

The Tribunal debated this with Mr. Flynn. In fact they chose not to increase the penalty, but they instead made a reduction of 10%, and we have been through those paragraphs already, and the reduction reflects the fact that there was no prior finding that this specific form of agreement had infringed the competition rules, and also at 11.59, reflects the passage of time, and we see the conclusion over the page at 11.60.

Further, moving on to 11.62, in relation to GSK, further, in accordance with step 4 of its guidance, the Tribunal, in order to ensure that the penalty was not disproportionate or excessive, the CMA reduced to zero, GSK's Chapter I Article 101 penalties combined, which were lower than the Chapter II penalty.

Then we see at 11.67 {V/1/477} so it went through the steps of calculating penalties for both the GUK and the Alpharma agreements, but at 11.67 it reduced the Alpharma agreement penalty by 85%, and then in fact it reduced to zero the entire Chapter I penalty and applied just the Chapter II penalty. So that is how the CMA approached the issue of proportionality. Then you see, going back to 11.61 {V/1/475}, you see there the CMA noting that:

> "It is entirely possible that in future similar cases where parties have significant turnover outside the relevant market and/or substantial gains would likely be made given the relevant circumstances set out at paragraphs 11.55 to 11.56 the CMA may consider that penalties should be increased at this step of a penalty calculation in order to achieve specific deterrence."

THE PRESIDENT: Can you help me on deterrence, because here you have drawn our attention to the passages, the deterrents under step 4, where the CMA considers: should one increase it to achieve deterrence; and deciding not to do so, as I understand it, for deterrence. Then, on the contrary, for separate considerations which I discussed with Mr. Flynn, they reduce it by 10%, but no uplift for deterrence.

MS. DEMETRIOU: That is right.

THE PRESIDENT: Is that right? That is the questions that is raised in 11.51 and the conclusion is in 11.60(a)?

MS. DEMETRIOU: Yes.

THE PRESIDENT: That is the approach on deterrence? That is right, is it not?

MS. DEMETRIOU: That is right. Save that when it comes to the Chapter II penalty, the CMA increases --

THE PRESIDENT: That is what I do not understand. On what basis then, when you come to 11.70, which is the equivalent step 4 in the Chapter II penalty, is it appropriate to increase it by, I think, 15%?

MS. DEMETRIOU: Here the focus is on the fact -- you see this from 11.70, the second sentence {V/1/578}:

The CMA has had regard, as a relevant circumstance of the case, to the fact that the Infringing Conduct involved repeated instances of a certain course of conduct ..."

You have the three agreements.

THE PRESIDENT: Under Chapter I you are looking at two agreements.

MS. DEMETRIOU: Yes, but in this sense, the abuse case is slightly different, in that it does involve a course of conduct.

THE PRESIDENT: But, I mean, it is materially different. That is why you have netted them off in the end, because essentially it is the same facts. That is why at the end you say that one should treat the two together.

MS. DEMETRIOU: Yes, I am not sure I can take it much further than the decision, which is to rely on the course of conduct involving value transfers to three potential competitors, and also, this paragraph refers back to the financial indicia in the previous paragraphs, and so there is obviously an eye here to the deterrent being effective in relation to GSK's overall size as well.

THE PRESIDENT: You know, deterrence when you are talking about something that happened, what, 14 years ago, the deterrence imperative rather weakens, does it not?

MS. DEMETRIOU: I am going to come to that point, if I may, because it is a point that Mr. Malek expressly raised, and I will come on to look at that.

THE PRESIDENT: There is a point about general lapse of time, but it also applies to what is the approach to deterrence.

MS. DEMETRIOU: Well, sir, can I deal with that legal point in a moment, because I am going to deal with the legal arguments raised against us. But I am not sure -- I do understand, sir, your question. I am not sure I can take it much further than what is said in those paragraphs of the decision, which is that the increase at that stage is due to the repeated course of conduct.

So, sir, turning to the appellants' arguments --

THE PRESIDENT: You see, the repeated course of conduct, that feeds into the duration, it is over a longer period because it goes back to the IVAX agreement. So you have covered the fact that there were three cases by the more extended period.

MS. DEMETRIOU: The more extended period is because the duration of the infringement is longer, because that includes the IVAX agreement.

THE PRESIDENT: Yes, so you have got the IVAX agreement in there.

MS. DEMETRIOU: Yes.

THE PRESIDENT: There we are.

MS. DEMETRIOU: I think the only other point I can make at this stage is, of course, at this stage, it is the end of the stage -- step 4 analysis and so the CMA appears to be taking a step

back, and having decided to write off the lower of the two penalties, is saying: well, overall, what is the appropriate penalty in this case, to what penalty constitutes a sufficient deterrence; and decides on the uplift at that stage in light of the repeated course of conduct. I do not think I can take it any further than that.

THE PRESIDENT: Yes.

MS. DEMETRIOU: Turning to the appellants' key arguments made against us and starting with novelty of the infringements. All the appellants make an argument based on the novelty of the infringements. The same argument turns up in various guises. It is said that this demonstrates that there was no intention on negligence, no fine should have been imposed because the case was novel or that the seriousness percentage point was too high.

These were all arguments advanced in *Lundbeck* and it is notable that the CMA's response to them is wholly consistent with that of the Commission and the General Court. So just starting with the CMA decision at paragraph 11.8 at {V/1/460}. We see there at 11.8:

> "The fact that a particular type of agreement has not previously been found to infringe the Act or the TFEU does not mean that the infringement cannot be committed intentionally or negligently. The CMA also notes that whilst at the time of the Infringements there had been no finding that this specific form of anti-competitive agreements (so-called 'pay for delay' agreements) infringed the Chapter I prohibition, Article 101 TFEU, the Chapter II prohibition or Article 102 TFEU, it was already well established that excluding actual or potential competitors from the market was likely to infringe competition law. The CMA has taken this into account in the round when calculating penalties in this case."

You have seen already that there has been the 10% discount which reflects that point, as well as the delay point.

THE PRESIDENT: Is the 10% discount, does it apply to the Chapter II penalty?

MS. DEMETRIOU: Let me just double check. It applies to both, yes. So starting with the Commission decision in *Lundbeck* which is at --

THE PRESIDENT: You say it does apply --

MS. DEMETRIOU: It does apply to both.

THE PRESIDENT: -- to Chapter II and the 10% reduction.

MS. DEMETRIOU: Yes.

THE PRESIDENT: Thank you.

MS. DEMETRIOU: Starting with the Commission decision in *Lundbeck* {Auth-F/16/1} volume 10 of the hard copy.

THE PRESIDENT: Can we go straight to the court, do you think?

MS. DEMETRIOU: We can go straight to the court. This is at {W/1/152} and starting with paragraph 755:

> "The applicants claim, first, that there are no earlier cases assessing patent settlement agreements and, secondly, that the judgment of 1 July 2010 in AstraZeneca v Commission (T-321/05, ECR, EU:T:2010:266) cannot be applied to patent settlement agreements, so that the imposition of fines in relation to them was devoid of any foundation in law and was contrary to the principle of legal certainty."

Then at 757, you see there the applicants' argument:

> "... first of all, that on the assumption that the Commission was correct to conclude that the agreements at issue had infringed Article 101 TFEU there was no valid ground for imposing fines on them in the present case, because of the novelty and complexity of the factual and legal issues raised, which moreover, the Commission acknowledges."

Then they say that this fails to observe the principle of legal certainty.

Paragraph 762 {W/1/153} we see that this point also goes to the question of intention or negligence. It is also made in that context too. At 762 the court says that:

> "... it is settled case-law that that condition is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty ..."

Then, at the bottom of the page, paragraph 764, the General Court held that:

> "In the present case, contrary to what the applicants claim, it was not unforeseeable that agreements by which the originator company was able to remove potential competitors from the market for a specified period, by means of significant reverse payments, might be contrary to Article 101(1) TFEU, whether or not they went beyond the scope of that company's patents ..."

Over the page {W/1/154}, 765 refers to the wording of Article 101 and points out --

THE PRESIDENT: Yes, I see they take that. We see that. Can you just tell me one thing on this section, at 771 and other places, what are the KFST documents?

MS. DEMETRIOU: Mr. Bailey says -- I am sure he's right -- it is the Danish Competition Authority's documents and the press release that they published.

THE PRESIDENT: Yes, no relevance to us.

MS. DEMETRIOU: So you see just going forward to the conclusion at paragraph 800 {W/1/160}, the conclusion that:

"... the Commission correctly classified the infringements in the present case as 'serious', in so far as they concerned restrictions of competition by object, whose harmful effect on competition was sufficiently established, consisting of paying competitors to stay out of the market for a specified period ..."

So we rely on that in relation to what is said by the appellants about the seriousness percentage applied by the authority. Then for completeness, going back to paragraph 780 {W/1/156}, this deals with a point made by the appellants also in this case about the effect of the *AstraZeneca* judgment. It is of interest to see how the General Court dealt with that case. So paragraph 780, the submission was -- the *Lundbeck* submission was that *AstraZeneca* meant that there should be no fines because there was no previous case law on point, and the conduct was not highly anti-competitive.

Then, if you go forward a page to paragraph 782 {W/1/157} it says there that Lundbeck was wrong to say that there was a bar on fines if the court had not ruled on the specified conduct. In 783, just to paraphrase, Lundbeck was also wrong about the anti-competitive nature of the agreements. The court says there:

"... just as in the case that gave rise to the judgment in AstraZeneca cited in paragraph 755 above (EU:T:2010:266), the applicants' conduct in the present case was clearly not part of normal competition, since they aimed to exclude potential competitors ..."

The court here is equating the conduct here with the conduct in *AstraZeneca*. That is how the arguments which are raised by the appellants in this case are dealt with by the General Court.

We say that these arguments about novelty have been dealt with by the authority in the same way as the authority's approach, which is to say that they do not undermine the finding of intention or negligence, and they do not warrant a lower seriousness starting point; have been addressed and dismissed by the General Court in precisely the same way as the authority has done in this case.

THE PRESIDENT: To what extent does section 60 bite on a European court's assessment of penalty?

MS. DEMETRIOU: It is fair to say that the penalty guidance applied by the Commission is a little different to the penalty guidance applied by the authority domestically.

So I do not think section 60 binds this Tribunal in terms of the precise result but we do say that in terms of the principle and the law and particularly the finding -- whether or not novelty undermines a finding of negligence, is binding on this Tribunal.

So we say that the key propositions of law have been dealt with by the General Court in *Lundbeck*. This is also true, and I am moving on to look at the argument on duration made by the appellants. So GSK argues, for example, that the authority failed to take account of when the generics could actually have entered the market and competed with GSK, and Lundbeck ran exactly the same argument before the General Court. We see that at page 162, paragraph 813 sets out the argument {W/1/162}.

You see that there. I am not going to read it out but it is the same argument reflected in paragraph 813. Then over the page {W/1/163} paragraph 815. So what matters for present purposes is that the Commission has shown, has sufficiently established for all the generic undertakings concerned that they had real concrete possibilities of entering the market, and they were therefore potential competitors of Lundbeck at the time of conclusion of the agreement at issue.

Then at 816, and I am not going to read it out, the general court rejected the challenge to duration. So that argument was also dealt with in *Lundbeck*. For your note it was dealt with also in the Ranbaxy case at {W/2/58}. The relevant paragraphs to look at are paragraphs 345 to 347.

We say that this conclusion drawn by the General Court provides an answer to the question that you posed, sir, yesterday to Ms. Ford, as to why the effects of the infringement are properly determined from when the agreements were entered into.

I think you made the point that duration should be addressed by reference to the effects of the agreements, rather than --

THE PRESIDENT: Do effects not come in somewhere?

MS. DEMETRIOU: We say they do not.

THE PRESIDENT: At all?

MS. DEMETRIOU: We say they do not. At least when it comes to the question of duration, they do not.

THE PRESIDENT: I understand that, but do they come in somewhere else?

MS. DEMETRIOU: They may come in somewhere else. So they may come in -- so they come in to gravity, to seriousness and if in a particular case, for example, it was shown that an agreement did not have any effect at all for some reason, then obviously that would be something taken into account.

THE PRESIDENT: Might it be a mitigating factor to say --

MS. DEMETRIOU: It might be a mitigating factor.

THE PRESIDENT: Because here, the fact that for all of -- at least on the Chapter I side anyway, but might be for both aspects, the fact that in your counterfactual of continued litigation or indeed deferred entry, perhaps even more deferred entry, there would have been in any event no prospect of entry in the market is not considered in the penalty section of the decision at all.

MS. DEMETRIOU: No, because in a sense it follows from the main point. It is the same point as the point on liability. So when it comes to the object case, then we say that simply does not matter.

THE PRESIDENT: That is rather different. The object case establishes an infringement, but when you are actually looking at what is the right fine to impose, one might think that if in fact you have kept someone out of the market for three years, it is more serious than if you have kept them out of the market in effect for one year, even if the object of what you are doing, (inaudible) still all constitutes an infringement. Stepping back, thinking about it broadly.

MS. DEMETRIOU: Yes, so we say it is significant that when it comes to duration, which is the part of the framework which expressly addresses length of time, duration we see that from paragraph 2.12 of the guidance, which is at {Auth-K/15/15}. This is the CMA's guidance. It is volume 20, tab 15. Paragraph 2.12 deals with adjustment for duration. What you see there is a clear reference to the duration of the infringement, not the duration of any effects. We say that it would not be sensible to have the adjustment for duration dependent on effects, because you only need to think of a few hypothetical examples.

THE PRESIDENT: I understand that, that it may not be appropriate to put it in there, which is what I suggested to Ms. Ford off the cuff, but it still seems to me it is something that might be reflected somewhere, because as in the example I just gave you, if for other reasons the effect is for a shorter period than the infringement, one might think that could be relevant.

MS. DEMETRIOU: Sir, of course, in this case, we have the point that the effect of these agreements was to put back independent generic entry, and so there was -- they had --

THE PRESIDENT: Yes, but it is not that they had no effects on that hypothesis, but that for part of the period of the infringement, there would not have been generic entry anyway, because of the temporary injunctions and an appeal.

MS. DEMETRIOU: Sir, we say that if that were a valid consideration in the generality of cases, then you would see -- you would expect to see in the duration part of the guidance, which expressly deals with that, a tying in of effects of an infringement with the duration of the penalty -- of the infringement for the purposes of penalty.

Now, we do not say that in an appropriate case, there could not be a reduction if, for example, it was shown that an infringement has no effect, but where you have a very serious infringement by object, then we say that the authority was amply justified in not making a deduction here in relation to that.

So that is duration. I am very conscious of time.

THE PRESIDENT: On duration, can you also just help me. Where does the date that you have in the decision at page 470 --

MS. DEMETRIOU: 30 November? Yes, I asked about that. It is a rounding backwards to the last calendar month from the date of 5th December which was the date of the judgment in *Apotex*.

THE PRESIDENT: They do not seem to round backwards on other aspects.

MS. DEMETRIOU: No, but they did on that aspect.

THE PRESIDENT: On what logical basis?

MS. DEMETRIOU: I am unable to assist at the moment.

THE PRESIDENT: Yes, okay.

MS. DEMETRIOU: Sir, I had two more points to address. The first was the turnover point made by Merck and by GSK. So Merck argues that the authority should not have taken into account the payments made to it by GSK in calculating its turnover, and GSK argues for its part that the CMA should have deducted these payments from its turnover.

In a nutshell we say that both of these submissions are wrong. So as to Merck's argument, then the payments formed part of GUK's relevant turnover, and so ordinarily failed to be taken into account, because they were turnover relating to the relevant products.

So there is no reason to exclude those payments, and of course there were very good policy reasons for taking them into account. We see that referred to, I am not going to turn it up, at Ranbaxy, paragraph 320 {W/2/55}.

As to GSK's argument, the CMA similarly applied an orthodox approach to calculating GSK's relevant turnover. There was no good reason to deduct the amounts paid to the generics when calculating turnover, because those payments simply formed part of GSK's costs, and costs are not ordinarily deducted from turnover for the purposes of step 1.

Finally, on that point, GSK tries to frame its argument as a discrimination argument, but this is -- we cannot understand it, it is poorly articulated, with respect, and it is impossible to see the basis for it, because the same approach was applied to GSK as to the generics. In each case an orthodox approach to calculating their relevant turnover was applied.

I am going to deal finally with the point raised by Mr. Malek and again, sir, by you today, about the passage of time, and whether that impacts upon the need for deterrence.

We make two points. The first point is that there is no reason at all to suggest that the passage of time could have reduced the need for a general deterrence. In other words, it would send out a bad message to say that as long as you do not get caught early, you get a lower fine.

The second point to make is Mr. Malek invited Mr. Flynn's team to identify case law on this point. It may be that they have done better than I have, but as far as I can see, neither the EU nor the domestic courts in a competition context have reduced penalties on this ground. I have not been able to find a judgment in which there has been a reduction of penalties specifically because of the reduced need for deterrence given the passage of time.

As far as the European courts are concerned, we have not found any case in which a fine has been reduced on that specific basis. Indeed, the recent practice of the European Courts is not to reduce fines at all on grounds of delay, even where the delay is due to the failings of the EU institutions, which is not the case here. You have seen at the beginning of the decision, a description in section 2 of the decision as to how the investigation took its course. You have seen that the reason for the passage of time is largely that this was only drawn to the CMA's attention by the Commission in 2010.

Turning very briefly to an authority which you do not have in hard copy, I do not think yet, which is at {Auth-Q/7/1}. You should have it in volume 27 of the hard copy; I think your hard copies may have been updated.

This is the opinion of Advocate General Sharpston in one of the Industrial Bags cases, Groupe Gascogne.

If you turn to paragraph 125. {Auth-Q/7/20}. So there, Advocate General Sharpston says:

> "The fine that is being challenged before the General Court was imposed for a specific breach of the competition rules. Assuming that none of the substantive grounds of appeal succeed, what is the logic behind reducing the fine? I can see none. To the extent that the undertakings can point to specific heads of loss ..."

Then a claim for damages may properly lie. This was a case concerning delay in the General Court:

> "But delay in the General Court is conceptually quite distinct from the anti-competitive conduct that led the Commission to impose the fine in the first place. For that reason, the undue delay plea before the General Court may properly be

characterised as inoperative. Even if it is well-founded in law and borne out by the facts of the case, it can have no effect on the outcome of the appeal."

Then if you go forward to paragraph 127 on the same page:

"Fining an undertaking for breaching the competition rules cannot be assimilated to imposing a custodial sentence upon an individual, where delay in the trial process can indeed appropriately be remedied ... Rather [again she says] if the undertaking has been harmed by the delay ..."

The remedy is an action for damages.

Then we see at paragraph 131 over the page {Auth-Q/7/21} that there, Advocate General Sharpston is saying in the last sentence:

"Delay in a procedure -- whether that be the Commission's delay during the administrative phase or the General Court's delay during the judicial phase -- has nothing to do with the undertaking's conduct or the gravity of the infringement."

This approach was followed by the court -- I am not going to take you to the court's judgment, but they follow what Advocate General Sharpston has said, and they do not reduce the fine.

In relation to the Tribunal's approach, I have not been able to find anything specifically on point, but I would note, without turning it up, that in the *Quarmby* case which is {Auth-B/17/1} and it is volume 7 of your authorities, although this point was not addressed head on, it is a case where there was a passage of nine years between the infringement and the decision. You see that just for your note from paragraphs 1 and 35.

It was a case in which the Tribunal disagreed with the Office of Fair Trading's penalty calculations in a number of respects and recalculated the penalty but this point was not taken and it was not a ground on which the fine was reduced.

So it may be that GSK's team has done better than me, but I have not been able to find a case in the competition context in which the fine was reduced specifically because of the need -- because the passage of time has led to a reduced need for deterrence.

Sir, helpfully Mr. Bailey points out again for your note, you asked a question about section 60 and fines.

THE PRESIDENT: Yes.

MS. DEMETRIOU: That is addressed directly by the Tribunal in *Napp* paragraph 455. Happily, I think the answer was as I suggested to you, the Tribunal, which is that in terms of general principles, then the Tribunal should follow.

Unless the Tribunal has anything further, those are our submissions in closing.

THE PRESIDENT: Yes, thank you very much, Ms. Demetriou.

Closings from the appellants tomorrow. 10.30 am tomorrow morning.