IN THE COMPETITION APPEAL TRIBUNAL

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

Victoria House,
Bloomsbury Place,
London WC1A 2EB

15 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

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

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

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THE PRESIDENT: I am sorry, we had a slight technical problem this morning.

MR. TURNER: Sir, at the end of yesterday you asked about anomalies in the table in the decision on Seroxat sales and profits, page 218. Mr. Sebastian has done a very short note on it which has been circulated. Would it be convenient if he addresses you for literally a couple of minutes on it to explain?

THE PRESIDENT: I think so, because it is the section dealing with market definition.

MR. SEBASTIAN: Mr. President, you should have the note before you.

THE PRESIDENT: Yes.

MR. SEBASTIAN: We have corrected tables on the last two pages of the note.

THE PRESIDENT: Yes.

MR. SEBASTIAN: All of the corrections are marked in red, but we also have certain figures that are marked in green. These are figures which remain the same, but they are figures where the CMA has adjusted the GSK data to arrive at its conclusion.

THE PRESIDENT: Yes. The original table is on page 218, is it not, in the decision?

MR. SEBASTIAN: That is right. Sir, if I can start with the first table, which is at page 3 of the note.

THE PRESIDENT: Yes.

MR. SEBASTIAN: This is the table for 20mg Seroxat.

THE PRESIDENT: Yes.

MR. SEBASTIAN: You can see there is only one correction in red. That is at the bottom row and that is to the total.

THE PRESIDENT: Yes.

MR. SEBASTIAN: What has happened there is the original 110.2 million figure was actually a total for six years. It was from 2000 to 2005, and you can see that in the title of the table. It was originally marked 2000 to 2005. The corrected figure of 82.2 is the five-year total.

THE PRESIDENT: Yes.

MR. SEBASTIAN: Now, there is one figure in green. That is in the second column, top row, 44.9, and that is GSK sales for 2001. That figure is lower than the figure you would see if you took the GSK data.

THE PRESIDENT: Yes.

MR. SEBASTIAN: The difference is around £7 million, and that is because of the missing rebates adjustment which we discussed extensively with Dr. Stillman and Ms. Webster.

THE PRESIDENT: Yes.

MR. SEBASTIAN: For your note, we discussed the missing rebates in paragraph 3.386 of the decision, and the Magnum reference is {V/1/167}.

THE PRESIDENT: Yes, thank you.

MR. SEBASTIAN: So that is table 4.2. If I can take you to table 4.3, which is on the last page of the note.

THE PRESIDENT: Yes.

MR. SEBASTIAN: This is the table for 30mg Seroxat. The first correction in red that I would like to highlight is the correction to the total, which is at the bottom row. There you see the total goes down from 85.2 to 70.1.

THE PRESIDENT: It is the same thing?

MR. SEBASTIAN: It is the same thing. The remaining corrections are in the second column for the years 2001, 2002 and 2003. The uncorrected figures, so the original figures, are taken directly from the GSK response. These are for volumes of sales of 30mg Seroxat. If you look at those figures, you will see that there is a huge jump from 2001 to 2002. So it goes from 21.6 million DDDs to 38.1 million DDDs. So that is a 75% jump within a year.

The CMA sought an explanation about this change from GSK. Perhaps I can take you to that question on the Magnum screen. The reference is {A2/18/7}. You can see there question 9.

The CMA asked:

> "Please outline why, in January 2002, there is significant increase in the sales of 30mg paroxetine packs. To the extent that this followed a change in GSK's marketing strategy please explain the reasons for this change."

What happens at that point is that GSK responds, indicating that there is indeed a discrepancy.

GSK states that:

> "9.1. GSK notes that its Finance department monthly data varies significantly from available IMS data ..."

Which GSK attaches there at annex 1. You can see that at the first sentence of its response.

Then GSK explains that:

> " ... the IMS data shows a broadly consistent level of sales of 30mg packs over the 2001-2002 period ..."

Then if you go to the end of that paragraph, it states that it has sought to establish the explanation for this discrepancy, but has not yet been able to do so.

In the next paragraph, 9.2, it confirms that there has been no change in the marketing strategy that would explain such an increase.

THE PRESIDENT: Yes.

MR. SEBASTIAN: So what the CMA did is it compared the IMS data to GSK's data and it saw that this discrepancy starts in October 2009 and disappears by February 2003. But for the remaining years, so for most of 1999, for most of 2003 and for 2004 and 2005, there is no discrepancy between the IMS volumes and GSK's volumes.

So what the CMA did is it used IMS volumes, rather than GSK volumes, just for that time period. This is reflected in the CMA decision at footnote 621. Perhaps we can turn it up. It is {V/1/174}.

So there at the bottom of the page is footnote 621, and the CMA explains that it:

" ... used IMS data for Seroxat 30mg sales volumes between October 1999 and February 2003 since the data provided by GSK appeared to be missing some sales."

THE PRESIDENT: Yes.

MR. SEBASTIAN: But what happened was when it came to populating this particular column in the decision, the CMA mistakenly used the original GSK volume data rather than the modified IMS data. That is the source of that error. We have corrected that and those figures are highlighted in red.

That leaves the green figures in table 4.3.

THE PRESIDENT: So they go up quite substantially from the figures in the decision?

MR. SEBASTIAN: Yes.

THE PRESIDENT: For the first two years. Yes.

MR. SEBASTIAN: That leaves the green figures, which are the GSK sales for those three years in the first column and the GSK costs for those three years in the third column.

Again, this is a function of the same adjustment. What the CMA did was they used the IMS volumes to scale up the sales and the costs that they found based on GSK data. That is why those six figures are marked in green. Again, just for your note this is described in the CMA decision. It is in footnote 622, which is on page {V/1/175} of the decision.

So that is an explanation of the corrections we have made.

THE PRESIDENT: Yes, I see.

MR. SEBASTIAN: What I should highlight is it makes no difference to the figures for GSK profits, and so we say it makes no difference to the overall analysis presented in paragraph 4.79 of the decision.

You can see that at {V/1/219}. If you look at the first sentence of 4.79, what the CMA was taking from that was simply an inference about the fact that the profit margin for 30mg did not fall as rapidly as the profit margin for 20mg.

THE PRESIDENT: Yes, but it does explain the higher sales of 30mg --

MR. SEBASTIAN: Yes.

THE PRESIDENT: -- Seroxat in the earlier years.

MR. SEBASTIAN: Yes, it does.

THE PRESIDENT: Therefore, the relative volumes of 30mg and 20mg.

MR. SEBASTIAN: Yes.

That is all I have to say about our note. You also asked for a clean copy of figure 4.1. There was a problem with the formatting and we have handed up what should hopefully be a cleaner version of that figure. Thank you.

THE PRESIDENT: Thank you very much.

Yes, Mr. Scannell.

MR. SCANNELL: Mr. President, the Tribunal will appreciate that we have just received this document ourselves. We did not receive it overnight, but that is not meant as a criticism at all, but we would ask for the opportunity to consider these amendments which are being made, as it were, on the hoof during the hearing and respond as needs be in the course of tomorrow with our own note, if necessary.

THE PRESIDENT: Yes. I mean, as far as the arithmetical mistake, which was picked up in the hearing, that seems a fairly obvious correction, I think. The total.

MR. SCANNELL: On an immediate view, that seems absolutely to be the case, yes.

THE PRESIDENT: That is all it is. So the significant change is the volumes of 30mg in 2001, 2002. The figures do not change, it is just a clearer explanation.

MR. SCANNELL: Yes, I appreciate that, but would not like to bind myself to an immediate response.

THE PRESIDENT: No, absolutely. No problem.

MR. SCANNELL: I am grateful.

THE PRESIDENT: If you want to say anything about it tomorrow.

MR. SCANNELL: Thank you. Opening submissions by MR. FLYNN on Chapter II

THE PRESIDENT: Yes, Mr. Flynn.

MR. FLYNN: Sir, turning, then, to the Chapter II case.

THE PRESIDENT: Yes.

MR. FLYNN: Turning to the Chapter II case, I understand from your direction last night that you would like a reasonably full opening on the legal issues and that is what I --

THE PRESIDENT: Yes. I mean, the difference between the experts is fairly confined on this, there is a sharp difference, but --

MR. FLYNN: Profound or stark, but yes.

THE PRESIDENT: My impression is that, and please confirm or correct if it is wrong, if the market is defined as all SSRIs, and perhaps Effexor, the venlafaxine, but it probably does not matter, then it is not suggested that GSK is dominant, Mr. Turner; that is right, is it not?

MR. TURNER: That is right. Ms. Demetriou is dealing with this part.

THE PRESIDENT: Ms. Demetriou, right. Well, the CMA team. That is the end of the Chapter II case. If it is only paroxetine, as the CMA contends, then I think you are not suggesting in that case that GSK was not dominant, you say there is no abuse, but you are not saying that in that case there is no dominance?

MR. FLYNN: I think that is right. It was 100% at certain levels for some of the relevant period, and of course it was rather lower than that for some of the relevant period. The authorised entry of the generics takes the shares down. It is nevertheless, I think, over 50%. So we have not --

THE PRESIDENT: You are not suggesting --

MR. FLYNN: We have not sought to make that as an argument.

THE PRESIDENT: No, so the critical question for much of it is really market definition.

I know there is then the separate point about the IVAX vertical agreements, exemption and whether you can take that into the Chapter II case. If GSK was dominant, but there is no breach of Chapter I because there is no pay for delay inference or whatever, then it would follow, would it not, that there is no abuse?

Is that right, Ms. Demetriou?

MS. DEMETRIOU: Yes, I think it would. Essentially our abuse case tracks the Chapter I object case. There are some differences, but I do not think that we can sustain a case if we are wrong on the Chapter I object case.

THE PRESIDENT: Yes. If the CMA case on Chapter I succeeds, then subject to the IVAX point and if GSK is dominant --

MR. FLYNN: Subject to market definition.

THE PRESIDENT: Yes. Then there is not really any independent argument of the significance against a finding of abuse, is there?

MR. FLYNN: Yes, we have legal argument about the nature of the effects that have to be shown under an abuse standard.

THE PRESIDENT: So there is that point. Okay. That is very helpful. Thank you.

Sorry, I just wanted to clear that all up before we go on.

MR. FLYNN: Absolutely, sir. They mirror each other to an extent and they fall out largely the way you have, I think, described it and Ms. Demetriou has confirmed.

THE PRESIDENT: That is very helpful. Thank you.

MR. FLYNN: So in relation, then, to market definition and reflecting the point really that you have just made, sir, we say that the CMA has approached market definition with the same narrow mindset as it has approached its Chapter I case, namely that really the only thing that matters is what Professor Shapiro referred to. I think it says in the transcript "the big game", but I think he might have said the big "gain", gain with a "n", which is the substantial price fall that you may expect when a patented medicine is fully genericised. We call this market definition by truism. We have described it as a fallacy. No one doubts seriously that that is likely to happen at some point in the future, but the question on the law, as well as the facts for the Tribunal, is whether the holder of patents relating to product or processes is dominant at the level of the molecule ahead of genericisation, which of course is the relevant period here. We are looking at the period before full generic entry.

The first point we make on the authorities relates to the burden and standard of proof which we set out in the opening of our skeleton. So perhaps I could, just to remind the Tribunal, take you to the authorities there. The principal authority we cite is the Tribunal's early judgment in *Napp*.

THE PRESIDENT: Can we take it from your skeleton?

MR. FLYNN: It is a short excerpt. I was going to just take you to the paragraphs leading to that conclusion.

THE PRESIDENT: Yes.

MR. FLYNN: That will be found, when I can find it, at {Auth-B/3/1}, volume 5. It is really the conclusion of a lengthy discussion, and I do not need to take you to it all, as to how the standard of proof should be applied, particularly in penalty cases under the Chapter I or Chapter II prohibitions.

Having said in paragraph 103 that neither -- which is on internal page 24; I think it is page 30 in Magnum {Auth-B/3/30}. Having found that neither article nor Human Rights Act oblige us to apply the criminal standard, the Tribunal decides what standard it should apply. They say it is the standard of proof to be decided according to the normal rules of the UK

domestic legal system. They point out that the infringements of the prohibitions are not classified as criminal offences. They say that that points to a conclusion that the standard of proof is the civil standard, normally known as the preponderance or balance of probabilities, notwithstanding that the penalties may have a deterrent effect.

Then at 106 {Auth-B/3/31}, the then President says:

> "We add that in many cases under the Act the factual issues before this Tribunal will often relate to such matters as determining the relevant market, whether dominance exists, and assessing whether conduct characterised as an 'abuse' is economically justified. Issues of that kind involve a more or less complex assessment of mainly economic data and perhaps conflicting expert evidence. It seems to us more likely that Parliament would have intended us to apply the civil standard of proof to issues of this kind, rather than the ... criminal standard ..."

He says there is no intermediate standard in paragraph 107; it is one or the other.

Then he says that:

> "Since cases under the Act involving penalties are serious matters, it follows from *Re H* [a case he has just discussed] strong and convincing evidence will be required before infringements of the Chapter I and Chapter II prohibitions can be found to be proved, even to the civil standard. Indeed, whether we are, in technical terms, applying a civil standard on the basis of strong and convincing evidence, or a criminal standard of beyond reasonable doubt, we think in practice the result is likely to be the same. We find it difficult to imagine, for example, this Tribunal upholding a penalty if there were a reasonable doubt in our minds, or if we were anything less than sure that the decision was soundly based. In those circumstances..."

This is the paragraph we do quote in the skeleton:

> "In those circumstances the conclusion we reach is that, formally speaking, the standard of proof in proceedings under the Act involving penalties is the civil standard of proof, but that standard is to be applied bearing in mind that infringements of the Act are serious matters attracting severe financial penalties. It is for the Director [as it was then, now the CMA] to satisfy us in each case, on the basis of strong and compelling evidence, taking account of the seriousness of what is alleged, that the infringement is duly proved, the undertaking being entitled to the presumption of innocence, and to any reasonable doubt there may be."

So --

THE PRESIDENT: I suppose if we are looking at this, one should read the next sentence --

MR. FLYNN: Yes.

THE PRESIDENT: -- that make inference. But I have to say it did not seem to me that this whole issue, market definition, is really a standard of proof issue, and if, as you said, the CMA has applied market definition by truism and a fallacy, in its approach of using the hypothetical monopolies to a SSNIP test, well, it is nothing to do with standard proof, it has just gone wrong. The facts really on this, there are not many disputed facts, if any, are there, on which this is based?

MR. FLYNN: No, I do not think there are many disputed facts. There are some disputed inferences.

THE PRESIDENT: But it is really what is the right conceptual approach, that is the fundamental question.

MR. FLYNN: There is the right conceptual approach, and we say, against the legal tests to be applied and taking into account the factual situation. I mean, we simply point out that in the discussion of all that, insofar as factual or other matters are referred to, Sir Christopher Bellamy was not suggesting there was anything different in relation to market definition. The whole case has to be brought in under that standard. So we say it is not enough for the CMA to say, well, as long as our economic analysis is good enough or robust, that does not meet what your predecessor was suggesting at that point.

The crux, I think, of the CMA's approach, which is the paragraph they quote in their skeleton, we find at the decision at paragraph 4.94, so bundle {V/1/225}, paragraph 4.94. The CMA there says:

> "The impact of independent generic paroxetine entry demonstrates that, prior to that event [independent generic paroxetine entry], competition from all other medicines in the treatment area had been insufficient to prevent GSK, as the only supplier of paroxetine, from sustaining prices and profits that were significantly higher than it could sustain following independent generic entry. An analysis of prior events (that of generic entry relevant to citalopram and fluoxetine, and the launch of escitalopram) suggests that other medicines constrained paroxetine prices and profits to a much lesser degree. Any constraint that other medicines did impose should therefore be considered in the context of paroxetine profits having at that time been at supra-competitive levels, and of other medicines becoming substitutes to a greater degree than they would have had prices and/or marketing of paroxetine been closer to competitive levels."

If I break that down into three propositions: the first is what we have called the truism that GSK was able to sustain higher prices and profits prior to full genericisation. We say that is normal, and furthermore we say it is in the public's interest pursuant to what we have called the IP bargain.

Then there is a sort of semi-truism, which is that prior events showing that genericisation of other SSRIs, that is the references to citalopram and fluoxetine, or the launch of a new branded SSRI, and that is the launch of escitalopram, constrain the prices and profits of paroxetine to a lesser degree, indeed to a much lesser degree.

Again, that is what you would expect, as we shall explain. Although it does recognise that there is some constraint even on prices and profits in those prior event analyses.

The last proposition we say is completely false: that any constraint that other medicines did impose have to be seen in the context of paroxetine profits having been at a supra-competitive level, and therefore becoming substitutes to a greater degree than they would had prices or marketing been closer to competitive levels.

We say that both includes a conclusion which the CMA is trying to demonstrate and is completely at odds with reality. In our view of the world, we say, based on the factual and expert evidence, the paroxetine profits prior to full genericisation, were the results of sales in highly competitive and actually unusually well-served sector. We say it is a market, which are these SSRIs, which were thought to all intents and purposes, functionally, therapeutically indistinguishable, together with -- you have already mentioned it, sir, and I probably do not need to mention it many more times today -- a drug in a different class, the SNRI, venlafaxine, or Effexor, I think, was indeed the trade name, which has an SSRI effect when given at low doses, as Professor Young explains.

If you were looking for SSRI effects, you would include venlafaxine in small doses, and that was a frequent treatment. But as I think you have indicated, sir, it does not make the crucial difference on the market definition, at least on the market share. So I shall not refer more than I have to to that feature. When I talk about SSRIs, though, that is what I mean.

We say and GSK, of course, would not have sold a single packet of Seroxat without competing intensively in that market. Seroxat has no special advantages over the competing products and it is in no sense a must-have or must-prescribe drug. To say that the profits that are realised are supra-competitive is to write off the very real competition and the spur to innovation in favour of a narrow theory that the only real competition is when you get full-on price competition, which is based on pricing in which the R&D originator costs play no real part.

Now, we do say this is the wrong approach as a matter of law. Our position, as you know, is that the central test is one of substitutability or interchangeability of products. We quote various authorities for that proposition, including the one that we quote which has itself references back to other case law at paragraph 9.5 of our skeleton.

That is a quotation -- probably we do not need to go to it because it is a reasonably full quotation -- from the *Tiercé Ladbroke* case, in which I see Mr. Kon appeared, but he is not here today to have any reflected glory on that. But that simply says that the relevant product market includes, by a long definition, products which are substitutable or sufficiently interchangeable with the product or services in question, not only in terms of their objective characteristics by virtue of which they are particularly suitable, satisfying the constant needs of consumers, but also in terms of the conditions of competition and/or the structure of supply and demand on the market in question.

As I say, there are references back to case law going back to the 1980s, and I suspect if one looked at those cases one would find references going further back than that.

We would particularly emphasise the importance in that exercise of looking at the conditions of competition on the market, the structure of supply and demand, and taking into account the consumers' point of view, which in our present context, as we shall come to, requires looking at the matter essentially from the prescriber's perspective, because it is the prescribing doctor, clinician, who will have the major say in what is in the interests of the patient, the consumer of the medicine.

THE PRESIDENT: Is most of the prescribing done by GPs? That is the impression one gets.

MR. FLYNN: It is. We can go to the details in Professor Young's account, but essentially, yes, someone who is feeling depressed or anxious is likely to go in the first place to their GP and have a short consultation at which the GP will say, "You seem to be depressed or anxious and I think we should try a first-line antidepressant".

THE PRESIDENT: The higher dose, the 30mg, I do not know if some of that is prescribed in hospitals?

MR. FLYNN: That, I believe, is also the case. It will depend on the patient, but I think, as Professor Young explains, it is likely that at least if you start with your GP, you will be put on an initial dose. A frequent reaction, if that does not seem to be working, is to up the dose of it. It may be to try another SSRI, but it is likely to be up the dose.

Mr. Scannell is helpfully pointing out it is page 29 of the decision, so the decision in bundle V {V/1/29}, and it is footnote 49, which says:

"In the UK, the vast majority of paroxetine was prescribed by GPs and approximately a third was prescribed by psychiatrists. For example, sales to hospitals --

THE PRESIDENT: Less than 3%.

MR. FLYNN: Exactly.

THE PRESIDENT: Which is probably why hospital purchasing is not really given any attention.

MR. FLYNN: It is not generally an inpatient condition, sir, although you might be referred to a consultant in a hospital or separate practices, again as Professor Young explains.

But in terms of the dosage specifically, I cannot immediately assist further than I already have. The initial dosage by a GP would be almost certainly at the 20mg level, and that is no doubt why that is where the focus of competition was at the pharmacy.

THE PRESIDENT: The CMA has not sought to draw any distinction or look separately at 30mg.

MR. FLYNN: Yes. Indeed.

Sir, just to finish, really, on the overall legal test, we do refer to the summary and conclusion in the *Aberdeen Journals* case, again at 9.7 of our skeleton. If you would like an authorities reference, that is {Auth-B/4/1}, volume 5.

THE PRESIDENT: Yes. You have quoted it in your skeleton at some length. Yes.

MR. FLYNN: Mr. Scannell is also pointing out, sir, just further to your previous question, in Professor Young's report, which is in {J/1/11}, at paragraph 42 he makes some reference there to prescriptions initiated by a psychiatrist --

THE PRESIDENT: Yes.

MR. FLYNN: He says there:

"It is impossible to state with certainty how many prescriptions overall are initiated by psychiatrists, because it is (and was during the Relevant Period) ..."

Which is the phrase he uses for the time covered by the decision:

"... a common practice for psychiatrists to make prescription recommendations to GPs which the GPs would then fulfil themselves. If a psychiatrist did write a prescription, this would usually be valid for between 1-3 months, with the patient's primary practitioner writing repeat prescriptions thereafter. Taking these points together, I can say that the suggestion that 1/3 of prescriptions were initiated by psychiatrists during the Relevant Period is improbably high."

So that is his take on the --

THE PRESIDENT: Yes, I was really asking with a view to hospitals. I think that is minimal.

MR. FLYNN: Yes, in terms of sales to hospitals. That is correct.

Sir, looking at the *Aberdeen Journals*, maybe it is convenient just to start at paragraph 86, which is on page {Auth-B/4/26}, internal 22. It just contextualises it.

He is surveying the relevant law:

> "In order to fall within the Chapter II prohibition, it must be established that the undertaking in question has a dominant position. As traditionally defined, a dominant position is:
>
> "'a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by allowing it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers.'"

THE PRESIDENT: That is dominance.

MR. FLYNN: That is dominance. It goes on to say:

> "... [it] does not preclude some competition ... but enables the undertaking which profits by it, if not to determine, at least to have an appreciable influence on the conditions under which that competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment."

Then he goes through the authorities; how do you reach a position or define a position of dominance by reference to the relevant market. He sets out the Commission's test, the one adopted by the director general, as it was at the time.

He quotes *Hoffman-La Roche* again at paragraph 91 {Auth-B/4/27}:

> "'"The concept of the relevant market in fact implies that there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned."

THE PRESIDENT: I think we can take it more shortly. It is all leading up to the quote at paragraph 94, which you have already taken us to from *Tiercé Ladbroke* which summarises it all really.

MR. FLYNN: Yes, he goes on to break that out a bit in the paragraphs to which I was going to draw your particular attention, paragraph 96 to 98 {Auth-B/4/28}. His summary of all this is:

> "The foregoing cases indicate that the relevant product market is to be defined by reference to the facts in any given case, taking into account the whole economic context, which may include notably (i) the objective characteristics of the products;

(ii) the degree of substitutability or interchangeability between the products, having regard to their relative prices and intended use; (iii) the competitive conditions; (iv) the structure of the supply and demand; and (v) the attitudes of consumers and users."

He then says:

" ... this checklist is neither fixed, nor exhaustive, nor is every element mentioned in the case law necessarily mandatory in every case. Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to answer what, at the end of the day, are relatively straightforward questions: do the products concerned sufficiently compete with each other to be sensibly regarded as being in the same market? Are there other products which should be regarded as competing in the same market? The key idea is that of a competitive constraint: do the other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm?"

He goes on:

"98. In cases where the products concerned have similar objective characteristics, and cater for similar groups of consumers, there will be no particular difficulty in finding that the products fall within the same market ..."

Then he gives examples.

So that, we say, is as good a summary as you are likely to find of the exercise that is to be carried out.

I think a particular point to retain is that the key idea is that of the competitive constraint. In our submission, when you look at the circumstances in which GSK was acting in trying to market and sell its paroxetine, the idea that it was able to act in complete disregard of other SSRIs or of its customers is unsustainable, and bearing in mind that the relevant time for this is before full genericisation.

Now, clearly there are particular features of the pharmaceutical sector which need to be taken into account, and there the authority on which we have spent a certain amount of time and may need to now is the *AstraZeneca* decision of the Commission and on appeal.

We say again that what the Commission did there in applying the law and the guidelines to which I have referred you was to say this question in pharmaceutical markets as well needs to be determined primarily by reference to demand substitution, with attention to particular features of the market, including prescribing practices, and your starting point is the so-called ATC level 3.

ATC, I believe, stands for anatomical therapeutical chemical classification. I think it may be sensible at this point to take out the *AstraZeneca* decision, which is in volume 9 of the authorities bundle. Its reference is F10.

THE PRESIDENT: The two key decisions seem to me to be *AstraZeneca* and now *Servier*.

MR. FLYNN: And Servier, yes.

THE PRESIDENT: Which actually address this {Auth-F/10/1}. So volume 9?

MR. FLYNN: Volume 9.

THE PRESIDENT: Starting with the Commission?

MR. FLYNN: Starting with the Commission.

Sir, if it helps to contextualise it, just to remind ourselves what the case was about, then you will see a quick summary in paragraphs 1 and following. I will not go over that in any great detail {Auth-F/10/2}, but the allegation was an abuse of dominant position for -- I do not know how to pronounce half of these substances, so you will have to forgive me on that.

THE PRESIDENT: It was Losec.

MR. FLYNN: Omeprazole-based medicines. The branded version, the AstraZeneca version, was Losec in a number of markets. The main argument is that AstraZeneca has prevented it from bringing therapeutically equivalent generic versions to a number of markets.

The particular abuses which were alleged were in connection with the strategy for extending protection by virtue of supplementary protection certificates, and a strategy in relation to a switch in formulation from capsule to tablets.

So that was the underlying allegation. The Commission, therefore, had to consider whether AstraZeneca was in a dominant position by reference to a properly defined market.

That section is to be found on Magnum page {Auth-F/10/85}:

> "In this section, the available information on the characteristics, use, sales and prices as well as other factors relevant to the competitive relationship between PPIs, H2 blockers and other medicines used for the treatment of acid-related gastro-intestinal diseases or conditions will be assessed ..."

PPI stands for proton pump inhibitors and I cannot remember what H2 blockers stand for --

THE PRESIDENT: They are antihistamines.

MR. FLYNN: -- but I imagine they block H2. They block a particular form of histamine, that is true.

So they quote the Commission notice on the definition of the relevant market. The main purpose is to identify, and in a systematic way, systematic way, the competitive constraints that the undertakings involved:

"More specifically, the objective is 'to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behaviour and of preventing them from behaving independently of effective competitive pressure' and 'demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a particular product, in particular in relation to their pricing decisions'."

It might be said that when the Commission there refers to "actual competitors", that is advisedly, as the Commission guidelines themselves at paragraph 24 say that you do not take potential competition into account when you are defining the relevant market. That is the point we have made a couple of times in our pleadings and in our skeleton.

So going on, the Commission says:

"(360) Second, the Notice on market definition provides that an 'analysis of the product characteristics and its intended use allows the Commission, as a first step, to limit the field of investigation of possible substitutes' but that this is not sufficient to determine whether two products are demand substitutes."

They quote the notice as saying that:

"Functional interchangeability or similarity of characteristics may not provide in themselves sufficient criteria because responsiveness of customers to relative price changes may be determined by other considerations also."

They say that:

"The type of evidence which is relevant to assess whether two products are demand substitutes includes 'evidence of substitution in the recent past'. When this type of evidence is available 'it will normally be fundamental for market definition'."

The Commission relies on the IMS data for that {Auth-F/10/86}, and refers to supply-side substitutability, but I do not think we need to turn to that now.

THE PRESIDENT: No.

MR. FLYNN: Then it turns its mind to specific features of competition in the pharmaceutical sector:

"(362) While the notice of the definition --

THE PRESIDENT: To save you reading this out slowly, if there are a couple of paragraphs, it might be quicker if we read them to ourselves.

MR. FLYNN: I would be delighted, sir.

THE PRESIDENT: Yes. You are starting with (362). How far would you like us to read?

MR. FLYNN: I was going to take you through the main points of their analysis, but you certainly need to read those two paragraphs and then I will --

THE PRESIDENT: We can read the whole of their analysis, but obviously you do not want to read it out because it would take a couple of hours as it is a very long decision.

MR. FLYNN: Yes.

THE PRESIDENT: This is only the first stage and then we have got General Court and the Court of Justice.

MR. FLYNN: The main thing is that this was upheld, and I do not need to spend a huge amount of time on the appeals but I think it is important to see how the Commission approached it.

THE PRESIDENT: Yes. So (362) to where?

MR. FLYNN: I was really going to take you through the headings, as you will see if you turn the pages. ATC system you have. That is above (371). Product characteristics as evidence of competitive constraints; therapeutic uses as evidence of competitive constraints, and probably stop there because once you get into demand and price factors in this case you really are getting into the deep weeds, I think, in the *AstraZeneca* case {Auth-F/10/90}.

THE PRESIDENT: Although it may be important to see how they approach price.

MR. FLYNN: Indeed, sir, and I will do that, but not, I think, by reference to the pages and pages of the national surveys and examination that they did.

THE PRESIDENT: But, I mean, it is interesting. I see here they talk about pricing in (365), (366).

MR. FLYNN: Exactly, and that is important, sir. I mean, absolutely, if the Tribunal wishes to read to itself at least to paragraph (399) over the break, we could do that if that is a convenient way of doing it.

THE PRESIDENT: Well, if this is the point at which you want to address it, would it be sensible for us to take our break just a bit earlier than we might and we will read (362) to (399)?

MR. FLYNN: If that is not inconvenient to the Tribunal, that would be a good way of doing it.

THE PRESIDENT: If that is the point you are at and that is logical and sensible for you, then I think we will do that and then you can move on.

MR. FLYNN: I am obliged.

MR. MALEK: Which volume?

MR. FLYNN: Volume 9.

(11.40 am) (A short break)

(11.53 am)

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

MR. FLYNN: Thank you, sir.

The points, then, that we would take out of it are that demand substitution is the almost immediate and effective disciplinary force on suppliers.

We drew particular attention then to the points in paragraph (363) in relation to the effect that the choice of prescription was of course by doctors being guided essentially by therapeutic considerations, appropriateness and effectiveness, rather than by price. The fact that there is a degree of price control in the market.

Now, all the analysis in *AstraZeneca* was really aimed at determining whether it was right to include in the relevant market both the PPIs and the H2 blockers, which are all at the same level, equivalent level within the ATC classification, as SSRIs. There is no suggestion of making the market definition at a lower level and no suggestion of relevance to that issue, that there had been genericised versions of Losec in at least Germany.

It was not the approach that the Commission took. It looked at it in order, product characteristics being modes of action, therapeutic effectiveness and appropriateness, therapeutic uses or functional interchangeability, and then, as you saw in a lengthy section, demand price and non-price factors of competition.

The Commission placed the primary emphasis on the first of those and said that that is what it had traditionally done, which you have seen -- I beg your pardon, you see in paragraph (373).

The Commission noted on that basis that there were substantial differences in the modes of action of PPIs and H2 blockers respectively, and that those differences accounted for differences in therapeutic effectiveness and appropriateness, and indeed led to a perception that the PPIs were far superior to the H2 blockers.

Then looking at functional substitutability or interchangeability, you will have seen that the Commission's conclusion confirming its view that there was a distinction to be drawn between PPIs and H2 blockers, was based on the therapeutic superiority of PPIs on their different modes of distribution. Because you could get H2 blockers over the counter. The fact -- and this is where their price analysis went -- was a much higher price for PPIs than for H2 blockers, suggesting a recognition of therapeutic superiority, and much of their detailed price analysis goes to how in each member state that they examined, that is what they were able to conclude from that study.

Most importantly, as you see from paragraphs such as paragraph (386) {Auth-F/10/91} but others as well, including paragraph (393), they say the available evidence on the file

indicates there is a significant patient population for which only prescription PPIs provide an efficiently appropriate and effective response to various conditions.

THE PRESIDENT: Yes.

MR. FLYNN: Which I shall not read on the record.

THE PRESIDENT: They place a lot of weight on prescribing trends.

At (391) {Auth-F/10/92}:

"A key argument for determining the existence of significant constraints between classes of products is the actual demand trends ... over time ..."

That is important, they say.

MR. FLYNN: Yes, and in (393) they note that, after looking at it, the PPIs expand across virtually all diagnoses whereas H2 blockers contract.

THE PRESIDENT: One sees the way that they approach it. They do in the next section, F, which we looked at briefly, so that the demand, price base substitution is not irrelevant.

MR. FLYNN: Yes.

THE PRESIDENT: When they do the UK, come to the UK, at paragraph (454), they look at the effect of a fall in the price of H2 blockers on PPI sales.

MR. FLYNN: Yes.

THE PRESIDENT: Saying that the fact that H2 blocker prices fell and entry of a generic, in what I take it is the form of H2 blocker, did not affect the price of the PPI and that supports {103} PPIs being in a separate market {Auth-F/10/103}. (456) as well {Auth-F/10/104}. So understanding your point that their initial focus is on all the areas you mention, they do go on, I think, to also attribute some weight to reaction of price of PPI to price falls of H2 blockers.

MR. FLYNN: Yes. I think in recognition that this is a confirmation of their view that they can be regarded as being distinguishable products falling in different markets. As the PPIs' superiority is recognised and spreads, then it has an inherent value which is recognised in the market, and reimbursement prices I think they are saying.

THE PRESIDENT: Yes.

MR. FLYNN: It serves to confirm their view of what the relevant market is based on the fact that actually therapeutically these are different. So it is used there in I think a confirmatory way and it is certainly not suggested that the only thing you ever have to look at is what happens to the price of a particular patented drug, PPI, if it goes generic. That is not the focus of their study at all.

THE PRESIDENT: Yes. Well, the (inaudible) did not quite do that, and there is a section, chapter 4, which is before you get to price, the qualitative section with a lot of examinations of trends and so on in volumes.

MR. FLYNN: Yes. I will come to that, obviously. But in effect what is said is, well, that may be so, but it counts for nothing in the face of the irresistible inference that once a particular molecule goes generic, your ability to hold prices or make profits is going to be severely affected, and that is the truism.

While, of course, they do go through those steps and, as we say, we may not be in substantial disagreement about how the market looked to those in it, we use words which they have picked us up on, using words like "disregard" or "ignore", but I think those are ways of saying that in their evaluation all those matters count for nothing.

THE PRESIDENT: On the qualitative analysis, one thing that I found slightly puzzling is one looks at the table on page 195 of the decision {V/1/195} showing --

MR. FLYNN: Sorry, are you talking about our decision or the *AstraZeneca* decision?

THE PRESIDENT: No, the CMA decision on Seroxat {V/1/195}. Or GSK.

MR. FLYNN: Yes.

THE PRESIDENT: At page 195.

MR. FLYNN: Yes.

THE PRESIDENT: There is a table showing the seven categories, I think, of condition.

Paroxetine or Seroxat are suitable for many more than the other SSRIs, and therefore has, one would have thought, certain advantages. Indeed, for depression accompanied by anxiety, citalopram apparently was not -- it says a licensed indication. I am not quite sure what that means, because the difficulty I have with that is that when one then looks at the table which we have had a better copy of today, at page {V/1/209}, showing how the same different drugs or products are actually being prescribed by value -- true, not by volume, but still -- and it looks as though for -- I do not know if depression accompanied by anxiety is "other anxiety disorders". I am not quite sure how they marry up.

MR. FLYNN: They may not marry up.

THE PRESIDENT: But in any event, the totals, if you take "depression" and "depression" and "other anxiety disorders" together, citalopram is not all that different. So I could not quite reconcile those two. It looks as though whatever the licensed indications are, GPs are actually prescribing it for depression accompanied by anxiety.

MR. FLYNN: That is precisely right, sir, and it is covered in Professor Young's evidence.

THE PRESIDENT: He does suggest that.

MR. FLYNN: I may need to go over that.

THE PRESIDENT: Well, I thought he says that. Maybe that is the --

MR. FLYNN: He says that what is called off-label prescribing is common, and that means the licence indications are not something in this category to which doctors have particular regard. They are likely to think that any of these antidepressants, SSRI function antidepressants, are likely to cope with any first-line condition.

I think he also says that in particular the social phobia and PTSD, post-traumatic stress disorder, indications, which are in table 4.1, would not have been seen very much or at all in the relevant period.

So, I mean, on that particularly, perhaps I can take you to paragraph 129 of Professor Young's report, which is in file {J/1/34}. He refers back in there to paragraph 98, which you might also like to look at, which is in his section generally on licensed indications {J/1/26}.

You will see in paragraph 129 --

THE PRESIDENT: Yes.

MR. FLYNN: -- those were almost unknown conditions, and anyway GPs were unlikely to diagnose it even if it presented, as well as what he has to say about off-label prescribing.

THE PRESIDENT: I am referring to the qualitative part of the decision, because even if you are right that the CMA placed undue weight on the SSNIP test approach, we have to consider whether the decision could be upheld nonetheless on the basis of the findings in it. So we would have to know what they have said about the qualitative aspect reflecting what you say is the approach in *AstraZeneca*.

MR. FLYNN: Just to finish your point on table 4.1, sir, the conclusion that the CMA draws itself is at 4.48:

> "When prescribing a medicine for one of the conditions for which paroxetine was licensed to treat, there were no clear-cut recommendations in the guidelines on which specific medicine should be preferred for a given condition and GPs would have faced a choice between a range of different antidepressant classes, and molecules within those classes ..."

{V/1/198}

THE PRESIDENT: Yes.

MR. FLYNN: The overall conclusion on the qualitative side is at 4.63, which is in a sense there is no conclusion, and I will come back to that. {V/1/206}

There you will see what the CMA says:

" ... GPs may value different characteristics differently and may therefore differentiate between products that appear to have similar characteristics, considering functional substitutability is insufficient to determine which products are capable of exerting a significant competitive constraint on paroxetine as this only provides information on how medicines may interact in theory, and is by itself inconclusive."

Then look at the assumption.

THE PRESIDENT: That is not out of line with *AstraZeneca*. That is not a hypothetical monopolist test, is it? That is consumption patterns.

MR. FLYNN: Yes, that is consumption pattern.

THE PRESIDENT: Which is demand trends.

MR. FLYNN: I will come to our, as it were, positive case on the qualitative --

THE PRESIDENT: Yes, I am just conscious of the time.

MR. FLYNN: I apologise, sir. I was given to understand that you wanted more of an opening than I had been thinking, and I only mean to assist the court in this.

Perhaps for that reason, then, I do not need to take you at any length to the upholding of the Commission's decision in the General Court at the *AstraZeneca* case.

THE PRESIDENT: Yes.

MR. FLYNN: I can do, and for your note it is in volume 15 and it is authorities {Auth-G/22/1}.

THE PRESIDENT: Perhaps we will look at it with Ms. Demetriou.

MR. FLYNN: Perhaps we will.

THE PRESIDENT: But I do not know, if you are dealing with law, if we should not look at *Servier*.

MR. MALEK: Mr. Flynn, on *AstraZeneca*, if there are any particular paragraph numbers that you want me to read, then just give me the numbers and I will make sure I have already read them. I have been through the authorities --

MR. FLYNN: Thank you, sir. I was going to take you to the review of the matters that we have looked at which are at 147 to 156 in relation to therapeutic use. You will also want to look at the section on price indicators when they essentially uphold the Commission's conclusion that the price indicators suggest that these products are in different markets.

You will find that is, of course, a lengthy section, but it is under that heading, starting above 157.

MR. MALEK: They start from there.

MR. FLYNN: The particular conclusion is at 183 and the review overall concludes at 199.

MR. MALEK: Yes, that is fine.

MR. FLYNN: Thank you.

So that is a case where the application of the tests did not lead to a finding of a single molecule market, which the Commission could have done. If that were the right analysis to take, you would not bother about substitutability, you would just look straight at the molecule on which Losec was based.

I do not think I need to take the Tribunal to the cases of *Napp* and *Genzyme* where narrow markets were found, but plainly on grounds of lack of substitutability and those have been the only available treatments for the conditions.

We say generally it is not right to say that if you apply the normal criteria and find, particularly on therapeutic substitutability, that you have a market and then you say, "Well, that is not good enough, I will bring out the price drop theory", that suggests that the analysis in all these cases was a complete waste of time because you could have gone straight to the shortcut price drop theory in the first place.

Now, in relation to *Servier*, sir, this has been, I think it would be fair to say, a bit of a sleeper in the CMA's presentation of the case, and really, of course, *Servier* is the CMA's only real friend in this area. The most the CMA makes of it is on page 91 of their skeleton. So it is the S bundle. I am afraid I forget which tab the CMA skeleton is. Number 6. {S/6/91}.

The CMA says at (c):

> "Contrary to our submission, the HMT has been applied in other cases involving the pharmaceutical sector."

It cites just one, being the *Servier* decision. That decision is of course under appeal.

THE PRESIDENT: I think to be fair they refer to the two: first *Servier* and then they do not rely on AstraZeneca.

MR. FLYNN: That is a fair point.

THE PRESIDENT: But I think only two.

MR. FLYNN: I withdraw the unfair point.

THE PRESIDENT: Yes.

MR. FLYNN: In relation to *Servier*, all we have from the CMA is this assertion that the:

> " ... the Commission employed a natural events analysis very similar to that conducted by the CMA ..."

And concluded therefore as quoted there.

MR. MALEK: Do we know how far this appeal has gone on *Servier*? When are you likely to get a decision?

MR. FLYNN: I know no more than the hearing date should be fixed quite soon, as I understand it --

THE PRESIDENT: Has it not been fixed?

MS. DEMETRIOU: It is fixed for 9th June.

MR. FLYNN: It has not been fixed. I had heard that June was likely. I was speaking to someone who was in the case yesterday who did not know that information.

THE PRESIDENT: Well, you can relay it back so they can book their flight.

MR. FLYNN: Hot off the press.

THE PRESIDENT: Yes.

MR. FLYNN: So that is the reliance that the CMA places on it, and perhaps I should hear what else Ms. Demetriou wishes to make of it.

On our reading of the *Servier* decision, and I am certainly not going to -- that is a vast decision which you will not want me to take you through in any other detail, but there are a number of indications in that decision as we read it that indicate that the Commission believes that Servier's hypertension medicine, perindopril -- which, again, I may not be pronouncing correctly -- was different from others around. Perhaps I could just either take you to or point you to a few paragraphs of the decision where we see --

THE PRESIDENT: Yes, that would be helpful because, as you say, it is very long. That is authorities bundle 11.

MR. FLYNN: It is authorities bundle 11, yes. So it is probably of a comparable length and possibly longer than the decision under appeal here {auth-F/17/1}.

I am going to make a few points rather than a systematic analysis of this, because I do not think I am very well placed to do that. But if you look at paragraphs (2204) and following.

THE PRESIDENT: (2204) and following.

MR. FLYNN: That is on page {Auth-F/17/533}, 522 internal. There is a section there on various studies relating to perindopril available in the early 2000s, suggesting, according to the Commission at (2207), that those:

> " ... Articles show that at the time of their publication there was already an important body of scientific evidence suggesting that perindopril should be regarded as a leading ACE inhibitor. Perindopril was equally good or better than other available therapies in terms of its ability to reduce hypertension. In addition, its therapeutic value was recognised as going beyond lowering blood pressure."

{Auth-F/17/534}

Then at (2208) and following they refer to some more studies, leading to a conclusion at (2216) in the Commission's view that those studies show that perindopril had a strong scientific evidence base throughout the 2000s, some additional evidence of strength added over time. It proved to be efficient in various ways. Perhaps we do not need to go into. Except I will say {Auth/17/536} number (iv), it:

> " ... being a valuable component in combination treatments, in particular with amlodipine and indapamide, effective in reducing various risks of cardiovascular patients."

Those were studies that were influential on GPs.

The Commission surveys GPs and concludes at (2451) {Auth-F/17/620}, this is the Commission's summary of its summary, as it were, of surveys of cardiologists, general practitioners and hospitals in various member states. They find that the majority of respondents, 71%, considered perindopril to be a preferred first or second-line treatment for essential primary hypertension, which is consistent with Servier's own appreciation of the position.

They also show that a significant part of the prescribers, two-thirds or so, regarded perindopril as a preferred first or second-line treatment for other conditions, and the Commission draws the conclusion that:

> "... widespread recognition of perindopril as a first or second-line treatment in its main indications and the conviction on the part of a number of responding prescribers about perindopril's particular efficacy confirm that Servier's perindopril was in a good position to be included in the initial trial period or added to existing therapies ..."

THE PRESIDENT: Sorry, you are reading at?

MR. FLYNN: 2453, sir.

THE PRESIDENT: Yes. 2453, which is on page?

MR. FLYNN: 620 internal, {Auth-F/17/621} Magnum.

THE PRESIDENT: Thank you, yes. We just did not have it up on screen.

MR. FLYNN: Yes, the essential point is that the 70% plus of practitioners thought that this was the best treatment and they also make something of the point that perindopril continued to be promoted. There was marketing expenditure behind it.

If one looks at (2521) {Auth-F/17/642}, they draw on evidence from Servier itself saying it is promotional expenditure was by and large stable and it remains stable despite several other producers stopping the promotion --

THE PRESIDENT: Sorry, this is paragraph?

MR. FLYNN: I beg your pardon, sir, (2521) {Auth-F/17/642}.

THE PRESIDENT: Starting at page 641. This is under "Other factors". Yes.

Before you get to other factors, there is a natural events analysis at page {Auth-F/17/623}.

MR. FLYNN: There is, and that is the CMA's point, that that was carried out. I am not sure that I can --

THE PRESIDENT: They seem to think it is a factor to take along with the others.

MR. FLYNN: Yes. I am really pointing out other factors that led to the conclusion, and so in addition to the impacts that the CMA refers to --

THE PRESIDENT: But am I right that you would say that that natural events analysis is inappropriate?

MR. FLYNN: I am not going to make detailed submissions on natural events analysis in *Servier*. I mean, we do consider that the events that the CMA analysed here are not especially informative of paroxetine --

THE PRESIDENT: It is a similar -- the reason I ask is it is a similar kind of analysis.

MR. FLYNN: Yes.

THE PRESIDENT: To the one that the CMA has performed here.

MR. FLYNN: I am sure it is, sir, but I think that only means that the points I would be likely to make about the *Servier* analysis are probably those that I would wish to make to you about the CMA's analysis, and as far as the detail is concerned, I am obviously uninformed.

THE PRESIDENT: Yes. One has an overall conclusion on page {Auth-F/17/645}, I think.

MR. FLYNN: That, I believe, is correct. Conclusion on the relevant product market.

The points I was making to you are the elements we would say on the Commission's analysis which suggests that, as it were, it is a drug in its own category by reference to prescriber preferences. It is the fact that it was promoted when others were not, and there is a great big table -- I have just lost it. It is on page {Auth-F/17/594} of the decision. Table 35 sets out the promotional expenditures.

THE PRESIDENT: You see, I am looking at -- you may say it is wrong -- but at what the Commission did on page 646, paragraph (2543) {Auth-F/17/647}:

> "Substitutability is an economic concept when examined for the sake of defining a relevant market. Economic substitutability only exists if changes in their relative prices (or other important economic variables) shift a significant proportion of the sales from one product to another."

Then at (2545), just below:

"The limited effectiveness of constraints imposed by other medicines stands in stark contrast to the strength of the constraint expected from (and eventually introduced by) perindopril's own generics."

In principle, a generic could challenge all existing sales of perindopril etc.

And (2546) on page {Auth-F/17/648}:

"The generic constraint must be regarded as critical for the assessment of the relevant product market in the case in which the objected practices were aimed at neutralising the very same constraint. The fact that the generic constraint outweighs by an order of magnitude all other potential constraints facing original perindopril naturally leads to the finding of a narrow market comprising only the medicine in question."

That is a similar approach to the one you have been criticising, is it not?

MR. FLYNN: It is indeed, sir. The point is made that a similar approach was taken in *Servier*. We have our criticisms of the approach taken by the CMA, and as I say, I daresay we would make the same ones of Servier, which, for the purposes of this Tribunal, plainly is a Commission decision which is something you can read and take account of but it is not binding.

THE PRESIDENT: It is not binding and it is under appeal.

MR. FLYNN: And it is under appeal, and we may know more but not for some time at this rate.

THE PRESIDENT: Yes.

MR. FLYNN: So the points I am making are that the ones that I think suggest that there are some differences between our position and the *Servier* position as described by the Commission, reflecting the views of practitioners and noting Servier's own promotional expenditure. This is a drug in a class of its own, which is not something one would simply not say, for example, that doctors would regard paroxetine as the preferred treatment at the time for any of the conditions that are likely to present. It is just not the must-have, must-prescribe best-in-class drug. It is one of a number of SSRIs with essentially equivalent functionality. I think that is a fact in the case.

Furthermore, in the *Servier* case, which is probably my last point on that, is the fact that it was sometimes a drug that was a preferred drug for co-prescription, and that one sees in the *Servier* decision around paragraph (2372) which is on page {Auth-F/17/597}, 596 internal. That essentially says that if someone was prescribed perindopril and it did not originally work, what you would do is prescribe another drug to go alongside it, co-prescribe, rather than switching away from it, and that is, again, a significant difference from our case.

I will come to it, but in the case of paroxetine -- and you will have seen Ms. Nicholson's evidence on this, Promotion was intensive by really all or most of the parties, and the volumes and prescriptions were exceptionally responsive to promotion, and that was something that GSK was very conscious of and continually monitored. A very different sort of situation.

THE PRESIDENT: Yes. So that is *Servier*.

MR. FLYNN: As I say, I do not think you want a deconstruction of that decision. We recognise the Commission seems to have taken a similar approach and it is perhaps no surprise.

THE PRESIDENT: Yes.

MR. FLYNN: Sirs, just to continue with the law for a minute, we say the approach that the CMA should have carried out here, following the *Aberdeen Journals* approach, applying it appropriately to the pharmaceutical sector in line with the approach taken in *AstraZeneca*, would lead to a conclusion that the SSRIs is the right market definition.

We also say that is essentially the approach that you took, sir, in your capacity as a High Court judge in the *Chemistree* case. I think I should turn that up, if I may.

THE PRESIDENT: You can, but I saw you cited it. Apart from the fact that I was in it, I am not sure it is hugely all that useful. I mean, it was an interim injunction.

MR. FLYNN: It was an interim injunction case.

THE PRESIDENT: It is a fairly short argument and I do not think --

MR. FLYNN: It was a short argument made --

THE PRESIDENT: -- there was any attempt to run the sort of case the CMA is running here.

MR. FLYNN: They did not come up to proof on establishing that it was -- the point I make, sir, is that the cases you cited are going to the question: is this drug in a must-have, must-prescribe sort of category? You accepted that it might be, that it was not absolutely excluded that a particular drug could be in a dominant position or that you could have a market at the molecule level, although that would be extremely rare, but they simply had not come up to proof on that.

Perhaps rather than turn up the first instance judgment, perhaps we could just have a quick look at the Court of Appeal.

THE PRESIDENT: Yes.

MR. FLYNN: Which is in authorities {Auth-D/11/1}, which is in volume 8.

THE PRESIDENT: Yes.

MR. FLYNN: Without taking it at undue length, your judgment in relation to that product market is considered in paragraphs 20 to 28 {Auth-D/11/5}.

THE PRESIDENT: Yes. You need to give the internal pages just because my colleagues are following it on the Magnum system.

MR. FLYNN: I beg your pardon. That is on {Auth-D/11/5} of that judgment. I do not see a page marking otherwise.

THE PRESIDENT: That is fine. If you give the Magnum page.

MR. FLYNN: Paragraphs 20 to 28. That is Magnum pages 5 to 8.

The appeal against that is described on {Auth-D/11/9}, 34 and following. You will see there that the argument was that you had fallen into error in regarding the prescribing doctor as a customer rather than as a pharmacist, and failed to have regard to evidence showing that prescriptions for the drug in question, Kaletra, were being written on the ground of clinical need rather than cost, such that there was no potential for the chemist/pharmacist to substitute a different drug.

So there the submission is described.

I shall not go into this at great length. But the response to it starts at paragraph 39 on page {Auth-D/11/10}, saying this was not an argument that had been put to you, but was anyway wrong:

> " ... the key to the identification of the relevant product market is the consideration of competitive constraint, namely whether 'other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm dominant firm'."

I only take this because these submissions are then accepted in general terms.

Page 11 now {Auth-D/11/11}:

> "In this case, the relevant inquiry is as to the extent to which competition from equivalent or similar drugs has a competitive effect on the supply of Kaletra: do such constraints have the effect of keeping its supplier up to the mark in terms of price, therapeutic effect, presentation, pack size, pill size, precise formulation and other considerations? The point of competition is to benefit the consumer – in this context, the patient - and it is in his interests that the relevant market is competitive. It is his perspective that is critical when considering an inquiry ..."

Then the pharmacist is described as an intermediary whose task is to supply the prescribed drug:

> "41. The inquiry as to competitive constraints is not answered by asking whether pharmacists do or do not have any choice but to buy Kaletra if they are to meet prescriptions for Kaletra. They only have to meet prescriptions for Kaletra if the

doctors prescribe it, with the ultimate burden of the cost of such prescriptions falling either on the patient or the budget holder. The relevant question is, therefore, whether the doctors have a choice as between Kaletra and other drugs, and to the extent that price plays its part in the choice ..."

Then it is the role of intermediaries is irrelevant for competition concerns.

This is paragraph 42:

"Mr. Peretz submitted further that if Mr. de la Mare's submission were right, it would follow logically that every patented medicine would represent a distinct product market on the basis that the pharmacist had no choice but to buy it in order to supply it to the consumer. The judge correctly rejected this as a notion ..."

It was added that there was no reported case in which that proposition had been given credence. Then the second submission is essentially a reworking of points that were made to you, sir.

Then at paragraph 46 {Auth-D/11/12}, Lord Justice Rimer, this is on page 12 now, with whom the other members of the court agreed, said:

"I agree with Mr. Peretz on 'the pharmacist is the customer' issue. The fact that such a point does not appear to have been taken in earlier cases does not mean that it must be wrong. New points often prove to be good, and were it otherwise the law would not develop as it needs to and does. The point that CHL is, however, either the, or a relevant customer in the relevant competition inquiry is misconceived. CHL is of course an ... customer, but it is not in the business of buying for its own consumption, or for the pleasure of admiring the boxes of unsold Kaletra on its shelves. It is a middle man buying exclusively to serve the needs of the end consumer, the patient. The cost of Kaletra is ultimately borne by the patient or budget holder, and the choice as to whether or not it is to be used for any particular patient is the result of a decision made by the prescribing doctor, either alone or in consultation with the patient. It is that part of the buying chain that either will, or will not react, to a SSNIP or other deterioration in the perceived qualities of Kaletra as compared with other drugs. The extent to which it does or does not so react will have a direct effect on the quantities of Kaletra that CHL will in turn need to buy and provide ..."

That is a point which I emphasise because it was not a point made at first instance but has the authority of the Court of Appeal. I think it is relevant to note that Lord Justice Rimer there refers to a SSNIP or other deterioration in the perceived qualities of Kaletra as

compared with other drugs. That, in my submission, is an insightful proposition and I will return to it.

So on the law, sir, we say that the cases that we have taken you to suggest a reason to be powerfully sceptical of the approach to market definition that leads infallibly to a conclusion, a single molecule market view of the world in essentially all cases of patented medicine. It is far too wide and unsafe.

To respond to the points you were making earlier, sir, the CMA, by referring to the future event, full on genericisation, dispenses with all the tests that are laid down in the case law and, as I have said, tried to formulate it, sets at nought issues such as the ATC classification, GSK's evidence of substitutability, the relevant features of the pharmaceutical market, which mean, amongst other things, that prices will be, may be expected to be higher while a drug is on patent, particularly if it is a successful drug, and all the competitive constraints to which GSK was subject prior to the expiry of patent coverage.

There is nothing in the authorities, in my submission, which suggests that everything can just resolve itself into a mechanical SSNIP test, and that that is the one and only way to address the relevant questions that Sir Christopher Bellamy formulated in Aberdeen *Journals*. It is something that you may wish to consider, but it cannot be regarded as the infallible and only way to the right answer.

Sir, I notice the time, and I am very much in the Tribunal's hands. We started a little later than we might have done. I was going to address you briefly, I have tried to keep it brief, on what I have called our positive case on substitutability and the reasons we say that those matters are not inconclusive, as the CMA says, but actually determinative of the issues in this case.

If helpful, I was going to address you briefly on the questions in relation to abuse, but you may wish to confine this session really to market definition as those are legal submissions which we have --

THE PRESIDENT: Well, there are the legal submissions on the implications of the IVAX agreement.

MR. FLYNN: Yes.

THE PRESIDENT: Being subject to the exemption.

MR. FLYNN: We have legal submissions and, as I have said, also the form of the effects test --

THE PRESIDENT: The effects test.

MR. FLYNN: -- appropriate in abuse cases and those are developed in the skeleton. I am more than happy to open them, but I do not want to take up time that the Tribunal does not want to spend at this stage.

THE PRESIDENT: Let me just ask my colleagues. (Pause)

I think we follow your positive case that you set out very fully in the skeleton and, indeed, in your Notice of Appeal. On the IVAX, the significance of IVAX being exempted, for the Chapter II case, I think we would appreciate some short submissions on that, if you would like to do that after lunch. I imagine you could do that in about 20 minutes?

MR. FLYNN: I imagine I am well able to do that.

THE PRESIDENT: It is not a big point, but it is a crisp point.

MR. FLYNN: It is a crisp point.

THE PRESIDENT: It is an important point. We will do that and then turn to Ms. Demetriou.

So we will come back at 2 o'clock.

(1.00 pm) (The short adjournment)

(2.00 pm)

THE PRESIDENT: Yes, Mr. Flynn.

MR. FLYNN: Sir, so following your indication, on our positive case, as I have called it, in other words, our reasons why we think the natural events analysis and so forth is uninformative, I will just rely on our unchallenged evidence of Professor Young, Ms. Nicholson, as well as the matters relating to that which are in Dr. Stillman's evidence which clearly has been engaged with by Professor Shapiro and no doubt will be discussed in the hot tub tomorrow.

Just to make sense of what might otherwise seem a throw-away observation before lunch, we say the charts in the decision and in Dr. Stillman's report and slides attached to Ms. Nicholson's witness statement show a clear competitive response and substitution as between SSRIs, including away from paroxetine in response, amongst other things, to a perceived deterioration in quality following adverse publicity.

That was what I had in mind when I said that the test that Lord Justice Rimer put forward in the appeal from your judgment in *Chemistree* was a perceptive remark.

THE PRESIDENT: Yes. He says that. If there is a health scare about a drug --

MR. FLYNN: I am sorry?

THE PRESIDENT: If there is a health scare surrounding the medicine, adverse publicity about side effects, and there is then a significant switch to other medicines, it may not really be substitutes. I mean, people, if they are worried about the adverse health implications of a

drug, they might switch to something very different, but they will just stop using it because people react quite strongly.

MR. FLYNN: They might. Of course it would depend on the circumstances. But in cases where the evidence before you is -- and I do not think it is controversial -- there are six or seven drugs which are pretty well interchangeable, what you would expect to see, if they take the pedal off the marketing, they have bad press in the medical journals or on television, or other things of that sort, there will be a reaction in the form of substitution, and that is what all those charts show in our submission.

You will also have seen the evidence that it would not be right to say that price was irrelevant in the marketing effort either. You will have seen all of that.

THE PRESIDENT: Yes.

MR. FLYNN: In relation to the point that you asked me to address you on, in IVAX and the vertical agreements order, in the context of Chapter II, can I just remind the Tribunal of our submissions in relation to the vertical agreements or the vertical agreements exclusion order. I do not intend to make at length, but it was a legal exclusion by statute and the legislator at the time took the view that vertical agreements for supply raised no competition concern under Chapter I if it did not restrict the buyers' pricing freedom, effectively.

So it is an extraordinarily wide exclusion reflecting a view held at the time by the legislator that cannot be wished away. In our submission, it is quite clear, and we went through the guidelines on this, that the exclusion order applied to exclusive distribution agreements or exclusive purchasing agreements, and agreements of that nature would frequently have clauses in them establishing the exclusivity.

That, in our submission, would not have taken away the benefit of the exclusion from such agreements. So we do not at all accept the submission made by Ms. Demetriou in opening that the CMA may have been over-cautious in just looking at the wording of the IVAX agreement in deciding that it was excluded. In our view, it is completely the other way round.

The CMA fell into legal error by not recognising the fact that the exclusion applied to the GUK and Alpharma case because of clauses in them designed to provide that GUK and Alpharma would take supply only from IVAX or otherwise from GSK.

We say the CMA has fundamentally misunderstood the nature and the ambit of the vertical agreements exclusion order, so-called, for good reason. When we come to Chapter II, our submission is that for the CMA to wish to apply the Chapter II prohibition to the entering

into of such an agreement, it has to find what we have called an additional element which allows it to characterise the entering into such an agreement of an abuse.

The only point that has been raised against this argument appears in the CMA's skeleton at paragraph 228 {S/6/101}, page, as opposed to room, 101.

The CMA says there plainly is an additional element here:

> "As explained above, the application of the [order] turned on an analysis of its express terms."

Not appropriate, we would say:

> " ... according to its terms, the IVAX agreement was a supply agreement only. However, for ... Chapter II ... [it] was not restricted to considering the terms of the agreement itself. But rightly took account of the relevant surrounding circumstances and the incentives of the parties. The CMA found that the IVAX agreement was intended to be an alternative to IVAX's independent entry."

It refers to the value transfers, their inability to be explained to the CMA's satisfaction, and the fact that GSK -- I think this is merely a supporting consideration -- GSK had the intention of restricting competition when it entered into the IVAX agreements.

That seems to be the CMA's case on this. Our response is that the parties' incentives for entering into an agreement covered by the order are matters that have been taken into account and considered as irrelevant by the legislator. Entering into a distribution agreement may well disincentivise a distributor from entering into the market independently. It is no reason to say it is not covered by the order.

In our submission, this is not an additional point. This is a factual circumstance leading to the entering into of a vertical agreement. We say just entering into that agreement cannot be characterised as an abuse, it effectively overrides the vertical limits exclusion order, which is a legal provision, not an administrative matter of discretion. The benefit of it was not withdrawn and we say it is legally impermissible.

In any event, you have our submissions on the facts in relation to IVAX, which I do not need to go over in detail. But essentially, IVAX wanted to get supply from GSK and that is what it got. We say it had no real and concrete possibility of entering otherwise. It did not have a product of its own, it had no scope for getting one from GUK nor, as it turned out, pursuant to its heads of agreement with Tillomed, the points we have made in a note to which so far no response has been made.

So as to IVAX's incentives, we say we know quite a lot about those anyway, even if they were a relevant consideration under the order, which, in my submission, they are not. So in

short, sir, that is why we say there is not an additional element into the analysis that would allow the entering into such an excluded agreement to be characterised as an abuse.

THE PRESIDENT: In your Chapter I appeal you say that the two other agreements are also within the scope of the order?

MR. FLYNN: Yes.

THE PRESIDENT: If you are right on that, then this point would cover them as well; it would mean that there can be no Chapter II abuse at all irrespective of market definition.

MR. FLYNN: That is what we have said, sir, yes. That is the implication of the argument.

THE PRESIDENT: Yes. Has this question of whether you can have an abuse because you are dominant through doing something that, as regards Article 101, is exempt been considered?

MR. FLYNN: Yes, it has, and the case we cite is *Tetra Pak* where you will recall that Tetra Pak, which was a company in a dominant position, had acquired for itself the benefit of an exclusive licence to competing technology.

THE PRESIDENT: Yes.

MR. FLYNN: The licence itself was within the terms, I think, of a block exemption.

THE PRESIDENT: Yes.

MR. FLYNN: The argument was made: well, you cannot say that that is an abuse. But the abuse was found not in the entering into of the licence agreement, but the acquisition of the company or the technology from the company that had the benefit of it.

So that was seen as an abusive strengthening of Tetra Pak's dominant position. It is not merely the entering into of the agreement, but the circumstances of acquiring the benefit of the licence, which was essentially the only other way into a market that was, for aseptic cartons, or whatever the right market is, which was otherwise dominated by Tetra Pak.

MR. MALEK: You give the reference to all that at 10.13 of your skeleton, do you not?

MR. FLYNN: That is right, sir.

MR. MALEK: Thank you.

MR. FLYNN: Yes, we do. You may have the advantage of me, sir, of having a hyperlink version --

MR. MALEK: Yes, we have the hyperlink version on the system.

MR. FLYNN: We can turn up the authority if that would assist, or I can at least open --

THE PRESIDENT: Tetra Pak, is that where the notion of an additional element comes from?

MR. FLYNN: I think there is reference in that case to an additional element. Yes, there is. The point made there is essentially in the case of an individual exemption which, under the system then applicable, would have required individual consideration by the Competition

Authority, then obviously it cannot make an inconsistent appreciation when applying the abuse of dominance prohibition.

In relation to the block exemption, that is a matter that applies to agreements, as it were, by category. But as I say, the additional element there was found -- it is not in the entering into of the licensing agreement, but it is the acquiring of it by Tetra Pak. So the agreement itself may be block exempted.

The problem is the impact on the market of Tetra Pak acquiring the exclusive rights to the only competing technology {S/2/218}.

So in our submission --

THE PRESIDENT: Yes, I am not familiar with that case particularly. It had not itself entered into the licence. It had already happened. So that did not arise.

MR. FLYNN: The licence was pre-existing, and I think it was a licence to technology originally developed by the British Technology Group, which had then been sold on and then Tetra Pak acquired it for itself.

So the abuse was seen in the acquisition.

THE PRESIDENT: Yes.

MR. MALEK: Can you just show us those passages in 10.13.

THE PRESIDENT: It is L/15 in the authorities, but I am not sure where that is in my ...

{S/2/219}

(Pause)

MR. FLYNN: I have it, it may be wrong, in authorities {Auth-G/1/12}; is that correct? (Pause)

THE PRESIDENT: Yes, thank you.

MR. MALEK: I could not see, looking at *Tetra Pak*, the bits with you seem to be quoting from at 10.13.

MR. FLYNN: I will endeavour to look into that for you, sir, if we have not been clear. The paragraphs to which we refer are 23 and 24.

THE PRESIDENT: Was the party that entered into the exclusive licence in a dominant position?

MR. FLYNN: I do not believe it was, sir, no.

THE PRESIDENT: Then obviously the entry into it, I mean, was not in issue.

MR. FLYNN: That is why it was the acquisition of the licence by Tetra Pak which was seen as a separate matter under Article 102, as it is now, which one sees at the end of paragraph 24, without taking you through the whole judgment {Auth-G/1/12}:

> "But the Decision in the present case does refer to the additional element that constituted an abuse within the meaning of Article 86 and justified its application. The

additional element lies in the very context of the case — in the fact that Tetra Pak's acquisition of the exclusive licence had the practical effect of precluding all competition in the relevant market. This was emphasized in the Decision and was not put in issue by the applicant."

THE PRESIDENT: But that starts out stating, paragraph 24:

"The applicants argue that there must be a supplementary element. It cannot be accepted ..."

MR. FLYNN: Absolutely. I accept that, sir.

Then they discuss the Ahmed Saeed judgment, saying that it is true there that concurrent application to tariff agreements referred to the existence of a supplementary element, and that this decision, the *Tetra Pak* decision, does refer to the additional element lying in the very context of the case.

Of course you can apply Article 85 and Article 86 to the same case. Indeed, you can apply Article 85, paragraph 3, 101.3, to the same case as you can apply Article 102, but they have to meet in each case their own term.

THE PRESIDENT: They talk at 29 about block exemptions.{Auth-G/1/12} as distinct from individual exemptions.

MR. FLYNN: In my submission, the legal exclusion is yet a third category, one has individual exemption: one has block exemption and one has legal exclusion.

MR. MALEK: Mr. Flynn, just for my own note, what you have done on the hyperlinking on paragraph 10.13, you put the reference to the judgment of the court, that is 14th November 1996, whereas the paragraphs you are citing here are from the Court of First Instance. So I think there is a problem with the hyperlinking. That is why I could not find it.

MR. FLYNN: Apologies for that.

MR. MALEK: I do not think you can do anything about it.

MR. FLYNN: Maybe we do not need to do anything about it, but that is -- apologies for that.

THE PRESIDENT: Yes, it is {Auth-G/1/1}.

MR. MALEK: Yes, but when you hyperlink on the skeleton you get the wrong decision. That is why I was confused.

THE PRESIDENT: Yes, there are several *Tetra Pak* decisions.

MR. FLYNN: Well understood.

THE PRESIDENT: This one was not appealed.

MR. FLYNN: Not on that point.

THE PRESIDENT: That is really the case that discusses this point; is that right?

MR. FLYNN: Yes. I think that is the case on which we rely. I mean, there are other cases such as *Ahmed Saeed* and *Atlantic Container Line*, which we referred to, which do discuss the relative fields of application of the two prohibitions. But this is the one on which we found the point there, the submission that I am making to you.

THE PRESIDENT: Yes. We will read that. Yes. It is mercifully short.

MR. FLYNN: Compared with other things that have been put in front of you it is quite digestible, yes.

Sir, unless I can assist the court further on that point?

MR. MALEK: Thank you very much, Mr. Flynn.

THE PRESIDENT: Thank you.

MR. FLYNN: Thank you, sirs. Opening submissions by MS. DEMETRIOU on Chapter II

MS. DEMETRIOU: May it please the Tribunal, I am going to start with market definition and then I have a few points to make on abuse, but we will see how we are doing for time on that. But I will start with market definition.

What I want to do is first of all explain, I hope quite briefly, why we say that in principle the CMA's approach is correct. Then I want to turn briefly to *Servier* and *AstraZeneca*, which, as the Tribunal has identified, are the two main authorities on point. Thirdly, I want to briefly address the key points that GSK makes against our submissions.

In addressing the principle, could I start by turning up the relevant CMA guidance, which is at bundle {H2/11/5} on Magnum. The paragraph I want to emphasise first is paragraph 2.1, which says that:

> "Market definition is not an end in itself but a key step in identifying the competitive constraints acting on a supplier of a given product or service. Market definition provides a framework for competition analysis."

The CMA's case is that when looking at competitive constraints and building a framework for the competition analysis, you need to do that with an eye on the issues that arise in the particular case.

In an abuse of dominance case, the role of market definition is to provide an input into the analysis of whether the firm is dominant; in other words, whether the firm is in a position to behave in ways that would prevent effective competition being maintained on the relevant market, or whether it is sufficiently constrained by its competitors or customers that it cannot act in such a way.

THE PRESIDENT: Are you saying the market definition is different in different cases?

MS. DEMETRIOU: Yes. So there may be a different approach to market definition, or rather the market definition exercise may yield different results depending on the context, and I will come back to that point.

But we say more particularly in this case, the issue is whether GSK abused its dominant position by excluding generic competitors from the market, and so the dominance question, in this case, is therefore whether those potential generic competitors were a significant source of competitive constraint such that excluding them would be harmful or, alternatively, whether the other SSRIs imposed a sufficient alternative constraint.

So that is the question in this case.

You saw, Mr. Flynn took you to the *Aberdeen Journals* case. I am not going to look it up again because you looked at the relevant paragraphs. But just to recall paragraph 97 where the Tribunal said that the key idea, the key idea in market definition, is that of a competitive constraint. Do the other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm?

We say that conduct must mean the conduct being examined in the case. Going back to the CMA's guidance and turning to page 6 of the Magnum reference --

THE PRESIDENT: You say the conduct must be the conduct examined in the case?

MS. DEMETRIOU: Yes. So here --

THE PRESIDENT: If a company is accused of abuse in tying a product, you define the market by asking whether other participants constrain it from tying its products?

MS. DEMETRIOU: Yes.

THE PRESIDENT: It is not normally the way things are approached. I do not know any tying case where you start by market definition saying: does it prevent the company from tying its products?

MS. DEMETRIOU: Yes. So what I mean is that we say that an issue here is what is the correct benchmark for starting the analysis, for applying the hypothetical monopolies test. What is the right benchmark --

THE PRESIDENT: The question in this case is, I think, whether it is right to apply the hypothetical monopolist test at all.

MS. DEMETRIOU: That is one question. The other question -- I do not think it is quite right -- I do not think there is a real dispute, but this will be explored in the hot tub as to whether conceptually the hypothetical monopolist test falls to be applied --

THE PRESIDENT: I think there is, Ms. Demetriou. That is my understanding.

MS. DEMETRIOU: Well, what is said is that a SSNIP test should not be applied. So it should not be done by reference to price. But conceptually, the same kind of questions are being asked, but what GSK says is that conceptually the questions that should be explored are in relation to competitive constraints that are being placed on GSK when it comes to things like quality and advertising and so on. But conceptually, we say that is a similar framework to a hypothetical monopolist test, but you are not focusing on price constraints.

THE PRESIDENT: I only meant one of the experts said the hypothetical monopolist test and the SSNIP test are the same. But if you are distinguishing between them --

MS. DEMETRIOU: I am distinguishing in that way. I am talking about a broader framework when I talk about the hypothetical monopolist test.

What we say in this case is when the very question/issue that is being examined is the exclusion of potential generic competitors from the market, that when you apply the hypothetical monopolist test then you must do so as against the benchmark of the generic price. That is essentially the CMA's approach.

Just going back to the CMA's guidance, paragraphs 2.5 and 2.13, and to summarise what is being said there {H2/11/6}, the guidance says that the principal conceptual tool that is used to conduct a market definition exercise is the hypothetical monopolist test and that, as the Tribunal is aware, you start with the focal product, which in this case is paroxetine, and ask whether it would be profitable for a hypothetical monopolist to sustain prices --

THE PRESIDENT: That is the SSNIP test.

MS. DEMETRIOU: -- above competitive level.

THE PRESIDENT: That is the SSNIP test.

MS. DEMETRIOU: That is the SSNIP test.

THE PRESIDENT: But I thought you were saying the hypothetical monopolist test was something broader?

MS. DEMETRIOU: It can be something broader. It can apply in a way that does not focus on price. If one were examining a merger, and this is a point that Professor Shapiro makes in his expert report, if you were looking at, say, a merger between GSK and Eli Lilly that produced Prozac, then in those circumstances you would be applying the hypothetical monopolist test as a conceptual framework. But you would not be primarily focusing on price perhaps, but looking instead at what happens when you might be asking, for example: what would happen if GSK reduced its development in advertising? What would the impact of that be? Would that result in an increase in Eli Lilly's shares?

So you would be examining the potential competition issues arising from the merger, still according to the hypothetical monopolist test framework but not applying a SSNIP test, so not focusing price.

THE PRESIDENT: So the market definition would be different?

MS. DEMETRIOU: It would.

THE PRESIDENT: Is there any authority for that?

MS. DEMETRIOU: Is there any authority for a different market definition --

THE PRESIDENT: For saying the market definition varies according to the conduct being examined.

MS. DEMETRIOU: Well, there is --

THE PRESIDENT: And therefore the same product could be in different markets?

MS. DEMETRIOU: There is not an authority saying that in terms, but of course we have the approach taken in *Servier* to a similar kind of case as this.

Of course in his report Dr. Stillman accepts that the market definition exercise may yield a different result depending on the circumstances. He accepts that in his report. I do not think that to that extent there is a dispute between the parties.

Of course in principle the point I am making is that the hypothetical monopolist test can be applied using quantitative evidence of prices and switching rates. It can also be applied by deriving more general inferences from qualitative information about substitutability between various different products.

An important question that arises at the very first stage of applying the hypothetical monopolist test is what competitive price level to use when answering the question of whether GSK could sustain prices that are 5% to 10% higher than the competitive level if it were the only supplier of paroxetine?

So if you are going to apply the SSNIP test, what is the competitive price that you start the SSNIP test from? So that is a question that arises at an early stage. The guidance says --

THE PRESIDENT: Your first question, then, is which hypothetical monopolist test should we use: a SSNIP test? That is question one.

MS. DEMETRIOU: Yes.

THE PRESIDENT: If the answer to that is no, then of course you do not start with the benchmark price. If the answer is yes, then you get to your question.

MS. DEMETRIOU: Yes.

THE PRESIDENT: So our starting point is: is it appropriate to use a SSNIP test?

MS. DEMETRIOU: Yes. I will come back to that when I come to the points made against us.

THE PRESIDENT: That is where one has to begin.

MS. DEMETRIOU: Yes. So we say, of course, that it is appropriate to use a SSNIP test, because the reason that we say that as a matter of principle is because what is being examined here is the potential exclusion of generic competition, and we all know, and it is common ground, that when there is independent generic entry the prices tumble.

So that is what is being examined, and so we say in principle it is appropriate to use a SSNIP test. Then the second question --

THE PRESIDENT: The question whether it is in principle must depend on the competitive constraints that --

MS. DEMETRIOU: Yes. So we say that the competitive constraints --

THE PRESIDENT: The question therefore is: is there pricing constraint at all in the market that GSK was in?

MS. DEMETRIOU: That is right.

THE PRESIDENT: Was it a market that was competing on price or competing on other things?

MS. DEMETRIOU: That is right.

I think it is common ground that the market was not competing on price and we know that GPs were not price aware, and indeed, GSK's case is that the competition going on at that stage was not price competition but was competition on other factors; so marketing and advertising, and so on.

THE PRESIDENT: Inevitably a SSNIP test is going to mean that you can sustain a 10% increase in price.

MS. DEMETRIOU: Yes.

THE PRESIDENT: So it just follows from the fact that the market is not competing on price.

MS. DEMETRIOU: Yes.

THE PRESIDENT: That the SSNIP test is going to be satisfied.

MS. DEMETRIOU: Yes.

THE PRESIDENT: So the question, therefore, is -- and therefore you say dominance full stop; sit down. But the question surely is: if this is not a market that is competing on price, is it appropriate to use a SSNIP test?

MS. DEMETRIOU: We say it is because we say that the conduct you are examining is the exclusion of generic entry, which we know results in huge reductions, drops in price.

So we say the question of whether or not there was competition in a qualitative sense, in a marketing sense or advertising sense beforehand, does not shed light on the market definition issue in this case. But perhaps I can develop it by reference to the guidance?

In this case, where the dominance question is whether potential generic competitors are an important, or may become an important competitive constraint, then we say that the benchmark competitive price level for the hypothetical monopolist test must be the price level with generic competition.

The hypothetical monopolist test is whether competition from other antidepressants is so strong that a monopoly supplier of paroxetine could not profitably sustain prices that are 5% to 10% higher than the level that would obtain under generic competition for paroxetine.

If the answer to that question is that other antidepressants are so substitutable for paroxetine that a monopoly supplier of paroxetine could not sustain high prices, then we need to include those competitive suppliers of the other antidepressants in our analysis of whether GSK is dominant.

THE PRESIDENT: If the generic price is very much lower than the patent product price, there are other competitors also patented. They are all at the same level as Seroxat. So clearly if you are looking at price against a Seroxat generic price, they are all way above 10%.

MS. DEMETRIOU: That is right.

THE PRESIDENT: Although they may be competing with each other and constraining each other.

MS. DEMETRIOU: But the question is whether what they are doing to compete with each other, which no doubt does impose some kind of competitive constraint, and we do not shy away from that, whether that competitive constraint is such as to render the action that is being contemplated in respect of generic entry unimportant.

THE PRESIDENT: But are you not confusing abuse and dominance --

MS. DEMETRIOU: No.

THE PRESIDENT: You are assuming that the conduct is suspect, and therefore one has to say: is it being prevented?

MS. DEMETRIOU: No, we are not confusing dominance and abuse. We are defining the market in context, and once you have --

THE PRESIDENT: In context of the putative abuse?

MS. DEMETRIOU: Of the behaviour being examined. But then the behaviour that you examine may or may not be abusive. So once you have defined the market and established that GSK is dominant, the behaviour may or may not be abusive. That is a separate question that requires separate analysis.

So I suppose in a nutshell what we say is that the CMA's approach is the correct approach to take because it provides a framework for analysing whether the exclusion of potential generic competition is problematic or not.

If it is not, then of course we do not need to go on to examine whether GSK has harmed competition by acting in a way that is different from normal competition or competition on the merits. If the exclusion of potential generic competitors would be problematic in terms of meaningful lost competition, then we do need to go on to examine whether or not there is an abuse.

Now, in this case of course the hypothetical monopolist test is easy to apply because we have got the prices that were charged by GSK as a monopolist and also the price that obtained under generic competition.

THE PRESIDENT: As I say, if that is right, this is a very simple exercise, the Commission and General Court were wasting a lot of time in *AstraZeneca*

MS. DEMETRIOU: I will come on to *AstraZeneca*, but what we say about *AstraZeneca* --

THE PRESIDENT: You say this is a very simple exercise.

MS. DEMETRIOU: Yes. So we say that because, essentially as stated in the joint statement, it is common ground that independent generic entry would cause competition to supply paroxetine in the UK and to become more intense leading to substantially lower prices, that is common ground and we see it in the joint statement, and that is of course because GSK's prices and profits before generic entry were higher than after generic entry, and that is why the CMA concluded that paroxetine is its own market and other antidepressants did not expose effective competitive constraints.

THE PRESIDENT: As I say, it is a very simply case. As with, probably, most successful patented drugs.

MR. MALEK: But it can be a very circular case.

THE PRESIDENT: Yes.

MS. DEMETRIOU: Can we come on to *AstraZeneca* and --

THE PRESIDENT: This could be true of a successful patent of drugs. It is well established that when generics enter, the price falls much more than 10%.

MS. DEMETRIOU: So it would be true of many successful patented drugs. That is correct.

So that is right. In lots of these cases, where what you are looking at is excluding potential generic entry, then this exercise will lead to a market definition that may be confined to that patented drug.

MR. GLYNN: But surely any patent that was successful or significant would have this feature, that if it were removed prices would fall?

So is the logic of what you are saying not that any successful relevant patent would ipso facto be a market in its own right.

MS. DEMETRIOU: That may be correct because of the pricing sensitivity of GPs.

MR. GLYNN: Just on the fact that the generic prices would come in much less, everyone agrees that.

You are defining the market in such a way that every patented drug, leaving aside irrelevant patents where the product was no use, would be a market, would you not?

MS. DEMETRIOU: Well, with prescription drugs I think that is likely to be the case. It may be different for non-prescription drugs that are available over the counter. That may be different because --

THE PRESIDENT: Because then you have price sensitive purchases. But certainly --

MS. DEMETRIOU: Yes, we do accept that in the majority of cases that is likely to be the outcome. But we say that it is necessary because otherwise you can't actually build a framework for analysing the issues at stake in the case which is preventing independent generic entry.

THE PRESIDENT: Well, you can because you can look at other ways of reaching a conclusion, as the Commission did in *AstraZeneca*, to see whether the patentee is dominant or not, as has been done.

The other problem I have, while we are on this, it can be important for a company to know whether or not it is in a dominant position because then it has a responsibility to behave in certain ways and not to engage in other conduct.

If it is dominant for the purposes of this conduct and not dominant for the purposes of another conduct, but potentially dominant for the purpose of third conduct, it happens to keep on every occasion it wants to do something, well, in respect of what we are doing now, are we not dominant even though we were not dominant for doing something else?

Usually, the understanding is that you are either dominant in a market or you are not, not that there is this multi- sort of shifting idea of dominance.

MS. DEMETRIOU: Sir, in terms of business certainty, of course I understand that as a matter of theory. But we are dealing with this kind of case, and in this kind of case, then my response to your observation would be that if a patent holder of a successful drug is taking action to exclude independent generic entry, then yes, it does need to be on notice that the competition rules might apply.

THE PRESIDENT: Yes, the competition rules might apply because you might be dominant, but not only dominant for that conduct and not for other conduct. If it is dominant, which can be established in other ways, it cannot engage in that practice. If it is not dominant, it still might not be allowed to engage in that practice because it might breach the Chapter I prohibition. Even so it cannot do it.

MS. DEMETRIOU: But of course, the upshot of the approach urged on you by GSK is that the market would be defined broadly because of competition on marketing and advertising, and so on. So a firm like GSK would not be dominant, and so this kind of behaviour, so behaviour to exclude generic entry, could not be tackled.

Let us move --

THE PRESIDENT: Well, it could if it is done by pay for delay agreement, as you call it, because it breaches, as we have heard at some length, Chapter I prohibitions.

MS. DEMETRIOU: It would if it were done by way of agreement, but one has to think beyond that to other ways of excluding generic entry that may not be easily tackled under Chapter I. In a sense you do not have to look very far because if you look at *Servier*, then there there were a sort of mass of different practices which together led the Commission to say that Servier was abusing its dominant position by engaging in a host of different strategies. Some of those comprised value transfer settlement agreements, which could have been no doubt addressed under Chapter I, but some of the practices were not easily addressed under Chapter I and so the buying of the API technology and the obtaining of different patents, the patent thicket and so on, this is all conduct which together the Commission held to be a strategy to prevent independent generic entry and not all of it could have been addressed under Chapter I.

Then, if you think sort of in a slightly different context but not a million miles away, of the *Intel* case -- so *Intel* obviously is a market exclusion case and in that case Intel was, you will recall the exclusivity arrangements and the naked restraints where --

THE PRESIDENT: I think you need to explain it a little bit. Not everybody recalls it.

MS. DEMETRIOU: So in the *Intel* case, Intel was paying its customers, one of the abuses tackled by the Commission and examined by the General Court, not to acquire the products of its main competitor. That is similar in kind to the type of market exclusion going on here. Of course it is a bit different, but it is similar in kind and it is not straightforward to see -- that is conduct which is more easily addressed under Article 102 than Article 101.

THE PRESIDENT: I thought it comes under Article 101, if you (inaudible) understanding that they will not come into the market or will not take their product. I thought it is caught by 101.

MS. DEMETRIOU: Some of it might be caught under Article 101, but looking at the range of abusive practices in *Servier*, then that is much more naturally conduct which falls under Article 102. If you were to define the market in a way which just focuses on non-price competition between competing drugs before generic entry, when the very issue you are looking at is whether it is abusive or not, whether it is fair, whether it is anti-competitive to exclude generic entry, then you end up in a position where you simply cannot use Article 102 and there is an enforcement gap.

MR. GLYNN: Forgive me, there is also a timing question I would like to ask, because if at the time when the -- you are addressing -- is there -- what is the market definition, if at that time the patents are in force then you would have one set of facts to consider. If you were later in time and generics were there, you would have another set of facts to consider. But is it not right that we should look at market definition at the current time or the time before generic entry?

MS. DEMETRIOU: The difficulty with that is that assumes that the patent is valid.

MR. GLYNN: Indeed.

MS. DEMETRIOU: Which is one of the questions at stake. So it is assuming the question at stake in the case, because what is being said here is that the abusive conduct comprises making value transfers to restrict entry in circumstances that do not reflect the strength of the patent.

MR. GLYNN: Let me put the question in another way. Is there not a circularity, which is perhaps what Mr. Malek was saying, in your approach that if there was an abuse or if the exclusion of generics was improper, then you would be in a world in which you would have dominance because you might naturally have a market which comprised the product and its generic competitors, that would be a very natural way of thinking in that world, but then you have assumed the answer to the main question. If the answer was different then you would not be in a world --

MS. DEMETRIOU: No, we put it the other way round. We say in order to ask yourself the question of whether this is abusive, you need to construct a framework which allows you to address that question, but it does not assume the answer to the question.

So there may be practices -- for example, taking exclusivity contracts or agreements, and so on, then looked at on their facts, on the facts of the case, those may not be abusive. But you

have constructed a conceptual framework which allows to you examine them under Article 102 because it is directed to the issue under examination, but it is not assuming the answer in relation to the issue.

THE PRESIDENT: If suppose the abuse alleged was that GSK said, well, you can only prescribe paroxetine if you also engage one of our contract nurses to come to the patient to administer it, what would be the test you would then apply?

MS. DEMETRIOU: Can I come back to that --

THE PRESIDENT: Because as I understand it, you are applying different tests to different alleged abuses.

MS. DEMETRIOU: No, we are not saying -- I am not going that far in my submissions. I do not have to. So I am not positing a range of different tests.

We say that the hypothetical monopolist test is the right conceptual framework, and so we say, as the guidance says, that that is the right conceptual framework, that is the framework that is generally applied. So, really, the question in this case is when you are applying the hypothetical monopolist test, what is the benchmark?

THE PRESIDENT: You say for a merger you would apply a different test?

MS. DEMETRIOU: But you may well apply a different test. Professor Shapiro says this much more eloquently than I do.

Can I just take you to his report at bundle {H/1/33}. If we start with paragraph 147. There, Professor Shapiro gives two examples involving firm A and firm B, which produce branded drugs, brand A and B, and those drugs are substitutes in the eyes of doctors.

Then paragraph 148 considers a proposed merger between firm A and firm B, and Professor Shapiro explains that the relevant market would be defined using the hypothetical monopolist test and focusing on patterns of substitution between drugs A and B and possibly other substitutable drugs. This enables the Competition Authority properly to scrutinise the effects of the merger.

Going on to paragraph 149, now consider a case involving the same firms and the same drugs, but this time firm A is accused of engaging in conduct to exclude a generic version of drug A which has been developed by firm G. In this scenario, it makes sense to define the relevant market which enables an authority or court to take into account the way that firm A is eliminating potential competition from firm G.

So what is being said in paragraph 50 is that market definition depends on the case in hand, but this is appropriate because it is the tool to help the assessment of competitive constraints, not an end in itself.

If we go to *Servier*, {Auth-F/17/637}.

THE PRESIDENT: Just a minute.

MS. DEMETRIOU: If you see the footnote, and halfway down:

"Servier argues --

THE PRESIDENT: I am so sorry. You are at?

MS. DEMETRIOU: I am at internal page 363, which is 367 on Magnum. Do you see there is a large footnote?

THE PRESIDENT: You are in the footnote. "Servier argues".

MS. DEMETRIOU: "... Servier argues that in the present case the Commission departs from its previous analysis of merger cases and sets a precedent for future merger cases. As already noted in footnote 3215, in its merger practice, the Commission has also tended to identify competition issues at the molecule level. It must be also recalled that the same methodology applied in a merger case and an antitrust case may lead to different boundaries of the relevant market. The antitrust analysis must take into account that competition might have been already distorted, while the merger analysis directly. Starts from the prevailing market conditions ..."

So this is the Commission making the same point that Professor Shapiro makes in his report.

Again, just to be crystal clear about our objection to GSK's approach, GSK's approach is to focus on the non-price competition between the SSRIs before generic entry took place and going back to the Intel-type facts that I posited a bit earlier.

Let us say that in the face of imminent generic entry, GSK entered into a number of deals with Boots and Lloyds and the large pharmacies, comprising naked restrictions. So they paid those pharmacies not to obtain supply from the generic companies.

That is clearly conduct which might be abusive, depending on the facts. The question arises, well, how should the CMA go about defining the market to examine that kind of conduct?

If, in fact, it is only the availability of generic paroxetine and nothing else that can constrain GSK to charge low prices for Seroxat, and if it is precisely the availability of generic paroxetine that GSK is trying to snuff out, then we say the competition between Seroxat and the other SSRIs on quality and advertising is neither here nor there. It is just not relevant to the issue at hand, because what you are looking at is snuffing out the only source of the price constraint, which is the constraint from the generic entry.

If you go as well, just on this point, back to the CMA's guidance at {H2/11/22} -- do you have that? Do you see in the margin there is a footnote? What this footnote is envisaging is that where you have, say, products A to E --

THE PRESIDENT: Sorry?

MS. DEMETRIOU: Do you see footnote 41? It is in the left-hand margin. Do you have page 22 on Magnum? It is page 20 of the internal document.

THE PRESIDENT: Yes.

MS. DEMETRIOU: What the footnote is envisaging is a situation where you have a range of products, A to E, which are all substitutes of each other to varying degrees. What is being said is that where a hypothetical monopolist test of three products next to each other in the chain could profitably sustain supra-competitive prices. So if you are looking, if B is the focal product then it may be the relevant market is A, B and C. But if you are investigating conduct of an undertaking, let us say, that supplies both products B and E, then the relevant market may be products A to E.

So this is another example of a situation where you are looking at the same product, same market, but you may arrive at a different market definition depending on the facts of the case in hand.

So to turn to *Servier* and *AstraZeneca*, we say of course that the Commission in *Servier* adopted precisely the same analytical framework to market definition as the CMA in this case.

If we could turn up *Servier*, which is at {Auth-F/17/5}, that is the start of it. You saw some of the relevant passages with Mr. Flynn, but can I just put some of those passages in context.

THE PRESIDENT: Just give me one moment.

MS. DEMETRIOU: Of course. I think it is volume 11 of the hard copy bundles, tab 17.

THE PRESIDENT: Yes, I think Mr. Flynn accepted that *Servier* is consistent with the approach the CMA has taken.

MS. DEMETRIOU: Yes. I just wanted to put some of the passages that you looked at in context. So the beginning of the section on relevant product market is on page {Auth-F/17/609} and it is recital~(2413). So that is the beginning of the section.

What that emphasises, again, from the market definition notice, is that:

> "... 'the main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face'. More specifically the objective is 'to identify those actual competitors of the undertakings involved that are

capable of constraining those undertakings' behaviour and of preventing them from behaving independently of effective competitive pressure'."

Then it goes on to say that:

" ... demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a particular product, in particular in relation to their pricing decisions."

Then going on to recital (2417) {Auth-F/17/610}, this points out that it is not enough that a product may compete in some dimensions for it to be included in the relevant market because the product must be capable of significantly constraining an undertakings' pricing behaviour.

If you go over the page {Auth-F/17/611}, you see that.

This is the end of the paragraph:

"Although differentiated products may 'compete' in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure."

Then recital (2418):

"Therefore, a comprehensive analysis --

THE PRESIDENT: Just one second. Yes. (Pause)

Yes. So (2418) requires a comprehensive analysis.

MS. DEMETRIOU: Yes.

THE PRESIDENT: Not just the price analysis, as I understand it.

MS. DEMETRIOU: That is right. So in this case, of course, the CMA -- you will have in mind -- did look at questions of therapeutic substitutability as well.

THE PRESIDENT: Yes.

MS. DEMETRIOU: But as in *Servier*, the critical factor was the price constraint. So, then moving on to recital (2461) {Auth-F/17/624}, shall I just let you read that paragraph?

THE PRESIDENT: (2461) (Pause).

Yes --

MS. DEMETRIOU: The footnote is also informative because what the Commission is noting there is that, of course, in *AstraZeneca* a natural events analysis was presented to the Commission by the appellants and the Commission took it into account -- and we will come on to this when we look at *AstraZeneca* -- but particularly took into account the very

significant impact of the market entry of generic omeprazole in order to form its view on the correct market definition.

Then if we move forward to (2463) {Auth-F/17/625}, that records Servier's criticism of the Commission's analysis of natural events, and what is being said there is similar to what GSK is saying in this case.

Mr. Flynn referred to it as a truism. What is being said here is the obviousness of its findings:

> "Servier and its economic consultant argue that the natural events based on relative changes in the prices of prescription medicines should not be expected to influence the sales of medicines due to the prescribers' disregard for prices. However, Servier's line of argumentation is inconsistent. In relation to the natural events analysis, Servier claims that prices are not a relevant factor for defining the market for prescription medicines. But, elsewhere in its response to the Statement of objections, Servier argues in favour of a broader market by referring to the fact that certain national authorities showed price sensitivity."

So that is a particular point in that case.

Then:

> "In this regard, the Commission wants to point out that the natural events analysis allows for the joint assessment of various factors, such as the prescribers' price insensitivity and the regulatory measures, affecting the demand. In particular the natural events analysis allows for assessing which factors prevailed in shaping the overall demand for perindopril at the relevant time. The Commission also considers that the prescribers' price insensitivity is in itself an important factor explaining the nature of constraints faced by Servier with respect to the sales of perindopril."

So too in this case we say the pricing sensitivity of the doctors is important because it demonstrates that prior to generic entry GSK was not subject to a price constraint.

THE PRESIDENT: Yes.

MS. DEMETRIOU: Then moving on to recital (2465) {auth-F/17/626}, it is the second point made in that paragraph. What is being said for context, you see at the beginning of the paragraph:

> " ... Servier also claims that the Commission uses the natural events analysis to override the finding of therapeutic substitutability between perindopril and other medicines ..."

Again, that is the argument we are facing in this case.

What you see in the second point that is made is that:

"... the Commission recalls that the functional substitutability must not be mistaken for the economic substitutability even if the functional substitutability is established, ie two products are known to be able to meet the same needs, it is still necessary to verify whether the two products are also economic substitutes. This requires a thorough examination of other evidence such as examples of recent substitution, behaviour of customers including their reactions to price changes, consumption patterns, etc."

THE PRESIDENT: Yes. I mean, they rely on both points, do they not?

MS. DEMETRIOU: They do.

THE PRESIDENT: They say this was not our only basis, there was another basis as well. It is only part of our analysis. Then they say: moreover, it is not inappropriate.

MS. DEMETRIOU: That is right, but then we will come on to recital (2546) where the Commission makes clear what is the decisive consideration for it. The Commission's overall conclusion starts at recital (2535), that is page {Auth-F/17/646}. Then at (2537) do you see, a few lines down:

"There were many other medicines with the same therapeutic use. Some used the same general mode of action. Others were more remote. None of them had clear evidence of superiority. Therefore at first sight, it may not seem completely intuitive that a medicine such as perindopril may constitute a market in its own right, where many other similar medicines were available. However, certain functional similarities do not answer the question whether those other medicines represented sufficiently close substitutes to constrain Servier's behaviour given the circumstances of the case."

Then (2543) {Auth-F/17/647}, again this makes a similar point about substitutability being an economic concept. At (2544) you have a similar point being made as that made by --

THE PRESIDENT: We looked at these with Mr. Flynn and I had made the point that this is your case here and he accepted that.

MS. DEMETRIOU: Yes. Just revisiting (2546).

THE PRESIDENT: We have seen that. I understand that. Always by an order of magnitude; all other constraints.

MS. DEMETRIOU: I remind you of that because of the point you mentioned, sir, of them having two bases, because this makes clear the generic constraint was critical for the Commission. That was the critical factor for the case.

THE PRESIDENT: We can see it supports the CMA's approach, and this is the Commission and we have to take account of it. It is under appeal.

MS. DEMETRIOU: It is.

THE PRESIDENT: Is it on appeal on market definition --

MS. DEMETRIOU: It is, it is.

THE PRESIDENT: Of course we would be bound by the court in its judgment.

MS. DEMETRIOU: That is right.

THE PRESIDENT: But it will not come.

MS. DEMETRIOU: That is right, that is correct. Of course at present, as things presently stand, you have a duty to have regard to the Commission decision under section 60.

Now, moving to *AstraZeneca*. That is at {Auth-G/22/10}.

THE PRESIDENT: That is AstraZeneca in the Commission?

MS. DEMETRIOU: No. But let us go to the Commission first. If somebody can give me the bundle reference to that. Volume 9 {Auth-F/10/1}.

Sir, I am reminded that at some stage we need to take a break. I do not know if you want me to deal with *AstraZeneca* first or whether you --

THE PRESIDENT: Would you find it convenient to have a break right now? Is that what --

MS. DEMETRIOU: That is fine with me.

THE PRESIDENT: So we will go with *AstraZeneca*, the Commission and then the two courts.

MS. DEMETRIOU: Yes.

THE PRESIDENT: Is that right?

MS. DEMETRIOU: The General Court.

THE PRESIDENT: It was upheld by the Court of Justice?

MS. DEMETRIOU: It was, yes.

(3.15 pm) (A short break)

(3.30 pm)

MS. DEMETRIOU: Sir, we are on AstraZeneca, Commission decision, which is {Auth-F/10/1}. You saw some of the recitals to that decision, but I wanted to take you to two or three more which are more directly on point.

If we could go to page {Auth-F/10/98}, we see here the context of this.

So at (420):

> "As mentioned, [AstraZeneca] provided an econometric study ('Lexecon study') purporting to prove that the relevant market in this case in inter alia Germany comprised both PPIs and H2 blockers. However, it is striking that the conclusions of

the study are not in line with certain key events on the German market as evidenced in the figures contained in the report."

Then at (421):

"These 'natural events' constitute important evidence of the existence of significant competitive constraints on the market as they allow for testing of AZ's hypothesis of a common relevant product market containing PPIs and H2 blockers."

Then we see there a reference to paragraph 38 of the notice saying that:

" ... [i]n certain cases, it is possible to analyse evidence relating to recent past events or shocks in the market that offer actual examples of substitution between two products. When available, this sort of information will normally be fundamental for market definition."

Then if we go over the page to {Auth-F/10/99}, we see at recital (429):

"Fourth, the launch of generic omeprazole in Germany as of April 1999 had a very significant effect on the volume of Losec sales as well as on Losec's market share."

They explain what that effect was, and then the last sentence:

"This 'natural event' clearly demonstrates that Losec was not constrained by H2 blockers nearly as much as by the closest substitute, ie generic omeprazole – at least not at this point in time."

Then at (426):

"Taken together, these natural events, which reveal actual developments on the German market in response to entry of respectively cheaper H2 blockers and PPIs, constitute very strong cumulative evidence that any competition from H2 blockers did not significantly constrain PPIs in Germany. The clear-cut nature of the effects of these events strongly indicates that the absence of significant competitive pressure exerted by H2 blockers existed before September 1994 and August 1995, ie the points in time when those events – ie the entry of significantly cheaper H2 blockers and PPIs – occurred."

So that is the Commission taking account of very similar evidence to the evidence it took account of in *Servier*.

Then if we turn up the General Court's judgment.

THE PRESIDENT: Just a minute. I am just looking at what -- you were looking at Germany.

MS. DEMETRIOU: Yes.

THE PRESIDENT: Then we have -- that is, what, the same for the UK at (454) on page {Auth-F/10/103}?

MS. DEMETRIOU: Yes, that is a slightly different point because the Germany example was looking at the launch of generic omeprazole, whereas the evidence in relation to the UK was looking at the fall in the H2 blocker prices.

That is the passage you looked at before. That is why I am taking you back to (425), because that is more directly on point.

Then if you could go to {Auth-G/22/1}, this is the General Court. If I could just take you through some of the paragraphs and then draw together threads and make my submissions.

Going, first of all --

THE PRESIDENT: Just a moment.

MS. DEMETRIOU: Of course.

THE PRESIDENT: Yes.

MS. DEMETRIOU: Just to give context to the points, if you go to page {Auth-G/22/10}, paragraphs 28 to 29 simply explain the issue; in other words, whether the Commission had defined the market correctly when it found that the antihistamines, the H2 blockers, did not exercise significant competitive constraints over the PPIs.

THE PRESIDENT: Paragraph 28?

MS. DEMETRIOU: 28 and 29.

THE PRESIDENT: It says the Commission based that finding on a series of considerations.

MS. DEMETRIOU: That is right.

THE PRESIDENT: Which took account of the features of competition in the pharmaceutical sector, which concerned principally intrinsic features of the product, therapeutic uses, continuous increase of PPI sales at the expense of H2 blockers, price factors and natural events in Germany and the UK.

MS. DEMETRIOU: That is right. So the natural events that I pointed to were one of several factors taken into account by the Commission in that case.

Then if we skip forward to paragraph 86 on {Auth-G/22/33}.

THE PRESIDENT: Sorry, which page?

MS. DEMETRIOU: Page 33. Of the judgment it is 2862.

THE PRESIDENT: Yes.

MS. DEMETRIOU: So the General Court here began by pointing out that it was necessary to place the argument and the circumstances in the theoretical framework adopted by the Commission in the notice on market definition for the purposes of determining competitive constraints.

Then at paragraph 87, the Commission states in the notice that:

" ... it seeks to assess demand substitutability in the light of a theoretical approach which presupposes a small (in the range 5% to 10%) but permanent relative price increase in the product on the basis of which the relevant market is defined, and to evaluate whether that hypothetical increase could be applied profitably by the hypothetical monopolist of the relevant product. According to that economic test, as set out in paragraph 17 of the Notice on market definition, if substitution were enough to make such a price increase unprofitable because of the resulting loss of sales, substitutes must be regarded as exercising a significant competitive constraint over the relevant product."

So that is the SSNIP test, of course.

Then on the next page {Auth-G/22/34}, paragraph 89, the Commission essentially applied the SSNIP test. So if you could just read that paragraph. (Pause)

Moving on to paragraph 90:

"Consequently, the Court finds that the Commission was entitled to take the view that in principle, the gradual nature of the increase in sales of a new product substituting for an existing product cannot, in itself, suffice to conclude that the existing product exercises a significant competitive constraint over the new one."

THE PRESIDENT: Yes.

MS. DEMETRIOU: Then at 91:

"Even if that conclusion is founded on reasoning which relies on an economic approach based on the observation of the reaction of demand to relative price changes it is also applicable to the present case and is not invalidated by the specific features alleged by the applicants, which characterise pharmaceutical product markets, namely, in particular, that prescribing doctors and patients display only limited sensitivity to price changes. Whatever the actual applicability of the theoretical approach set out in paragraph 87 above to pharmaceutical product markets, and without needing to adopt a position in this respect, the Court notes that the assertion that prescribing doctors and patients are not sensitive to relative price changes does not affect the validity of the view that, in principle, the gradual nature of the increase in sales of a new product substituting for an existing product is not sufficient to conclude that the existing product necessarily exercises a significant competitive constraint over the new one."

So --

THE PRESIDENT: They are not taking a view.

MS. DEMETRIOU: No.

THE PRESIDENT: They are saying, "We do not decide whether you should apply the SSNIP test".

MS. DEMETRIOU: That is right, they have left it open.

THE PRESIDENT: They have left it open, yes.

MS. DEMETRIOU: But they have found that the particular features of the pharmaceutical market relied on by AstraZeneca did not undermine the Commission's approach.

THE PRESIDENT: On this particular point.

MS. DEMETRIOU: On this particular point.

THE PRESIDENT: All they are saying is, as I understand it, AstraZeneca were arguing, well, look, there is a rise in sales of the new product and you look at what that does to the existing product, and the court is saying, well, you can tell as a matter of principle that that does not dispose of the question.

MS. DEMETRIOU: That is right, so --

THE PRESIDENT: Because it would not in a case -- I think that is what they are saying. So that that particular argument does not apply. But they are not saying, and they are careful not to say, that we should apply a SSNIP test for market definition. They leave it open.

MS. DEMETRIOU: Sir, that is right. They leave it open, but insofar as it is said against us that *AstraZeneca* is authority for the proposition that it is inappropriate to apply a SSNIP test in the pharmaceutical market, we say that that is not authority because the court has left it open.

Then --

THE PRESIDENT: What they have done is applied a lot of other tests.

MS. DEMETRIOU: Yes.

THE PRESIDENT: Including tests -- well, we can go through it -- that the CMA has not troubled to apply.

MS. DEMETRIOU: Sir, can we just be clear about what it has done? We say that the test applied by the Commission and by the court in the case is the hypothetical monopolist test. So that is the conceptual framework, but they have applied that test by looking at evidence of therapeutic substitutability. It is not that they have applied a totally separate conceptual framework. They have applied the HMT, but they have looked at questions of functional substitutability in order to apply that test.

THE PRESIDENT: How do absolute prices fit into the HMT?

MS. DEMETRIOU: Because the HMT can be applied otherwise than by a SSNIP.

THE PRESIDENT: If you are looking at whether the absolute prices of different drugs are the same.

MS. DEMETRIOU: Because you can apply the HMT test by looking at non-price competition.

THE PRESIDENT: Yes, but they are looking at prices here.

MS. DEMETRIOU: Yes.

THE PRESIDENT: One of the things they say is relevant because of the -- as I understand it -- one can look at it here. I think it is about paragraph 130 {Auth-G/22/51}.

That, I think, is the Commission's argument, not the court's finding, because they were challenged by AstraZeneca saying you are looking at absolute price levels.

The Commission says:

> "... the specific features of European pharmaceutical product markets do not lend themselves to an approach which consists in testing consumers' reactions to changes in relative prices."

MS. DEMETRIOU: Yes. But, sir, then if you turn --

THE PRESIDENT: Thus, in the light of the peculiarities of the sector, absolute price differences give a significant indication of competitive constraints since companies offering a superior class of product in terms of therapeutic efficacy are normally able to negotiate higher prices with buying organisations.

That was the Commission's argument as to why they were not particularly relying on the SSNIP test, I think. The court comments on that, does it not, and I think accepts it?

I think the court's --

MS. DEMETRIOU: So the findings of the court begin at paragraph 147, I think {Auth-G/22/58}

THE PRESIDENT: Then they take the three complaints, three issues. Excessive attention paid to price indicators. That is the second one.

MS. DEMETRIOU: Yes.

THE PRESIDENT: That starts on page {Auth-G/22/62}. The Commission criticised for the assessment of price related factors.

The court says at 158:

> " ... it is necessary to bear in mind the regulatory framework of the pharmaceuticals sector, as set out in the undisputed findings in the contested decision."

They summarise those in 159.

They explain:

"The Commission found, in this respect, that a firm's ability to obtain high prices is particularly strong to the extent that its product is necessary to adequately treat certain conditions ..."

They talk about the reimbursement price.

The Commission found at 162 {Auth-G/22/63} prices in PPIs were significantly higher than than those of H2 blockers over the relevant period.

MS. DEMETRIOU: Sir, what we say about this is that they are still applying the same conceptual framework of trying to assess the competitive constraints.

THE PRESIDENT: It is all about competitive constraints, but it is not a SSNIP test.

MS. DEMETRIOU: No, that is right.

THE PRESIDENT: It is looking at absolute prices, and what it does is to say that the Commission found and the court upheld this approach that the absolute prices were significantly different, and that therefore indicated that they may not be treated as being therapeutically equivalent.

MS. DEMETRIOU: So no --

THE PRESIDENT: That is what they are doing. It is therapeutic equivalence is what they are looking at; is that not right? Paragraph 165 {Auth-G/22/64}.

MS. DEMETRIOU: Yes, that is correct.

THE PRESIDENT: Has the CMA done that?

MS. DEMETRIOU: Well, the CMA has taken the view that, in this case, it is not informative to look at the prevailing prices of the drugs.

THE PRESIDENT: The court says it is very useful. It is indeed one of the tests that -- given the peculiarities of pharmaceutical pricing, it is a very valuable approach. The Commission took that view in *AstraZeneca*. AstraZeneca challenged it and the court said the Commission is right. My question is: has the CMA done that?

MS. DEMETRIOU: Sir, the CMA looked at the evidence of therapeutic substitutability and did find that there was, at the prevailing price --

THE PRESIDENT: But did it look at absolute prices? Is there anything in the decision that compares the patented prices of the different -- because I could not see anything.

MS. DEMETRIOU: I do not think there is anything in the decision. Of course the approach that the CMA took -- so the reason that it did not consider it to be informative to be applying a SSNIP test from the prevailing price in this case --

THE PRESIDENT: I say this is not a SSNIP test. It is another way of checking, given the peculiar way that pharmaceutical product prices are set and the role played by the national regulatory authorities, of looking at substitution and competitive constraint.

That is ultimately what it is all about. The SSNIP test is another means. It is not an end in itself. It is all looking at competitive constraints.

MS. DEMETRIOU: Yes, we agree.

If you look at figure 4.4 in the decision, which is at page 214 of the decision, that does appear to be comparing the prevailing prices. {V/1/214}

Of course, they did look at in the natural events analysis. They did look at, for example, when Prozac, when there was generic entry of fluoxetine, what effect that had on the prevailing price of Seroxat. We see that at 4.86 of the decision {V/1/220}.

(Pause)

THE PRESIDENT: I mean, figure 4.4, it is a little hard to imply from it -- but it looks as though that fluoxetine is -- I do not know if fluoxetine was still a patented product at that time. That is Prozac, is it not?

MS. DEMETRIOU: So you can see the vertical line where it goes off patent.

THE PRESIDENT: So fluoxetine was subject to generics. So that has been pushed down by generics. It does not tell us what Prozac was charging when it was branded.

MS. DEMETRIOU: What we see is that paroxetine stayed high.

THE PRESIDENT: So paroxetine and citalopram look not that far apart until, of course, generics come in, which suggests that the UK price regulation of those in setting the prices seemed to treat them, on this approach, as equivalent.

The advantage of that is that you have some outside objective standard, not company marketing spend, which might be subject to all sorts of things.

I think there is nothing in the decision explaining how the UK -- how NICE approves drug prices. We cannot see anything at all. But we can get a bit more from the Commission's decision --

MS. DEMETRIOU: I think there is something. Somebody will find that for me.

MR. GLYNN: The impression that the prices in the UK were broadly similar, if that is right, would be consistent with what we have from Ms. Nicholson's evidence I think.

MS. DEMETRIOU: Yes. So the decision at 3.103 and following explains the pricing framework.

But, essentially, the broad point is that the prevailing prices were examined and the CMA took account, for example, of the entry of generic fluoxetine and found that the Seroxat price, the paroxetine price, did not move very much. These were factors that were taken

into account but from that it was concluded that there was no significant competitive constraint on paroxetine until independent generic entry.

Moving ahead in AstraZeneca to paragraphs 212 to 213 {Auth-G/22/79}, you see there, at 212, the reference to the entry of generic omeprazole in Germany in 1999 and the reference back to recital (425) of the Commission decision, that that event resulted in a decline in Losec's sales volume of around 60% and negatively affected the sales of the other PPIs.

Over the page, 213 {Auth-G/22/80}:

> "The Commission rightly states that the very significant impact of the market entry of generic omeprazole both on sales of Losec and on its price must be viewed in con-junction with the absence of any effect of the introduction of the generic H2 blocker ranitidine on prices and sales of PPIs. Although the applicants claim that the Commission could not rule out that H2 blockers exercised a significant competitive con-straint over Losec, they have failed to adduce evidence capable of overturning the Commission's findings."

There we find an acknowledgment by the court that that evidence was significant evidence.

But to draw together our submissions on *AstraZeneca*, what we say about that is that the Commission had no need to define the market more narrowly in this case because of the very substantial market shares that AstraZeneca held even on the broader PPI market. So the debate between the parties was whether the market was the market for PPIs or whether it was the expanded market including H2 blockers.

If you look, for example, at {Auth-G/22/92} of the court's judgment, you see a series of paragraphs starting from 246, in fact on the previous page {Auth-G/22/91}, going through to 253.

THE PRESIDENT: This is under dominance?

MS. DEMETRIOU: This is under dominance, it is explaining the market shares. You see in each case they range from between around 85% to in some cases 100% depending on the market. There was simply no need in that case to define the market more narrowly than the Commission did. Of course, we have seen that both the Commission and the court did think that the quantitative evidence relating to independent generic entry was very important and we have looked at recital (425) and so we say that this is not an authority compelling GSK's approach. This is simply what the Commission did in that case because it had no need to go any further and the fact that it is not -- certainly the Commission does not consider it to be an authority requiring GSK's approach, because we can see that from its decision in *Servier*.

I think I came out of my order of submissions. So one point that I forgot to make in relation to the CMA guidance, we do not need to go back to it, but just for your note it is at paragraphs 5.4 to 5.5, is that, of course when applying the HMT, then the competitive price level that is used is of course not necessarily the prevailing price because of what is known as the cellophane fallacy.

In other words, if the firm in question does have substantial market power, then its current price is likely to be much higher than the competitive level and so applying the HMT to the current price level would always result in the conclusion that the market included at least some other products. You see that in the CMA guidance.

Of course, that is why, in this case, if the HMT had simply been applied using the prevailing price, then the CMA would have fallen prey to the cellophane fallacy. That would not have been an appropriate approach in this case.

Turning now to the objections made by --

THE PRESIDENT: Should we not finish *AstraZeneca*?

MS. DEMETRIOU: We finished *AstraZeneca*.

THE PRESIDENT: Should we not go to the Court of Justice?

MS. DEMETRIOU: We can go to the Court of Justice. It does not address this point. It simply does not address it, as far as I recall. But we can identify the relevant paragraphs for the Tribunal.

Whilst Mr. Bailey is doing that, can I proceed just to look briefly at GSK's objections to the CMA's approach.

THE PRESIDENT: I am just looking at it. I am looking at -- which is in volume 19, I think.

MS. DEMETRIOU: Yes.

THE PRESIDENT: At --

MS. DEMETRIOU: Tab 46.

THE PRESIDENT: This is 19I for India at 46.

MS. DEMETRIOU: Yes. I think it is paragraphs 36 on onwards {Auth-I/46/1}.

THE PRESIDENT: There is quite a lot about market definition I think because one of the main grounds of appeal was market definition.

MS. DEMETRIOU: It upholds the General Court's approach. {Auth-I/46/9}. (Pause).

THE PRESIDENT: If I am looking on page {Auth-I/46/13} paragraph 57:

> "However, the General Court also observed, at paragraph 191 of the judgment under appeal that it was apparent in any event from the findings made at paragraphs 171 to 175, 177 and 178 of that judgment that H2 blockers were not capable of exercising a

significant competitive constraint over PPIs by means of lower prices, in view (i) of the limited sensitivity of doctors and patients to price differences on account of the importance of the role played by therapeutic efficacy in the choice of what to prescribe, and (ii) of the regulatory systems in force in the relevant States, which were not designed in such a way as to enable the prices of H2 blockers to exert downward pressure on sales or prices of PPIs."

58:

"Even if, contrary to what was held by the General Court, the Commission had committed a manifest error of assessment by taking into account the price of medicinal products over an identical period of treatment and, moreover, the general cost of PPI-based treatment, as the appellants claim, did not in actual fact exceed that of H2 blocker-based treatment, the fact remains that H2 blockers were not liable to exercise a significant competitive constraint over PPIs having regard, in particular, to the weight given by doctors and patients to the therapeutic superiority of PPIs."

{Auth-I/46/14}

59:

"It must also be added ..."

The next paragraph it seems to me to be quite important.

MS. DEMETRIOU: If you see in paragraph 59 --

THE PRESIDENT: They say at the end:

"The error of law allegedly committed by the General Court at paragraphs 189 ... of that judgment, which relates specifically to the appraisal of only one of those items of evidence, is not, in any event, such as to call in question the result of that overall appraisal."

So they are upholding it because there was a whole series of factors which led the General Court to conclude that the Commission was correct to find that H2 blockers are not in the same market.

MS. DEMETRIOU: Sir, yes. You will see in the middle of paragraph 59 that one of those factors was other price indicators, such as the fact that the strongest impact on the demand for omeprazole produced by AZ was caused by the price of the generic version of omeprazole.

THE PRESIDENT: Yes. They are recognising a potential error without necessarily concluding that there was one and saying, well, it would not matter because there are enough other factors, I think. Is that what they are doing in the final sentence?

MS. DEMETRIOU: No. I think what they are doing is they are saying that all of these factors were taken into account and in light of all of these factors the ground of appeal --

THE PRESIDENT: The last sentence says:

> "The error of law allegedly committed by the General Court ... which relates specifically to the appraisal of only one of those items of evidence, is not, in any event, such as to call in question the result of that overall appraisal."

MS. DEMETRIOU: Yes.

THE PRESIDENT: So, even if one party is wrong, because there are so many other aspects in totality, you cannot impugn the decision.

MS. DEMETRIOU: That is right. So you have our submission which is that this case is not authority for the proposition that an identical approach is required in all cases. In fact, what it does do is highlight or refer to the importance of the price drop observed when generic omeprazole entered the market.

The fact that the Commission chose to follow this approach in this case, on different facts, in circumstances where there was no need to define a narrower market is not authority for the proposition that that is required as a matter of law in all cases such as this.

Sir, this ties into one of GSK's objections to the CMA's approach, which is that the CMA failed to give sufficient weight to the evidence on therapeutic substitutability.

We say that that submission misses the point because the dispute in this case between GSK and the CMA is not whether one should look at therapeutic evidence on the one hand or quantitative evidence on the other hand to apply the hypothetical monopolist test. In principle you can apply that test using either types of evidence or both types of evidence, which is what the Commission did in *AstraZeneca*.

But the question in this case is, when you are applying the hypothetical monopolist test, what is the appropriate competitive benchmark against which to apply it?

THE PRESIDENT: If you apply the first test, about therapeutic equivalence --

MS. DEMETRIOU: Sir, we do not accept that that is a different test because we are saying that is applying the hypothetical monopolist test, that by looking at different evidence in relation to therapeutic substitutability. So in each case you are asking the question: what would happen if GSK were the hypothetical monopolist of paroxetine -- if you are not looking at price and you are applying the hypothetical monopolist test, you ask yourself: what would happen if it were to reduce its investment in the drug or stop advertising or take that kind of measure? So what would the impact of that be?

You are still applying the same conceptual framework but you are doing it by reference to evidence on therapeutic substitutability instead.

THE PRESIDENT: Looking at the ATC category is a form of hypothetical monopolist test?

MS. DEMETRIOU: It is a starting point because one is looking at the ATC category in order to start forming a judgment as to what drugs might be exercising competitive constraints because they are addressing the same therapeutic need.

THE PRESIDENT: Yes.

MS. DEMETRIOU: We say that the criticism levied at the CMA by GSK, that it should have taken more account of the therapeutic evidence, we say that misses the point because the hypothetical monopolist test is the correct test. You can apply that test using a variety of different evidence, but really the question between us is: what is the competitive benchmark -- what is the benchmark against which you apply the test?

THE PRESIDENT: What is the benchmark that you apply to the therapeutic test?

MS. DEMETRIOU: So do you use the patent position pre-generic entry to ask yourself the question -- to pose the hypothetical monopolist test? Do you use the pre-generic entry patent position to say, for example: what would happen if GSK stopped investing so much, reduced its investment, reduced its advertising spend, etc? Would it still be a monopolist or would Eli Lilly, with Prozac, gain more of the market?

That is still the same conceptual test, but you are doing it by looking at factors such as marketing and advertising spend and what doctors do.

THE PRESIDENT: But when you are asking whether they are therapeutically equivalent, are you looking at marketing spend?

MS. DEMETRIOU: No. I see it in two stages. So you are asking, first of all, whether they are therapeutically equivalent in order to get the ballpark of which drugs might be exercising imposing a competitive constraint. That is why you look at the ATC and so on.

Once you have identified the range of drugs that might be imposing a competitive constraint, then you apply the HMT framework.

THE PRESIDENT: So the therapeutic equivalence, you are not suggesting that is a hypothetical monopoly, an HMT, you are saying it is a preliminary inquiry you have got to make to identify the products to which you then apply the HMT? Have I understood that correctly?

MS. DEMETRIOU: Yes, so you identify the category of products to which you apply the HMT. Then you ask yourself the question which is: what is the benchmark against which you apply the HMT? We say that it is wrong to use the patent position as the benchmark when

the very question in the case is whether anti-competitive steps have been taken illegitimately to extend the patent position.

MR. GLYNN: If I may. If you are right about the benchmark to be using, then, if you use the therapeutic substitutability, you would be comparing the therapeutic substitutability of branded versus generic paroxetine, would you not?

MS. DEMETRIOU: Exactly.

MR. GLYNN: The only question really that is important is whether the benchmark is the one that is after the patents have been assumed away or whether the benchmark is the one while the patents are in existence. That is really all your point?

MS. DEMETRIOU: That is precisely my point. That is exactly my point. We say that if, taking those alternatives, if the benchmark were the patent position, then we say that GSK would be pulling itself up by its bootstraps because the very question in this case is whether it is taking steps illegitimately to extend its patent position.

Once it has accepted that the benchmark is a situation of competition with generic paroxetine, then, whichever source of evidence is used, shows that the presence of generic paroxetine makes a very big difference to the competitive constraints on GSK and that is because of your point, Mr. Glynn, that generic paroxetine is perfectly therapeutically substitutable for Seroxat, which is why it can be dispensed in response to a paroxetine open prescription.

THE PRESIDENT: Is that the only criteria for therapeutic substitutability, that it could be dispensed on the same prescription?

MS. DEMETRIOU: No, it depends on which benchmark you are taking.

THE PRESIDENT: But even if you take a benchmark after generic entry, take that, what does therapeutic equivalence then mean?

MS. DEMETRIOU: Then there is very little --

THE PRESIDENT: What is the question? When you are asking: is it therapeutically equivalent, what do you mean? What are you asking?

MS. DEMETRIOU: We are not asking that question. We are saying that the right approach is to apply the HMT, recognising that what is important here is the fact that, pre-generic entry, there was no price constraint imposed on GSK by the other SSRIs or very little price constraint. That is the important thing in this case. So --

THE PRESIDENT: But I thought you said -- I am sorry if I am going round in circles or if I am failing to understand it -- that there are two ways which one can apply the HMT. One is on price, the other is by therapeutic equivalence.

MS. DEMETRIOU: Yes.

THE PRESIDENT: I am now focusing on that second one. The therapeutic equivalence. You say it is important then whether one applies it before or after generic entry. Let us apply it after generic entry. You are applying the therapeutic equivalence test. You have got paroxetine, you have got Seroxat, you have got branded citalopram, which I cannot now remember the name and you have got --

MS. DEMETRIOU: Cipralex.

THE PRESIDENT: Thank you. And you have generic citalopram. What is the question on therapeutic equivalence?

MS. DEMETRIOU: The question is whether the other SSRIs are so similar that they stop GSK, that they impose a price constraint on GSK and stop it from pricing above competitive level. That is the question. So that is the question in this case, in a nutshell.

THE PRESIDENT: Yes, but we have got -- (Pause).

I am not sure that is the therapeutic equivalence test.

MR. GLYNN: If you were in the world when the patents have gone and your question was: do the still patented alternatives to paroxetine exert a competitive constraint on the generic price of paroxetine? That would be a possible question, it would not be a terribly interesting one, I imagine.

MS. DEMETRIOU: Exactly. We say the same approach has to be taken, or the same conceptual framework has to be taken here because it does not matter that you are looking at the position pre-patent because the very issue you are focusing on is the potential exclusion of generic entry. So you have to ask yourself --

MR. GLYNN: If you were wrong on assuming the patents had failed, because you are no longer there and you are in the world where the patents are still in place, is the CMA's view that there is dominance in that world? Do you accept the definition of a market is including the SSRIs and this other drug we heard about?

MS. DEMETRIOU: So your question is if the patent is --

MR. GLYNN: If we are assuming that the patents are still there and you are thinking about the market definition, are you in agreement with what has been said on behalf of GSK that the SSRIs plus this other drug would be the relevant market? Based primarily on therapeutic substitution.

MS. DEMETRIOU: Not if the anti-competitive conduct that is being examined is whether or not anti-competitive steps are being taken to extend --

MR. GLYNN: I understand that, but if your assumption was that the patents were upheld, assuming the answer you do not agree with to that question, then are you in agreement that the SSRIs plus this other drug would be the relevant market based on all the kinds of evidence of therapeutic substitutability and so on which we have been hearing about?

MS. DEMETRIOU: So it is hard to think how that would arise in practice because if you are looking at circumstances where generics are trying to enter and trying to challenge the patent, then in those circumstances what is being examined is whether or not illegitimate steps are being taken to prolong the patent life.

MR. GLYNN: Just on the market definition.

MS. DEMETRIOU: On the market definition point. So on this hypothesis, it is simply not known whether or not the patent is valid or not because steps are being taken --

MR. GLYNN: I understand that.

THE PRESIDENT: If GSK came to you and said, "Ms. Demetriou, you are an expert QC on competition law" and they come to you in 1998, "We have got this wonderful drug, Seroxat, we have learnt a bit of competition law and we understand that if you are in a dominant position you have a special responsibility, whatever that means, to behave in certain ways and not do other things, are we -- this is the market, this is how it works -- are we in a dominant position?

As I understand, you would say, "I cannot tell you unless you tell me what sort of conduct you are contemplating"? Could you answer the question?

MS. DEMETRIOU: So you could -- yes. So if the conduct that is being contemplated is the kind of conduct in this case, which is aimed at keeping out generic entry --

THE PRESIDENT: I say they did not tell you what conduct, they just wanted to know whether for the purpose of the way we run our business are we dominant? And these are the other SSRIs and the prices --

MR. GLYNN: Other doctors prescribe.

MS. DEMETRIOU: So my answer would be if the conduct that you are contemplating, or your business conduct, is concerned with the market as it exists, so competition, if the competition issues are issues that arise between you and the other SSRIs, then that is the proper benchmark.

But if what you are doing, if the issue that is being examined relates to deferring or extinguishing independent generic entry, then you have to ask yourself the question whether or not the constraints that are being imposed by the other SSRIs are sufficient such that snuffing out or deferring independent generic entry does not matter.

THE PRESIDENT: Perhaps the answer does depend on -- they would have to tell you what conduct they had in mind before you could tell them whether they were dominant?

MS. DEMETRIOU: Yes, that is the logical conclusion of our argument.

Now, we are not saying, of course, we are not going so far as to say that there is a different market definition. There are hundreds of different market definitions depending on conduct. But in this specific case when the conduct you are looking at is conduct which is concerned with deferring or distinguishing independent generic entry, we say simply looking at the non-price competition during the life of the patent between the other SSRIs does not have a bearing on that question.

Because the question is: what is the price constraint? Because what we are talking about here, if generic entry occurs, are significant falls in price. So are the other SSRIs imposing a sufficient price constraint on GSK? If the answer to that is "no", then it matters. It matters if independent generic entry is extinguished or deferred.

So drawing together our case --

THE PRESIDENT: Can I stop you for a moment. Sorry to keep interrupting.

Going back to therapeutic equivalence. Perhaps I have a simple mind. I understood that as a rather basic idea as discussed in the -- I have still got open the Court of Justice in *AstraZeneca*, which is {Auth-I/46/10}.

At paragraph 41:

> " ... it was apparent from the statements of the medical experts produced by the appellants during the administrative procedure that, although between ... H2 blockers were administered to treat the same conditions, PPIs were generally prescribed to treat severe forms ..."

MS. DEMETRIOU: Yes.

THE PRESIDENT: That is directed to therapeutic equivalence and a finding they are not quite therapeutically equivalent. It is a fairly simple sort of -- that is what I understand therapeutic equivalence means.

MS. DEMETRIOU: I agree, and sorry if I was not clear. We accept that that type of evidence may well be relevant, but what you are looking at in each case is identifying the competitive constraints on GSK.

So if, to take a hypothetical example, the SSRIs were so perfectly substitutable that they imposed a very great competitive constraint on GSK, then one would expect that when generic entry happened very little would happen because the competitive constraint

beforehand would be so great, including on price, that independent generic entry would make no difference.

THE PRESIDENT: That is where I struggle, because that seems to me to ignore the way competition takes place. They might be perfectly substitutable therapeutically, but doctors have preferences and they take views, some prefer one, some prefer another, and so they will write -- but those views are not formed by price.

MS. DEMETRIOU: That is right.

THE PRESIDENT: They might be formed by marketing, by representatives of these companies, that is why they put all this effort, presumably, into marketing and promotion, and they might be haphazard depending on what article the doctor had recently read, and so on. Then once they have written their prescription, the pharmacy cannot do anything about it. They are never going to be constrained by price in that way. Once generics come in, the whole point is that then it is not the prescribing doctor who has the influence, because most prescriptions are written generically, and there is a great effort to get doctors to prescribe generically.

It is then the pharmacist who has a choice and the pharmacist is price sensitive. So that is why you have this change. That is what is going on.

MS. DEMETRIOU: So I accept all of that, and we do accept of course that pre-generic entry there was competition between Seroxat and the other SSRIs, and we accept that that competition was not really price competition for the very reason you give, sir.

But the competition took the form, for example, of marketing to GPs to try to persuade GPs that Seroxat was better than Prozac, for example, and that there were some competitive constraints imposed on Seroxat as a result of that. But what we say is that when we are looking at what is at stake here, which is deferring independent generic entry, which we know results in huge price reductions, then given that is the competition issue that has to be resolved, we say that marketing constraints, constraints imposed by the therapeutic substitutability of the SSRIs in non-price terms, do not have a bearing on that question. Because they did not present a sufficient competitive constraint largely -- maybe primarily, even, for the reason you give, which is that GPs are not price aware, are not price sensitive, do not prescribe on price.

So there was no price constraint before and that is why this issue is so critical. That is why when you apply the HMT you do it by the benchmark post-generic entry. We say moreover that if you do not adopt that approach and if you say we are going to ignore that and we are going to say that GSK was constrained, because if it had marketed a bit less to GPs then

Prozac may have gained a couple of percentage points in the market, if you approach it on that basis, then conduct which matters or which may matter in competition terms very much in terms of price and prices to consumers, prices to pharmacies, namely independent generic entries, simply could not be tackled under Article 102.

So, sir, your question to me or your observation, which I apprehend you find unattractive the proposition that you might have different market definitions depending on the conduct, we would say quite simply that if what is being considered is conduct relating to deferring or extinguishing independent generic entry, then this is the appropriate market definition and that is plainly what the Commission in *Servier* thought was critical too.

Sir, that was all I was going to say on market definition. I had some points on --

THE PRESIDENT: It does raise this conundrum for us. You both address submissions on the basis that that is the approach the Commission is taking in *Servier*, and *Servier* is on appeal. We are not bound by *Servier*. The English courts are still bound by what the General Court might decide. The General Court will presumably decide in December/January next year, something like that, given that their pace of work now has speeded up, of whether that is something we should consider referring. Because it may well be whichever way we decide this, and we would have to reach a view whether we follow *Servier* or we do not, someone will appeal, quite possibly. In which case that might be the route in any event, or the General Court will have decided and there might be a further appeal and the whole thing gets dragged out, and it is preferrable it goes to the Court of Justice as quickly as possible. At some point you might consider whether that is -- both sides -- appropriate because it looks as though this sort of argument is going to be addressed in *Servier* to some extent.

MS. DEMETRIOU: Yes, a market definition certainly is under appeal in *Servier*. I do not know precisely what arguments are being advanced.

THE PRESIDENT: One can see the approach they have taken.

MS. DEMETRIOU: Exactly.

THE PRESIDENT: I think it is likely to give rise to the same sort of argument, perhaps not done as well as you and Mr. Flynn. But the advantage of the reference is that you will be able to do it and it will be tailored to the circumstances of this case, which is helpful.

MS. DEMETRIOU: Sir, we understand that point. Can we reflect on that?

THE PRESIDENT: I am not expecting an instant answer.

Anyway, I think it might be sensible -- you have finished with market definition?

MS. DEMETRIOU: I have.

THE PRESIDENT: So you have this point on the vertical agreement, which is fairly short.

MS. DEMETRIOU: It is a short point. I can deal with that very quickly.

THE PRESIDENT: How long would that take?

MS. DEMETRIOU: Five minutes, ten minutes.

THE PRESIDENT: Just a moment. (Pause)

We will go for another ten minutes, yes.

MS. DEMETRIOU: So the VAEO, can I just turn it up at {A5/75/2}.

THE PRESIDENT: Yes, give me just a moment. Thank you.

MS. DEMETRIOU: The first point we make is the rather obvious point that on the face of the order it states that it is clear that it applies, the exclusion applies to the Chapter I prohibition only.

So if it had been intended to apply to agreements that might attract the application of the Chapter II prohibition, then it could have said that.

When we turn to the OFT guidance, which is at {Auth-K/14/2}, paragraph 1.9 at the bottom of the page states that:

> "There is no exclusion from the Chapter II prohibition for vertical agreements and restraints. The Chapter II prohibition applies to conduct which amounts to an abuse of a dominant position. Part 6 describes the possible application of the Chapter II prohibition ... to vertical agreements and restraints."

So we say it is clear on the order itself, on the face of the order itself and from the guidance, that it is not intending to exclude agreements which might be the subject of the Chapter II prohibition.

Then, also, we say that it is clear from the nature of the order itself and how that works that it did not require an individual assessment of the purpose and effects, the object of an agreement in context. It was rather a more mechanistic exercise which was carried out according to the express terms of an agreement.

So for that reason too, the exclusion does not go further than it says on its face.

You were taken to *Tetra Pak* 1 by Mr. Flynn. Could we just go back to that. {Auth-G/1/1}

If we can go to paragraph 21. I am not sure what page that is on.

{Auth-G/1/10}, thank you. So we see here the court saying:

> " ... notes at the outset that the problem of reconciling application of article 86 with enjoyment of block exemption, which is the crux of the present case and arises because of the need for logical coherence in the implementation of articles 85 and 86, has not yet been expressly determined by the Community Court."

Just pausing there.

There is an authority that does deal with this head on which is not in the bundle, but we shall make sure that you have copies and that it is uploaded on to Magnum, which is *Compagnie Maritime Belge*, the Court of Justice.

They deal with it at paragraphs 129 to 131, and in a nutshell what the court says in those paragraphs is that these are different provisions and the fact that you may have an exemption under Article 101 does not preclude the application of Article 102. So it deals with the point head on and it dismisses it.

Going back to Tetra Pak 1 and then going forward to paragraph 23 over the page {Auth-G/1/11}, the question that the court was addressing, first of all, was whether the acquisition by a dominant undertaking of an exclusive licence per se constitutes abuse.

The court held that it does not constitute abuse and something further is required. Now, that is a point which is unrelated to the question of exemption. That is just a matter of interpreting Article 102. So Article 102 does not preclude dominant firms per se from acquiring exclusive licences. You need to show that the Hoffman-La Roche test is met.

Then moving on to paragraph 24 {Auth-G/1/12}, it is in that context that this question of a supplementary element is then considered.

So you see from the final sentences of paragraph 24 that:

> "The additional element lies in the very context of the case — in the fact that Tetra Pak's acquisition of the exclusive licence had the practical effect of precluding all competition in the relevant market."

That was the Hoffman-La Roche test being made out.

Paragraph 25:

> "In these circumstances, this Court holds that in the scheme for the protection of competition established by the Treaty the grant of exemption, whether individual or block exemption, under Article 85(3) cannot be such as to render inapplicable the prohibition set out in Article 86. This principle follows both from the wording of Article 85(3) which permits derogation ... and also from the general scheme of Articles 85 and 86 which, as noted above, are independent and complementary provisions designed, in general to regulate distinct situations by different rules."

That is essentially the gist of what the Court of Justice itself says in *Compagnie Maritime Belge*.

THE PRESIDENT: Yes.

MS. DEMETRIOU: In a nutshell, our answer is it is plain on the face of the order that exclusion under the order does not protect an undertaking from scrutiny under the Chapter II prohibition, and we say that the Court of Justice has also made that very clear.

THE PRESIDENT: Yes. I do not think Mr. Flynn was saying that it is impossible that because you are within the order you are excluded from Article 102. He was saying in those circumstances you need to have something else as well.

MS. DEMETRIOU: We say there is something else when read in proper context. What the court is looking at for the something else is just approaching the question of the breach of Article 102. It is addressing the submission that it is saying that the acquisition of an exclusive licence by a dominant undertaking is not per se abusive.

Even leaving aside questions of exemption under Article 101, you need to show that the acquisition of the licence then leads to a distortion of competition within the Hoffman-La Roche test. That is all the court is saying. It is not saying that where you have an exemption then something supra added to that is required. But even if it were, then we say that the CMA's decision does establish that entering into these agreements has tended to restrict competition within the Hoffman-La Roche test. We say on the facts, in any event, that is made out.

Just before you rise, at the outset you asked me whether or not we accept that if we lose on the Chapter I case we also lose on the Chapter II case. I took your question to mean if we lost on the facts on the Chapter I case, and the answer is yes. There is no additional large factual plank that would salvage the Chapter II case.

However, thinking about it, it is a slightly more complicated question potentially, because if we were to lose, for example, the Chapter I object case on some legal argument, for example one of the arguments made by GSK is that you can only have an object infringement if there is some pre-existing established category of cases in which it falls, if we were to lose on that kind of legal basis, then we would not accept that the Chapter II case would fail.

I hope that is clear.

THE PRESIDENT: Yes.

MS. DEMETRIOU: We do not think that there is any additional factual material that by itself would make good the Chapter II case.

Sir, I was prepared to address the Tribunal on other submissions made by GSK in its skeleton argument relating to, for example, the competition on the merits test in *Hoffman-La Roche*, and they make some points on *National Grid*. But I am quite content to leave

those for closing if that is convenient, and we move straight on to the hot tub tomorrow morning.

THE PRESIDENT: I think so. Thank you very much.

So we will have the concurrent evidence of the two experts tomorrow. We may well, given the more limited nature of the reports on this, not require the whole day for that but we will see how we go.

So we will start at 10.30 am tomorrow.

MR. FLYNN: Sir, presumably the arrangement will be as before, I take it?

THE PRESIDENT: Yes.

MR. FLYNN: We will step back.

Could I just say, I think formally I would have a right of reply on the authority which I have not seen. I may not need it, but perhaps --

THE PRESIDENT: On Compagnie Maritime Belge? Yes, but we have not seen it either.

MR. FLYNN: Precisely, so perhaps we should see it first and I will tell you first thing if there is anything I need to say.

THE PRESIDENT: Yes. Thank you very much.