IN THE COMPETITION APPEAL TRIBUNAL

Case No.: 1407/1/12/21, 1411/1/12/21-1414/1/12/21:

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Tuesday 22nd November-Friday 23rd December 2022

Before:
The Honourable Mr Justice Marcus Smith
Professor Simon Holmes
Professor Robin Mason
(Sitting as a Tribunal in England and Wales)

BETWEEN:

Appellants

(1) ALLERGAN PLC ("Allergan")

(2) ADVANZ PHARMA CORP. LIMITED & O'RS ("Advanz")

(3) CINVEN CAPITAL MANAGEMENT (V) GENERAL PARTNER LIMITED & O'Rs ("Cinven") (4)

(4) AUDEN McKENZIE (PHARMA DIVISION) LIMITED ("Auden/Actavis")

(5) INTAS PHARMACEUTICALS LIMITED & O'RS ("Intas")

AND

Respondents

COMPETITION AND MARKETS AUTHORITY ("The CMA")

A P P E A R AN C E S

Mark Brealey KC (On behalf of Advanz)

Daniel Jowell KC & Tim Johnston (On behalf of Allergan PLC)

Sarah Ford KC & Charlotte Thomas (On behalf of Auden/Actavis)

Robert O'Donoghue KC & Emma Mockford (On behalf of Cinven)

Robert Palmer KC, Laura Elizabeth John & Jack Williams (On behalf of Intas)

Marie Demetriou KC, Josh Holmes KC, Tristan Jones, Nikolaus Grubeck, Michael Armitage, Professor David Bailey & Daisy Mackersie (On behalf of the CMA)

Wednesday, 21 December 2022

(9.00 am)

Closing submissions by MR JONES

THE PRESIDENT: Mr Jones, good morning.

MR JONES: Object. You will recall that the CMA found that the 10mg agreement had the object of restricting competition because in summary it aimed to exclude AMCo from independent entry. Thereby, protecting Auden's ability to charge high prices and of course, on the other hand, and in return, to share the monopoly profits with AMCo via the supply arrangements.

I intend to address first the law on object infringements and then the appellants' arguments.

Starting with the law, of course you are well familiar with the cases, and I will take the first couple very quickly, but I just want to highlight a couple of important points which arise from them.

The first important case chronologically for our purposes is the *Irish Beef* case, the Bids case, decided in 2008.

The facts there were very straightforward. A group of meet processors got together, and the stayers paid the leavers essentially for leaving the market. That was an object infringement and the reason it continues to be important is that it is cited repeatedly for the

principles which it establishes on market exclusion cases. It is cited in *Carte Bancaire*. It is cited in the pay for delay cases that I am going to come to, and of course, it is cited in this case by the CMA.

To some extent, it is obvious why a market exclusion agreement of that nature would have the object of restricting competition. You are excluding a competitor from the market. But there is a slightly more subtle point that also emerges from the case and that is what I want to show you.

Could we go to {M/65/14}, please. You will see at paragraph 34, so just down the page, what is said is:

"That type of arrangement conflicts patently with the concept inherent in the EC Treaty provisions relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the common market. Article 81(1) EC is intended to prohibit any form of coordination which deliberately substitutes practical cooperation between the undertakings for the risks of competition."

I show you that because that is what is echoed in some of the later cases and it is also, you will remember, a point which Ms Demetriou touched on several times in her submissions yesterday, so I just wanted to

anchor that in the case law and in particular in Irish beef.

The next case which is important chronologically is the *Carte Bancaire* case. That is 2014. It is helpful for several reasons. It brings together many of the essential principles. My learned friends have mentioned those. We have cited those in our submissions. I do not intend to go through *Carte Bancaire* for those basic principles on object infringements, but I do want to emphasise a point about the facts of *Carte Bancaire* and just what actually happened in that case.

The position there was the Commission had decided that the measures restricted competition by preventing entry on to the issuing market. That was their focus, the issuing market. That was the reason why there was, if you like, a market exclusion element, because it was entry into that market.

The answer to that complaint in broad terms from *Carte Bancaire* was, well, those measures which you are complaining about are intended to stimulate competition on the acquiring market. Of course, in a payment system you need both: you need an issuing market, and you need an acquiring market.

So, there were in a sense restrictive components, but on the other hand, what you might call

pro-competitive elements of the arrangements.

The basic reason why in that case one could not look at it and say there was an object infringement was that you have to look at those in the round. That is what the court says in summary, is that you have to look at the issuing market, but you also have to look at the acquiring market. I am not going to ask you to turn it up, but just for the note, paragraph 73-75 of the judgment really encapsulate that point.

Now, we then come chronologically to the pay for delay cases. They are much more recent, but they are of course much, much closer on their facts to the case which we have before us now.

But it is important to put them in that line, because they do follow very much the same line of development from *Irish Beef* through *Carte Bancaire*. Of course there is a market exclusion element but there is also, importantly, sometimes pro-competitive arguments, so comparable in a sense to what you see in Carte Bancaire.

So it is worth looking at those as well. The case that I want to spend a good chunk of time on, because it is so similar to our case and raises so many similar points, is the *Paroxetine* litigation.

You will know *Paroxetine* is an antidepressant drug.

It was subject to a CMA Decision in 2016. It went to the CAT for a decision in 2017. It was referred to the Court of Justice which gave judgment in 2020 and there was then a further CAT decision in 2021.

The broad position was GSK had a patent over *Paroxetine* which was a blockbuster, it was called a "blockbuster antidepressant drug". GSK entered into agreements with three generic suppliers. We only need to be concerned with two of them. There was the GSK, GUK agreement the GSK, *Alpharma* agreement. Both of those companies, GUK and *Alpharma*, were potential competitors. They had not yet launched their products. They were both in patent litigation with GSK and they each reached an agreement with GSK under which, in broad terms, the patent litigation came to an end. They agreed not to enter the market with their own products and value was transferred from GSK to those companies.

Now, of course part of these cases is about the patent context. But, as I will show you, part of the cases was not about the patent context, it was about the nature of object infringements more generally and, in particular, in that particular case, what one does when one faces a supply arrangement, as we do in this case, and where value is transferred via a supply arrangement.

Could we look first please at the CAT decision.

{M/144/1}. I want to go, please, to page 16. {M/144/16}. The reason I am starting here is just to show you the various terms of the GSK, GUK agreement. They are listed in paragraph 32. There are several means there, several means of transferring value. The one which I just want to highlight is the one at (3):

"GUK would enter into a sub-distribution agreement with IVAX ..."

IVAX was a company which had already been appointed as a distributor by GSK, so what is being described here is basically "the supply agreement". They had to enter into it with IVAX rather than GSK. GSK then had to amend its agreement with IVAX, but that is the supply agreement, and part of the value was transferred to GUK through this arrangement.

Then at 5, if you go down slightly, you will see 5 is the market exclusion element of it, because in return for this transfer of value GUK was not going to supply *Paroxetine*, other than that provided to it by GSK.

I then want to show you the *Alpharma* agreement. Can we go to page 20, please. {M/144/20}. It is paragraph 41 and, again, you will see the distribution is at paragraph (1) so that is the supply agreement. There are also various other forms of payment and then if you go down to (6) -- I cannot remember if this is on

this page or the next page -- there it is. On (6) there is the market exclusion element.

By this point, by the point it had got to the CAT, there had been some General Court judgments regarding pay for delay. There were various outstanding appeals, so, the Tribunal says at paragraphs 87 and 88, which we do not need to look at, but what the Tribunal says there it has decided to make a reference to the CJEU, but before doing so it will decide all issues of fact in the case.

One very important set of factual issues arose, because the appellants argued that the supply arrangements which they had entered into were in fact pro-competitive and we see that on page 104, please. {M/144/104}. If we go down, please, to paragraph 263. I will just pause, sir, for you to read that if I could. Paragraph 263.

THE PRESIDENT: Yes, of course. (Pause). Yes.

MR JONES: There were various reasons why this arrangement was said to be pro-competitive. We can see them, please, page 108, paragraph 274. Four reasons are listed there. So four different arguments were put forward. Now, most of these arguments arose on the very particular facts of *Paroxetine* and they would not arise here and do not arise here and have not been argued

here.

As an example, the first one was about new generics leading to a change in categorisation under the drug tariff, which of course is not an issue which arises here.

So there were some particular arguments, but you will see the fourth argument is essentially the argument which is run here:

"Additional competitive pressure on GSK through loss of volume."

As it happens, that was the only one of these four arguments that the Tribunal rejected entirely on the facts in *Paroxetine*.

We can see that if we pick it up, please, at {M/144/119}. I have jumped into the section where that fourth argument is being discussed. But in summary, you will see what is said. Paragraph 300 is essentially saying: there is no suggestion that GSK thought that the supply agreements would lead to downward pressure.

At 301 what is being said is that there was actually no evidence of downward pressure on prices.

Then could we go to paragraph 303, please. {M/144/120}:

"The reason why GSK entered into the agreements was because of the risks caused by the challenges to its

patents. Since under the Agreements the quantities supplied by GSK to the generic companies were capped and total demand was fairly inelastic, we do not accept that the Agreements can properly be regarded as giving rise to any meaningful competitive constraint on GSK. The Agreements amounted to a monopoly supplier -- the patent holder -- agreeing to share a significant but limited part of the market with independent distributors of its own product, which it knew they would price at below its own list prices."

Just to complete the picture, there is an overall conclusion on benefits on the next page, please, at paragraph 306. {M/144/121}. You will see, that is just the summary, but essentially what they are saying is that they accept that there were some benefits. The most significant is the saving by reason of reallocation under the drug tariff and various others, which do not arise in our case.

So that is the factual background as decided by the Tribunal in that case.

Now, the case then of course went to the CJEU for various legal questions to be decided against that factual background.

Can we have a look at that, please. It is {M/168/7}. We are looking here at the questions which

were referred. Now, question (3) is where restriction by object issues begin. You will see that question 3 is basically, a question about the settlement of patent litigation. Question (4), the same. Question (5) though picks up on this supply point. Could we -- thank you.

Again, because my voice is going slightly, I am just going to pause and invite you to read question (5) to yourself, sir.

THE PRESIDENT: Of course. (Pause). Yes.

MR JONES: The way these questions are addressed is as follows: if we look at page 15, please, {M/168/15}, paragraph 68 refers to the essential test in *Carte Bancaire*. 69 and 70 summarise the important context in this case, in the *Paroxetine* case, but you will see it is very similar to the context in our case because it is all about generic entry into pharmaceutical markets.

There is then quite a lengthy discussion on the settlement of patent litigation, where in broad terms the answer is that it cannot be settled on terms which involve the patent holder paying the generics company not to enter the market.

For our purposes, I want to emphasise two important points. Firstly, there is a point about uncertainty and

object infringements, because of course one of the features of the patent context is that you cannot actually know for sure what competition would have emerged in the counterfactual. The reason you cannot know that is what if the patent was valid? There would not have been competition in the counterfactual, because the patent would have been enforced.

That is a point which is discussed at paragraphs 99 and 100, for which I unfortunately do not have a page reference. I apologise. Could we go down a couple of pages and see if we can find those. {M/168/18}.

THE PRESIDENT: Shall we read 99 and 100.

MR JONES: Please, thank.

THE PRESIDENT: If we could get both pages on that would be very helpful. (Pause). Yes.

MR JONES: So you will see there the echos of *Irish Beef* and the significance of uncertainty in competition. One can never know for sure how competition will unfold, but an important element of these cases is that there is a process, an uncertain process, which is protected. Now, that will be true in different ways in every case and you can see the echos in our case, because one point that the appellants make is that they did not know, for example, how much market share they would get through entry. I am going to return to that when I come to

address their arguments, but you will see that one part of the answer, at least, is: well, yes, you did not know, we accept you could not have known for sure, but that is the nature of competition. There are always risks and uncertainties, and the process is protected through these rules.

The second point I wanted to pick up on in *Paroxetine* is going back to the relevance of alleged pro-competitive effects, because you will recall how significant that was in *Carte Bancaire* to look at both sides and this case is a very helpful counterpoint.

If we go, please, to page 19 {M/168/19} and look at paragraph 103, you will see that what is said there is that:

"Where the parties rely on pro-competitive effects, they must ... be duly taken into account ... insofar as they are capable of calling into question the overall assessment of whether the concerted practice revealed a sufficient degree of harm to competition and, consequently, whether it should be characterised as 'restriction by object'."

But of course, there is a threshold. One takes them into account, but one needs to actually look at them and test them and see whether they exist.

If you look down at paragraph 107, you will see what

is said is:

"If such effects are demonstrated, relevant and specifically related to the agreement concerned, those pro-competitive effects must be sufficiently significant, so that they justify a reasonable doubt as to whether the settlement agreement concerned caused a sufficient degree of harm to competition, and, therefore, as to its anti-competitive object."

In *Paroxetine* itself the court then goes on to express some doubts about whether the findings there were sufficient at 110. Of course, it then goes back to the Tribunal and the Tribunal decides that although it had found there to be some pro-competitive components in that case, they did not meet that threshold.

I am not going to look at the CAT's further decision, but just for the note that is at {M/183/1}.

There are then several further pay for delay cases, which really make very similar points. I have been calling this *Paroxetine*, but of course it is the case which is frequently referred back as *Generics UK* in the later cases. The only one which I want to look at very quickly, and I am going back to it because Ms Demetriou went to it, is the *Lundbeck* case which is from September 2021. That was an appeal against a Commission Decision and there are two points I want to

pick up on there.

{M/181/37}, please. If we can go down to paragraph 129, so this is the first point. There was an argument run that there was a lack of decision-making practice sufficient to lead to an object infringement finding. Again, I am afraid I am just going to pause and invite you to read from 129 to 132 over the page. So perhaps we could have both pages side by side, please.

THE PRESIDENT: So, 130-132.

MR JONES: 129-132. (Pause).

THE PRESIDENT: Yes.

MR JONES: I am grateful. The second point that I wanted to pick up on in *Lundbeck* is that it was argued there that The Commission should have looked at the counterfactual and that argument is rejected. It is page 39, please. {M/181/39} and I am going to invite you to read 139-141. (Pause).

THE PRESIDENT: Yes.

MR JONES: That is the legal part. I am now going to the turn to the appellants' argument. I will remind you there have been a lot of arguments addressed in writing and I am going to address you now on what I think the six main ones which were developed, in particular, in closing oral submissions by my learned friends.

They break down broadly into three points of law and three points of what you might call market context or economics.

The first one is an argument about the nature of the analysis that is required. Now, this argument was emphasised in particular by Ms Ford and her essential argument was the CMA has not done a detailed enough analysis to ground its object case. This particular submission started with a submission about the need for a counterfactual analysis. I am going to address that first.

I think in the end, that point about a counterfactual, is really a semantic point rather than a point of substance and I will unpack it a bit and explain why I say that.

Now, Ms Ford accepted, I think, that the point of an object analysis is that a full effects analysis is not required. So, therefore, as the court explained in *Lundbeck* in the passage you have just looked at --

THE PRESIDENT: The question is it may not be the point, it may be the consequence.

MR JONES: Yes, yes. I accept that, sir. I accept that. So in an object infringement, if one is doing an object analysis, one does not do a full blown effects analysis counterfactual.

THE PRESIDENT: It is a really different beast to an effects infringement.

MR JONES: Yes, precisely. So a counterfactual analysis in which you identify what would have happened in the counterfactual, which is what you do in an effects case, one does not do that in an object case.

THE PRESIDENT: I mean, take an example, Mr Jones, let us suppose one has a cartel that fixes prices, but it is actually, an incompetent cartel such that if you had a free market, the prices would actually be higher than as fixed in the cartel. I would have no problem in saying that was a by object infringement, for which one should be penalised, because you are even though the outcome might be said to be in the short run beneficial, price fixing is so inimical to the way our competitive market should work that it is an infringement, even though there are actually no short-term anti-competitive effects.

MR JONES: Yes, absolutely, that is exactly right. I should say, on these points of substantive principle, I do not think there is really any distance between myself and Ms Ford, which is why I said this is a semantic point. I am just going to spend time on it, because it is an important semantic point, because it is saying you did not do a counterfactual analysis and you should have

done. I just want to unpack that a bit to see where it really goes.

I do not think that Ms Ford would disagree with anything you have just said or that I said on this theme, so far. Ms Ford's point was rather that even when you consider the object of any particular measure, you must be mentally comparing it to something, even if at a high level. So, in the example which you just gave me, sir, one would not do an analysis of exactly what would have happened in that case but for the cartel, but to categorise that cartel as an object infringement one is mentally contrasting to it a world where there is not a cartel. That is why one gets to the point of describing cartels as object infringements. That point of generality, of course, I have to accept. How can one characterise anything as object infringement without having some notion of what would be there if you did not have the measure in question.

In this case, what you are contrasting the agreement to is a world in which AMCo has not agreed to forego independent entry. You are not nailing down precisely what would have happened. That would be an effects analysis, but you obviously need some point of reference to carry out the analysis.

That of course is what the CMA had in mind. The

possibility of entry by AMCo is what the CMA was explicitly comparing the agreement to in the section on object. That is why the CMA said, you will recall, that independent entry would have been in principle favourable to competition. So it must have some anchor point to look at.

So, so far so good. We agree. Ms Ford's next point I think was, well, you could call that a counterfactual. It is not the same kind of analysis, but you could call it a counterfactual.

Again, I mean, of course I have to agree with that. This is why I say it is just a semantic point. You could call it a counterfactual. In fact, I would go further. I did call it a counterfactual when I was discussing this with Mr Bennett, because one needs words to describe these concepts. "Counterfactual" is a word which has different meanings in different parts of competitive law. We are all familiar with that and so calling that sort of counterpoint, a counterfactual is fine. But the important point is if you refer to a counterfactual in an object case, you are not referring to the same kind of counterfactual as you would be in an effects case. That is the point.

You are not carrying out the same kind of detailed analysis of what would in fact have happened but for

these arrangements. That is what the court is referring to in *Lundbeck* and that is what the CMA is referring to when the CMA says, like the court said in *Lundbeck*: we do not need to do a counterfactual analysis. They are not saying we do not need to think about any alternative universe at all. They are just saying we do not need to do the effects analysis, the counterfactual analysis.

THE PRESIDENT: Mr Jones, I am sure you are right that there is a problem of terminology here, but the reason I do not like the use of "counterfactual" in by object infringements is because the essence of a by object infringement is that we have inbuilt into our competition DNA a sense that a market system is the best way to ensure consumer benefit. The competition between rival suppliers competing for market share with an elastic demand on the other side is the way one gets the best quality goods, the best price for people and that is a system that we buy into.

By object infringements are things which are inimical to that system and that is why you do not have to look at the effects.

MR JONES: Precisely.

THE PRESIDENT: You are seeing something which is just inconsistent with the way we do things and that is why price fixing or dividing up the market in other ways by

agreement and why communication between competitors are so dangerous, because you are supposed to be acting as independent entities.

So I quite understand why you use the term counterfactual, but I think inimical with the market system is actually the touchstone to why one goes for a by object label. It is when you have got a more difficult case, when you do not know that it is inimical to the system, that you move down to an effect where you have to say, well, look let us work out what actually is the consequences of this agreement are and there, of course, you do have to do a counterfactual, because you have to eliminate the offending provision or the offending agreement and work out what would have happened had it not been there.

MR JONES: Sir, I entirely agree and, perhaps more than that, the CMA would entirely agree, and I am sure that when I use the word counterfactual for discussion purposes with Mr Bennett there would have been people at the CMA bristling for precisely those reasons, because although one can use the word, sir, the way you have just put it is entirely the way that we see it here.

The substantive question, going back to Ms Ford's submissions, is whether or not the analysis which the CMA did was sufficient to categorise this as an object

infringement, not whether it included what one might call a counterfactual, but was the analysis sufficient.

I am not in the time that I have got going to take you back through the analysis. I will remind you that it is in the Decision pages 806-826, building of course on what is said elsewhere. It includes an analysis of the market context.

It is not right to say, as Ms Ford said, that it is "not premised on any factual basis whatsoever". I mean that was thrown out there, but if you read those 20 pages, you will see they are all about the factual elements of this market.

What is very telling here was the answer which was given to the question posed by Professor Holmes, because you, sir, asked a question: what more would the CMA have needed to do to be able to categorise this as an object infringement? That was a very pertinent question, but it was a dangerous question for Ms Ford, because if she had said anything in line with the case law, if she had said, well, they needed to examine the market context more, which is what the case law says one needs to do, that would be fatal, because that is what the CMA actually did. So instead, what Ms Ford said is, no, you cannot do an object assessment here. You can only look at effects.

In my submission, one really only needs to think about that for a moment to see that it cannot be right. It would mean that all those pay for delay cases, much more complicated than this one because of the patent context, they with appropriate analysis can be object infringement cases, but here, Ms Ford says, one cannot do an analysis -- and this was put forward really as a legal point -- one cannot do an analysis which leads to an object finding. One could only address this on an effects basis and, for the reasons that I have given, we say that that just cannot be right.

That is the first argument.

The second of my six arguments that I want to go through is an argument about the lack of prior case law. I can deal with this very briefly, because I have already shown you the answer to it. This was an argument made by Mr O'Donoghue. It was a related point which was to the effect that you cannot find an object infringement here, because there is not prior case law sufficiently closely on point. That is what Mr O'Donoghue said. The answer to the point is that no such case law is required. That is what the court said in *Lundbeck*, as I showed you, and indeed of course in those pay for delay cases one did not start with a series of cases looking at effects and then

incrementally moved into object. The focus there was always on whether there was coordination which is by its nature harmful to the proper functioning of competition. If you go back to basic principles, you go back to Irish beef, you apply the lens which you summarised, sir, a moment ago, and that is enough. One does not need a pattern of decisions.

The third argument is the argument that the pay for delay cases can be distinguished because of the supply arrangements which we have in this case and the particular nature of the supply arrangements in this case.

This was really was Mr O'Donoghue's main point on the law. He called it the day before yesterday "the crucial and fundamental distinction" he said between this case and the pay for delay cases.

What Mr O'Donoghue contends is that in the pay for delay cases whenever some of the value transfer took place through a supply arrangement, there was some other feature of the arrangement which meant that the supply could not have led to competition. That was what Mr O'Donoghue emphasised. And it is easiest to see how this is put in their written submissions.

Can we look, please, at {IR-L/3.1/134}. It is 239. It is at the bottom of the page. So there has been

a description of various pay for delay cases and the ones which have this particular discussion about the supply arrangement is of course *Paroxetine*:

"It is not difficult to see how such agreements may well be problematic. A cash lump sum pays the generic not to compete. A supply agreement protected by a profit guarantee means that the generic still gets paid even if it does not compete."

So that is the key point of distinction with *Paroxetine*. It was emphasised in oral submissions. They say, okay, there were supply arrangements, but there were profit guarantees, they say, so the generic would get paid whether or not it competed, by which they mean whether or not it sold the product, the generic company was going to get profits anyway. So there is no possibility, in contrast to our case, there is no possibility in the *Paroxetine* cases that the supply arrangements would lead to competition.

The argument just is not right. It is not right on the facts. There were no profit guarantees of that nature at all.

What they are referring to is two particular provisions in the *Paroxetine* case and you can see those provisions on the previous page, {IR-L/3.1/133}. If we look at the bottom of the page, you will see where they

summarise what they say these agreements are:

"Finally, whilst supply agreements also accompanied the lump sum cash payments, there were profit guarantee clauses in both agreements whose purpose or effect was to delay entry even further, even when the generics were in principle free to enter."

So they are making a slightly different point there about delaying entry even further, which is also wrong, but the main point they make here and in oral submissions, is about how these profit guarantee clauses mean that there is no incentive to sell product. These are their descriptions of the clauses:

"(i) GUK received an express profit guarantee of £2.85 million per annum; and (ii) in the event that *Alpharma* terminated its supply with IVAX, it would be reimbursed for up to two months' loss due to the market price falling below a certain level, up to £200,000 per month."

Now, let me just take those in reverse order, because the *Alpharma* one, even as it is described here, does not do what they say. So there is a term which they have landed on which says: if *Alpharma* terminates the supply agreement, it will get two months' loss if the price falls below a certain level, up to £200,000 a month. I simply say: so what? It is impossible to

see how a clause of that nature would mean, as Mr O'Donoghue says it means, that they are somehow incentivised not to sell the product which has been supplied to them.

So there just is not a clause anything like what they say in the *Alpharma* case. They lead therefore with the GUK guarantee and you have seen they describe that in a way which indicates that it may be just a blanket profit guarantee, so perhaps that does have the effect they are suggesting, but in fact that is also wrong.

The profit guarantee -- the point was not debated in the case, I should say, so this particular issue did not arise in the *Paroxetine* litigation. But we can see the profit guarantee clause in the *Paroxetine* Decision. So {M/117/134}. There is the clause 4.3, top of the page. (Pause).

So you will see it is a profit guarantee which kicks in if, and only if, the price falls below a certain amount. Now, once you know that, again, it is impossible to see how that can be said to incentivise GUK not to sell its product. I mean, it is not a point which has been debated, but if one thinks about it, in my submission, it works in the opposite direction, because actually they can sell the product without any concern about prices falling, because if prices do fall

they are going to have a profit guarantee.

So this supposed point of distinction, which was the linchpin of Mr O'Donoghue's arguments about *Paroxetine*, does not work. It does not stack up.

The fourth argument run by the defendants, the appellants, I apologise, is that independent entry would not have led to price falls in any event. I am moving now to what we might call market context or economic argument. So independent entry would not have led to price falls in any event. I am back really with Ms Ford, because this was her second big point. What she said was: there is no evidence that entry by one entrant alone would have led to "a steep fall in prices". The simple answer to that is that the CMA never said that entry by one entrant would lead to a steep fall in prices.

What the CMA said was that entry by one entrant could be expected to be the start of a process which would in principle lead to falling prices.

Now, the reason Ms Ford pitched her argument so high, "steep fall in prices", is because she then took the Tribunal to two articles which she relies on. Does not have an expert to make these points, but two articles which she relies on, which she says undermine the idea of a steep fall in prices.

Yes, they do undermine the idea of a steep fall in prices, but they are entirely consistent with what the CMA actually says and actually found, because what those two articles which Ms Ford took you to actually say is that the first entrant will start a process of decline in prices. One does not even need to read the articles to see that. If one looks back at Ms Ford's own summary of them, this is what she said. The articles both say prices will fall a bit with the first entrant and then they will fall more with later entrants. That is the CMA's case. It is a good thing for prices to fall a bit with the first entrant, but it is also a good thing for the first entrant to arrive and therefore start a process of further falls.

So had AMCo entered independently, prices would have fallen in principle, may have fallen a bit, yes. But it would have been, as it were, the Alissa, so it would have been instead of Alissa being the first entrant, AMCo would have been, so the whole process that comes afterwards would have been speeded up.

So the fact that the first entrant is the start of a process is a point which the CMA relies on, not a point which undermines it.

THE PRESIDENT: It may not matter, but is the reason for that curve in the price level because it is easier in

a two-party market to gauge how much you as the new entrant should supply to keep margins at the highest, whereas that is actually rather harder when you have got multiple competitors who are each on different data working out how much they should pump into the market by way of supply so one gets competition working? In other words, it is easier to protect your margins in a two competitor situation than in a five competitor situation.

MR JONES: Yes, precisely. That is why more competition is better than some competition and some is better than none.

THE PRESIDENT: Yes.

MR JONES: The fifth argument is an argument about the size of the contestable market. This was really Mr Brealey's main argument. It had a couple of dimensions. Firstly, there was the point that 50% of the market we now know by volume was not contestable by the skinny label product. Mr Brealey said that this poses a legal conundrum. We do not see any conundrum. The agreement precluded the prospect of that competition which could have taken place from taking place. AMCo plainly did not need to be able to compete for the full market in order to have a competitive impact and, indeed, we have seen very clearly what a dramatic impact competition can

have, even when it plays out in respect of that part of the market which is contestable.

Secondly, Mr Brealey said that AMCo had what he called an ethical objection, even to competing for that part of the market which has turned out to be contestable.

Now, one needs to be very careful here about how one characteries what Mr Beighton said. He did not say for ethical reasons we would never have entered anyway. He did not say that. Ms Demetriou has shown the Tribunal all of the evidence which demonstrates AMCo did not decide not to enter for ethical reasons. It decided not to enter, because it saw that there were risks associated with entry and it preferred to avoid those risks by entering into the agreement.

As I have already alluded to, it is precisely the same dynamic as we see in the pay for delay cases. You decide to substitute practical cooperation for the risks of competition.

I should just say finally on this fifth point to Mr Brealey's suggestion that the CMA is somehow saying to AMCo: you should have gone after the contestable part of the market -- it is a point Mr Brealey made. We thought it was unethical. The CMA is telling us we should have gone after it or it is unreasonable -- this

is another thing Mr Brealey says -- of AMCo not to enter the market and try to get the contestable part.

To be clear, the CMA is saying no such thing. Undertakings can decide for themselves whether to compete, just as, by the way, entirely consistently, pharmacies can decide for themselves what approach they are going to take to dispensing. The CMA is not telling anyone where they have to compete or what they have to do. That is the normal process of competition.

What they cannot do, what AMCo cannot do is accept payment from their horizontal competitors not to compete. So if AMCo really did have a firm ethical conviction, did not want to enter this market, fine. It is its choice. They do not have to. No one is forcing them to. That is not what happened here, as Ms Demetriou explained.

THE PRESIDENT: What you are saying is that it is not enough to decide not to enter. That may be a relevant feature in trying to infer what was agreed. What you have to show is that there was a promise not to enter the market.

MR JONES: Yes, yes.

THE PRESIDENT: That may be evidenced by what you might say was otherwise an irrational decision not to enter or something like that, but that is simply the evidence

that goes to feed the promise that is found.

MR JONES: Yes.

THE PRESIDENT: Let me be clear, I am not talking about a formal promise. I have well in mind the fact that arrangements are enough. We are not talking legal argument here, but that is what you have got to show.

MR JONES: Absolutely, absolutely.

The sixth and final argument is an argument about the consequences, the practical consequences, of the supply agreement. We are back with Mr O'Donoghue, because I have already addressed the legal point that he made trying to distinguish this case from *Paroxetine*. But there were then these factual points or economic points, if you like, about what is the actual consequence of the supply agreement?

We have talked about the potential competition in independent entry, which anyway is self-evident, but there is then a question which arises: could there be competition under the supply agreement? Is there some potential pro-competitive aspect to this?

Now, the CMA's position on this is really simple. The agreement was entered into in order to ensure that profits remained at their maximum monopoly level and given that there is fixed volumes and there is a fixed volumes supply agreement, that is achieved by these

agreements. To put the point very simply, if you share a market in fixed shares between two supposed competitors, there will not be competition on price, because they do not need to compete on price because they just carve the market up between them. So it is the same as having, in economic terms, one monopoly provider. So it is really simple.

It has been said that I spent a long time cross-examining Mr Bennett on object. Fair enough, I did and I did that because Mr Bennett had a very -- Dr Bennett, I apologise, had a very particular theory about this and a response. He was the only expert to address this object issue in any detail and he really did have his own take on this. It is what I am going to call the volumes theory, because faced with that proposition that I just put to you, that if you carve a market up into two you are going to still have monopoly pricing, what Dr Bennett said was, well, yes, but that would not happen here because Auden would supply AMCo and then Auden would increase its own volumes so as to compete with AMCo, because it would have some sort of incentive to clawback those sales from AMCo.

That was what was said in his report. It is said probably most clearly at paragraph 96 of his first

report, but that was the foundation of all of his arguments about object and that was why I spent time with Dr Bennett, because I wanted to unpack that because on the face of it it is such a surprising proposition.

You will recall, at least in my submission, it did take Dr Bennett to some rather surprising places. But, ultimately, it foundered on two rocks, a theoretical rock and a factual rock. The theoretical rock was this: ultimately, Dr Bennett did not have a good answer to the point that it would simply not be rational for Auden to shoot itself in the foot in that way. That was the theoretical rock.

The factual rock --

THE PRESIDENT: What you are saying is there is a fundamental inconsistency in that you do not supply a competitor in order to compete with them.

MR JONES: That is it. That is it. In circumstances where if what you are doing is trying to share value with the competitor, you can keep the monopoly profits at monopoly profit level and you can do it by restricting volumes. If you start competing, as Dr Bennett suggests, you lose the monopoly profits. So that was the sort of basic theoretical point.

There was then the factual point which was, firstly, prices did not fall. So you can look at the evidence,

prices did not actually fall following the agreement. Secondly, there is no evidence that Auden actually increased its volumes or intended to increase its volumes or that AMCo thought it was going to increase its volumes or that AMCo thought that it might lose volumes. On the contrary, as we set out in our written closings, the evidence is all going in the other direction. AMCo thought it would always be able to sell the volumes it was given. Auden in interview talked about wanting to maintain the volumes, but did not talk about increasing the volumes.

So that was Dr Bennett's theory. Now, I am calling it Dr Bennett's theory, because it is not a theory that has ever really been embraced by any of the appellants, including his own legal team. I am going to show you that, because they have a different approach to this and it is really important. We did spend a lot of time on Dr Bennett, because he had this particular idiosyncratic view of things. The legal team for Cinven have a different approach. It is just they do not have an expert who is willing to support it.

The easiest way to see this is in Mr O'Donoghue's closing submissions. If we can bring up the transcript from {Day15/18:1}, please. Look at line 20, Mr O'Donoghue is here addressing the point I have just

made to you about there is no evidence that they increased volumes. The next point, if we go back to the CMA's closings, this says:

"There is also no evidence to suggest that either Auden or AMCo expected Auden to increase its volumes so as to compete with AMCo."

But we say that attacks a strawman. This is a market in which the patient cohort, subject to I think a single digit increase year on year, is essentially fixed. So the suggestion that the market did not expand and that tells you anything, we say is misplaced.

Just pausing, of course the point was not that the market did not expand. It was that Auden did not increase its volumes. But anyway, if we go on:

"The critical insight, we say, is that in a situation where AMCo has -- about 16% of the market in that situation obviously they are incentivised to sell their quantities as much as they can and the fact that Auden is selling a bit less than it might otherwise does not tell you anything about whether there is competition. Again, we say that AMCo has to persuade customers to switch from Auden and it has done that by offering a discount, albeit a small one."

So just pausing there. You do not hear anything about the volumes argument or evidence that there was

any increase in volumes from Auden. What Mr O'Donoghue says instead is that the reason there is going to be competition is essentially even if volumes are fixed, AMCo is for some reason going to need to price a bit below Auden in order to attract sales from Auden.

THE PRESIDENT: That is a question that I asked a few days ago.

MR JONES: Prices I am coming to. I am going to come to that.

THE PRESIDENT: Prices and data.

MR JONES: We do have the answer.

THE PRESIDENT: I am grateful.

MR JONES: It founders on the same set of rocks. I mean just on the theoretical point, the rock of theory, Mr O'Donoghue has not said why. Why on earth would AMCo need to price lower? He says it would be to attract customers from Auden, but we are talking about a fixed market. So Auden has given AMCo some of the fixed market. Why? Why does AMCo need to price lower?

THE PRESIDENT: Identically branded products.

MR JONES: Identically branded product. There is no difference between them. So that is the theoretical point and I assume that is why there is no economist who is willing to sign up to this.

But the second one is the factual point. We can see

how AMCo priced. Can we go to {IR-L/9/14}, please. AMCo we have got in the orange and Auden we have got in blue and, obviously, you would expect them to be roughly the same. They are sharing monopoly profits, but insofar as you can discern any real difference between them, what you see is AMCo most of the time is more expensive. So I mean, our essential point is they are sharing monopoly profits and you would expect to see a bit of jumping around on prices, but in response to the suggestion that actually no, AMCo is cheaper, it is just not right. The opposite is the case.

THE PRESIDENT: Well, it is probably 50/50 on that.

MR JONES: Sir, I think I am right to say actually that AMCo is for significantly more time more expensive and we can get the exact breakdown of that, sir, if it would assist.

THE PRESIDENT: Yes.

MR JONES: Remember just the context of these sorts of arguments, but back to *Carte Bancaire*, where there were pro-competitive arguments, back to *Paroxetine*. Pro-competitive benefits can be relevant to the object analysis, but they need to be (a) actually proven and (b) enough to lead to the conclusion that there is not an object infringement and the argument here simply does not get off the ground. Dr Bennett's volumes theory was

hard to follow and fails for the reasons I have just given and Mr O'Donoghue's preferred theory has essentially the same kinds of flaws. It does not work as a matter of theory and it just does not work when one looks at the facts either.

Unless I can be of further assistance, those are my submissions. It might, I should say be sensible to pause for a bit of a movement of the deckchairs.

THE PRESIDENT: That is very helpful. Two points. One is just an indication that the parties are likely to be met with a request for the data underlying graphs such as this. The reason we are going to make such a request is because when one is making findings, and I am not saying we will ask about this graph, but when one is making findings about how the market worked, it is rather easier to refer to tables and figures than it is to refer to the third kink on the left in the graph. So do not be surprised if we start asking for that sort of material, because it is simply going to be the way we want to approach the evidence.

Secondly, more substantively, I have been trying to work out why yesterday I was so troubled by the what I will call the dishonesty question or, perhaps more neutrally, the question of subjective intention when Ms Demetriou was making her submissions. Normally, when

you enter into an agreement containing a term infringing competition law, then you infringe and are liable for a penalty simply by virtue of the agreement: so interchange fees or indeed, had the result gone the other way, compare the market. The agreement there in black and white is enough to show that you have infringed and it is not enough as a response in a defence to say, well I did not know. I thought it was pro-competitive or whatever if it's anti-competitive, then that is that.

The problem that we have here is that there is a debate about what the agreement said and I am going to unpack that problem by using the formal language of offer and acceptance, but I make clear that I am doing that to lay out the problem rather than to suggest that a formal agreement is needed. I am just doing it so that you can understand where you are coming from or where I am coming from.

So let us suppose that Auden was offering a market exclusion agreement to AMCo and was paying for it by way of value transfer. So Mr Patel saying in terms: look, AMCo, if you promise to stay out of the market, I will supply you with X amount of product at a very low price and you can make a very large profit on the market. But if you want this supply, you have got to stay out of the

market.

Now, that is a hypothesis. We obviously have to work out whether that was in fact something that was in Mr Patel's mind at the time, but let us assume that that was in Mr Patel's mind. So you have got one half of the equation.

In order to pass the infringement line, in order to succeed, the CMA have got to show that AMCo accepted that offer. In other words, in order for it to be a term of the agreement, the offer has got to be accepted.

The question then is: how much of a problem and what must the CMA show if it is not there in black and white, which it is not? If it was in black and white or if it was an implied term arising out of the black and white, then you do not have a problem. You say, look, there is the agreement. If, objectively construed, it is an infringing provision then you are home and dry.

But we do not have an express term. We do not have an implied term. What we have got is a contention, an assertion, a finding by the CMA that this is what was agreed. What I am asking is, is it enough for us to say that someone in AMCo's position ought to have known that that is what was being offered by Auden or do we have to show that there was an actual acceptance, a subjective

acceptance of that offer?

Now, I must say that my present thinking, and I put it down because I am inviting pushback on this, my present thinking is that it is not enough to say that Mr Beighton ought to have known. You have got to go further and you have got to say that this was the deal and that is why, it seems to me, questions about what AMCo did after the event matter so much, because if you can show -- these are the hypotheses that I put to Ms Demetriou -- if you can show an irrational non-entry into the market by AMCo, then that goes to feed the inference that Mr Beighton subjectively agreed or someone in AMCo subjectively agreed to the offer I am hypothesising Auden made.

If on the other hand, you have got a conduct which is simply consistent with AMCo regarding themselves as having a massively good deal and taking a gift horse in the mouth, then of course staying out of the market is altogether rational decision.

I of course appreciate that some inference can be drawn from the oddity of the pricing. I mean, it is on the record from both Mr Sully and Mr Beighton that the pricing was odd and they could not understand what Auden was up to.

Now, that may be enough to carry the CMA over the

line that one can infer a subjective intention to stay out of the market, to promise to stay out of the market from that. That is a question we will have to take home and think about very carefully.

But the point I think I am articulating is that it is not enough for us to sit here, look at all the facts and say, well, if I had been in Mr Beighton's shoes, I would have got wind. I would have understood what Mr Patel was offering and I would be, by going through the agreement, accepting it. I do not think that is enough, but I am putting it out there so that there can be pushback, because it does seem to me that if we are talking about a subjective state of mind on the part of, say, Mr Beighton, we are very much in certainly the area of subjective intention and probably in the area of dishonesty.

Whereas if it is an objective test that we have to decide what a reasonable person in Mr Beighton's or AMCo's shoes would have known, then we are outside the area of subjective intention and dishonesty and we are simply applying an objective test.

I do not want a response now.

MR JONES: I am going to sit down and let Ms Demetriou answer.

THE PRESIDENT: Ms Demetriou, I do not know whether you

should answer it now, because -- if you have a clear answer then by all means.

Further closing submissions by MS DEMETRIOU

MS DEMETRIOU: Can I have a go and if it still leaves you with questions, then I will take the opportunity to have another go later.

THE PRESIDENT: All right.

MS DEMETRIOU: So there is quite a lot in what you said, sir, in terms of just breaking it down. So first of all, just starting with one of the points that you made, so if -- you hypothesise -- I know I take it as read the caveat you put at the beginning that you are positing this in terms of offer and acceptance, but you acknowledge that that is not what is needed --

THE PRESIDENT: I acknowledge.

MS DEMETRIOU: So I am putting that to one side.

THE PRESIDENT: I appreciate the notion of a non-contractual arrangement is enough and it makes the factual question of state of mind a degree of magnitude harder. I quite accept that, but I very much want to get my ducks in a row in terms of analytical process.

MS DEMETRIOU: I understand. So, sir, taking the hypothesis that you put to me of Mr Patel offering the gift horse, so offering the low price, but I am assuming on your hypothesis not saying, well, I am giving you this on the

basis that you stay out of the market but just offering --

THE PRESIDENT: That must be right because that would -- the trouble is we do not know, but let us take the hardest case for you. If we found that we can infer from all the circumstances that it is likely that there was an express oral offer by Mr Patel to Mr McEwan and Mr McEwan accepted it, well, you know, the problem does not arise. So, yes, I think you have got to assume nothing more than do you want the supply at this price.

MS DEMETRIOU: Yes. So taking that hypothesis, if something like that happened, so if Mr Patel simply said here is the gift horse so we are giving you -- I am offering you supply on this very low price and if Mr Beighton had simply said thank you very much and walked away, then on that basis, absent any other evidence, then we would accept that there is not the requisite crossing of the line that we talked about yesterday.

This is in fact the appellants' case. They say it is purely unilateral what was going on.

So the pointing starting point is there has to be a common understanding, so there has to be a crossing of the line. You have seen on the case law that that can be tacit and it can go without saying.

THE PRESIDENT: Ms Demetriou, I do not want to go across --

sorry, I do not want to cut you short, but I certainly do not want to go back over the evidence yesterday. I mean, I think the real question is: is it a subjective or is it an objective test?

MS DEMETRIOU: Then it becomes difficult, because it depends what you mean by subjective. So you have in mind the submissions I made yesterday, which I am not going to repeat about bluff.

THE PRESIDENT: No.

MS DEMETRIOU: So if it is the position that Mr Beighton on this hypothesis -- so to take what actually happened, and you will have in mind what we said yesterday about Mr Beighton's express leverage in the negotiations and the point about bluff. Obviously, one of the submissions we make is that objectively speaking he was not bluffing, but let us say he was bluffing. This is the legal irrelevance point. Let us say Mr Beighton subjectively, his subjective view was that they would not have entered the market in any event. That does not prevent there being a common understanding.

So I think, sir, you have to be very careful about what is meant by subjective and objective, because if on the basis of an objective view of the interactions between the parties -- let us say Mr Beighton had been bluffing -- I went through this yesterday. I do not

want to repeat myself, but just to sort of locate it in the question you have asked me.

If Mr Beighton was bluffing because he would not have entered the market in any event, there is, nonetheless, looking at the state of affairs objectively, a common understanding between the two that this supply is given by Auden in return for non-entry, even if Mr Beighton subjectively thinks we would not have entered anyway. I gave you the example yesterday, and we looked at *Sumitomo*, of cartelists at a meeting going along with things which they are not intending to do. That is still anti-competitive, because, looked at objectively, they have reached a common understanding.

THE PRESIDENT: Ms Demetriou, that is fine. All of that we have got on board. But I mean, I think you are agreeing that although it is difficult and although one has got to go through a myriad of perhaps conflicting tensions, the test is a subjective one.

MS DEMETRIOU: Sir, I do not think I am quite agreeing that.

THE PRESIDENT: All right. What are you saying then?

MS DEMETRIOU: You have to look at -- there has to be a crossing of the line.

THE PRESIDENT: Yes.

MS DEMETRIOU: You have to look objectively as to whether that happened. So if you looked at it purely

subjectively, then the bluff would be relevant, because if it were purely a matter of subject -- of Mr Beighton's subjective state of mind, if he was saying something and meaning something else, then you would look at what he was really meaning. Subjectively, if he was thinking, I am going along with this, because I want to accept the gift horse, but actually I was not going to enter the market anyway, that is his subjective intention. That is not the key question.

So if it were all --

THE PRESIDENT: Mr O'Donoghue put something from an *Oxera* report. It is {M/21.1/2} and what attracted my attention is:

"Manufacturers confirmed that the licence -- "

Here we are. So if you look at the point that is there being made, is that a competitor can use the potential for competition to leverage price. In other words, they say: look, we are going to get into the market ourselves, unless you provide product at a certain price and that is said in terms. "The ability to self supply a drug is the most effective and credible threat with which to negotiate supply terms from another manufacturer."

Now, one can see the force in that and that is why we had the debate yesterday about the significance of

price.

MS DEMETRIOU: Sir, yes.

THE PRESIDENT: Let me finish the thought.

MS DEMETRIOU: Of course.

THE PRESIDENT: It could be the case that Mr Beighton, or let us say AMCo to avoid being too subjective, that AMCo had the state of mind that they were being offered, quite literally, the gift horse. They were wanting supply and they got it at an unbelievable price for reasons that they could not understand, but they took it and they did and promised nothing more.

MS DEMETRIOU: Yes.

THE PRESIDENT: Now, if that is the case, then it seems to me we are agreed you lose.

MS DEMETRIOU: Yes.

THE PRESIDENT: The question is: was that or was that not the bargain?

MS DEMETRIOU: That is the question.

THE PRESIDENT: There is all sorts of extrinsic evidence that we have got to go into in order to understand what was or what was not the bargain.

MS DEMETRIOU: Correct.

THE PRESIDENT: The question I am putting to you is: do we use an objective set of lenses in order to understand this very difficult question or do we try to work out

what was in the state of mind of, let us say, Mr McEwan and/or Mr Beighton or the people who were negotiating the deal?

Now, I fully appreciate that it is an extraordinarily difficult set of questions either which way, but the way one analyses the facts is remarkably different, depending on which set of lenses one is using.

So I quite take your point that even if we go down the subjective route, there is an enormously difficult job in disentangling what was or what would have been in Mr Beighton's mind.

My question to you at the delta, right at the beginning, between the objective and the subjective, which route do you say we should go down?

MS DEMETRIOU: The answer that we give is you have to understand -- in order to assess the evidence, you have to seek to understand the subjective state of mind of person A and person B, but then the question of whether there is a common understanding is an objective test.

For example, take a price fixing cartel and you have party A and party B that meet, no written agreement, meet to discuss fixing prices. So you have to understand that both person A and person B are intending to meet to reach agreement to fix prices.

But when you are deciding whether or not there is a price fixing agreement, the critical point is, well, looked at objectively, what did they agree? So even if person A is going into it intending to cheat so even if -- the example I gave yesterday -- even if person A thinks, well, I would have priced this at £10 anyway, really what I am trying to get is person B to agree the same thing, but this is what I would have done in any event and he goes in and they reach an agreement between the two of them to fix prices at £10 each, objectively that is the agreement they have reached, even if subjectively it is what person A would have done in any event.

So the answer is, I am afraid it is not a black and white either or answer. It is always an objective test, whether or not there is a common understanding, but to get to -- to understand the evidence you do have to enquire as to what the parties were trying to do, what was in their mind.

So that is the answer we give to you, sir. Now, you made another point about dishonesty, because you --

THE PRESIDENT: I am not sure I think that is right. I mean, if you have got a written agreement or if you have got express words crossing the line, you know what was agreed, and I absolutely accept that the

interpretation of what was agreed is an objective test. I mean, we have been in the *Tamplin v James* territory: I agree to sell you a bit of land and I say it is that bit of land over there and if you have a view that it is a particular lump of land and I have a view that it is a different bit of land, then the court is going to construe what we both meant. It may be what neither actually thought they were agreeing that the court finds. So that far I am entirely in agreement with you.

But I do not think you can stretch that back to saying that an objective test colours what it was that crossed the line. I fully accept that it is very difficult to interpret what was agreed when it could be an unspoken arrangement, but it does seem to me that the unspoken arrangement has got to be viewed subjectively as to what they thought was crossing the line, because otherwise, one has simply got to independent thinking.

We are at the very cusp of where does unilateral action end and unlawful agreement or arrangements begin?

MS DEMETRIOU: Sir, the difficulty we have that with that is it is connected to the bluff argument, if I may respectfully say so, because the difficulty you have with that is that -- take the case or let me give you another analogy, but take the case law on information

exchanges and so you have a position where somebody at a meeting is giving confidential information, commercially sensitive information about what they are going to do, and somebody else at the meeting just sits there and listens to the information and does not publicly distance themselves from it.

It is difficult to say that person has any subjective anti-competitive intention. They have just been at the meeting and they have not distanced themselves from it.

THE PRESIDENT: No, I do not accept that. If you are sitting in the meeting and it is articulated plain and simple, then you are in up to your neck. Equally, if Mr Patel had said, look, my understanding is that I will offer you the price at 1.78 provided you stay out of the market, if Mr Beighton had not said, I am not doing the deal, and did not do the deal at that price, I think he would be on the hook, frankly.

MS DEMETRIOU: So of course, you have our submission on the evidence that Mr Beighton, from Mr Beighton's part you are approaching it as in Mr Patel giving an offer.

THE PRESIDENT: Well, of course, I appreciate that -- the reason I am doing it that way, Ms Demetriou, is because it is the way to frame the very difficult distinctions that we are trying to draw. I completely accept that

I am putting to you a stylised point. The reason I am doing that is because unless we do it this way, we are not actually going to work out what the right questions are.

MS DEMETRIOU: Sir, I understand the question, but let me go back to the bluff, because this is why I am having difficulty accepting that it is purely a subjective question.

THE PRESIDENT: Right.

MS DEMETRIOU: So let us assume, on your stylised example, that Mr Beighton was bluffing because he could not enter the market and knew that he could not enter the market, which obviously you know that we do not accept. Let us assume that his subjective intention was that he was never going to enter the market in any event and so it did not matter what Mr Patel told him.

THE PRESIDENT: I think we are slightly at cross-purposes here. You are obviously right that intention does not matter.

MS DEMETRIOU: I thought you were asking me, sir -- we probably are at cross-purposes, because I thought you were saying it all turns on subjective intention.

THE PRESIDENT: Yes, in terms of what the man was agreeing to.

MS DEMETRIOU: Sir, I am not seeing the distinction, because

if subjectively he was not agreeing to stay out of the market because he could not stay out of it anyway, because he could not enter the market anyway, so subjectively he is going into this stylised meeting saying -- and he is not subjectively, as far as he is concerned, agreeing to stay out of the market, because as far as he is concerned, he is not going to enter it into any event. That does not matter. That is not the critical point.

THE PRESIDENT: I accept that.

MS DEMETRIOU: Okay, so then I am not --

THE PRESIDENT: You nevertheless have to have -- this is why we are getting into increasing difficulties when one has an absence of communication.

MS DEMETRIOU: Yes.

THE PRESIDENT: That is why I fully appreciate that the absence of communication and the bluff, these are all difficulties which we are going to have to approach, but they are further down the road.

MS DEMETRIOU: Right.

THE PRESIDENT: The basic question that I am asking is: if you have got an implied offer from Auden to AMCo, and it has to be implied for this to work, because if it is express the problem resolves itself, so if there is an implied offer, does AMCo have to appreciate subjectively

that that offer is being made?

MS DEMETRIOU: Yes, sorry. I have been at cross-purposes and sorry if I have been --

THE PRESIDENT: This is very difficult.

MS DEMETRIOU: Yes, they do have to be on the same page. So they have to appreciate that that offer is being made, whether impliedly or expressly. So, yes, there has to be -- that is what I have called the crossing of the line.

THE PRESIDENT: Yes, but it is a subjective, not an objective crossing of the line. In other words, if we get to a situation where I say that if I had been in Mr Beighton's shoes, it is pretty plain to me what Mr Patel was offering, because you look at the price and you say: this is just too much of a gift, he must be expecting something in return and what he is expecting in return is this, if that is the objective outcome then the question is: do we have to ask the next question which is, was that in fact what Mr Beighton understood to be the case?

MS DEMETRIOU: Sir, yes, I am sorry it has taken me so long to get there, because I was mixing it up with the next question about bluff and so on.

THE PRESIDENT: So we have a whole lot of other problems down the line.

MS DEMETRIOU: Mr Beighton -- they both had to understand that that was in play. The value transfer --

THE PRESIDENT: If Beighton was, let us say, either peculiarly dense, naive or simply allowed pounds shillings and pence to influence himself without thinking further, in other words, if he was simply taking the gift horse without asking any questions, even though those were questions which an objective person in that situation would have asked, then he is out, you lose.

MS DEMETRIOU: Then we lose. Sir, may I just add one rider to that?

THE PRESIDENT: Of course.

MS DEMETRIOU: It is not by way of proviso to anything I have just agreed to, but it relates to the question of dishonesty. We say it does not follow from that that the CMA has alleged or has to allege any dishonesty. In the same way that one has a plethora of Chapter I infringements, be they price fixing cartels, express agreements, smoke filled room oral agreements or whatever, dishonesty is not, as you know and as we canvassed yesterday, is not a requirement to show that.

So one could have a situation in which an agreement like this is reached and this is frequently the case. The Competition Authority does not allege dishonesty and

that is not a necessary finding. So it is important to keep the two points separate, in my respectful submission.

THE PRESIDENT: I do understand why you make that point, but we are now back to where I started.

MS DEMETRIOU: Yes.

THE PRESIDENT: Which is if you have it written down or it arises by necessary implication from what was written down or indeed if you have a tape recording of what was said, then I agree. But you do not have that here. We are going to have to look at what was in Mr Beighton's mind and one then moves very closely to the question of was he or was he not telling us the truth in the witness box. I do not see any reason of avoiding, at the moment, a conclusion that if we say it is a subjective test and you win that he was not telling untruths in the witness box.

MS DEMETRIOU: Sir, two points on that. First of all, I am grateful for the clarification, because there is a distinction, as you have just put to me, between dishonesty in the witness box, which is a separate matter, and dishonesty in terms of the agreement in the first place, which is never anything that the CMA has alleged. So I understand that you are looking at dishonesty in the witness box.

On that, of course you have my -- it is for the Tribunal to decide whether or not he was dishonest looking at all of the evidence in the round, but you have my submissions from yesterday, which are that he -- Mr Beighton very clearly said in the witness box that he used the threat of entry as leverage in the negotiations. That was something he said. He did not deny that.

THE PRESIDENT: No, he did not, but -- again, we will think about that, but that is not in and of itself enough I do not think, is it?

MS DEMETRIOU: We disagree and those were the submissions I made yesterday, sir, without repeating them. We disagree because that is the crossing of the line. You have the very low price that is being offered and you have Mr Beighton saying in negotiations: if you do not supply us on these preferential terms, we will enter the market.

THE PRESIDENT: So do I take it from this that you consider that the paragraph in the *Oxera* report beginning "manufacturers" is simply wrong.

MS DEMETRIOU: Sir, I want to come back to the *Oxera* report because I have not focused on this, and I do not want to say anything about it without reading the whole report. But I would say that our case is, just as a matter of

law, if there are competitors or potential competitors and one of them is agreeing to stay out of the market in return for value transfer that is anti-competitive.

THE PRESIDENT: Yes, of course that is right, but that is not what I am putting to you, and it is not what the *Oxera* report is saying. What we are saying is -- well, let us read the relevant sentence:

"The ability to self-supply a drug is the most effective and credible threat with which to negotiate supply terms from another manufacturer."

So Beighton is going in hard saying, we are really nearly there, we can produce a rival but give us a price and, you know, the decision which we retain to make, the decision to go in or go out will be affected by the price that you offer.

That is legitimate. What is illegitimate is to say if you offer this price, we promise not to go in.

MS DEMETRIOU: Sir, as I say, I want to read all of this in context. I will come back to answer this, but what we say -- just returning to my submissions yesterday, and in a nutshell without repeating them, the reason why we say what Mr Beighton acknowledged in the witness box in terms of what he said in the negotiations, so he said, if you do not supply us, we will enter, the reason why that was enough is seen in context, that could only have

meant, if you do supply us, we will not enter. That is our essential point and you have that. I made those submissions yesterday, but that is why we say it is enough.

THE PRESIDENT: My thinking is that what is critical here is, as you said yesterday also, is the price. I mean, it is one thing -- I asked you yesterday, and you very wisely I suspect did not answer, what would be the case if one has Auden selling at, let us say, £30 a packet and Mr Beighton goes in, bangs the desk saying, we are going to go in unless you supply us, and they do a deal at £28. I do not think the words that you have drawn attention to would have very much traction in those circumstances.

MS DEMETRIOU: Sir, they may not, and I am not -- in saying that -- in drawing attention to those words I draw attention to them because they demonstrate the crossing of the line but of course we rely on all of the context and particularly the extremely low price and what happened next which is they did not enter.

THE PRESIDENT: Of course, you are saying it in the round but what you are coming dangerously close to submitting, and if you are submitting I want it clear on the table, is that the communications that you have drawn our attention to that Mr Beighton accepted were made in the

witness box in and of themselves, irrespective of the price, get you home, and I am simply indicating that I have some difficulty in accepting that.

MS DEMETRIOU: No, I am not submitting that. I am submitting -- so what we have, just in terms of the building blocks of the case are the 97%/98% discount to the market price, the extreme otherwise commercially irrationality of Auden doing this deal when it was the market incumbent and then what we know. What I am facing is from the appellants, as I said yesterday, they say oh well, yes, this was about disincentivising Mr Beighton not to enter the market but it was all unilateral.

THE PRESIDENT: Ms Demetriou, do not get me wrong. I know we have to look at things in the round, but it is important to us that we understand the minimum level at which you say you succeed. What I am putting to you is that the sentence that I have just read out to you, the ability to self-supply a drug being the most effective way in which to negotiate supply, is something that at least *Oxera* regard as legitimate and not illegitimate.

So what I am saying is of course I accept that as an element going to the overall conclusion that sort of threat is helpful to you. But I am also saying that without the other factors it is not enough in and of

itself to get you home because if it was the case that that was enough, then you would be saying there is an agreement to stay out of the market if the price was much closer to the market price that Auden were selling at, and I am saying I have some difficulty with that.

MS DEMETRIOU: Sir, there may or may not be depending on all of the other factors.

THE PRESIDENT: Of course.

MS DEMETRIOU: But that is not our case. We are not saying that what Mr Beighton said by itself and just seen in isolation is the CMA's case.

THE PRESIDENT: You are relying on other things.

MS DEMETRIOU: We are relying on other factors. We do say, therefore, there is not necessarily -- obviously this depends on the view the Tribunal takes of the facts overall but it does not seem to me, at least, that the Tribunal necessarily needs to find that Mr Beighton lied in the witness box because when you look at all of those other factors and what he acknowledged he said we say that that is enough.

THE PRESIDENT: Well, yes. I mean --

MS DEMETRIOU: Obviously it is a matter for the Tribunal.

THE PRESIDENT: It is. What I wanted to establish was -- we may be able to decide in that case differently but what was troubling me overnight was I felt we were seeing

this delta, subjective/objective in very different ways and it was important to me to understand which particular delta you were going down.

MS DEMETRIOU: I am sorry it took me a while to get there but I hope now I have clarified.

THE PRESIDENT: Because of course if it is the objective delta, then absolutely clearly the questions that are troubling me about honesty/dishonesty, subjective do not arise. They do arise obviously on the other way and they are particularly tricky, particularly, and we have not discussed this and I am not inviting discussion on it, particularly when one has got a corporate entity rather than an individual in the frame. That raises the sort of questions that Ms Ford was identifying in terms of attribution. We will not go there but that is another problem that we have in mind.

Mr Brealey.

MR BREALEY: I am not going to get into the debate, but just on the subjective, objective we deal with this in our notice of appeal, which you probably picked up. It is {IR-A/234/1}, paragraphs 95 to 103 where we refer to the *Bayer* case and the Court of Appeal in *Unipart* and it is quite clearly a subjective test for agreement, objective test for whether it is construction.

THE PRESIDENT: Yes, thank you very much.

MR BREALEY: That is the law supporting what Ms Demetriou said on the subjective.

THE PRESIDENT: The reason I felt that the CMA was going down the subjective route was because of the paragraph 3.5 for instance and the reliance on the 20mg agreement, all of these things are rather more valuable if one has to trace a subjective rather than an objective test, but I am very grateful, Mr Brealey.

Thank you all very much. I am sorry it has taken so long. Mr Holmes is no doubt waiting patiently outside. Mr O'Donoghue, go on.

MR O'DONOGHUE: I was wondering whether might I be excused from the pleasure that is excessive pricing?

THE PRESIDENT: Of course.

MR BREALEY: The same for me.

THE PRESIDENT: Also of course. We will rise for ten minutes to rearrange the seating. Thank you very much.

(10.41 am)

(A short break)

(10.55 am)

MR JOWELL: Chairman, I just wanted to check one thing and mention one thing which is the check is that we have sent a note in response to the Tribunal's note on excessive pricing. I just wanted to make sure that the

Tribunal had it.

THE PRESIDENT: We have it, and we also have, just to make sure that no one is worried, a letter from Linklaters agreeing with bits, but noting certain regrettable corrections that needed to be made have not been made so we have that as well.

MR JOWELL: I am grateful. I wanted to just mention one thing about it, which is that we have focused on the issue that the Tribunal requested in its note that we focused upon, which is the extent to which the comments in the Tribunal's notes are inconsistent with existing authority, but I am also very conscious of course that the Tribunal's note does go into the economics of excessive pricing and there is literature on the economics of excessive pricing generally stressing the very limited situations in which it should be applied.

I am not sure that all of that is in the bundle. Some of it is referred to in Advocate General Wahl's opinion in *Latvian Banks* which is in {M/132.1/1} and you will see in the footnotes there references to articles by distinguished economists such as Professor Massimo Mota and David Evans and Xorxe Perdia and in those articles you will also find further references to articles by, for example, Dr Amelia Fletcher, who has also written on this subject. I do know in the bundle

there is an article by Professor Jenny, I think it is {M/129/1} on excessive pricing. I am very conscious there is a large-ish literature out there from a number of distinguished economists and since the note does dip its toe in economic concepts, I just draw that to your attention.

THE PRESIDENT: That is very helpful, Mr Jowell. We will be delighted to read more on this. It is something we are quite clearly thinking about, because we put it in a note to the parties. We note the point that was made in Intas's footnote 1 noting the timing and that the suggestion that none of the economic experts had been able to consider and comment on the proposed approach.

We will bear that in mind, but I do not, at the moment, regard that as something that precludes us to think about this, because it is something that was in the ballpark in terms of how the economists viewed things. We have the highlighter example, which I think triggered this line of thought. So we are not not going to go there and so the more material we have to read the happier we will be.

MR JOWELL: Yes, perhaps the parties can give some thought as to whether we should provide you with a reading list of the economic literature.

THE PRESIDENT: That would be helpful. To be clear, we do

not want anyone to feel that they are being closed out from commenting by virtue of the timing of the note. So we are more than happy to have more wide-ranging responses if you feel that it is in your client's interests to make those.

MR JOWELL: I am grateful. We will take that away and consider it and I think it is important for the Tribunal to appreciate that almost all of the economic literature does stress -- I think does agree with the general thrust of our note, which is that it is only in highly exceptional circumstances that it is economically desirable to have a rule against excessive pricing and to apply it against excessive pricing and some, for example, say it should only apply where there is no central powers and some stress there should be no fines ever imposed for it. So I think it would be perhaps helpful if we could highlight those.

THE PRESIDENT: No, we would be very grateful. Thank you very much, Mr Jowell.

Mr Holmes.

Closing submissions by MR HOLMES.

MR HOLMES: Thank you, sir. So we are now turning to the Chapter II side of the case and the finding that Auden/Actavis charged prices that were excessive and unfair. I propose to address you in turn on the topics

of market definition, dominance and abuse. I should say immediately in response to what Mr Jowell has said that there are a number of pieces of paper flying around that I have not had an opportunity to consider, and I doubt whether I will have an opportunity to consider them all before I conclude my oral submissions and it may, therefore, be necessary to supply you with written submissions on them if due course.

Before I embark on market definition, could I go back to a question that you asked, sir, about figure 1.4 of the Decision. I think you called it the mountain figure.

THE PRESIDENT: Yes.

MR HOLMES: For clear and obvious reasons. You asked the parties if they could supply an explanation of that. Just so we can get it up on the screen, it is {IR-A/12.1/ 22}.

EPE OPERATOR: It is only 17 pages.

MR HOLMES: Sorry, yes, if we could just rotate it. {IR-A/12.1/1}. That is the one. Perfect, thank you. This shows the upward march as Auden/Actavis's prices rose over the eight-year period from April 2008 until the end of 2015 and then a relatively gradual unwinding as Auden/Actavis reduced its prices while, as we say, still pricing significantly above its competitors.

Now, you asked the parties to explain this evolution. We agree the note is a striking one and it is worth pausing over it for a moment just to tease out what it shows.

On the left you see the MSD reimbursement price which stood at 70p a pack for 30 10mg tablets, so about 2.5p a tablet and the 20mg price was £1. Of course, the actual selling prices would therefore have been lower.

Then looking across the page, you see at the bottom of the page some lines relating to cost. The Tribunal asked me, sir, at one point what measure of cost was employed there and I said the cost of production. To be clear, it is the total cost, that is to say it includes an allocation for common costs. It is not just the direct costs, but also the indirect costs, so the CMA's calculation and attribution of a share of the common costs.

It is not the cost-plus measure. So it does not include the reasonable rate of return, but, as we will see, that would have made a negligible difference as to where that line sits on the page.

THE PRESIDENT: Right. Just for our note, because having done a few *Lyric* cases, I know that common costs are enormously difficult to allocate. There is presumably somewhere in the Decision a statement of exactly how

those common costs have been allocated.

MR HOLMES: Yes, indeed, sir. Fortunately, it is not a matter that is under appeal, but I will give you the references in due course, if I may.

THE PRESIDENT: That would be helpful, thank you.

MR HOLMES: Then looking at the Auden lines, you see those are the blue and the red lines, solid lines, the red line is the 10mg price and the blue line is the 20mg price, and you see that when Auden took over the product in April 2008 and debranded it, it chose a price point of £4.54 for the 10mg pack. That is to say 15p a tablet, 18 times higher than the price that MSD had charged.

Over the next six months prices were increased from £4.54 to around £23, so an increase from the initial Auden price of over five times to about 77p a tablet and the infringement was found to begin at above £20, so you see the light blue on the right-hand side of the first vertical line.

By July 2009, only 9 months later, you see that Auden had increased its price again from £23 to £30, so tablets under Auden's ownership had by that time risen from the initial Auden price of 15p each to £1 a piece.

Over the next two and a half years, Auden then enjoyed the fruits of this inflation without significant

further increases, but then from the start of the 10mg agreement you see that Auden in October 2012, the third vertical line from the left, Auden began to raise its prices more steeply and by early 2014 they stood at £43 a pack, so a tenfold increase on Auden's initial price following debranding and a per tablet price of nearly £1.50.

In January 2014, by which time Auden was aware of the effects of the orphan designation on potential entrants' marketing authorisations, you see a further rapid escalation. So by May 2015 when Mr Patel and his sister sold Auden for more than £300 million the price stood at £55 per pack for 10mg. That is £1.80 a tablet and nearly £65 for 20mgs.

Under the ownership of Actavis, now Allergan, the undertaking took prices up another gear and you see the really massive increment in July 2015, so that prices ultimately peaked at over £70. You see that prices increased in the period after independent entry to over £2.30 for each individual tablet, which is more than 15 times the price at which Auden introduced the product and 100 times the MSD reimbursement price.

Then some six months after independent entry you see that the direction of travel finally changes, but the prices then take a considerable period to come down.

So two and a half years later in July 2018, when the 10mg agreement ends, you can see that Auden/Actavis's 10mg price was over -- it was £20 when the infringement ended and over this period, we say Auden/Actavis was really continuing to enjoy supra-competitive profits during that process of reduction in prices.

They were charging prices that were higher than the rest of the market, enjoying a substantial premium, whilst still supplying volumes amounting to 50% of demand.

In total, it took five years from independent entry to bring Auden/Actavis's 10mg price down to levels similar to those at the time of debranding.

Now, you put it to the parties, sir, that this figure is one which requires an explanation and we respectfully agree. We say that it lies at the heart of the Chapter II case.

If I could offer our thoughts on that question, beginning with the assent, the upward march, and then what happens after entry.

One way of considering the explanation for the way up between 2008 to 2016 is by a process of elimination, considering possible explanations for price rises from an economic perspective and seeing whether they might apply in this case.

So taking matters in that way, one possible explanation would be if there was some change in the nature of the product itself, some innovation or development which increased its value to consumers and/or its costs of production.

Now, the product remained the same, so we can dispense with that explanation. Auden/Actavis made no investments in research or improvements to hydrocortisone tablets. It is the same tablet supplied throughout. As Mr Stewart explained, Auden was a virtual company without research activities. So hydrocortisone tablets, although they were essential and not in any sense an innovative treatment, they are the same old drug which has been supplied in the United Kingdom since the 1950s and has been off patent since the 1970s, nothing in the nature of the product changed that could explain the price increases.

I will return to this theme when I come to consider economic value, but I do say it is striking to see the similarity in the level of the bookends, as you called them, on either side of these extraordinary price increases.

In April 2008 when Auden launched its debranded product, it was content to supply the product at around £5. That was a price freely determined under conditions

of monopoly and in the absence of price regulation. In April 2021, under conditions of effective competition, Auden's product was priced at £2.99, same product, similar price.

A second potential explanation would be if there was some change in demand for the product and that, sir, as we understand it, would be the Covid mask scenario which you canvassed during the course of the case as a contrasting example of extreme pricing. That is to say a situation in which sudden and temporary spikes in demand led demand to exceed supply so that prices rise for a short period, pending either a fall in demand to previous levels or an increase in supply to meet the new demand or some combination of those two.

But as you observed, sir, the position in relation to hydrocortisone tablets is quite different from that scenario and here it is relevant to consider two of the market features which you canvassed with the parties.

The first point is that demand is finite. As you put it, sir, there is a relatively fixed volume required by patients and the second is that the demand is, at least in this market, price insensitive. The existence of both of these features is well illustrated by figure 4.3 of the Decision. If we could go there, please, it is {IR-A/12/320}.

If we could enlarge the figure at the top of the page, please. While we are waiting for that, you can see that the lines show the price trend, a slightly smoother presentation of the mountain, and the bars show the volumes dispensed, red is 10mg, by far the bulk of the markets and the blue is 20mg.

As the Tribunal has seen, the volume trends remain broadly constant throughout the period. They rose slowly and steadily at around 4% a year in the case of 10mg tablets reflecting the number of new patients requiring treatment for adrenal insufficiency and 20mg volumes were essentially flat.

These volume trends remained constant, immune both to the price rises and the price falls.

There one sees the price insensitivity to which you have referred, sir, the overall demand for hydrocortisone tablets is insensitive to price. I will return to the reasons for that in the context of market definition, but for now I would observe that, for whatever reasons, this figure captures considerations that are key both to market definition and to dominance.

The steadiness of the volumes underscores the fact that doctors were, as a matter of fact, continuing to prescribe hydrocortisone tablets as the clinically preferred treatment choice for adrenal insufficiency,

notwithstanding its price. They confirmed the evidence on clinical use, which I shall show you in the Decision when addressing Auden's market definition grounds.

There is no evidence here, for example, that the launch of Plenadren in 2012, that is the delayed release hydrocortisone product from Shire, had any effect on hydrocortisone tablet prescribing patterns. There is equally no evidence of switching to other steroids, although, as Ms Ford showed you, they were cheaper and, again, that confirms the price insensitivity of this product.

Looking at the price trends and volume trends together, it is clear that Auden was not constrained in its price rises, either by doctors switching prescriptions to other potential treatments or by customers ceasing to purchase at all.

For present purposes, what is certainly clear is that the price increases cannot be explained by a sharp spike in demand comparable to the Covid mask situation.

PROFESSOR MASON: Mr Holmes, thank you for the clear explanation. Just to chase that last comment down and this is a hypothetical, but you could imagine a slightly oddly shaped demand curve that, as you say, is very, very flat initially, because it is price inelastic, up to a fixed volume, which is the number of patients in

the country that need hydrocortisone for their condition and that is it, so you have a sort of step curve for demand.

You could imagine the top plateau of that being determined by views taken as to -- we heard it earlier on a previous day -- QALYs and the statistical value of extended quality of life. Is there any evidence that you are aware of that that kind of -- that view of this particular condition changed during this period, because that would be -- you have not spoken about it, but that could be an explanation for a shift up in demand.

MR HOLMES: No, sir, there is no evidence that QALY was used at all, to my knowledge, in evaluating the value of hydrocortisone tablets. If I may, sir, I might consult with the economists and come back to you if there are any qualifications or further points to add in response to that question.

PROFESSOR MASON: That would be fine. I raise it now, because you are trying to take us through the factors that you say are not sufficient to explain any shift in demand and that seems to be one missing.

MR HOLMES: I have not finished running through the factors that we say are in play, but what I will certainly show you is the clinical considerations which informed demand for hydrocortisone tablets and which, in my submission,

explain why it remained the preferred choice of prescribing doctors throughout the relevant period.

I think there is actually some common ground between myself and Ms Ford, whose appeal it is, in relation to the substitutability of other treatments. I think she accepts that the objective characteristics or clinical attributes of products are very important and that, generally speaking, prescribers are less influenced by price than they are in other markets.

I will show you the clinical evidence, the clinical and other practical considerations that were seen to influence prescribers in this sector and that explain why hydrocortisone tablets were the preferred treatment, the first line treatment, adopted for the overwhelming majority of people with this particular condition, adrenal insufficiency.

As a third point, there were no changes in availability of supply. There were no capacity constraints in this market, so supply was sufficient to meet demand. Again, this is a reason why the Covid mask scenario is, in my submission, inapposite as an explanation for this very lengthy period of price increases.

A fourth obvious potential explanation would be if there were any change in the underlying costs of

supplying hydrocortisone tablets. When Auden's price rises first attracted attention in the Daily Mail article, which you have seen reference to, in July 2010, that was certainly an explanation which Auden's owner and manager, Mr Patel, reached for in order to defend his firm's pricing decisions. We can see that in the Decision at {IR-A/12/504}.

Looking at the foot of the page, paragraph 5.299, if we could just enlarge that, you see that reference is made to the Daily Mail article on 18 July 2010.

THE PRESIDENT: Yes, but it carries on to the next page too.

MR HOLMES: Yes, I am going to take you over the page, if I may, sir. You see the Decision notes:

"In response to the Daily Mail's questions, Mr Amit Patel attributed the price increases to Auden's investment in a new manufacturing plant and indicated that Auden had needed to increase prices in order to recoup that investment, following which prices would fall."

You see what is set out there, what he said in italics:

"For hydrocortisone, there is a very specific raw material required. Basically, the plant that made that was no longer prepared to do that. There had to be a multi-million pound investment put in to ensure that

[production] continued.

"This sort of product cannot be made in a general facility. There are dangers of cross contamination. A new manufacturing plant had to be put up.

"Either we just let this product go, just let it die. But it is crucial to certain patients, so we cannot do that. Now the majority of the investment which has been made has been recouped.

"So now you will steadily see [the price] coming back down. It will creep back down because the company has recouped what it needed to. It was not simple and it was a very expensive process."

So that is the explanation that Mr Patel offered back in July 2010 right at the beginning of this upward assent. The Daily Mail article, looking at the next paragraph, noted that Mr Patel had "refused to give further details of his company's spending that he said had led to the price increase."

In fact, you see the CMA's unchallenged finding at paragraph 5.301:

"Auden/Actavis made no material investment in hydrocortisone tablets."

As footnote 1768 records, there is the point, if we could go down, please, to the footnote, there is the point -- it is boxed in red, but those are old

confidentiality markings, sir. The content of the footnote is in fact a matter of public record. There is the point that whilst payments of some £13.7 million were made by Auden to offshore accounts legally owned by Mr Patel and his sister under the description of research and development, Mr Patel admitted in subsequent legal proceedings that the payments were made against sham invoices which dishonestly attributed the payments.

I do not raise these matters simply because they are prejudicial, sir, and I do not rely on them as similar fact evidence or anything of that kind. I will show you in a moment they are relevant to the explanation of the price increases.

Although Mr Patel's increasing costs story had no basis in fact, you see from paragraph 5.302 that Auden continued to advance it in subsequent communications with customers when prices, far from creeping back down, continued to rise steeply.

If we could go, please, to {IR-H/175/1}. This is an email from Mr Alan Barnard to a buyer at Alliance Healthcare from January 2013 and you see there price increases to four product lines, two of them Dexamethasone, one hydrocortisone and one Thiamine and you see the hydrocortisone 20mg price is increasing to

£34.50. Then you see the explanation given:

"We are seeing considerable increase in our API [that is the active pharmaceutical ingredient] and production costs ... "

If we could also go to {IR-H/397/1} you see another similar email from 15 months later. Again, new pricing said to be due to increased manufacturing costs and here hydrocortisone 10mg, now at £50 and 20mgs at £55.

If we could go back to the Decision and pick it up where we left off at {IR-A/12/507}. On a page, please. As the Decision records at the top of the page, 5.303, Auden provided no evidence to substantiate the claim that Auden's costs were increasing and in interview both Mr Patel and Mr Barnard were unable to point to any cost increases for hydrocortisone tablets.

The true position is that Auden/Actavis at all times outsourced the manufacture of hydrocortisone tablets to a third-party contract manufacturing organisation or CMO called Tiofarma and any cost increases in relation to manufacturing or production of the kind that we saw Auden claimed to exist, should therefore have been reflected in the prices charged by the CMO.

If we look at 5.304 in the final sentence you see the point that:

"Auden's costs remained broadly constant, with its

cost of goods actually decreasing slightly during the period in which Auden informed some of its customers that its costs were increasing."

The relevant figures are on {IR-A/12/448} of the Decision at table 5.8. You see that with storage and distribution costs included, the per pack direct costs varied from £1.07 and £1.25, the red marking is again superseded, and for 20mg they ranged from £1.40 to £1.61.

So, these claims of increased manufacturing costs are false.

Yet, even now, an echo of them can still be found in Auden's defence of these proceedings. If we could go back to page 506 of the decision and look at paragraph 5.305. You see there that:

"Auden/Actavis also submitted that price increases were required in order for the supply of hydrocortisone ... to become commercially viable."

You will recall, sir, that last Tuesday, I think this was Ms Ford's explanation for the mountain -- for your note, sir, this was transcript {Day11/92:4-7}. She said:

"The explanation for the pattern of price rises is the commercial unviability of the product supplied prior to Auden's acquisition of it at MSD's prices."

Now, in my submission, that assertion is in the same bucket as Mr Patel's immediate response to the Daily Mail's enquiries, in which he prayed in aid the crucial nature of the product and invoked unspecified investments in a state-of-the-art facility.

As paragraph 5.305 of the Decision records Auden launched its hydrocortisone tablet product following acquisition of the marketing authorisations at £4.54 for 10mg and £5.14 for 20mgs. As I have said, no price regulation at that time. Auden the only supplier. There is no reason to suppose that supplying the product at that price was anything but profitable for Auden and it was many multiples of the price that was charged prior to acquisition by MSD.

The CMA has also analysed the total costs of supply, and this goes to your question, sir, plus a reasonable rate of return throughout the relevant period. The figures are given in 5.306. If we could go down the page. You see that for 10mg they ranged from -- the entire costs, the cost-plus, so direct costs, indirect costs and apportionment of common costs and the reasonable rate of return ranged from £2.17 to £4.45 per pack of 10mg tablets and from £2.91 and £5.20 for 20mgs. In fact, they trended down.

The CMA of course only found an infringement when

prices were above £20 and by that point, they exceeded cost-plus by a margin of four or five times.

So despite Auden's assertions that the price increases were needed because of the costs of supplying the product, it is clear that the price increases cannot be explained by any change in the underlying costs.

Now, a fifth and related explanation advanced by Auden is that the huge profits that were earnt in relation to hydrocortisone tablets were needed to cross-subsidise other unprofitable lines.

THE PRESIDENT: This is the portfolio pricing point.

MR HOLMES: Indeed, sir, yes. It is said that this was to the benefit of the NHS and patients. That is how the point is put.

I will address you on the legal aspect of that claim later when I come to abuse. For now, can I deal with the factual position.

There is no contemporaneous documentary evidence that Auden in fact priced on a portfolio basis during the period of the increase in prices. Nor is there any factual evidence before the Tribunal to that effect from Mr Patel or anyone else at Auden. You referred, sir, to the example of supermarkets offering loss leaders. That is to say, some products priced below cost to woo in customers, but in that case, sir, it is clear that the

customer is buying a basket of produce, a bundle if you will, and it does so because of the savings to be obtained on some of them.

Here, Auden has brought forward no contemporaneous evidence that it dealt with its customers in this way during the pre-entry period, offering good prices on one product to justify its price rises on another. You saw the emails notifying Alliance of price rises for hydrocortisone and other lines on a product by product basis with no assessment of overall value across a basket.

The Tribunal will have well in mind that in this context wholesalers are ultrarational customers. They are not engaged in the kind of broad-brush impressionistic assessment of a supermarket shopper who may be lured in by individual bargains. Nor is there any regulatory foundation for a portfolio pricing claim. The emphasis is placed on the benefit to the NHS and to patients.

But the product was debranded by Auden and the effect of debranding was precisely to avoid the portfolio price regulation which applies under the PPRS. It was to liberate this product from that Constraint that it was sold on, and it was debranded.

Now, during the investigation, Auden's advisers did

make some attempt to claim that there were cross-subsidies at work based on a high level after-the-event accounting analysis. The analysis aimed to show that other products supplied by Auden were not profitable in some years based on the cost allocations to hydrocortisone adopted in the Decision's cost-plus analysis.

Now this is addressed and considered in the Decision. If we could go, please, to {A/12/498} and look at paragraph 5.279 at the foot of the page. You see the finding in the first sentence:

"The claim that Auden was loss-making on products other than hydrocortisone tablets is not supported by the evidence."

In the third line you see a reference by the CMA to Auden's analysis, which purported to show that in the initial part of the infringement period Auden incurred operating losses of £22.7 million on other products. Towards the end of the paragraph, one sees in the following three years the other products were profitable to the tune of £53 million. You see the figure of £52.9 million, four lines from the bottom. Massively exceeding the alleged losses in the initial period and generating an overall operating profit margin of 18.1%.

So even taking Auden's adviser's calculations at

face value, the investments in the other products relied on were in fact profitable when considered over a reasonable recoupment period. They hung by their own heads and did not support the portfolio pricing hypothesis.

Auden has not brought forward any expert evidence relating to its accounts by way of rebuttal of the CMA's analysis and finding in that paragraph.

Given that dishonest transfers of nearly £14 million were made over the relevant period under the guise of research and development payments, equivalent to two-thirds of the alleged losses on other products, it is perhaps unsurprising that they have not sought to back up their accounting base claims with any further evidence or analysis.

Nor of course is there any expert economic analysis before this Tribunal suggesting the operation in this case of any waterbed effect. But given the factual findings in the Decision and the lack of evidence from Auden on the point, we say that the portfolio pricing point goes nowhere in this case, whatever view the Tribunal arrives at on the law.

It is perhaps relevant here briefly to consider what the contemporaneous documents do show about Auden's business model and the performance of its profit.

If we could go, please to {IR-A1.1/8/8}. This is a document the Tribunal has seen before. This is the financial and tax due diligence report from December 2014 in connection with the acquisition of Auden by Actavis. So, this sets out how the business was operating for the bulk of the pre-entry period when it was under Mr Patel's ownership. If we turn to page 7. {IR-A1.1/8/7} you see at a glance at the top of the page PwC's views of the business:

"The target is a highly cash generative selling niche high margin drugs primarily to UK-based distributors. The product portfolio has historically been based on a hydrocortisone range, but management has invested in the development with third parties and acquisition of product licences and in-licensing to expand the range."

Then on page 10, {IR-A1.1/8/10} you see the background to the company. It was set up in 1999. Owned by Mr Patel and his sister. It operates out of a warehouse facility in Ruislip and primarily sells high margin drugs in the UK to distributors and pharmacies.

Then moving on to page 17, you see at the top of the page that the company has "successfully implemented significant price increases towards the end of last 12 months to 2015. These are in part driven by moving

the price point up the pricing curve" and looking down you see hydrocortisone is shown in the top graph and the rest of the portfolio at the bottom showing increases in prices and volumes.

On page 22, the top 10 skews, that is product lines, stock keeping units, by sales, generated over 70% gross margin in the last 12 months to 2015. Hydrocortisone generates the highest absolute gross margin and PwC's view is that -- on the right-hand side of the page:

"The company has been successful in ensuring high margins across the top ten skews."

Nowhere in this document is there any suggestion of large losses accruing in relation to other skews in the portfolio.

So to come back to the simple point, none of the evidence before this Tribunal supports a case that, contrary to the CMA's findings in the Decision, Auden needed to price its hydrocortisone tablets high in order to cross-subsidise unspecified other products that were loss-making on a sustained basis. On the contrary, this product was debranded and sold on to escape portfolio pricing under the PPRS.

Stepping back, we say that none of the most obvious potential explanations for price increases therefore works to explain what Auden was doing in this case. The

explanation that remains after that process of elimination for the price increases amounting to a 10,000% increase from the levels prior to Auden's acquisition of the product is that Auden did what it did because it could. It was the only supplier of the product. It was a monopolist until independent entry. It enjoyed inelastic demand and it exploited its market power by massively increasing its prices at the expense of the NHS.

There are two further pieces of the jigsaw that I should mention. The first piece of the jigsaw concerns the regulatory framework applicable in the context of pharmaceutical pricing. As you observed, sir, this is a sector where one needs to attend carefully to regulation. There is a mass of different layers of regulation in play.

Now, as we will see, however, in relation to unbranded generic products, regulation proceeded on the basis that competition will generally operate to discipline prices. The suppliers of such products were left to set their own selling prices in the market. There was no profit regulation of the kind which applies to branded products under the PPRS and there was no mechanism whereby the reimbursement prices would be brought down in the absence of competition, so if you

had a monopoly, the reimbursement prices did not present a difficulty.

It was this lack of regulatory constraint which Auden/Actavis was able to exploit in its supply of hydrocortisone tablets, as we say.

The second piece of the jigsaw concerns the lack of any competitive response. Why is it that Auden's conduct was not disciplined by market entry, as in the Covid mask situation, where the market self-corrects within a reasonable time frame? It is worth bearing in mind, sir, the length of time that the mountain graph covers before any independent entrant. It is eight years. This was not a market which was self-correcting on any reasonable time frame.

Here, another of the features of the market which you identified, sir, certainly has a role to play. There is undoubtedly a barrier to entering this market that is presented by the need to obtain a marketing authorisation in order to supply products. In the context of this market, we do say that this should not be overstated. It is clear that the barrier was well capable of being surmounted and once rivals spotted the opportunity, a number of them did enter the market, as we have seen.

But in this case, whatever view one takes of the

agreements, they did result in independent entry being staved off; first, the agreement with Waymade and then with Waymade and AMCo. The agreement strategy was continued by Auden/Actavis as long as it could. Indeed, it sought to deal with Alissa in the same way, but it failed to enter into an agreement with them. That is Decision 7.763-7.767 for your note.

At around that time, independent entry eventually did occur in the latter half of 2015.

What is clear, however, is that this process of entry, which was eventually sparked by the extraordinary price increases, took time and Auden was able to sustain its extreme pricing without independent entry for a period of over seven years, costing the NHS many millions of pounds in the process.

Following entry, Auden/Actavis's strategy was to maximise its ongoing exploitation of its market power, raising prices when competitive entry first occurred and sustaining its prices at a substantial premium over those of entrants.

THE PRESIDENT: Mr Holmes, if there is in the record, and we just need the references, any description of how marketing authorisation is obtained, the procedural hurdles, regulatory hurdles one has to jump through and an idea of cost, that would be helpful as background

information.

MR HOLMES: Yes, perhaps after the short adjournment I can give you the references to that and also return to Professor Mason's question which I have not forgotten.

THE PRESIDENT: Thank you.

MR HOLMES: Pausing there, you asked for an explanation in terms which would be comprehensible to a man on the Clapham omnibus. We should perhaps say person in these times.

THE PRESIDENT: The economist on the Clapham omnibus.

MR HOLMES: I understand why you framed the request in that those terms, and I have sought to give some economic explanations by reference to the feature of this market that the Tribunal helpfully adumbrated, but price increases of the kind observed in this market over a seven-year period, we say, call not only for an economic explanation, but also for an explanation in law.

I heard what Mr Jowell said about the economic literature. The fact is, however, that in our system of competition law the legislature chose to establish a system for the control of prices that are unfair and excessive. Section 18 of the Competition Act follows Article 102 in prohibiting dominant undertakings from imposing unfair purchase or selling prices or other

unfair trading conditions.

By the time Section 18 was enacted, it was well established as a matter of European Union law that Article 102 applied to prices that were excessive and unfair.

It therefore prohibited not only exclusionary abuse, but, by choice and design, it also banned exploitative abuse, that is to say the imposition of pricing and other terms which are harmful to customers.

This case is an involved one. There are many details and large numbers of parties and submissions on many topics. I was reminded, sir, as we heard the very eloquent submissions that were made by the counsel along the line here who sit at different points on the mountain, it is easy to lose sight of the stark reality, as Chancellor Vos put it. I was reminded of what Chancellor Vos said in the *Phenytoin* case. Easy in that detail to lose sight of the stark reality of the price increases that were applied in this case.

So that is why we say you were absolutely right, sir, to return us to the mountain. But as I will be will submitting, the core case of unfair and excessive pricing arising from Auden's price increases on the way up is really a simple and straightforward one. There are well-established principles and recent authoritative

guidance in the pharmaceutical context which the CMA followed. They applied it to the case at hand and there was only one conclusion that could reasonably be reached. This, in my submission, is an open and shut case, a clear and egregious example of unfair and excessive pricing. But I will come back to that and develop submissions in support to that overarching point.

Can I now turn to the price trends during the post-entry period and how they are to be explained. On this the Tribunal will already have gleaned, I think, the broad outline of our case. We say the shape of the price trends is explicable on the basis of three main considerations. I will give you the headlines now and return to them subsequently.

First, the arrival of competing suppliers exerted some competitive pressure on Auden's full label prices. Secondly, price reductions by skinny label suppliers and by Auden/Actavis also had the effect of reducing the level of the drug tariff in the case of 10mg tablets, but not 20mg tablets which were in a different category of the drug tariff.

Thirdly, there was therefore some downward pressure on Auden/Actavis's prices. That is clearly found in the Decision and I do not demur from it for a moment. But

it was significantly muted. On the one hand, competition was softened by the operation of the orphan designation, the feature which you aptly described, sir, as introducing a distinction without a difference. Auden was the only supplier of 10mg full label tablets and there were a number of pharmacies, for all of Mr Palmer's extremely eloquent and he is a very able advocate, for all of his efforts there were a number of pharmacies, it is really an unavoidable fact, who felt they needed to buy full label tablets rather than skinny label tablets because they did not consider that they should dispense off-label. It is simply impossible to get away from that on the factual record.

On the other hand, the way in which the drug tariff was calculated meant that Auden/Actavis's prices carry disproportionate weight in the post-entry period because only some of its competitors' prices were feeding into the tariff. This is the point that you had to be a member of Scheme M for your data to count and a number of the skinny competitors were not in Scheme M and that meant that the downward pressure from the drug tariff was attenuated, enabling Auden to price at a substantial price premium above its competitors.

The result was that Auden/Actavis was able to glide down from the peak of the mountain at a lofty height

above the other suppliers. It was partially insulated from competitive pressure and it used that protection to keep its prices well above the rest of the market.

We say those are the market features which explain the price trends post-entry.

Their combined effect during this period we say was to confer continued market power or dominance, so there is no difference between the economic and the legal concepts at work here on Auden/Actavis. It was able to act to an appreciable extent independently of the competition. Prices in absolute terms remained extremely high, continuing to generate very high profits. The cash-cow, if you like, was continuing to be milked.

I will return to that point when responding to Intas's case on dominance and abuse, but for now unless the Tribunal has questions on that explanation of the Matterhorn, there was some debate before you came in, sir, over which mountain this best described. I am afraid I am not enough of an alpinist to express a view, but on any view, it is one of the whoppers.

For now, can I turn to consider the topic of market definition.

THE PRESIDENT: Indeed. I am conscious that we have been running through since 9 o'clock. I wonder whether we

ought to rise for a short break just to enable the shorthand writer to have a further rest given we started at 9.

MR HOLMES: I am in yours and the shorthand writer's hands.

THE PRESIDENT: I do not require her to state her position. We will rise until midday and resume then.

MR HOLMES: I am grateful.

THE PRESIDENT: Thank you.

(11.53 am)

(A short break)

(12.03 pm)

MR HOLMES: Sir, a few quick references, if I may before I turn to mark definition. First, I gave you one wrong reference. The passage in the Decision which relates to the attempts to enter into an agreement with Alissa is at paragraph 6.763 and following.

Secondly, indirect costs are analysed in paragraphs 5.101 and following of the Decision. That is {A/12/449} and that is not under appeal.

The MA is described in paragraphs 3.150 to 3.151. That is at {IR-A/12/84-85}. The orphan designation is explained in paragraphs 3.152 to 3.157 at {IR-A/12/85-86}.

Can I then turn to market definition? The CMA's overall conclusion is summarised at paragraph 4.35 of

the Decision at {IR-A/12/308}. If we could go there, please. You see there that the CMA defines the market as:

"The supply of 10mg and 20mg hydrocortisone tablets (including both full label and skinny label 10mg and 20mg hydrocortisone tablets) in UK, with a combined market for 10mg and 20mg strengths prior to the entry of competing suppliers, and separate 10mg and 20mg hydrocortisone tablet markets following the entry of competing suppliers."

As the Tribunal has seen, that summary encompasses three separate decisions, each of which is under challenge in these proceedings. The first concerns whether the market extends beyond hydrocortisone tablets to other treatments for adrenal insufficiency and you see that the CMA has not included any other treatments.

The second concerns whether 10 and 20mg hydrocortisone tablets are in the same market and you can see that the CMA's approach is to define a single combined market prior to independent entry in 2015 and separate markets following entry.

The third is whether following the entry of skinny label suppliers, full label and skinny label hydrocortisone tablets competed in the same market or in separate markets. The CMA's conclusion is that the

market includes both.

Now, all three decisions under challenge. The first two are contested by Auden and the third is opposed by Cinven and Advanz.

Now, may I first tease out an important difference which affects the assessment underlying those three decisions. We know, sir, that market definition is about assessing which products are capable of exerting a competitive constraint upon the focal product. It is not an end in itself. It is an intermediate step prior to assessing market power and evaluating conduct.

The assessment requires careful attention to be paid always to the specific features of the economic activity in question.

In relation to prescription pharmaceuticals, you noted, sir, an oddity about this market, which is that the demand side exhibits some particular characteristics. This is one of those areas of economic activity, of which there are a number, it is not unique, in which the person paying, here the NHS, differs from the person consuming the product, here the patient.

There is a further specificity, the selection between products is made by yet another person or in fact two other groups of people: first of all, a choice by the doctor as to which product to prescribe and in

some cases also a further choice by the pharmacist as to which product to dispense where a choice remains based on the prescription.

Now, in situations like this, where the demand side is segmented, there are in my submission two questions that fall to be addressed when assessing the extent of the competitive constraints on the focal product. The first is who decides in a given case whether the product in question, or the other product that you are considering for inclusion in the market, is to be selective and the second is what selection criteria do they use. Those questions enable you to focus on how competition works in practice in a given market; what are the parameters on which the product may compete with other products?

For example, if the choice is made by a person who is not at all influenced by price, you will need to look elsewhere to understand the nature and extent of any competitive interaction between the product and another potential substitute product. I think that was the point, sir, that you canvassed in argument.

To make this concrete in the context of pharmaceutical products, can we please go to the Decision at {IR-A/12/60}. This is where the Decision explains this trichotomy, this distribution of demand.

You see that the Decision here distinguishes between prescribing, dispensing and funding in the heading at the top of the table. As the Tribunal's questions rightly apprehended, we say that this is a basic and fundamental feature of the relevant market context.

At paragraph 3.62 the point is made that the clinical decision to prescribe a medicine to a patient is made by a doctor or other healthcare professional: in the case of hydrocortisone tablets, in fact nearly always a hospital consultant, an endocrinologist.

At 3.63 a prescriber can choose how prescriptive they are to be. They can write an open or closed script and the open script will specify which drug is to be prescribed, but in generic form and a closed script will specify a particular brand or supplier.

At 3.64 prescribers are generally encouraged to write open scripts: so, for example, hydrocortisone tablets. Just as a minor qualification, because it is of relevance when we come to consider the 10/20mg distinction, they do typically also prescribe the strength of the product, so that question is taken off the table before you reach the pharmacist.

Now pausing there --

THE PRESIDENT: So they will say 10 or 20mg?

MR HOLMES: The prescribing doctor's prescription will

nearly always specify whether the product is a 10mg hydrocortisone tablets or 20mg. So the pharmacist could not dispense 20mg tablets in response to a prescription for 10mg hydrocortisone tablets.

Now, pausing there, paragraphs 3.62-3.64 show us that the person who chooses between hydrocortisone tablets and other treatments, such as Plenadren or alternative steroids like Pregabalin, is the prescriber. As I have just explained, the same is true of the decision whether to prescribe 10 or 20mg hydrocortisone tablets.

So if you want to understand the nature and extent of the competitive interaction between hydrocortisone tablets and other treatments and between hydrocortisone 10 and 20mg tablets, that is the first two of the three market definition decisions that were made by the CMA, you need to consider the selection criteria which weigh with the prescribers. They are the person who chooses.

As we will see, those selection criteria --

THE PRESIDENT: Sorry, to interrupt, but just because I have been interested in the different levels of supply between 20 and 10mg, the fact is that one can infer from this that the vast majority of persons requiring treatment by way of hydrocortisone tablets have a need for hydrocortisone at the lower, rather than at the

higher level.

MR HOLMES: You have hit the nail on the head, sir, and I will show you what the evidence that was before the CMA had to say about that, about why prescribers chose 10mg, except in a very narrow use case, over 20mgs.

I was just coming on to say in relation to prescribing, the selection criteria that the prescribing healthcare professional uses will be focused primarily on clinical considerations and to that extent we can agree with what Auden has to say about that, but there is, it is important to note, still potential for price considerations to shape prescribing activity in various ways where products are clinically substitutable.

So where there is a choice between two alternative therapies to treat a condition, it would not be correct to say that the selection is entirely insensitive to price. I will show you why that is the case. So it would be wrong to think that price is irrelevant when assessing the extent of the competitive constraints that other treatments may excerpt on hydrocortisone tablets. They do weigh and they weigh in a concrete way, which I will show you.

Now, turning over the page, paragraph 3.67 and following consider the position of dispensing and 3.67 explains that pharmacies purchase medicines from

wholesalers or in some cases vertically integrated manufacturers with a wholesale arm.

At 3.68 pharmacies are then reimbursed by the NHS, specifically the clinical commissioning groups, local bodies, that are responsible for paying for drugs for the people who live within their localities.

At 3.69 the pharmacies profit margin is the difference between the price it paid to purchase the product and the amount it is reimbursed.

At 3.70 you see the point that pharmacies therefore have an incentive to purchase the cheapest medicine available in order to maximise their profits. They get the reimbursement price and they will buy as cheaply as possible in order to maximise the margin between the two.

That is the general situation. So it shows that where there are several options available for dispensing a prescription, as there will be generally in the case of generic products, several products which conform with the prescription, having the same active ingredient, the same strength and the same form, it is the pharmacist who is the relevant person who makes the selection and the pharmacist's choice will be informed by price, at least as one important consideration, although as the Tribunal has seen, not the only consideration.

This means that when determining the nature and extent of competition between full and skinny label hydrocortisone tablets for the purposes of that part of the market definition, the third and final of the questions before the CMA, the correct focus is upon the pharmacies and the criteria which inform their choice.

While there is an intermediate level, the wholesalers, I think it is common ground that their demand will be derived from the demand of the pharmacies they serve. That was something that was canvassed with the experts and I do not think anyone seriously pushed back on that proposition.

Finally, looking down the page at 3.71, the Decision considers the position of who pays and, as explained there, once the prescribing decision is taken, the NHS has no choice but to fund the product and specifically the funding is by the CCG and, as noted in 3.72, it is funded principally by taxpayers.

As we will see, the NHS does try to influence prescribers' choices so that they prescribe in a cost-effective way. That is why prescribing is not immune, not completely immune, to price considerations. So that is a feature of the market definition prices which needs to be borne in mind. Part of the Decision is made by the CCG as well as by the prescribers.

Now, patients will also contribute to the overall drug budget insofar as they pay for prescriptions. But as you noted, sir, they pay a flat rate where they pay at all, which may be above or below the cost of the drug: the aspirin situation you described. So, where payable, the prescription charge is more in the nature of a flat rate tax or levy on consumption of drugs than a price in any meaningful sense. In fact, patients on hydrocortisone tablets for adrenal insufficiency, as Mr Palmer alluded to, do not in fact pay for prescriptions, because it is a lifelong condition and it would be unfairly burdensome to impose prescription charges on them. It is one of the conditions for which medical exemption certificates are available.

But from the point of view of market definition, we say that prescription charges are in any event not relevant. That is because the patient does not make any decisions about what drug they get and insofar as they pay a prescription charge, it is not a price and the prescription charge is therefore a contextual factor and we apprehend that is why the Tribunal sought our submissions about it, but it does not affect the nature or extent of the competitive interactions that will determine the appropriate market definition.

So with that framing discussion in place, that

distinction between the three decisions, the first two concerning the selection that is made at the prescribing level and the third, the full skinny concerning a decision that is made at the dispensing level, can I now turn to consider the first two decisions, that is to say, the exclusion of alternative therapies and the CMA's approach to the 10-20mg distinction.

These are put in issue by Auden's market definition appeal.

If we could please go to the transcript on {Day11/21:17} to see how Ms Ford puts Auden's case. You see there at line -- that is a wrong reference. I am sorry, it is {Day11/19:16}. You see there that she says that the various interrelated errors of law to which she points are "illustrative of an overarching error in approach" and that is wrongly to prioritise price and economic considerations over other considerations in the circumstances of this case. Those other considerations are clinical substitutability. That was the force of her point.

Auden's position is that clinical substitutability is the key issue and not price. As they put it in paragraph 55 of their written closings, they accuse the CMA of an excessive preoccupation with price to the exclusion of factors such as clinical substitutability

and Auden also maintains that the CMA failed to have proper regard to the anatomic therapeutic chemical or ATC system, which is a system for classifying different medicines. They say that it should have taken level 3 or possibly level 4 of that system as its starting point and then considered the clinical substitutability of each listed product in turn.

You will recall that the ATC system has various levels, five levels, and levels 3 and 4 group active substances according to the pharmacological or therapeutic groups, while level 5 identifies a specific chemical substance. Ms Ford specifically criticised the CMA for adopting a market definition narrower than level 5, in that it excluded other formulations of the same active ingredient, including Plenadren. I think that is a fair summary of Auden's case on this topic.

In terms of outcome, Auden claim that is the CMA's alleged focus on price and its neglect of clinical interchangeability led it to define the market too narrowly in two respects. On the one hand, by confining the market to hydrocortisone tablets and excluding other treatments having a common clinical use, in particular Plenadren and Prednisolene and, on the other hand, by treating 10 and 20mg as sitting in different markets tables following independent entry, although, as Ms Ford

put it, nothing had changed about their functional characteristics.

Now, we say that Auden's case on market definition is without merit. The short answer to it is that the CMA did not focus exclusively or unduly on price. I will go shortly to the reasoning in the Decision to show that Auden's complaint is really a caricature of the CMA's reasoning.

In fact, the CMA paid very careful regard to the clinical and other practical considerations which actually influenced prescribers' decisions when selecting between different treatments and doses. It is right to say that the CMA also had regard to quantitative measures, like volumes and prices, but I say that it was absolutely right to do so. Those measures are of relevance when defining markets in the pharmaceutical sector as in other areas of economic activity. The volumes provide the best available information about the choices prescribers actually made when selecting between products and that is an important indicator of whether they were or were not viewed as substitutes in the real world.

In this case, they substantiated the CMA's assessment of clinical substitutability.

As regards the prices of the various treatments, we

say they are also relevant because, as we will see, they can have some effect on prescribing decisions as between products that serve the same clinical need. The selection of pharmaceutical products is not entirely insensitive to price at the prescribing level.

In this case, the available price and volume data, taken together, show that prescribers were not influenced by price to select other products in place of hydrocortisone tablets. They clearly and emphatically opted for hydrocortisone tablets over the potential clinical substitutes. I will come to that evidence shortly.

Before I do so, however, I should address the submissions with which Ms Ford began on the law relating to market definition in the pharmaceutical sector. She sought to bolster her case by showing you various authorities which were said to show that particular considerations apply when defining markets in the context of pharmaceutical products. In particular, she sought to draw two points from the case law. First, that the assessment of functional substitutability should generally take place at the third level of the ATC system as its starting point and, secondly, that, and I quote "a great deal of care has to be taken", as she put it, when placing reliance on pricing factors.

So those were the two points she took from the case law.

For our part, we make five points on the law. Can I give you them and then show you them in the cases. First, we say that market definition in this pharmaceutical sector has the same underlying objective as in any other industry; namely, to identify the competitive constraints that apply to the focal product.

Secondly, product characteristics are obviously relevant when identifying potential substitute products in this context as in others. For pharmaceuticals, that partly involves a consideration of therapeutic use, but one needs to be careful with that term. It is a holistic assessment of clinical substitutability, which also encompasses side-effects and other practical considerations which influence prescribing decisions.

Thirdly, one relevant resource in assessing therapeutic use is the ATC system as a basis for identifying potential clinical substitutes, but it is only a starting point or preliminary indicator and there is no particular need to focus on level 3 or any other level of that system.

Fourthly, you cannot stop with the objective characteristics of the product. The aim of the exercise, here as elsewhere, is to assess the extent of the competitive constraints on the focal product: does

a potential substitute supply a sufficient constraint on the focal product to be capable of constraining its market power?

The fifth and final point, quantitative information about volume and price remain relevant when assessing the sufficiency of competitive constraints in the pharmaceutical sector as elsewhere.

In this case, as the Tribunal has seen, the economists all focused on volume and price trends and, in my submission, they were not wrong to do so. Both price and volume may shed valuable light on the degree of competitive interaction between potential substitute products in the pharmaceutical sector.

Turning to the cases to make those points good. Ms Ford took you first to the Commission's Decision in the *Astrazeneca* case. She took you to some recitals which appear a little way into the discussion of the relevant product market, but it is important to see them in their context. If we could go, please, to {M/43/85}, which is where the discussion of product market begins.

You see that the first section sets out the well-known principles governing market definition from the Commission's notice. So, at recital 359 down towards the bottom of the page, you see that the main purpose of market definition is to identify in

a systematic way the competitive constraints that the undertakings involved face and 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.

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, secondly, in recital 360, the important point that an analysis of the product characteristics and intended use limits the field of investigation, but it is not sufficient to determine whether two products are demand substitutes:

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

So instead, one needs to look at the evidence of how customers behave in practice.

In this connection, the Commission proceeds, starting at the foot of the page, to identify one type of evidence as particularly relevant to assessing

whether two products are demand substitutes; namely, evidence of substitution in the recent past. I am sorry. That is at the top of the following page, yes.

Such evidence will be normally be, you say they say, "fundamental for market definition".

Looking down the page to the heading, the Commission next turns to consider how this framework applies in the specific context of the pharmaceutical sector.

We come to recital 362, which Ms Ford did show you. The Commission says that while the notice on market definition comprises all industrial sectors, the assessments of the case in question needs to take due account of features specific to pharmaceutical markets, differentiating the sector from other industries.

As we will see, the Commission certainly does not mean to suggest that those features are such that the basic and fundamental principles set out in the proceeding recitals do not apply in this context.

Various features are then identified. Ms Ford emphasised two of them. The first is the existence of the ATC system, which groups products according to the functional interchangeability and, second, in the 12th line in the paragraph, is that in their choice of medicines prescribing doctors are the main determinant of demand in pharmaceutical prescription markets; the

point I just discussed.

She also emphasised the final sentence in the paragraph:

"In choosing between different medicines prescribing doctors were, at the relevant period, primarily guided by the therapeutic appropriateness and effectiveness of different medicines rather than their price."

Now, pausing there, we of course accept that the ATC system, and prescribers as the main determinant of demand, are relevant features when applying the market definition framework to pharmaceutical products.

I will come to the ATC system in a moment. But to first focus on the role of prescribers. There are two points to make in relation to this feature. If we might first look at the immediate conclusion that the Commission draws from the role of prescribers on the demand side. You see the sentence to which Ms Ford took you, identifying prescribing doctors as the main determinant of the demand. Looking at the next sentence the Commission says that:

"Actual trends in the consumption of medicines prescribed therefore constitute a key factor in assessing competitive constraints between categories of medicine."

So in other words, the volumes actually prescribed

are key to assessing competitive conditions, because they show what prescribers are actually doing in practice. As we will see, this was something the CMA attended to carefully in its market definition in the present case.

As regards the final sentence, the Tribunal will note that the Commission was careful to say that the prescribing doctors were at the relevant period primarily guided by therapeutic considerations rather than price.

This is clearly a specific observation by reference to the time period the Commission was considering in that case and the geographies. It is not a universal truth about the extent to which price plays a role in prescribing decisions. Where there are several products available to doctors, one can well imagine that price can weigh in the balance and in this case it did. You see that from the recital referred to in the final sentence on the page, recital 130. So that is on page 29. If we could go there, please. {M/43/29}. You see in 130:

"Apart from rules on pricing and reimbursement, the authorities in the EEA have also attempted to encourage doctors to prescribe generic products rather than the original versions. Such attempts have tended not to

involve formally binding rulings. Instead, campaigns, maximum budgets and guidelines have been applied."

We will see there were such guidelines in this case:

"In the United Kingdom, at least, such measures appear to have borne fruit with time."

So in the Commission's view, at least measures to promote cost-effective prescribing in the UK have had some effect. The *Astrazeneca* Decision concerned the period from 1993 to 2000. We will come to see that in this case cost-effective considerations did play a role and did shape the market, the substitutability of products, the competitive constraints on hydrocortisone tablets.

So, the interplay of price as well as volume is a relevant indicator when assessing the degree of competitive constraints imposed on the focal product. It is the sort of real-world evidence which the Commission identified as fundamental for market definition.

In the *Astrazeneca* Decision, defining the relevant market, even despite the price insensitivity of the prescribers at the time in question, the Commission nonetheless gave significant weight to price as an indicator of whether products are to be viewed in the same market. I do not have time to take you to them

now, sir, but for you note on page 87, recitals 364-366, all considered price factors when defining the market.

The Commission's conclusion at recital 370 is worth bringing up. If we could go, please, to page {M/43/87}. You see the Commission there recalls that:

"The relevant market is not determined on the basis that certain products competed against each other in a broad sense, but on the basis of whether such products were sufficiently substitutable to significantly constrain each other's market power, in particular, as regards pricing."

So, it is clear that the Commission in *Astrazeneca* approached the market definition exercise as one of assessing the sufficiency of competitive constraints and it regarded price and volume trends as relevant indicators when assessing whether functionally substitutable products should in fact be regarded as falling within the same product market.

If we could now turn to the ATC system. Ms Ford showed you recital 371, which introduces the system. It is down at the foot of the page. She placed particular reliance on the bottom three lines on the page:

"The third ATC level allows medicines to be grouped in terms of their therapeutic indications, ie their intended use. This level is generally used as the

starting point for enquiring about market definition in competition cases."

But reading on, the Commission makes clear that there is no hard and fast rule here:

"However, it is appropriate to carry out analyses at other ATC levels if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at another level, and that, therefore, there are indications that the third ATC level does not lead to a correct market definition."

So as one would expect, one needs to see what all of the circumstances of the case show about the sufficiency of competitive constraints in the case at hand. Indeed, in *Astrazeneca* the Commission concluded that the third ATC class was not the right focus.

Looking at recital 372, the Commission noted that the third ATC class covered only one of the three main disease areas relevant to the product at issue. It in fact confined the market to PPIs, which corresponded to the fourth level of the ATC.

So in my submission, there is no particular magic about the level of the ATC. It is a relevant piece of evidence, but it needs to be considered and weighed alongside other relevant evidence to see what is the

correct market definition. That is exactly what the CMA did in this case.

The market definition in the Commission's Decision was appealed to the EU courts. If we could very briefly look at the General Court's judgment, please. It is at {M/79/58}. Picking it up under the heading "Findings of the Court" you see the grounds of complaint essentially were grouped around three issues and the first two are similar to those advanced by Auden in this case. First, an alleged failure to take sufficient account of therapeutic use and, secondly, excessive attention paid to price indicators.

So very much the same arguments that Auden is running.

Under the first head one of the grounds of complaint was related the Commission's analysis of the ATC system. If you go to {M/79/61}, you see at paragraph 154 the complaint that the Commission departed from its previous practice of taking account of the third ATC level.

At paragraph 155 you see that the General Court had no truck with this. The contested Decision had explained why it had not taken the account of the third ATC level and in the final sentence of the paragraph:

"The Court also points out that the taking into account of the ATC level in which the medicines are

placed constituted only a preliminary step in the Commission's analysis."

So a starting point or preliminary step, but nothing more.

The court then turns to consider whether the commission went wrong by considering price-related factors. It rejects that complaint as well. The overall conclusion is at page 70 at paragraph 183 {M/79/70}. You see there at 183 the General Court finds that:

"The specific features which characterise competitive mechanisms in the pharmaceutical sector do not negate the relevance of price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context."

We respectfully agree with that. As we will see, that is exactly how the CMA approach matters.

There is a further appeal to the Court of Justice, but it did not affect the General Court's statement of principle.

Ms Ford also took you to the *Servier* judgment of the General Court. She took you first to a passage relating to the ATC system. I am afraid I have lost the reference to *Servier*. It is {M/105/159}. Looking at paragraph 142.8. Sorry, it is {M/154/159}. You see at

paragraph 1428 that the Commission defined the relevant market at the fifth level, not the third level. That is the individual active ingredient level, Perindopril, and the General Court clearly states that the definition at the fifth level of the ATC is not open to criticism in itself. It depends what the totality of the evidence shows.

That is entirely consistent, in my submission, with what the Commission and the General Court said in *Astrazeneca*. The ATC system is only a starting point or preliminary step. When defining the relevant market what matters is the overall body of evidence before the authority and what it shows about demand-side substitutability in particular.

Ms Ford also took you to the consideration of a role of price in defining pharmaceutical markets on page 181 and she referred you to paragraph 1567. If we could please look at paragraph 1575, it shows a more nuanced approach than she suggested. The general court there states that:

"Doctor's freedom of choice, between the originator medicinal products available on the market or between originator medicinal products and generic versions of other compounds, and the priority of focus of prescribers on therapeutic aspects permit, where

appropriate, the operation of significant qualitative and non-price competitive constraints in addition to the usual mechanisms of price pressure."

So, in other words, other qualitative factors may operate in appropriate contexts in addition to price, but price may still be relevant.

We have seen from the *Astrazeneca* Decision the extent to which prescribing decisions are influenced by price factors depending on the factual circumstances of the case and that will differ from time to time and from place to place. In my submission, the CMA's examination of the relevant market, therefore, needs to be judged based and the factual material on the file of this case and I will come to that shortly.

As Ms Ford mentioned, the General Court's judgment is in any way under appeal. We are still awaiting the judgment of the Court of Justice, but the Advocate General has disagreed in quite firm terms with this aspect of the General Court's assessment and so it needs to be treated with some caution.

If we could go briefly to her opinion. It is at {M/190.3/49}. You see at paragraph 370:

"The Advocate General considers that the General Court's reasoning relating to the price factor is not only insufficient, because it does not make it possible

to understand the significance of that factor in its overall analysis, but also contradictory in that the General Court accepts, in principle, the role of the price factor, on the one hand, whilst exclude that factor from that same analysis without providing reasons."

Paragraph 372:

"The Advocate General considers that the General Court disregarded the principles established by case law regarding the definition of the relevant market."

Paragraph 373, the market is defined with a view to determining the boundaries within which to assess dominance.

Over the page at 374, it is a question of assessing competitive constraints, taking account of the objective characteristics of the product in question, but also competitive conditions and the structure of supply and demand and, therefore, all the indicators of potential competitive constraints.

At 375, confirmation by reference to *Astrazeneca* that those principles also apply in the case of pharmaceutical markets because "the specific features of those markets do not negate the relevance of price-based indicators."

At 377, a reference to natural events in the market as a relevant piece of evidence for market definition.

At 378:

"When conducting such an exercise, factors such as ... the evolution of the prices in perindopril [the focal product] and of the other ACE inhibitors, which show that products can theoretically be substituted for the product at issue have not exerted a significant competitive constraint on that product, cannot be ignored."

This is key in responding to Ms Ford's case, because she points to other products that theoretically could be substituted. What the Advocate General is saying here is you need to look at whether in practice there is a significant competitive constraint based on whether there is substitution in practice, looking at the evolution of prices among other things.

We say in the light of all these cases, market definition in the pharmaceutical sector is about determining the sufficiency of competitive constraints on the focal product, taking account certainly of the available clinical evidence, but also the quantitative evidence, while always of course interpreting the evidence in a way which is sensitive to sector-specific features.

With that overview of the case law, can I turn now to consider how the CMA arrived at its conclusion that hydrocortisone tablets are in a separate market from other adrenal insufficiency treatments. This is to show you the careful attention that the CMA paid to clinical considerations.

Can we go, first, to {IR-A/12/73}. So, this is where the CMA introduces and describes the various treatments for adrenal insufficiency. You see the heading "Adrenal insufficiency and the drugs that treat it." Then at 3.116, a general summary of the position. At (a), this is at the foot of the page:

"Adrenal insufficiency ... is treated in almost all cases with hydrocortisone tablets, which are considered to be the most appropriate steroid to replace the missing hormone in the body."

At (b) the point that:

"Other treatments are used in exceptional circumstances or for marginal numbers of patients with specific needs."

Turning on a page to 74, there is a description of adrenal insufficiency adrenal as a condition and at paragraph 3.119, at the foot of the page, one sees that hydrocortisone is the first-line treatment for patients with either of the two types of adrenal insufficiency,

primary or secondary. In other words, it is the treatment on which patients are routinely and habitually initiated.

Then turning over a page you see why; a range of clinical reasons for preferring hydrocortisone over other steroids are identified. It is the closest imitation of what the body normally produces. It is absorbed quicker than other steroids and it is easily measured in the bloodstream, making monitoring easier.

The Decision then turns to consider specifically hydrocortisone tablets and in paragraph 3 --

THE PRESIDENT: Just pausing there, Mr Holmes. Probably it is best if we put names to faces. You are talking about beyond hydrocortisone tablets here, are you not?

MR HOLMES: Yes, we are talking about hydrocortisone as a class. Those paragraphs are saying that hydrocortisone is preferred over other corticosteroids like Prednisolone and Dexamethasone. I will deal separately with other forms of hydrocortisone.

THE PRESIDENT: Indeed, because Ms Ford placed most of her emphasis on Hydrocortistab and Plenadren.

MR HOLMES: That is a different stage of the case. She certainly relies on Plenadren as part of her market definition case. She does not rely on Hydrocortistab, because it is common ground it is not actually used to

treat adrenal insufficiency, save in exceptional cases. That is something she relies on as a comparator in relation to the unfair when compared limb of the abuse analysis.

THE PRESIDENT: Right, that is because of its injectable form.

MR HOLMES: It is an injectable form used to treat arthritis. It is overwhelming not used to treat adrenal insufficiency. So it is not used for the same condition as hydrocortisone tablets. So there are two products she relies on. One is Prednisolene and the other is Plenadren. Plenadren is another form of hydrocortisone. Prednisolene is another different corticosteroid. Those are the two products that Auden relies upon for its market definition. I see Ms Ford nodding.

THE PRESIDENT: Because what prompted the question was, if we go back a page, we have the assertions. If you take, for example, 3.119 where it says:

"Hydrocortisone is the first-line treatment for the replacement of hormone deficiency."

That assertion tells us nothing about why it is first in line.

MR HOLMES: No, sir.

THE PRESIDENT: So you are obviously coming on to that.

MR HOLMES: Those are paragraphs I just showed you

subsequently. If you go on a page, sir, you see three clinical reasons are given. It is at 75, please. So the next page then explains. You see that there are three reasons why hydrocortisone is preferred over the other corticosteroids, so this goes to the Prednisolene point. It does not go to Plenadren point. I will come to that separately. You see three clinical considerations that weigh heavily in favour of hydrocortisone over the other corticosteroids, in particular in Prednisolene, which is the one relied on here. Dexamethasone I think reliance is not placed on that. The closest imitation of what the body normally produces. Absorbed in the body quicker.

THE PRESIDENT: We are still on the wrong page, I think.

MR HOLMES: I am so sorry, on a page. Is it freezing? Yes.

So there you see closest imitation of what the body normally produces, absorbed into the body quicker than other steroids and easily measured in the bloodstream, making monitoring easier.

Just to be clear, sir, you described those as assertions or the earlier points as assertions. They are of course findings based on evidence on the file and one of the points I will be making to you, sir, is there is no evidence to contradict those. There is no clinical expert evidence of the kind that can certainly

have been called if any of that were disputed.

The Decision then comes to consider the particular form of hydrocortisone, which is the focal product here, hydrocortisone tablets. At 3.121 it notes that the Society of Endocrinology, that is the clinical body, the body of clinicians who are active in this area who prescribe products, estimates 95% of all adult patients with adrenal insufficiency are treated with hydrocortisone tablets.

If we could turn on to page 77, {IR-A/1/12/77} there is a discussion of the alternative form of hydrocortisone sold under the brand name Plenadren. I think this was the point that you were canvassing with me, sir, whether other forms of hydrocortisone tablet might be substitutable from a clinical perspective.

Paragraph 3.129 on page 77 {IR-A/12/77} notes that Plenadren is a modified-release tablet formulation. It releases hydrocortisone over a longer time period to match the body's natural daily steroid profile. It is a once daily product and in recognition of that innovation it received orphan drug status in this 2011.

3.130 explains that:

"Modified-release ... means that Plenadren is potentially more beneficial for a particular subset of patients in the term of convenience and patient

compliance ... Specifically, [it] is an option for patients experiencing 'severe compliance problems'."

You see that this is supported with various evidence that the CMA gathered. By "severe compliance problems" what is being referred to there is patients who struggle to maintain their dosing schedule, dosing throughout the day, for example, because of cognitive problems.

THE PRESIDENT: Yes.

MR HOLMES: Some clinical commissioning groups, the local bodies within the NHS who pay for medicines, have made this a prerequisite for prescribing Plenadren. As a consequence, one sees on the next page the extent to which Plenadren is used in practice at {IR-A/12/78} 3.131. It is given to a very small number of adrenal insufficiency patients. It is not recommended or endorsed for use at all in two of the four home nations.

THE PRESIDENT: Yes.

MR HOLMES: You see in the tables that follow the very low levels of prescribing, peaking at 628 packs per month in 2019, and that contrasts with the 91,746 packs of hydrocortisone tablets prescribed in that year.

You see from the second table Plenadren has always been below 1% as a proportion of Plenadren and hydrocortisone tablets used.

There is no real indication of any substitution

pattern between hydrocortisone and Plenadren.

Then at 3.133-various reasons are given for the very low usage of Plenadren. Subparagraph (a) there are very few clinical advantages, turning over the page, save for a specific subcategory of patients, those with severe compliance problems. Indeed, it is in fact less effective than a regular two to three times a day dosing with ordinary hydrocortisone tablets with less absorption, potentially leading to undersubstitution and therefore, requiring closer monitoring.

At (b) it is not recommended by NICE or the clinical reference group for endocrinology and at (c) it is subject to prescribing restrictions. It is not included in the clinical commissioning group prescribing formularies, which contains the list from which health professionals are able to prescribe.

At footnote 186 you see that the Society of Endocrinology, at the foot of the page nearly 90% of GPs are not allowed to prescribe Plenadren and in some instances stringent criteria must be met before Plenadren is recommended for hospital use, including at least two hospital admissions in the last 12 months due to unstable primary adrenal insufficiency. So it is a treatment of last resort even in hospital.

The reason is reflected in the explanation given by

a group of CCGs at the end of the paragraph: the limited potential benefits, the clinical benefits, and they are not significant enough to justify the considerable extra cost associated with prescribing Plenadren.

This brings me back to the point that prescribing is not immune to cost considerations. So part of the market definition exercise needs to consider price as a dimension of competition and it is quite clear, given Plenadren's limited benefits, its role for only a small subset of patients and it is very high price, even compared with hydrocortisone tablets, it is not viewed as a substitute on the demand side of this market and that explains why it has achieved so little traction, why the volumes prescribed are minuscule. It is not capable of exerting any meaningful competitive constraint on immediate use hydrocortisone tablets and that is the short answer to Ms Ford's case by reference to Plenadren.

THE PRESIDENT: Well, it is quite a good point for me to give you a somewhat long question.

MR HOLMES: Yes, sir.

THE PRESIDENT: Can I make clear that I am using Plenadren as a good example of the general question that I am going to try and put to you.

So market definition is, as we have all read many

times, a tool rather than an outcome. It is a means of answering later questions that arise down the line. Typically, we have evolved tests for defining the market which presuppose a normal market where you have got not perfect competition but demand and supply curves that are conventional upward sloping, downward sloping with price in the middle and one really has to just work out elasticities of demand if one is talking about the demand side in order to work out whether there is substitutability because one uses price as the determinant of substitutability.

Of course, it involves a degree of hypothesis because you are applying a hypothetical price, a SSNIP to work out what will happen, but one has a degree of objectivity in terms of analysis. One might disagree about the precise things that one is doing, and one might disagree about elasticities but at the end of the day the intellectual process is one that all can agree upon.

Now, the problem that we have got here, and you have all articulated it, is that one has an odd demand-side, and you put it very well, I think the trifurcation between consumer, the patient, the payer and the informer of consumer choice in the shape of the doctor and the pharmacist are all problems because you have

lost the connection between demand and price.

So, what you are all trying to do is to work out what one does with this difficult market which is not conventional. What I think the CMA have done is they have looked at a range of other factors and they have sought to define the market in the way that they have by reference to those factors and I think you put it on page 121 of the transcript that ATC, you were talking about at the time, is a relevant piece of the evidence along with other factors, and you have been articulating the various other factors as we go.

The problem is that this sort of test involves a degree of uncertainty in terms of how you define the market which is perhaps inevitable but the risk that it has is that it imports subjectivities in that one person can define the market in one way looking at certain factors and another person can define the market in a very different waying looking at other different factors, and so one immediately has a problem which does not arise with a SSNIP about who is right and who is wrong.

Now, Plenadren is I think a very good example of this sort of subjectivity. You have said a couple of times that Plenadren is only prescribed where it is indicated because of the very specific nature of the

patient. You have touched upon disadvantages to prescribing it to other people and that is something which is clearly significant but let us ignore that for the moment. Let us assume that actually Plenadren is indicated for a tiny minority of patients, let us say 1 in 100 where Plenadren is positively beneficial compared to, let us say, 10mg hydrocortisone.

But let us assume, I appreciate that is not what it says on the page here, but let us assume that actually Plenadren is as good as 10mg hydrocortisone for the other 99. On what basis are you excluding Plenadren on that hypothesis? The reason you are excluding it from the market is as it seems to me that it is more expensive than hydrocortisone and the question, it is a short question, but I raised it a few days ago, which is: to what extent should one exclude what is objectively by reference to say functionality a competitor product, an alternative, a substitute, simply on the basis of price?

Obviously I can understand why the figures are so low for Plenadren compared to 10mg hydrocortisone. They are very low in significant part, I would suggest, because of the price. Plenadren is significantly above the others and that is why your clinical commissioning groups will be saying, look, be very careful about

prescribing this stuff because it is so expensive or because it is materially more expensive than an alternative which is as good.

Really a long lead up to a short question. Ought one to be placing so much reliance in defining the market on a product which is higher priced than otherwise? It goes back to my Rolls-Royce/Mini example. If you are assessing the market for Minis the price, let us say, £35,000, do you simply exclude from your market definition exercise the Rolls-Royce because its price is way above that of the Mini and you just end the enquiry there or do you need to be more nuanced even when you are applying a SSNIP? Here of course you are not applying a SSNIP. You are excluding it on the basis that it is not used very much but one of the reasons it is not used very much is price. So it is the same question slightly repackaged.

I see the time. I am not going to -- and please take your time as to when you come back to it but it will be of assistance to have the CMA's position on that.

MR HOLMES: It deserves a considered answer, sir, and I will return to it after lunch.

THE PRESIDENT: A harder question, you have heard I think that we had the aspiration of ending, if we could,

1 1 o'clock on Friday. How are you doing, Mr Holmes,
2 because --
3 MR HOLMES: Sir, I should say immediately I am very
4 concerned about time. I am concerned about whether
5 fairly it will be possible to respond in the time that
6 is available even -- the Tribunal acknowledged I think
7 when it set this timetable, it recognised that there was
8 a difficulty. There are a lot of appeals here, a lot of
9 detailed points and also the Tribunal, understandably in
10 a case of this breadth and complexity, has offered its
11 own perspectives and has asked for assistance on various
12 market features. I have a real question in my mind now,
13 sir, whether it will be possible fairly to conclude
14 within the time available before the Christmas break.
15 THE PRESIDENT: Right.
16 MR HOLMES: You said that you would revisit even in closing
17 the time that is allowed but I am just very, very
18 conscious. This material is important and it needs to
19 be addressed. These are aspects of Auden's appeal which
20 I need to deal with and this is only the beginning.
21 This is one, the first of three market definitions. The
22 second one she took quite lightly but you have asked for
23 the assistance on the relationship between 10 and 20mg.
24 I then have the question of full and skinny which was
25 the subject of days of expert evidence. I then have

countervailing buyer power which was the subject I think of a very extensive set of submissions, understandably, I do not criticise them for it, by Auden.

THE PRESIDENT: There is no criticism at all.

MR HOLMES: And that is before one gets to Intas's case and abuse.

THE PRESIDENT: What I think you are saying, in a way that makes life rather easier. I mean, my question was initially, can we save Friday afternoon given the time? What you are coming back to is you are saying actually there is no question of that. It is a question of how far one runs into the new year.

MR HOLMES: I hate to say it, sir, because it is obviously against the personal interests of everyone in this room, the thought that we might need to return at some point, but speaking as an advocate in the interests of my client I am concerned at the moment that there will not be the opportunity fairly to respond to all of the points that have been put.

THE PRESIDENT: You may want to think about this and we will certainly do so. You see what I was leading up to is how far could we stretch the time available by cutting back short adjournments and starting, for instance, at 9 o'clock tomorrow but I think what you are saying is that actually these are not going to be sufficient.

MR HOLMES: I should take instructions on this, because I am speaking here personally as an advocate based on the material that I have remaining to deliver and I obviously need to hear what those behind me have to say.

I would say that an aspect of fairness is to consider both for the counsel that are appearing before you but also for the Tribunal, the level of concentration that is required, the intricacy of the case, whether extending the hours of sitting are really practicable solutions in this case. I fear that fairness may again arise in relation to that suggestion, sir, and I do not make that submission lightly or in criticism of anyone here present.

THE PRESIDENT: No, that is entirely fair. I mean, we are very conscious of that with witnesses and we certainly do not stretch days with witnesses. If it was a question of your saying look we need another hour and a half, two hours then I think I would be saying we will stretch the days and sort it out. But you are saying something more than that. You are saying actually we need significantly more time than that.

MR HOLMES: I fear that may be the case, sir. The concern is that, and again I understand entirely why the Tribunal did this, it may have been possible in some

worlds to get what we had to do comfortably done in the space of three days by comparison with the six days that the appellants had been allotted. You can imagine where there are overlapping appeals that that might be perfectly possible as a matter of fairness or where the issues are straightforwardly met by the Tribunal and there are not difficulties or concerns that need to be addressed during the course of discussion.

But given the way in which the hearing has unfolded I, personally speaking, do have a concern about the fairness of the process that we are now embarked upon and whether you can fit into three days of submission, even into three days, never mind the half day that I understand may need to be made up on the last day, whether you can fit into three days of submission a response to six days' submissions on the other side of the Bar.

THE PRESIDENT: A point further to consider over the short adjournment: are you confident that if you had Friday, by which I mean the whole of the day, you would finish or is that something which you would not feel comfortable saying now?

MR HOLMES: At the current rate of delivery, sir, this is the first file that I have and I am only halfway through the script after the morning.

THE PRESIDENT: Yes.
MR HOLMES: Sir, I will take stock, if I may, over lunch.
THE PRESIDENT: Take stock and I think what I would like an indication of is how much time you need.
MR HOLMES: Yes.
THE PRESIDENT: We will of course hear from the other parties about that, but speaking entirely for myself, and we will discuss it ourselves, I am not comfortable in cutting short submissions in circumstances where we are gaining benefit from those submissions and you are not wasting our time, and to be clear, no one has wasted our time here but if you were making points that were not helping us, then I am afraid you would be getting a rather different response, as would any of the advocates, but we are assisted by this. So, you can take it that we would be looking sympathetically to finding more time, but I think --
MR HOLMES: I am grateful for that indication, sir.
THE PRESIDENT: The problem that you have repackaged now is we may be able to respect the fact that we are coming up way beyond the end of term in a different way. If one is going to overrun anyway into the new year then we obviously do not stretch hours and we can reflect the fact that we are already using two days of non-term time in any event. But we will discuss it later on.

We will rise until 2 o'clock.

(1.14 pm)

(Luncheon Adjournment)

(2.04 pm)

THE PRESIDENT: Mr Holmes.

MR HOLMES: Sir, may I first of all return to the housekeeping issue that we canvassed before the short adjournment.

THE PRESIDENT: Yes, of course.

MR HOLMES: I have discussed with my colleagues and the position is that on penalty and on the Allergan hold-separate point, my learned friend Mr Bailey has at least half a day of material to accommodate. I am not confident, given the current rate at which my submissions are progressing, that I can comfortably accommodate my submissions in the time available, even assuming that the replies are postponed, working on the basis that I know the Tribunal has indicated that your preference would be to stop at -- for completely understandable reasons -- lunchtime on the Friday.

THE PRESIDENT: Yes.

MR HOLMES: We have thought of a few possible ways forward. I have not, I am afraid, had an opportunity to canvas these with any of the other counsel and you may wish to hear from them in relation to these options.

One solution would be for me to continue with market definition today and get that out of the way. We could deal with part of dominance perhaps, countervailing buyer power, which is a discrete topic. That would be an option and one then could perhaps interpose Mr Bailey, who has a discrete block of material which can be contained without a risk of it overrunning into the new year on the hold-separate question and on penalties. We could then resume with further time to deal with the remainder of dominance and the abuse at a convenient date in the new year.

There is a further piece to the jigsaw, which is that you invited Ms Demetriou to comment on the *Oxera* report, which she has now considered, and she has ten minutes of submissions, which, with the Tribunal's permission, she would wish to make at some point.

THE PRESIDENT: Yes.

MR HOLMES: There is also an option, it is one to consider, that we could have replies in relation to the agreement side of the case this side of Christmas, which is effectively now concluded, but we could bifurcate the case, if you like, and resume the balance of dominance and abuse in the new year.

While it is regrettable, sir, I do, I am afraid, having taken stock, reiterate my submission before lunch

that it is difficult to see how fairly the submissions of the CMA can be contained within the available time.

THE PRESIDENT: Frankly, Mr Holmes, what you have been saying is you can re-order the time in various different ways but however you re-order it, you still need more time in the new year. So I am not going to comment on the re-ordering, except to say it sounds to me like it is a little bit too fiddly to really work.

We have discussed this over the short adjournment and what I am saying now I am going to obviously allow the other parties to push back on, but I am reminded of the exchange that Ms Ford and I had at one of our case management conferences where Ms Ford indicated in pretty clear terms the value that her clients attached to oral advocacy and I hauled up the white flag of surrender and said I was not going to pushback too hard on the adequacy of written submissions.

I think the past few days have shown that Ms Ford is right and I am wrong, that there is significant value to be attached to oral submissions, no matter how good, and they are obviously all good, the written submissions that we receive in both opening and closing.

So our provisional view is that we must find more time. The difficulty is finding it. I am not going to go into the ins and outs of the diary problems that we

all have, but you can take it that they are substantial.

MR HOLMES: Yes.

THE PRESIDENT: So what we are prepared to do is we are prepared to find three days to accommodate all of the remaining submissions in this case. The hope would be that we can preserve an early removal on Friday so we can debate that, but the aim would be to rise at 1 o'clock on Friday and then have three days, one day of which would be allocated to replies, the other two would be for the CMA.

I am afraid we would have to look at the diary over the January, February and March period and that is, I readily accept, highly unfortunate, but I am afraid we would not be able to manage consecutive days. I will not go into the ins and outs of why. Take it from me we have obviously got on board the desirability of that, but we cannot do it. That is why we have got this protracted period of three months in which to conclude these submissions and the reply submissions.

If we could find three days at the beginning of new year, well that would be fantastic, but I am afraid that is just not possible.

So I am going to invite you, I think, to continue. I am not going to order this, but I am going to let the other parties consider whether they want to pushback on

that or not. I should indicate that although this is a provisional view, it is a reasonably firm provisional view, because I am not comfortable in imposing a guillotine on you, Mr Holmes. I obviously have the power to do so, but I do not think it would be judicially the right course to do so. That is why you are not getting the sort of pushback that you might otherwise have expected, but the parties should know where I am coming from. Obviously we will hear from you if you want to make an argument that these days are not necessary, but I think you should proceed on that basis and carve up your submissions as you wish, but my feeling is probably best to stick to plan A and just go through it in the order that you were thinking about, but on that regard, I am in your hands.

MR HOLMES: I am very grateful, sir, and I will confer if I may with the rest of the team, because there are specific diary reasons why it may be necessary to rejig things and take them in a slightly unusual order.

THE PRESIDENT: I understand.

MR HOLMES: If the Tribunal is content with that.

THE PRESIDENT: Absolutely, I mean, I think we all know our own diaries and they are always problematic. If you can do anything to make the position less worse, then that is obviously helpful.

MR HOLMES: I am grateful, sir. So I will resume then where we left off with your question, if I may, and let me do the best with it that I can. I have no doubt the Tribunal will push back with further queries if I do not do it justice.

The first point, first and foremost, we say that in all instances of market definition the task is determining the sufficiency of competitive constraints. I do not think your question was in any way suggesting that that was not the case.

The second point is that as part of that process there is invariably an element of considering product characteristics. I said that we did not take issue with that submission of Auden's insofar as it went. One needs to look at the clinical substitutability of products.

That need not, I think, be characterised as subjective, because there will often be authoritative guidance to which reference can be made. In this case, the indications from bodies within the prescribing community, which present a fairly concordant picture, and that will be of some assistance.

Moreover, the Tribunal has the point that the findings in the Decision in relation to clinical substitutability are not really the target of any

challenge by way of appeal in these proceedings. There is no clinical evidence suggesting that the CMA got it wrong.

It is true that Ms Ford took you to some contemporaneous documents and I will need to go to them as well, but in my submission, they do not come close really to calling into question the findings on the clinical questions that were made in the Decision. Of course, I do not need to say this to you, sir, you are aware that this is not a de novo appeal and insofar as findings in the Decision are not subject to challenge then they stand.

THE PRESIDENT: Indeed. Let us take a case where you do not really have a close functional equivalence, but, nevertheless, you have substitutability. Let us take modes of transport and we have, let us say, for the underground a SSNIP applied, because one needs to work out what the substitutes are for the underground. One might have all kinds of alternatives, cycling, walking, the train, or cars, which are not, in terms of the way they work, very clear substitutes for one another. Obviously, there is a broad similarity, but actually you do not know ex-ante what actually is a substitute for the SSNIP to the tube price without actually doing something of the enquiry.

The concern I have got about functional equivalence and the subjectivity label that I attached to it is that one is saying, yes, they are the same, but at the end of the day the predicate of market definition is substitutability in the eyes of the consumer.

MR HOLMES: Yes.

THE PRESIDENT: The problem we have got here is we do not have a typical consumer so we are going to have to do something different in order to work out market definition. Of course I understand that you are saying the CMA has found these to be clinically speaking similar. Fine, I do not think anyone is pushing back on that. I think it is more the degree of insight that that gives to the question of substitutability.

MR HOLMES: Yes, I understand, sir, and it brings me to my second point. Obviously, what the CMA has found is that there are differences in clinical substitutability which set other products apart from hydrocortisone tablets and I will take you through what is said about that.

THE PRESIDENT: Yes.

MR HOLMES: But in any event, what one looks at for the purposes of defining any market, once one has identified particular products with similar objective characteristics, is how in terms of consumption patterns and in terms of price different possible substitutes are

seen to interact with the focal product. So you might, having defined your examples of alternative transport modes, look at particular natural events that illustrate how demand switches between the focal product, here the London Underground, and other options which exist as potential substitutes and have been identified at your first stage.

One example might be, for example, how London bus volumes increase, if their price is held stable or is subject to a different increase, and that will all shed light on how the competitive constraints operate.

If you see that passengers continue to travel by the tube and there is no discernible impact on the numbers of people travelling by bus, that tells you something very useful about the degree of competitive interaction between the tube and buses.

In the same way, we say, the data on volume trends and price trends can be instructive in relation to pharmaceutical products, notwithstanding the trifurcated nature of demand. Because when looking at the prescribing level, it is not as though there is any one person in the driving seat in reality. There are the consultants, but the consultants work within the NHS and the NHS has its own priorities and concerns which are partly motivated by price and they will determine the

extent to which they seek to influence prescribers so as not to prescribe certain products in preference for other products.

So you are left with, as in many, many markets, different considerations pulling on the demand side which will influence the choices that are made. On the one hand, clinical substitutability: are the products good at treating the patient? Then there will also be considerations about the price of the product: so is the advantage of one product over another product sufficient to justify paying a very significantly different price?

The volume data do in my submission in this, as in other contexts, provide something resembling an objective measure. Obviously, they need to be carefully assessed. They need to be considered in their context having regard to the complexities that we have just been discussing. But they still provide a clear indication of the choices that are actually being made, the revealed preferences of the consumer side of the market, understood as the NHS, which is concerned both with treating patients in the best possible way and in carefully stewarding the NHS's scarce resources.

So that is the way in which the data on consumption patterns, volumes and prices, in my submission, are to be read together with the clinical indicators.

My submission to you will be that that combined package presents a pretty compelling case in favour of concluding that the market is confined to hydrocortisone tablets and it goes back to the pricing insensitivity and steady volume trends that we saw earlier. That shows both that prescribers are consistent with the clinical evidence that we have seen, the first line nature of hydrocortisone, the fact that hydrocortisone tablets have particular clinical advantages over other corticosteroids and over Plenadren. Prescribers are opting for hydrocortisone tablets rather than those other things in overwhelming numbers. That is the overwhelming proportion of where the demand choices are going in this market considering who is in the driving seat, the person making the choice.

That is partly conditioned by price. It is obviously right to consider price and what that shows is when you take into account the clinical considerations relating to Plenadren on the one hand and hydrocortisone tablets on the other, and the price, there is no prescription of Plenadren beyond a tiny proportion reflecting a specific category of patients for whom hydrocortisone tablets and Plenadren are not substitutes. They are not substitutable for clinical reasons, because the specific advantage that Plenadren

has is this narrow use case where the patients will not maintain compliance with thrice daily dosing. It is more expensive even than the very high prices that hydrocortisone tablets reached.

In consequence, people were not buying. There was no competitive interaction between Plenadren and hydrocortisone and that, we say, is conclusive evidence that they are not in the same market, notwithstanding the very specific characteristics of the pharmaceutical sector.

Now, you may well come back on that, but can I just briefly address you on the Rolls-Royce instance?

THE PRESIDENT: Yes, please do.

MR HOLMES: The Tribunal has well in mind that in broad differentiated product markets, consumer product markets in particular, like cars or laptop computers, you are going to have products ranging from the budget to the bespoke. You are going to have a huge range of price points in between with different quality attributes along the way.

THE PRESIDENT: Yes.

MR HOLMES: Depending on the purpose for which you are defining the market, you will very often conclude that there is a broad market and the reason for that is a specific methodology which is often applied in those

types of market to which Professor Valletti made reference, the chain of substitution methodology, where you consider a series of SSNIP analyses, sometimes quantitively, sometimes in a more qualitative way, to see whether there is a chain of substitution between the different products so that each constrains the other between the two extremes.

That is how you can end up with a conclusion in these markets that a high-end laptop is in the same market as a low-end laptop or a Mini in the same market as a Rolls-Royce, not always. You may find that the links are just too wide, that there is a break in the chain of causation and then you have two separate markets. This is all set out in the notice on market definition, as you are aware, and in the OFT guidelines.

So that is a way in which this is dealt with. There is guidance on it, which we can provide you with a reference to in a case that I was involved in before this Tribunal, one of the *BCMR* cases, an appeal brought by BT where there was discussion about how this chain of substitution process is to be applied and the Tribunal's economist, no doubt sensibly, rejected the submission I was making about that and gave guidance on how you go about chain of substitution analysis in differentiated markets.

But this case is not a case where chain of substitution, in my submission, is a particularly helpful one, because there is not really a chain of products, there is not a range of products that we are considering here.

There is the corticosteroids and we will see when they are prescribed and they are really prescribed as alternatives in a different use case and there is Plenadren, which is again prescribed in a different use case. We accept that Plenadren and hydrocortisone tablets could be used in a common use case, albeit with some specific medical disadvantage, clinical disadvantages, for Plenadren, which make it particularly suited to a hospital setting, the monitoring problem.

But the fact is that the price points are wide apart and there is no evidence of any substitution in practice between them when you look at the volume trends in this market, despite the rising prices in hydrocortisone tablets.

So we say that the market definition is robust here, really applying standard techniques in a way which is, nonetheless, modulated to reflect the specifics of market context. I was reminded that of course the case law makes very clear that one always needs to consider matters in the light of the relevant context. You look,

for example, at the formulation in *Aberdeen Journals* which Ms Ford showed to you.

It is something we can perhaps pick up as we go along, but that would be any initial stab at an answer to your question.

THE PRESIDENT: No, that is helpful. I suppose the only question I have got at this stage is I take your point about a chain of substitution analysis. That works in a situation where you can be confident that the prices of the differentiated products are operating in a competitive market. One obviously needs to be extremely careful in using price as an indicator where there is a concern that the price of the products, the focal product and of course the potential substitutes that one is looking at, are not at a competitive price. It is a sort of a variant on the cellophane fallacy.

So the reason I am pressing you on Plenadren is not so much because it is a better product, bearing tangential relationship with the Rolls-Royce and the Mini. The reason I am pressing you on it is because I am concerned that one cannot reliably regard the price of Plenadren, as well as the price of hydrocortisone, as necessarily a competitive price, not because of any allegation of market abuse, anything like that, but simply because of the peculiarities of the market that

you have described very clearly this morning.

So really what I am saying is, leaving on one side the clinical differences that you have mentioned and which I am sure you will go to, if one leaves that on one side, one has got a product, Plenadren, which is better for a small subset of people, but on my assumption equally good for everyone else, and the reason it is not prescribed or recommended to be prescribed is simply because it is more expensive.

If you are worried about the excess price of Plenadren, then you could say you are placing too much weight on that as a differentiating factor that renders it not a substitute.

MR HOLMES: So, taking that in stages, sir. First of all, as we will see when we come to abuse, which now I know may be some way down the line, the CMA indeed relies on a lack of competition in relation to Plenadren as a consideration when one comes to look at comparators at the unfair when compared limb of the *United Brands*' test.

But looking at the market definition stage of this process, market definition is obviously the art of the possible. There is what prices might ideally be and what prices actually are. Sometimes markets need to be defined in the context of existing dominance and that

raises the spectre of the cellophane fallacy.

To be clear though, on the topic we are on here, we are looking not at -- so we have got hydrocortisone tablets and my submission is that despite hydrocortisone's rising price, its high price, there is no substitution away from it to other products.

So, the specific concern that arises in relation to the cellophane fallacy, which is a concern that you will see switching away from the focal product, because its price is already so high and that will lead you to defining an overly broad market, just does not arise in relation to this specific piece of the jigsaw.

On the contrary, what you see is extreme price insensitivity for hydrocortisone tablets, which explains the conduct that we see here. That is why you see these enormous price increases, because the demand side does not go anywhere.

There is a question I can see about whether Plenadren might compete with hydrocortisone tablets if it were at a different price point, but I am not aware of anyone having suggested that for the purposes of defining competitive constraints on the focal product, one needs to try to arrive at an assessment of the competitive price for the other substitute products. You are trying to understand the competitive constraints

on hydrocortisone tablets and the fact is that Plenadren, because of its price and it is targeting of a specific use case, is just on another planet. It is not in the same market.

It is no part of a sensible market definition exercise to understand the competitive constraints on hydrocortisone tablets that one has to abstract away from that reality in relation to a substitute product, rather than the focal product.

THE PRESIDENT: Yes, thank you.

MR HOLMES: That I think allows me to address a submission that Ms Ford made that because Plenadren is not included in formularies and is not available, it is unsurprising that there is no switching and that switching is therefore, uninformative for the purposes of market definition. The possibility of switching has been ruled out. That was her submission.

But in my submission that rests on the fallacy that price is not a relevant consideration for deciding the choices that are made. Part of the demand side here is the CCGs who pay and they are helping to shape the choices that can be made by prescribers. They inform which products are substitutes. It is precisely because, as one of the factors, Plenadren is at a different price point, a higher price point, that even

despite the audacious price increases that we have seen, hydrocortisone tablets have never seen a competitive interaction with Plenadren.

That is part of the process of market definition on standard principles and to leave it out of account would be to ignore how competition actually plays out, the choices that are being made which determine the competitive constraints that operate, what parameters of competition these products compete on. It is partly price. The choices that are being made on the demand side are ruling out Plenadren, because it is too pricey and that is why you do not see substitution. There is no competitive interaction there and it is why Plenadren is outside the market, among other reasons.

Another important piece of the jigsaw is the clinical differences which we have seen, which then also inform the assessment of the data, the lack of switching, the volume steadily rising, despite rising hydrocortisone tablet prices. You have not reached a point where anyone is switching away to Plenadren.

I have to say if you ever did reach that point then maybe the cellophane fallacy would come into play, but it is not the fact situation which we faced when the CMA was deciding whether other treatments are within the same product market as hydrocortisone tablets.

If we could go back to the Decision, please. We were considering the analysis of Plenadren and that was on page {IR-A/12/78}. You have seen the tables with the very low usage of Plenadren. The Decision then proceeds to consider other forms of hydrocortisone. I do not think I need to dwell on those, because the two products that are relied upon as potentially falling in the same market, in defining the errors that the CMA supposedly made, are Plenadren on the one hand and the corticosteroids on the other.

So, I think I can go to the discussion of the steroids, which begins at page 81. {IR-A/12/81}. You see at paragraph 3.137 that like Plenadren they are low volume alternatives used only in specific situations with clear clinical drawbacks. Specifically, they are prescribed in exceptional circumstances where a patient is intolerant or allergic to hydrocortisone or alternative treatment is needed, again for compliance reasons.

The drawbacks are in paragraph (a) of 3.137:

"It is not possible to monitor drug levels in a patient's blood and therefore determine if the correct dose has been administered; and

"their longer half-life [of the other steroids] increases the likelihood of adverse metabolic and

overtreatment-related side effects."

Then if you look down the page to footnote 201, you see the basis on which these findings are made in the evidence and you see it is a response from the Society for Endocrinology, the specialist body that consists of clinicians active in this field.

At paragraph 3.138, a further difficulty. These alternative steroids are also unsuitable for young patients with adrenal insufficiency as they may cause growth retardation.

The consequence of these clinical problems is, as seen as 3.139, they are used in no more than 5% of patients with adrenal insufficiency. So again, a consideration of the clinical evidence.

Ms Ford's case is the CMA should look at the clinical substitutability of these products. In my submission, that is exactly what the CMA has done. It has looked at objective characteristics and this ground of appeal therefore fails *in limine*, because it misrepresents what the CMA did as part of its market definition exercise.

So that is the CMA's consideration of the relevant context. In my submission, it shows a careful supply session of clinical interchangeability by reference to the other available treatments for adrenal

insufficiency.

In the light of that evidence, the CMA turns to consider whether the other treatments were in the same product market as hydrocortisone tablets in section 4 of the Decision starting at page 311. {IR-A/12/311}. As can be seen from the heading above 4.41 at the foot of the page, the CMA begins by looking at the qualitative evidence and at 4.41 itself one sees from the final three lines that:

"This includes examining whether other products were perceived by prescribers to be substitutable with full label hydrocortisone tablets from a therapeutic perspective."

So again, the suggestion that we have looked exclusively at price or focused unduly on price to the exclusion of other non-price factors, in particular clinical considerations, it is just not true. On the contrary, they were a key plank of the CMA's examination.

Turning over the page at 4.42, the CMA turns to consider the ATC classification and prescribing with a particular focus -- sorry, the two heads at 4.42:

"The ATC classification, and.

"Prescribing: product characteristics and a medical recommendations."

So, an unpromising basis for Ms Ford's contention that those were overlooked.

Immediately below, the CMA explains the ATC system. It notes at 4.43 in accordance with the case law the ATC can be regarded as a starting point for defining the relevant product market in the case of pharmaceutical products. We have seen what the *Astrazeneca* case showed about that.

At 4.44 the levels of the ATC system are explained.

At 4.45 the point that which level is used depends on whether medicines in a certain class have the same therapeutic use as well as other factors, such that using level 3 or 4 may be appropriate in different circumstances. As we saw in *Servier*, no criticism attached to the use of level 5, the specific active ingredient.

Then at the foot of paragraph 4.45, the CMA identifies various medicines from the fourth level class -- I think we have to go down, sorry, to the following page -- glucocorticoids. They are hydrocortisone in its various forms, Prednisolone, Dexamethasone and various other corticosteroids.

So, the CMA did have regard to the ATC system and it looked specifically at level 4.

Ms Ford sought to advance two criticisms of that.

First, she suggested that the CMA had only paid lip-service to the ATC system. You will recall that was her submission. It was, she said, required to do a more granular assessment, taking each of the 16 products identified at level 4 in turn, seriatim.

With respect, we say that is an obviously formalistic approach. The CMA was entitled to focus on the specific products which the wider evidence before it showed to be serious candidates as potential substitutes. Auden has not identified any specific candidate drug which it says the CMA should have considered as a serious contender but did not. On the contrary, the only two products on which Auden focuses were both ones that the CMA did consider carefully and in detail.

Secondly, she criticised the CMA for going beyond the ATC system and considering separately different forms of hydrocortisone and excluding them from consideration: Plenadren for example.

But again, this is to put form over substance. The CMA's consideration of the evidence showed that prescribers did differentiate between the various forms in which hydrocortisone is administered. The CMA obviously could not ignore that evidence. It was right to consider it and to assess its implications for the

relevant market as part of the very exercise that Ms Ford says should be at the heart of market definition for pharmaceutical products, looking at the clinical use.

The fact that the market definition arrives at an assessment which does not match any level of the ATC system is not in itself, in my submission, a valid legal objection. There is no formal legal requirement to focus on any particular level of the ATC system. What matters is the substance of the CMA's market definition and whether that is right. The ATC system is only a starting point, a preliminary indicator. The CMA had regard to it, but was not required to define the market by reference to the ATC system or any particular level of it.

Returning to the Decision, the CMA next considers prescribing considerations and at 4.47 you see that it recognises that:

"Any decision to substitute between hydrocortisone tablets and other potential medicines ... would be made by prescribers, [typically a specialist consultant in a hospital setting]."

The prescriber takes account of a range of considerations, range of factors, including therapeutic substitutability and individual patient response to

treatments.

At 4.48, you see that the discussion covers hydrocortisone tablets, Plenadren, other forms of hydrocortisone and other corticosteroids.

At page 314 the CMA draws conclusions from the evidence set out in section 3, which I have shown to you.

At paragraph 4.50 you see the point that hydrocortisone tablets are considered the first line treatment and that a decision to switch patients with adrenal insufficiency away from hydrocortisone tablets or commence treatment with a medicine other than hydrocortisone tablets would need to be made by an endocrinologist, a hospital consultant, and would only be done in rare instances where a patient is not able to tolerate hydrocortisone tablets. That is the CMA's finding on the clinical evidence, given what it was told by the doctors.

So, from the point of view of clinical substitutability, it is clear that Auden's complaint that the CMA neglected this factor and focused unduly, or exclusively, on price is simply wrong.

At 4.51 and 52, the specific evidence relating to Plenadren is rehearsed.

At 4.52 the CMA records that Plenadren is not

routinely or commonly prescribed. Not recommended by NICE or the specialist clinical body. Much more expensive and the combination of price and lack of data on efficacy have resulted in its not being recommended, which explains the very low volumes prescribed and dispensed.

At the end of the paragraph, I think over the page or I think just --

Not included in the formularies and that further limits interchangeability between the two products for prescribers using those formularies.

Then moving down the page at 4.54, the CMA analyses -- (Pause).

Sir, I can give you the references, but I will soon be going to other documents so it may be worth sorting this problem out before we continue.

THE PRESIDENT: Yes. (Pause).

MR HOLMES: Sir, there appears to be a technical issue.

THE PRESIDENT: There does. Would it assist if we rose?

EPE OPERATOR: Yes, five minutes, please.

THE PRESIDENT: All right, we will rise for five minutes.

MR HOLMES: I am grateful.

(2.52 pm)

(A short break)

(2.57 pm)

MR HOLMES: Sir, doing the best we can, what we are going to do is work off a copy of the Decision which I understand is local here, but fairly soon I am going to run out of road on the Decision and then it will be into documents and then, unfortunately, I do not know quite if things have not resolved themselves we may then be in some difficulty.

THE PRESIDENT: Is help on its way?

EPE OPERATOR: It is.

THE PRESIDENT: Okay, we will proceed.

MR HOLMES: So if we could go, please, to page 314 of the Decision document {A/12/314} and look at paragraph 4.54, maybe the next page. So this is where the CMA turns to consider the other corticosteroids and again it notes the clinical disadvantages: the inability to monitor, cannot be monitored accurately, and increase in the likelihood of adverse metabolic side effects.

At 4.55 the consequence for demand. Other corticosteroids are only recommended as a second line treatment where hydrocortisone tablets are not well tolerated and, therefore, used only for a small proportion of patients where hydrocortisone tablets cannot be used.

So the Tribunal has the obvious point that they are therefore, not substitutes at all. They cannot be used

in the same circumstances as hydrocortisone tablets, because of their clinical drawbacks. They are used where hydrocortisone tablets cannot be used, so not potential substitutes.

So in overview, the CMA did look at clinical substitutability and it had good evidence, unchallenged in these proceedings, to show that Prednisolone was not a good substitute for hydrocortisone tablets from a clinical perspective and in the case of Plenadren, it was not in fact prescribed, because of its price, its clinical drawbacks and the fact that its clinical advantages arose only in one narrow use case; namely, inability to comply with dosing regime.

Now, in conducting this assessment, the CMA had appropriate regard to the ATC system. It identified other treatments at level 4 of the system and considered them and, in my submission, Auden has failed to show any error, legal or otherwise, in any aspect of that qualitative assessment.

The CMA then turns to consider quantitative evidence and it looks at volume trends for hydrocortisone and it looks also at how pricing affects those volume trends and you see that on {A/12/320}. This is the figure we saw earlier, the price and the volume trends.

You have my submission on this. The volume trend

does not show any significant interruption or variance. Notwithstanding the price increases or the price falls, the demand is stable and inelastic.

Turning on to page {A/12/322}, you see the conclusions that the CMA draws from that in paragraph 4.72:

"Had other medicines in the relevant treatment area been substitutes for full label hydrocortisone tablets, it would be expected that hydrocortisone tablet volume trends would change after prices changed. Therefore, taken together, these price and volume trends show that there was little or no substitution between hydrocortisone tablets and the other potential medicines in the treatment area."

So, the quantitative evidence bears out the qualitative evidence available to the CMA on prescribing practices. No evidence of other products being prescribed in any significant volume, notwithstanding the huge increases in price of hydrocortisone tablets. If the other products were appropriate clinical substitutes for any significant number of patients, one would have expected to see switching away from hydrocortisone as prices rose. We have seen that price was a factor that influenced prescribing with CCGs. They decided not to include Plenadren in formularies for

precisely that reason.

Further quantitative evidence confirms the lack of any specific interaction with Plenadren and that is set out at 4.73. At (a) Plenadren shows stable low usage below 1% since launch in September 2012.

At (b) Plenadren did not affect prices or volumes of hydrocortisone tablets.

So in my submission, no fair criticism can attach to the CMA's consideration of quantitative evidence, alongside the qualitative evidence on clinical substitutability. The volumes show what prescribers were doing in practice and the lack of any impact on volumes as prices rose then fell, reinforces the point that hydrocortisone tablets were not realistically replaceable by any other steroid or treatment. They were a market of their own.

There is one further aspect of Ms Ford's case on the alternative treatments that I should deal with. She tried to suggest that the CMA was wrong in its assessment of therapeutic substitutability. She did that by showing you various snippets from an assortment of documents. Now, as an initial observation that, with respect, is a desperate strategy. The CMA's views were informed by the evidence of the Society of Endocrinology, the professional body in this field, and

they were borne out by the volume data.

Auden has not put in any expert evidence to gainsay the CMA's assessment of clinical substitutability and casting around for passing references in documents is no substitute for that.

In any event, if one looks at the documents, they are not at all helpful to Auden's case. We need to go through them one by one and for this I will need a return to the electronic bundle. Is it now working?

EPE OPERATOR: It should be all right.

MR HOLMES: Excellent, good.

So if we could go, please, first of all to one of the documents she showed you, the Society of Endocrinology's response to the CMA's request for information. That is at {H/915/1}. She laid emphasis on the response to the second bullet of question 3. So if we could enlarge the bottom of the page, you see the question is:

"What alternative treatments/medicines are considered, if any (including other corticosteroids or modified release hydrocortisone tablets)?"

She notes that Prednisolone is mentioned there, but if you look at the first bullet the question is:

"What treatments/medicines (if any), are used prior to considering whether to prescribe hydrocortisone

tablets?"

The response is:

"None. No other prior treatment option as hydrocortisone is the most appropriate first line treatment [option]."

Then look at what is said under the second bullet about Prednisolone. The Society explains that it is used when patients are intolerant/allergic to hydrocortisone or for circadian dosing in some patients with a specific condition, congential adrenal hyperplasia:

"Prednisolone is considered if compliance is a problem with multiple dosing as it has a longer half life, however, this also means it has potentially higher glucocorticoid over treatment-related side effects."

So, what this document in fact shows is that hydrocortisone is the preferred treatment. There is no other product, no other treatment considered prior to it. The other products have specific drawbacks, including overtreatment-related side effects.

Moreover, Prednisolone is not identified as a substitute for more patients, but as an alternative therapy where hydrocortisone cannot be used because of intolerance or allergy or compliance problems.

Looking up the page at the response to question 2,

that explains why 95% of patients are on hydrocortisone with only the remaining 5% either on Prednisolone, Dexamethasone and 1% are on Plenadren.

So this evidence is entirely consistent with the conclusions arrived at in the Decision.

She also took you to {H/900/1}. This was the response of a consultant in endocrinology to an information request from the CMA. She relied on the statement in response to question 3, if we could enlarge question 3, please, in the middle of the page:

"Hydrocortisone is the only treatment that is accepted widely in endocrinological circles for the treatment of Addison's disease and hypopituitarism."

She did not rely on that at all. That is what I rely upon, sir. What she relied upon is the statement that Prednisolone is occasionally used. You see that in the second sentence of paragraph 3.

But the point is that if you look at the first sentence:

"Hydrocortisone is the only treatment that is accepted widely in endocrinological circles for the treatment of Addison's disease ..."

That is adrenal insufficiency:

"Occasionally Prednisolone tablets are used."

It is true that it says that, but then the drawbacks

that we saw also in the previous document:

"They cannot be monitored so accurately whereas hydrocortisone can be measured in the blood."

So again, the alleged substitute product, Prednisolone, relied upon by Auden has a clear clinical drawback and for that reason it is used only occasionally.

Again, this casts no doubt on the CMA's market definition. She took you to {H/816/1}. These are practice guidelines from the Endocrinology Society dating from 2016. She took you to page 2, paragraph 3.3. {H/816/2}. If we could enlarge the middle of the page. You see that identifies Prednisolone as an alternative to hydrocortisone.

But could we please look at page {H/816/11} in the right-hand column where a further explanation is given of this page. If you look at the end of the paragraph under "Evidence" so if we could just -- on the right-hand column, "Evidence", end of the first paragraph. You see that it says there:

"In most industrial lied countries hydrocortisone is the preferred pharmacological replacement agent, but cortisone acetate is also in widespread use. In a number of countries, only Prednisolone is available."

So the point is that these guidelines are written

for use around the world and in many countries Prednisolone may have to be used. It may be the only available product. But in the developed world it is quite clear, consistent with all of the clinical evidence in the Decision, hydrocortisone is the preferred agent. So this does not detract in any meaningful way from the CMA's findings as regards the situation in the UK.

Ms Ford also took you to a BMJ editorial at {H/564/1}. She relied on the conclusion on page 2. {H/564/2}. You see there midway through the final paragraph:

"Plenadren is the least cost effective and hence has no current place in the treatment of adrenal insufficiency. Hydrocortisone was the most cost effective option until 2008, when its price increased 60-fold, but prednisolone should now be the first line option for glucocorticoid replacement therapy."

You see that, sir. So three points about this. First, it does show that cost considerations are actively considered when deciding how to prescribe. In my submission, that supports the CMA's reference to price data when deciding whether alternative treatments are in the same market as hydrocortisone tablets. So it is a reason why Auden is wrong to suggest that the CMA

paid undue regard to price when assessing the borders of the relevant market in this case.

Secondly, this paragraph also supports the CMA's conclusion that Plenadren is not in the relevant market. The conclusion is really trenchant:

"Plenadren is the least cost effective and hence has no current place in the treatment of adrenal insufficiency."

That is borne out by the very low levels of prescribing recorded in the Decision, less than 1%.

Thirdly, although the authors favour switching to Prednisolone, it is clear from the evidence in the Decision that that represents a minority view. The price increase did not lead to such switching. That was my point about the objective measure that is provided by the volume data. The clinical drawbacks identified by the Society of Endocrinology led to Prednisolone not being prescribed in place of hydrocortisone. There were no volume effects observed in practice on hydrocortisone's volumes, despite the price increases.

When considering the sufficiency of the competitive constraints on hydrocortisone tablets, this evidence, this BMJ editorial piece, clearly cannot be preferred to the weight of opinion and quantitative trends recorded

in the Decision.

Finally, Ms Ford relied on NICE guidelines at {H/998/13}. You see in the second bullet that glucocorticoid and mineralocorticoid replacement are needed. Sorry, in the first bullet, rather. Glucocorticoid and mineralocorticoid there at the top of the page.

At the second bullet there is consideration of glucocorticoid replacement. Hydrocortisone is usually used, but longer lasting glucocorticoids, such as Prednisolone and Dexamethasone, are sometimes used.

Then looking down the page you see that only dosages for hydrocortisone are given. In my submission, that is again, entirely consistent with the CMA's market definition. Hydrocortisone is the preferred treatment. Prednisolone or Dexamethasone are occasionally used and we have seen elsewhere when that tends to happen in cases of intolerance and what the drawbacks are in terms of ability to monitor blood levels and risk of overdosing.

But this document, and indeed none of the documents to which Ms Ford took you, detract from the conclusion that hydrocortisone tablets are in a market of their own.

So, we say the conclusion is clearly right and it is

a striking fact that none of the experts called into question this aspect of the market definition, although they were all alive to the role of prescribers as the first line decision makers. Auden has not advanced any clinical or economic expert evidence in support of its market definition case.

That leads me to the second market definition question, unless you have any questions on that aspect of the case.

THE PRESIDENT: No, thank you.

MR HOLMES: This concerns the CMA's conclusion as regards 10mg and 20mg dosage of hydrocortisone tablets and, specifically, Auden challenges the CMA's conclusion that there were separate markets for 10mg and 20mg tablets following independent entry from mid-2015.

Auden's point was that nothing had changed about the clinical attributes of 10 and 20mg tablets following entry: so why the change of market definition?

Ms Ford took this point lightly in her oral closing submissions, but, with the Tribunal's permission, I will spend a little longer on it, because it was one of the features that you identified, sir, on which you indicated the Tribunal was interested to hear submission.

THE PRESIDENT: Yes.

MR HOLMES: You said it was an oddity that 10 and 20mg tablets are treated differently in the Decision and I quite understand why you said that. They are the same active ingredient, just different doses.

So, I should explain to you why that is. So the Decision followed a familiar pattern in analysing 10 and 20mg tablets. It did so by reference to clinical considerations on the demand side and, for these purposes, the focus is again on prescribers as they specify the dosage, thereby binding the dispensing pharmacist's hand.

If we could go first, please, to {IR-A/12/74}. You see at paragraph 3.123 hydrocortisone tablets are immediate release so that hydrocortisone is rapidly absorbed and delivers peak court sol values in the blood approximately half an hour after administration.

At 3.124 the standard adult daily dose is between 15 and 25mgs and that needs to be taken two or three times a day to sustain blood cortisol levels. So, typically, 10mg on waking, because that is when you have the cortisol spike, 5mgs at lunchtime and 5mgs in the late afternoon and that reflects the body's natural rhythm where cortisol is highest in the morning.

This is done, as explained in the next sentence at the top of the page, by halving or quartering tablets.

Then the key point:

"Due to the frequent need to split the tablets into small doses (for example, 5mg or 2.5mg), 20mg ... tablets are not commonly used in practice, other than in specific cases when higher dose ... are [needed] on a short term basis."

The consequence, at paragraph 3.125, for the comparative demand for the two strengths. 10mg are the strength that is most commonly used, accounting for 96% of all packs of hydrocortisone tablets and that is then the first point that explains the market definition in relation to 10 and 20mg tablets.

There is a practical consideration that affects clinical prescribing. 20mg tablets are harder to split to an appropriate dose size. So as a result, they are not what doctors use. They are only used where higher doses are needed and so you do not need to do that fragmenting. As a result, because higher doses are only needed on a short-term basis and for occasionally uses, they account for a tiny fraction of the overall demand for hydrocortisone tablets in the UK.

Of course, that lack of substitutability, from a clinical perspective, the point on which Ms Ford lays emphasis in her appeal, points to separate markets and the CMA found that after entry. So that is the demand

side.

The second point which explains how the CMA define the 10 and 20mg markets concerns supply-side conditions for the two doses. They are treated as separate products for regulatory purposes and in order to supply each dose, a supplier needs a marketing authorisation in respect of that dose. So it is not necessarily the case that every supplier of 10mg can also supply 20mg. You need separate marketing authorisations.

In fact, if you look at the supply side of the two doses, you see that there are some notable differences. That is in tables 3.4 and 3.5 in the Decision at {IR-A/12/98}. Looking at table 3.4 you see the details of the MAs, the marketing authorisations, for 10mg. Auden/Actavis's MA was granted in February 1999. AMCo's MA dates from September 2012, but, as we know, it did not pursue independent entry because of its arrangement with Auden. So, Auden was the only supplier for the majority of the infringement period.

Alissa was the next entity to be granted an MA in November 2014 and then looking at the second column, you see that all of the entrants are skinny label. The only full label supplier is Auden/Actavis.

Looking down at table 3.5, you see that the supply conditions in relation to 20mg are initially similar,

but then they diverge. Auden, the incumbent, again has a longstanding marketing authorisation, so that matches the position with 10mg. So that initially it was the only supplier. It is true that there is another longstanding authorisation held by Waymade, but, again, Waymade's independent entry is held off until June 2015 by its arrangement with Auden.

So to that extent supply-side conditions remained broadly aligned until mid-2015: two authorisation holders, but one not pursuing independent entry as a result of an arrangement with the incumbent and, therefore, Auden preserving its monopoly.

From mid-2015 onwards, there are some differences. So you see that Waymade enters with a full label product, its authorisation having predated the orphan designation. That is in July 2015, looking at the second table, 3.5. So another full label competitor following independent entry.

There are also some more marginal differences in the timing and identity of entrants: Alissa, for example, held a licence for 10mg but not 20mg and a couple of the entry dates differed somewhat.

So supply-side similarities ending with entry and then turning now to the Decision's analysis of whether 10mg and 20mg tablets are in the same relevant market.

The CMA summarised its conclusions at 4.36 on page {A/12/309}. You see that it notes that the evidence suggests separate markets following independent entry. That is the conclusion that Auden takes issue with in this appeal. As regards the period prior to independent entry, the CMA suggests a single market, but it then goes on to note that the market definition does not make any difference in relation to dominance assessment prior to competitive entry.

That of course is because there was a single supplier in each case. Auden was the only show in town for both strengths.

Turning on to page {A/12/357}. Can we go down to paragraph 4.149, please. The CMA explains its reasons for finding a single market prior to entry and a split market post-entry.

So, at 4.159 the CMA considers the evidence regarding the demand side and you see its conclusion that there is a lack of interchangability. Four points are made in support of that conclusion.

First, while the two strengths are used to treat the same conditions, the CMA recalls that 10mg are mostly used and 20mg are only used by doctors on a short-term basis where higher doses are needed, so a different clinical use case.

Second, there is the limited substitution owing to the difficulty of dividing 20mg into 5mg or 2.5mg doses for the frequent small doses that are needed throughout the day.

And, third, there is the point that prices did not differ significantly for most of the infringement periods and that may also reflect differences in demand for the two products, given that 20mg have twice as much active ingredient, but the CMA notes that it could also be for supply reasons; namely, that while the direct cost of the active ingredient is likely to be higher for 20mg, the other costs are similar. So it did not attach much weight to that consideration.

Then over the page, fourthly, on the demand side, the important point that prescriptions tend to be by tablet strength and there is no scope for substitution by pharmacists when dispensing.

So in practical terms, the CMA found that there was limited substitutability between these products on the demand side. Doctors prescribe 20mg in specific situations and not for run-of-the-mill adrenal insufficiency cases and dispensers typically cannot select which strength to supply. That would ordinarily weigh strongly against defining them as falling within the same market. So it would support the market

definition, which is specifically challenged by Auden, the finding of separate markets from 2015 onwards.

But at 4.160, the CMA turns to consider the supply side and, as the CMA notes, supply side conditions change following entry.

THE PRESIDENT: Just pausing there. The demand-side characteristics at 4.159, they -- correct me if I am wrong -- they appear to have remained constant --

MR HOLMES: They did indeed, sir, yes.

THE PRESIDENT: -- throughout the period.

MR HOLMES: Yes.

THE PRESIDENT: So that is not a basis for differentiating between before and after independent entry?

MR HOLMES: That is true, but the specific error that is alleged by Auden is the definition of different markets post-2015 and this argument -- this evidence supports different markets. Arguably it supports them -- excuse me.

THE PRESIDENT: No, point taken, but if one is looking, as we will do, at the general robustness of a market definition test, even if the outcome is defensible in terms of its outcome, one does want to be assured about the reasoning process. In other words, one wants to be satisfied that the CMA is right for the right reasons, not right for the wrong reasons.

MR HOLMES: Yes.

THE PRESIDENT: Because it might mean that the CMA is wrong for the wrong reasons, which would be -- It does seem slightly odd that one has a consistent set of demand-side parameters and yet -- I am interrupting you -- So does the explanation lie in the supply side?

MR HOLMES: It does, sir, but I should say, just in response to your observation, I fully agree. We endorse the point that you are making that the demand-side characteristics all point strongly in favour of different markets. The other point I would make, sir, I know that you have this point in mind, you can uphold the CMA's Decision if it reaches the right conclusion for reasons which are partly wrong.

In my submission, that is not the case here, but I would say that this set of reasons does weigh very strongly in favour of different markets and I quite understand why, if the CMA had gone wrong in its reasoning, the Tribunal would want to be very cautious to understand if the result were, nonetheless, robust, so I do not demur from your question.

THE PRESIDENT: I am grateful.

MR HOLMES: But, yes, the supply side considerations are the ones that weighed in this case with the CMA. You note at 4.160, over the page, that:

"The evidence on competitive conditions on the supply-side changed during the Infringements, following the entry..."

For the period prior to entry, you see at 4.161, the CMA notes that the prices of 10mg and 20mg were similar. I think if you turn on there may be a graph that illustrates that. Yes, so the red and the blue lines representing 10 and 20mg prices are broadly in step and the black line, dotted line, which is the ratio of those prices, is not far off 1, I think. So it indicates a fairly close lockstep alignment.

Then at 4.162 the CMA notes that these prices do not suggest that there were different competitive constraints during that period.

Down the page at 4.163 the CMA notes that:

"Given ... there are no other suppliers or either strength ... it makes no difference whether 10mg and 20mg hydrocortisone tablets are considered separately or as a combined product market for the dominance assessment."

Then at 4.164, for the period prior to entry, the CMA therefore adopts the widest possible market definition and treats 10mg and 20mg as in the same market. As the CMA explains in the final sentence of that paragraph:

"Given that the primary role of market definition in this case is to determine whether Auden/Actavis [are] dominant, adopting the widest possible definition errs in Auden/Actavis's favour -- if it is dominant in a wider market then it will be also have been dominant if the market is defined more narrowly."

So in brief summary, common supply conditions led the CMA to err in a favour of a single product market up until competitive entry, but that conclusion really does not affect matters, because there is clearly a monopoly for either strength during that period.

Then at 4.165, the CMA turns to consider the position following entry. It notes that the segments evolved differently from then on. The supply-side differences that emerged during the post-entry period are noted, in particular the presence of Waymade on the 20mg side leading to different competitive conditions.

At 4.166, the CMA's conclusion that based on a lack of demand-side substitutability and different competitive conditions between 10 and 20mg tablets they were in separate markets following entry.

So in other words, post-entry both demand and supply side conditions align in suggesting separate markets for 10mg and 20mg hydrocortisone tablets and that is where the CMA came out.

In my submission, for the period after entry that definition is unimpeachable, both demand and supply-side conditions point very strongly in favour of separate markets: all of the demand reasons why they are not used as substitutes and all of the differences in competitive conditions showing differences emerging in the price trends in the interaction as a result of the fact that Waymade is present in one and not the other.

Now, for the period prior you can argue the toss. The demand side was still different. It still suggested different markets, did throughout. So Ms Ford is right to say that nothing changed, but what did change was the supply-side conditions. So that whereas it did not matter before entry and the CMA found -- given the competitive conditions were the same, it erred in favour of Auden/Actavis in defining a single market. After entry, there were differences and it therefore did not adopt that approach.

Now, whether that is right, or it is wrong, we say it does not affect the period post-entry, which is what is specifically challenged. But in my submission, it is a perfectly defensible conclusion. Where supply-side conditions are the same, it is non-unorthodox to put products in the same market.

You may remember a case we did years ago, sir, the

TalkTalk case. Do you remember the different geographic markets where you had these hyper-local markets at the level of individual local exchanges and they were sorted into buckets according to the competitive conditions in each being aligned on the supply side. It is exactly the same argument that is being deployed, but nothing really, in my submission, turns on it, which is perhaps why Ms Ford spent so little time on it in her closing submissions.

I only develop it now because the Tribunal --

THE PRESIDENT: No need.

MR HOLMES: -- rightly expressed a desired to understand why 10mg and 20mg, although they are the same active ingredient, do fit in different buckets.

THE PRESIDENT: Yes, very grateful, thank you.

MR HOLMES: Sir, that brings me to the final of the three markets, the full versus skinny label tablets. This concerns the question relating to choices made by pharmacists, rather than prescribers, because here the person in the driving seat for the choice between the focal product and the substitute product is not the prescriber or the CCG. It is the dispenser. There are open scripts, open prescriptions, and the dispensing pharmacist therefore has a free-hand subject --

THE PRESIDENT: Provided they are open. But if one has

a closed prescription of course --

MR HOLMES: Indeed, there is a small group of cases in which -- and you may recall in the Boots note, there has been so much evidence in this case, but in the Boots note one of the points that was referred to there was sometimes people present prescriptions at the pharmacist that does specify a product, because they have asked for it and they are anxious about getting a different product or because the doctor has some particular preference for reasons that are hard to discern. But there the choice is taken out of the hands of the dispenser.

THE PRESIDENT: Yes, it doesn't matter because they are such a tiny part of the overall number of prescriptions that we are looking at.

MR HOLMES: Quite so, sir, nobody has suggested that it is a material consideration for the purposes of market definition in this case.

On this topic of course the appellants are Advanz and Cinven and I would like to take the topic in three stages, if I might.

First, I will briefly revisit the analysis in the Decision. Secondly, I will address you on the expert evidence and where that came out and, thirdly, I will consider whether this market definition question makes

any practical difference to the substantive analysis of the case.

So, starting with what the CMA says. The context is that at the administrative stage the CMA was faced with contrasting submissions, just as this Tribunal is. Intas argued there was a single market for full and skinny label tablets following entry, whilst Cinven and Advanz maintain that the market bifurcated into two separate markets following entry.

The CMA analysed the evidence and concluded on balance that full and skinny label tablets were in the same relevant market.

If we could pick it up, please, in the Decision at {IR-A/12/327}. The first point at paragraph 4.88 is that full and skinny label tablets are bioequivalent. They are the same product. The distinction without a difference point.

4.89, in consequence prescribers do not generally draw a distinction. They prescribe open scripts, the point you were just exploring with me, sir.

Turning over the page at 4.91, the substitution decision is therefore taken at the point of dispensing by pharmacies. So to get back to the earlier discussion, this is one of those cases where the person selecting is the pharmacist and you need to look at

their selection criteria.

The CMA then considers evidence on how pharmacies approach their choice. We will need to consider this in more detail in the context of dominance in due course. But for now the Tribunal is well familiar with the headlines, which are at page {A/12/331}. Paragraph 4.100 you see that independent pharmacies switched to purchasing skinny label based on price considerations.

At 4.101, the point that a number of the large pharmacies considered they had no choice but to purchase Auden/Actavis's full label tablets.

At 4.102, the reasons are explained. At (a) they believed they could not dispense off-label for regulatory reasons. At (b) they did not wish to stock full and skinny for reasons of administrative ease and to reduce the risk of errors in dispensing.

So just to take that a little bit more slowly. The first point is that they considered they could not dispense off-label and, therefore, for adult patients, they considered that they had to use the full label product, because that was the only product with an indication for adult adrenal insufficiency.

I should say now, I noted in the note from Cinven on the competitive landscape, I think was the title it

used, that it said that from the point of view of market definition it does not matter whether they were right or wrong about that consideration. I see Mr O'Donoghue is looking askance at that. I may be wrong, but I thought that was the position they took. There has been so much paper. If that is their position, we fully agree. It does not matter. The fact is that a large number were not prepared to -- I will find the reference. I do not want to set hares running. I can see Mr O'Donoghue clearly thinks I am wrong.

MR O'DONOGHUE: I do not want to call an open market definition, but I may be losing it.

MR HOLMES: The features of the market, you remember the oddities, but anyway we will come back to.

THE PRESIDENT: More to the point though, Mr O'Donoghue, do you agree or disagree with what words Mr Holmes has put in your mouth?

MR O'DONOGHUE: If he can say it again, it will certainly help me.

MR HOLMES: The point is it does not matter for the purposes of market definition whether the pharmacies are right or wrong about the regulatory position. What matters is what they believed to be the case and how that affected their purchasing decisions.

MR O'DONOGHUE: Yes, sir, I think that is fair, maybe

subject to a requirement of reasonableness.

MR HOLMES: Thank you. I am grateful. Then in relation to that portion of demand which was not subject to a perceived requirement to use full label, the paediatric use case where skinny could on any view legitimately be dispensed, this is where the administrative ease and the reduction in the risk of errors in dispensing comes in.

So, some of the pharmacies recognised that they could use skinny when prescribing to children and of course prescriptions will ordinarily indicate the age of the patient. So a pharmacy could identify the prescriptions where skinny label could be prescribed, but they chose not to do so, because of the risk that skinny label tablets might then be supplied in meeting an adult prescription, resulting in off-label prescribing.

It would also be the problem that you would have to have two separate product lines in stores, two separate skews, pharmacies would need to attend to this and that explains where the administrative ease and the reduced risk of errors in dispensing comes in.

Does that make sense to the Tribunal?

THE PRESIDENT: It does. Just to backtrack a little to paragraph 4.101. We have got, clearly, a difference in

approach between the large pharmacy chains and the small, maybe even individual pharmacies, in that the large chains go for full label.

MR HOLMES: Most of them.

THE PRESIDENT: Mostly, I am talking generalities clearly, and the small providers, small pharmacies, go for skinny label which is explained -- well, it seems to be explained by all parties that there is a different evaluation of regulatory risk desirability on the part of the small pharmacies as opposed to the large, in the sense that the small pharmacies see the additional revenue that they generate by going off label as sufficient to, well, offset the desirability, let us call it that, of full label. I say desirability because I do not want to get into the precise reasons for the difference between the two products.

That suggests that there is a greater degree of desire to be whiter than white in regulatory terms on the part of the large pharmacies and that may well be one explanation. But Mr O'Donoghue has mentioned on a couple of occasions the additional price control that exists in terms of margins over pharmacies and the reason I have been interested in that is I am wondering whether that could be an explanation for the increased sensitivity on the part of the large pharmacies to this

regulatory difference and let me unpack that.

If, for instance, they get more money by going for skinny label, but it is taken away from them by virtue of a moreover arching control over profits, then they may well think why not go for something which is marginally better, because it is better in terms of compliance, but if we were to get the sort of differential in terms of revenue that the small pharmacies get then we might do exactly what the small pharmacies do.

Now, I put that out there. Of course, we have no information at the moment about the way this works and it may be that it is something that we cannot take into account because there is no evidence on this anywhere, but it was a thought that occurred to me and, for that reason, seemed to me appropriate to at least put it to you so that you can deal with it.

MR HOLMES: Absolutely, sir, and I am grateful for the opportunity and the reminder. I think it arose as a result also of a question of Professor Holmes. I think he indicated that that could be a possible explanation if the clawback or it may have been you, sir --

THE PRESIDENT: The question was out there.

MR HOLMES: Yes, indeed. Two points. There are two ways in

which margins are periodically revisited for the pharmacies. The first is through margin reviews in the context of the drug tariff. Those are prospective. They affect the drug tariff price and they hit all pharmacies equally.

The second is via these periodic clawback arrangements, where attempts are made to recapture any supra-competitive profits, but again my understanding is that those are across the sector as a whole and they would apply equally to independent pharmacies and to the multiples.

So to my knowledge, and it is something that I have asked my client about, but on the basis of the research that we have done so far there is no difference in the way that the clawback operates as between the multiples or the independent pharmacies. So while one can readily see how this mechanism could work to change the price sensitivity of the multiples and the independents, our understanding is that in practice that is not how it works.

But of course, if anyone has relevant evidence on this point, we would be interested to see it and to understand it, but that is not how I understand it to work.

MR PALMER: There is a paragraph in the Linklaters letter of

this morning which deals with that point.

THE PRESIDENT: I am very grateful, Mr Palmer. I confess I have not had an opportunity to read that yet. But you are absolutely right, Mr Holmes. The point only has traction if the regime, which I am sure applies across the board, has a material difference in terms of the size of the pharmacy in question and if one has got, for instance, a regime that applies to all pharmacies, but does so in a manner that is more aggressive as far as the large pharmacies are concerned, then that might be an explanation for the divergent things, but --

MR HOLMES: Yes, if they are going to lose the profit, they would not bother.

THE PRESIDENT: Exactly so. But at the moment at least, that is not a consideration that bears, because we have got no material to identify that sort of difference existing.

MR HOLMES: Yes, indeed. We will consider the -- I must admit I am in the same position as you, sir. I have not yet reviewed the link from Linklaters' letter, but if there is anything we have to add, obviously we will do so.

So, returning to a review of the Decision, at 4.103 you see the conclusion that full and skinny were therefore perceived by some pharmacists as

interchangeable and by some other pharmacies as differentiated products. There is then a consideration of the quantitative data and, again, picking up the headline points on page 338, we see volumes dealt with in paragraph 4.132. {A/12/338}.

You see there skinny label tablet suppliers have been able to win around 50% of the sales volumes. This shows they are being dispensed to adults, ie being dispensed off-label, given that paediatric uses -- there are a range of different estimates -- it is much lower than half of all volumes.

At the end of the paragraph, the conclusion that a significant number of pharmacies regarded full and skinny label tablets as interchangeable.

Then as regards prices on page 345, at paragraph 4.130, the Decision notes at (a) that both full and skinny label prices declined following skinny label entry. The declines followed at (b) similar trajectories for both full and skinny, but (c) Auden retained a price premium.

As the Tribunal has seen, the CMA recognised that there were two elements at work in driving this decline. That is set out at page {A/12/346}, paragraph 4.133. The Decision notes that it was skinny entry that led to full prices falling, reversing the upward trend until

that point and the CMA notes that the falls can be attributed to two factors, though the size of each effect was unclear: at (a) direct price competition and at (b) the indirect price constraint arising from the drug tariff mechanism.

So full label volumes falling, full label prices falling, all of this due to skinny entry and two effects at work.

Turning on to page 348, if we could look at the end of paragraph 4.139, you see in the final three lines the CMA turns to consider the ultimate question for market definition; namely, competitive constraints on the focal product, here full label, and its conclusion in the light of the price and volume effects, the 50% loss of volume and the prices falling over time, is that skinny imposed a sufficient competitive constraint on full such that they should be included in the same relevant product market.

So that is the conclusion and the analysis in the Decision.

Can I now turn to the debate between the experts, and I hope that I can cut through this in the light of where we have arrived following the helpful note, *CRA* note, the third and final riposte in that sequence.

THE PRESIDENT: Yes.

MR HOLMES: The division was initially between Professor Valletti and Mr Bishop who agreed with the CMA's approach and with its conclusions. Mr Holt and Dr Bennett disagreed with the CMA's ultimate conclusions. There was a significant degree, I think it is fair to say, of common ground that emerged along the way. There was general agreement that the products are clinically interchangeable and that pharmacies made the relevant decisions as to which product to dispense. There was also agreement that it was the arrival of skinny label products on the market that caused the volume of shifts and price falls.

For your note, the relevant transcript references from the oral evidence are set out in paragraphs 219 and 220 of our written submissions.

So, the debate between the experts really centred on two matters. The first was the extent to which both the direct and indirect constraints were at work and the second was whether the indirect constraint, resulting from the drug tariff, should count for the purposes of market definition. I think that fairly captures the key dividing lines.

Starting with the balance between direct and indirect constraints. Mr Holt, like Professor Valletti, addressed this by reference to the quantitative data on

price and volume trends. I think it is fair to say he did not rule out some direct constraints, but considered that indirect constraints were the key driver.

Dr Bennett also took the view that it was the drug tariff that was doing the work. In his two reports, he was the only expert who sought to rely on what he described as a SSNIP assessment.

Professor Valletti however was adamant that what Dr Bennett had done was not formally speaking a SSNIP. Dr Bennett simply compared the price points for two different product, full label 10mg and full label 20mg, and noted that the former was more than 10mg above the latter.

A SSNIP would involve assessing whether a small but significant increase on a non-transitory basis to the price of full label 10mg would result in sufficient switching to 10mg skinny label to render the price increase unprofitable.

As Professor Valletti explained, a comparison of two static price points cannot show that where they reflect a degree of product differentiation.

Professor Valletti similarly regarded Dr Bennett's separate critical loss assessment as uninformative and, amongst other matters, he felt that it did not proceed on the basis of any SSNIP assessment and it did not

feature any assessment of the applicable demand function.

In the course of his oral evidence, Dr Bennett tried a different tack. He suggested that Auden's prices more closely followed the drug tariff than competitors' prices, based and a visual analysis. I think you, Professor Mason, was kind enough not to describe it as eyeballing -- it was a bit more than that -- of the graphs. The Tribunal invited him to supplement his evidence, including with an econometric assessment of the relationship when if drug tariff trend and the price tariff trend.

He provided a note which undertook a correlation analysis and he found a higher correlation between Auden's contemporaneous prices with the contemporaneous drug tariff prices than between Auden's prices two quarters ago and the contemporaneous drug tariff price.

For its part, by way of response to Dr Bennett's note and in accordance with the Tribunal's request, the CMA did undertake an econometric or a regression analysis. It considers that the analysis is difficult for various technical reasons, but that the results are consistent with the proposition that Auden's prices were influenced by the price of skinny label competitors, at least to some degree.

That is also of course the position that was arrived at in the Decision.

It is interesting to see how Dr Bennett now regards the role of the direct constraints, as they are set out in his latest note. If we could go to that, please. It is at {IR-D3/4/12}.

THE PRESIDENT: Do you need to use the IR prefix?

MR HOLMES: I apologise, it is {IR-D3/4/12}. If we could enlarge, please, the top of the page and look at his conclusion together. So in conclusion he says:

"I remain of the view that the falls in Auden's pricing following skinny label entry were driven predominantly by the Drug Tariff, and not by a positive desire on Auden's part to reduce its prices to compete directly with skinny label. It is also important in my view that the above technical discussion regarding regression should not obscure some rather basic points which strongly suggest in my view that there was very limited direct competition between full and skinny label products for 10mg hydrocortisone tablets."

So, on my reading of that paragraph, Dr Bennett, who rightly had the last word, does accept some role for direct competition and the debate is confined to trying to work out the balance of the effects.

On the difficulties of undertaking this assessment

by econometric means, he agrees with the CMA's reservations.

If we could turn back to page 6 of his note in paragraph 13 {IR-D3/4/6}, he notes in the final sentence:

"The CMA's recognition of the potential difficulty in running an econometric model given the small sample size and the potential causality issues... "

That is a caveat that he agrees with. In the following paragraph, he raises some concerns in relation to the CMA's analysis, which lead him to doubt the robustness that the direct constraint was a significant determination of Auden's pricing. But, again, he does not there suggest that it played no role.

So, in my submission, where the debate leaves us after this consideration of regression is very much in the same place which was arrived at in the Decision itself. There is undeniably an indirect constraint at work. Everyone agrees that the drug tariff did have an impact on the prices and volumes of full label tablets.

You can see that, for example, from Cinven's note on the questions raised by the Tribunal on the competitive landscape at paragraph 7. We need not go there. There is likely also some direct constraint at work. Having seen the CMA's econometric analysis, Dr Bennett in his

last word did not suggest otherwise.

Untangling the two effects is agreed on all sides to be difficult, but the balance of the evidence certainly does not suggest that the CMA was wrong in finding both direct and indirect constraints in play.

That brings me to the second question regarding the relevance of the indirect constraint to market definition.

PROFESSOR MASON: Mr Holmes, sorry to interrupt your flow.

MR HOLMES: Not at all.

PROFESSOR MASON: It just took me a few moments to check things. So let me take you back to the point you just made about paragraph 14 of Dr Bennett's second econometric analysis. You put particular emphasis on Dr Bennett doubting the robustness of the conclusion that the direct constraint from skinny label was a significant determinant of Auden's pricing.

MR HOLMES: Yes.

PROFESSOR MASON: Could I just check with you your understanding of what mode the word "significant" is being used in there? I had read that as being related to statistical significance rather than magnitude.

MR HOLMES: That may be the case, but the conclusion, which I also showed to you, is perhaps a clearer indication of where the debate came out. I do not know whether it

would be helpful to go back to that, the final page of --

PROFESSOR MASON: You referred to that earlier though, did you not?

MR HOLMES: I did. You have the point there. That indicates that the preponderant cause is the drug tariff, but I think, on a fair reading of that paragraph, Dr Bennett's evidence does not go so far as to exclude a role for a direct competitive constraint. Having considered all of the evidence, that was my reading in any event of that paragraph.

PROFESSOR MASON: Okay, thank you.

THE PRESIDENT: Looking at it and clearly one cannot read paragraphs like this as if they were legislation, what I am getting from this is that he is certainly not endorsing the CMA's analysis. He is indicating a degree of disagreement, but he is not able to go so far as to say that the CMA's analysis is wrong. He is saying I am not sure it is right and I am concerned for these reasons.

So there is a degree of fuzziness in terms of his opposition to the CMA's position. I think that is the point you are making. That it is not an unequivocal: you are wrong. It is much more nuanced than that, which gives you the wriggle room to say, well, it is very

difficult, but at the end of the day looking at everything that is being said, there is a dual effect and what is unknown is the extent of one versus the other.

MR HOLMES: Yes. I think that is fair, sir, and the conclusion is obviously the place, ultimately, to look to see where he comes out on balance, having looked at all of the evidence. His language there is carefully chosen and well judged, I think reflecting his careful attempts to provide independent to the Tribunal. He says that the effects are driven predominantly by the drug tariff and there was very limited direct competition. I think he is a man who chooses his words carefully and it is quite clear there that he is not excluding a role for direct competitive conditions.

Then standing back and looking at the evidence as a whole, you have two experts here who are quite t adamant that there were direct competitive constraints in play.

MR O'DONOGHUE: While it is open, it may be useful to look at paragraph 2 of Dr Bennett.

THE PRESIDENT: Paragraph 2.

MR O'DONOGHUE: Yes.

THE PRESIDENT: Let us look at that.

MR HOLMES: Yes, sir, so he is still relying on his SSNIP

analysis, as he terms it, and you have my submissions about that, but I had taken it that was really a preliminary. It was not a consideration of the econometric analysis which the Tribunal for understandable reasons --

THE PRESIDENT: No, I understand this and, Mr O'Donoghue, do correct me if I am misreading this. I see this as a sort of boilerplate provision saying: I am not changing my views on this other point, but I am only addressing the question that the Tribunal asked him to flesh out, to which the CMA responded, to which he then replied. That is my reading of this paragraph.

MR O'DONOGHUE: Obviously, it is not a statute, but I would suggest if one looks at paragraph 2 and if one reads all of paragraph 14, the bottom line is pretty clear.

THE PRESIDENT: Okay.

MR HOLMES: Sir, this is -- we can --

THE PRESIDENT: We will read it.

MR HOLMES: I do not want this to be a never-ending debate. I think you have my submission on the weight of the evidence.

THE PRESIDENT: Yes.

MR HOLMES: It brings me to the other dividing line, which is whether the indirect constraint has relevance when determining the competitive constraints in this rather

unusual market context.

THE PRESIDENT: Yes.

MR HOLMES: In my submission, the ultimate question is whether the focal product is constrained by the presence of other products on the market. That is where you go to ultimately. I thought Mr Palmer put it very nicely, if I might say so, during the course of his closing submissions on the point.

In this case the drug tariff is an unusual feature of the market. It is one of the complexities or oddities which we all have to grapple with. It is still an economic area of activity. Competition law applies. So we have to do our best to apply the framework of analysis, but there are difficulties. There are wrinkles and the drug tariff is one.

It ties the pricing of the focal product to the other skinny label products in the market. Just as the products have differentiated by regulation, in the form of the orphan designation, so they are connected by regulation in the form of the drug tariff. Neither form of regulation should be ignored when assessing the boundaries of the market.

Moreover, the indirect constraint of the drug tariff by intention reflects and reinforces the competitive process by bringing down the price of all suppliers of

a given drug.

In my submission the CMA was entitled to take this undeniable constraint on a key parameter of competition price, resulting from the launch of skinny label products, into account when defining the boundaries of the market here, especially given the difficulties acknowledged on all sides of disaggregating, separating out, the causal factors in play. To do otherwise, we say, would be divorced from reality.

The case law is clear that the relevant product is to be defined by reference to the facts in any given case, taking into account the whole economic context. Again, that can be found in *Aberdeen Journals* at paragraph 96. I will give you the reference, but we need not go there. {M/25/28}.

If I am right that in the circumstances of this market both constraints should be considered when assessing the market definition, the other points advanced by the appellants really fall away. Their reliance, for example, on the cellophane fallacy goes nowhere where the constraints have continued to operate when the prices have fallen, all the way from £70 to £2 on the latest available data.

As Professor Valletti opined in this case, the cellophane fallacy, he said, it plays no role. It is

a very academic debate.

But to some extent I wonder if this is a question of expert judgment at all. It is almost a philosophical question how one approaches market definition where there is this unusual feature in play. The defining task is to assess constraints. The CMA cut the cake as it did. You can see there are other ways in which you could divide up the analytical framework. I think Mr Holt and Dr Bennett both suggested you could take this into account when it came to countervailing buyer power and see how it weighed at that stage of the analyses.

But really the CMA's approach was, in my submission, a reasonable one and we do have in mind the point that you made, sir, in the *BGL* case that market definition is partly a science, but it is partly also an art and there is a margin of appreciation in relation to how it is conducted.

THE PRESIDENT: That anticipates a point I was going to put to you, which is in *BGL* we gave, for reasons that are obvious, a lot of consideration to Lord Justice Green's analysis of margin of appreciation and the extent to which the Tribunal should intervene in an appeal on the merits and what we got from that, specifically as far as market definition was concerned, was that there are

a number of ways of slicing the cake, as you put it, and we ought not to be too dismissive of what is simply a different way of doing things. In other words, we ought to adopt the CMA's market definition, provided it is one of the ways of doing it that is not wrong. It is only if it is wrong in a material way that we ought to re-invent the wheel and do our own job, which is what we said in *BGL*, and there of course concluded that we did not like the way the market had been defined.

But what I am putting to you, and I am anticipating from you enthusiastic agreement, but I put it out there so it can be adopted in reply, that that is the approach we would be minded to take on market definition here. In other words, even if we thought there might be a different and perhaps better way of doing it, provided the CMA's approach works, then we ought not to re-invent the wheel.

MR HOLMES: Sir, you rightly anticipate my position and given that very articulate expression, I am not sure there is much that I need to add to it. We wholeheartedly endorse the view you have canvassed with me.

That is in particular the case in light of the third topic that I would like to discuss in relation to this third market definition, which is the degree to which

the full versus skinny question actually makes any difference to the underlying assessment. In other words, if you cut the cake differently, would it really affect things?

Now, there was no dispute among the experts that market definition is not an end in itself. It is a point you have touched on several times. It is really trite. Mr Holt accepted it was an intermediate step. I think the way you put it, sir, if I noted it correctly, was that it serves to identify the ambit of your enquiry in terms of whatever question you are asking next. That seems to us absolutely right, if one might say so.

If we could go, please, in the Decision to {IR-A/12/308}. You see at paragraph 4.35, we have seen this before, it sets out the overall market definition and you see from the bracketed text in the final two lines the CMA's conclusion that full and skinny are in the same market. We have seen the reasons why.

Faced arguments either way, as I have said, and it came to a landing.

Could we please now look at footnote 1166 at the foot of the page and enlarge that. As this explains, the CMA also considered that ultimately the question was an academic one. It did not affect the subsequent

stages of the competition assessment. It says:

"For the avoidance of doubt, even if skinny label tablets did not excerpt a sufficient constraint on full label tablets to form part of the relevant market, that would not change the CMA's conclusions in this Decision."

It explains why, focusing first on the question of dominance:

"As the sole supplier of 10mg full label tablets nets (ie 100% market share of full label tablets) and one of only two suppliers of 20mg full label tablets (with market shares by value of around 80% of full label tablets), Auden/Actavis would still be dominant on a market definition separating skinny and full label tablets."

So, basically, a separate market definition would only strengthen the conclusion that Auden was dominant. Indeed, it would be viewed as a monopolist with insufficient constraints from skinny label for them even to be found to fall within the same market.

The preponderance of the expert evidence, in my submission, aligns with that view. Mr Holt readily accepted that if full label tablets were in a market of their own, Auden would be left with 100% share for 10mg with an assured customer base of the regulatory

Focus Pharmacy multiples.

Dr Bennett went further. If we could go, please, to the {Day6/52:22}. So, you see I asked the question:

"I think you agree then that the logic of your position on market definition, this bifurcation, if you like, or this lack of ongoing competitive constraint, is that you are left with a full label market in which Auden is insulated from competition and is able to price, as you said, well above the competitive price and in a monopoly position?"

And his response:

"Yes, that is correct."

Line 4. Professor Valletti, for your note, took the same position in the joint expert statement in response to proposition 44.

I am not suggesting, sir, that this is in any way conclusory of the debate on dominance. We still have to see whether the Tribunal's conclusions were robust in assessing constraints in an outside market, but I do say that if we were wrong about this market definition, it would not really affect the terms in which that debate is to be had.

Mr Palmer suggested yesterday that a complete re-evaluation of dominance, or the day before yesterday now, that a complete re-evaluation of dominance and

abuse would be required if the market were narrower, but he did not provide any specifics and the CMA in the Decision itself finds that the dominance position would not be affected. So, it actually factored this into its assessment and one can readily see why all the factors in favour of dominance would still weigh with the same with stronger force.

As regards infringement abuse, we say the conduct would be identical and all the considerations weighed by the CMA in assessing it.

Returning if we could to the Decision {IR-A 12/308} and looking at the balance of footnote 166. We have seen what is said about dominance, but picking it up in the fifth line we see that the CMA also proceeded to consider the consequences for the assessment of the conduct under the Chapter I prohibition. On that top it says:

"Changing the market definitions such that skinny label tablets were not the same relevant market as full label tablets would also not change the CMA's conclusions that AMCo and Waymade were potential competitors to Auden/Actavis when they entered into the 10mg agreement."

Then turning over a page and then a 10mg has as its object -- so down to the footnote, please:

"Restriction or distortion of competition. Significant volumes switched from full to skinny label tablets and skinny-label suppliers therefore competed for a significant part of the volumes that were first supplied exclusively by Auden, regardless of the market definition which is adopted. It is not necessary for an undertaking to be in the same relevant market in order for it to be a potential competitor, and nor can it be said with certainty whether they will be at the time a market exclusion agreement is concluded. By definition a potential competitor has not yet entered the market and therefore, the competitive process that would follow that entry has not yet taken place. In the present case it has been possible to observe what happened after skinny label entry did occur, and it is clear that this led to Auden/Actavis losing significant volumes to those entrants and to prices falling. That process was delayed by the 10mg agreement."

Now, again, I am not suggesting that this is at all conclusory of the questions that you have to consider when deciding whether there is a Chapter I infringement, but what I do say is that it cannot be the case that merely because the market bifurcated after entry those seeking to enter or agreeing not to enter on the CMA's case beforehand were not potential competitors of

Auden's. They won 50% of the volumes that Auden was supplying. Auden's prices crashed. They offered a competitive choice to the pharmacies that Auden was serving before entry. They were in a process a competition. Potential competitors are already in a process of competition. What they were competing to do was to enter the relevant market that Auden was at the time supplying. Anything else is semantic and formalistic in the extreme, in my submission.

Now, you reach your own view on whether there was an agreement that infringes the competition rules, but the competition analysis of that question cannot turn on this market definition point. It really cannot. What that means is that a lot of ink has been spilt challenging something which actually does not assist either Advanz or Cinven. They have to win on the other aspects of their appeals.

So that is my submission on whether it makes any difference. The Tribunal's task, to go back to the earlier point, is only to correct material errors, as you observed. If there is any error here, if the CMA put the indirect constraints in the wrong box, sliced the cake in a way that you decide on balance is the wrong way, by taking account of indirect constraints at the market definition stage, it is a paradigm example in

my submission of an immaterial error.

Subject to any questions from the Tribunal, including tomorrow, that concludes my submissions on market definition, subject -- I am afraid in all of the excitement I have not yet reviewed the transcript and come back with a properly considered answer to Professor Mason's question on QALYs, but I shall do so, with the Tribunal's consent, tomorrow.

THE PRESIDENT: No, thank you very much.

Without prejudice to going into new year we ought still, I think, to cut our cloth as broadly as we can. We will certainly start at 10 o'clock, but would 9.30 present any insuperable difficulties to any of the parties.

MR HOLMES: I put in a heartfelt plea, if I may, for 10 o'clock, in view of the preparatory work that needs to be done overnight. I appreciate that I am in the Tribunal's hands, but my own preference, given that I think there is now a clear view that we will need to go into the new year, I would find the extra half an hour very much appreciated.

THE PRESIDENT: Okay, we will say 10 o'clock, but I am conscious that we should allow pushback, if there is to be pushback, in terms of next year. I see two people standing. What I was going to suggest was that I do not

want to lose time that is properly for closing. If there is going to be an objection, should we have 20 minutes argument at 1 o'clock tomorrow?

MR HOLMES: That seems very sensible for my part, sir.

THE PRESIDENT: Does that -- I do not want to cut anyone off now. Mr Palmer, have you anything?

MR PALMER: I am happy to save objection to 1 o'clock tomorrow but it may affect Mr Holmes' progress tomorrow. That is my concern, because, if I may respectfully say so, whilst fully recognising that he must have time to make his submissions there is a balance to be struck between what is said orally and what has been said already very fully in writing. The Tribunal will recall as I was allowed, I think a little bit less than four hours in total to deal with dominance, abuse and penalty and what we have had so far is four hours from Mr Holmes and he has dealt with market definition. It is worth noting he took I think three and a half hours to get to the end of Ms Ford's ground 1, a ground which Ms Ford dealt with in 50 minutes. In my submission the pace will -- I have looked up the transcript and she did -- the pace will need to increase.

Now, the significance I am raising at this point now is I do not object to Mr Holmes being allowed more time than he was originally budgeted, which I understand was

one and a half days and he has had one of those days effectively, but the question would be how much time. The Tribunal mentioned the possibility of up to three days in the new year but they are having to be individual days and possibly go into February and even March which is starting to give rise to real prejudice.

My submission would be in all fairness I think between all of the appellants on the unfair pricing side of the debate we had a total of about three days and I see no reason why Mr Holmes should not have the same. That of course includes a good chunk of penalty as well. That would indicate a further day in the new year, assuming Mr Holmes goes up to Friday or the CMA between them go up to Friday lunchtime, an extra day for the CMA and still one day for the appellants.

If it was going to be more than that for the CMA in the new year, then there may have to be more time for the appellants in reply as well to be fair, and things start getting out of proportion.

I did a lot of my submission by saying: please look at the following paragraph of our closing submissions, and just trusting that that is what the Tribunal will do, as I know it will. If we go at this pace, we will be in difficulty and we will need to go much deeper in

reply into the evidence in order to be fair.

Certainly, my clients are concerned about having put me, as it were, if I can use an analogy, into a Mini, which I do not object to, but Mr Holmes seems to have taken command of a Rolls-Royce and that is not striking my side as entirely fair in all the circumstances.

THE PRESIDENT: Mr Palmer, if I understand your point, it is more that you do not like the idea of three days next year but you do not push back very hard on two.

MR PALMER: Two.

THE PRESIDENT: Is that right?

MR PALMER: Particularly if that meant it was easier to finish the case earlier. Because with the best will in the world there is not just the additional cost of one extra day in court but each time we come back, particularly if it is after January and February and March, we have all got to get ourselves back up to speed.

THE PRESIDENT: Mr Palmer, you are pushing at an open door there. In terms of the two versus three days point you are merely reiterating what Professor Mason made as a point during the short adjournment which was, "why on earth give them three days?", and my response to that was, look, we have got enough problems finding dates, the last thing we want to do is to have someone nibbling

at the end to say, I need more time for my submissions than two days. Let us sort it out now.

If the parties can agree that come any eventuality it will be no more than two days, then we are very happy, more than happy to proceed on that basis because it makes things easier from our point of view.

MR PALMER: If the Tribunal allowed the CMA the days it was originally allocated to appellants replies, which is a full day, plus an extra day in the new year, so that is two extra days over the original budget, in other words, five in all, which is as long as we had between us for our submissions and then we have a day in reply which makes five versus six Mr Holmes would say but that is entirely normal to have a little bit extra time for the appellants to make their case in reply than the respondent does.

MR HOLMES: Sir, I will say that and in addition Friday is not a full sitting day as I understand it. It is a half day.

THE PRESIDENT: Aspiration here. We can stretch it to 4.30 as usual.

MR HOLMES: Right. I had understood it was --

THE PRESIDENT: What I proposed was we draw stumps at 1 o'clock on Friday and we have three days perhaps to be apportioned as maybe agreed but I suggested two days for

the CMA of those three and a day in reply. Now, that was a suggestion.

MR HOLMES: Yes.

THE PRESIDENT: What I really want to get sorted out because it matters as to your position is if there is going to be an application that we actually apply a guillotine and say, I am terribly sorry, Mr Holmes, the CMA will have to sit down without any time next year, I do not think anyone is actually saying that but if they are I think we need to know now.

MR BREALEY: For the record, for Advanz we do not push back on doing replies in the new year, so that is just so that the Tribunal knows.

THE PRESIDENT: I am very grateful.

MR HOLMES: I am grateful for the acceptance of further time in the new year and I appreciate that it is not convenient for anyone. It is not an ideal state of affairs. I do not think the Tribunal needs to hear me on the fairness of allowing more time. I hope that my submissions have been useful to the Tribunal in explaining the CMA's position on points that are important.

It achieves only an equal allocation of time in a case which has proven to be complex and on which there have been many questions. I only began today, sir,

at 11. There was a good portion of today that was devoted to agreements. But we hear what you say and what Mr Palmer says. We will discuss with the appellants and it may be that agreement can be reached on two days in the new year.

THE PRESIDENT: Look, that is very helpful. We will therefore leave it at that. We will not make any arrangements diary-wise now and we can have a debate whether we need to find three rather than two or two rather than three later on, but I am not closing out either possibility.

What I do want to close out is anyone at the end of these proceedings leaving the court room feeling that they have not had a proper hearing and to that end of course we will be reading the written submissions again and again, but we have well in mind the point that a number of parties have made now, that oral submissions matter also and that is why we are having this conversation.

Mr O'Donoghue.

MR O'DONOGHUE: Sir, just to round this off. Sir, of course we understand the sentiment that no one should feel short-changed when they leave. But there has to be limits. I did guillotine my submissions. There was a lot of stuff on market definition, indirect effects,

indeed, on object that I would have liked to have said and it would have equally open to me to say it is fair that I should be allowed to bang on a bit longer, but I cut my cloth to measure with an effective guillotine.

Now, if we are in a three-day scenario that does mean effectively the CMA has six days versus five for us and as a basic equality of arms proposition that is fundamentally unfair and we do say that quite firmly.

But if we end up in a position whereby it is two days and therefore there is parity, and we have time to do our reply, then I do not object to that extent.

There is one short point. There is a suggestion Ms Demetriou might pop up yet again on *Oxera*. I mean, we have mentioned this in our notice of appeal, written closings, oral closings, she had a question on it. The idea she gets a fifth bite of the cherry seems to us unfair.

MR HOLMES: Sir, I had understood that you raised a question with Ms Demetriou on which you wanted some assistance and she is keen indeed to come and help the Tribunal. It will only take ten minutes.

THE PRESIDENT: Provided it comes out of the CMA's time I have no problem with that.

MR HOLMES: Yes, I am grateful.

THE PRESIDENT: So what we are going to do is we are going

to leave it that there is no objection to going into next year so we do not need an argument at lunchtime tomorrow. I shall leave it to the parties to hammer it out what is and what is not fair, and we will, if necessary, resolve the dispute as between two versus three days. Obviously, we would all prefer it to be two rather than three. It keeps the costs down. It makes the diary problems altogether more manageable and it means that we can probably get this knocked on the head early in the year rather than later.

But to be clear, the problems of the diary and stretching into March are not of the parties' makes, they are of ours, but you will expect as a consequence of that we will be pretty ruthless in terms of party availability to make sure that only the absolutely critical players' diaries are taken into account when we are arranging the days next year simply because otherwise, we will be stretching this out to the crack of doom and that is really not appropriate or fair or cost efficient.

MR HOLMES: Yes, that is well understood, sir.

THE PRESIDENT: Very good. Thank you all very much.

10 o'clock tomorrow morning.

(4.40 pm)

(The hearing adjourned until Thursday, 22 December at 10.00 am)