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)

Tuesday, 13 December 2022

(10.30 am)

Housekeeping

THE PRESIDENT: Ms Ford, good morning. Before you begin, just two very short points of housekeeping.

We have received, though I do not think we have digested, the CMA's response to Dr Bennett's paper. I think I made it clear on the transcript but I just want to repeat that he does not have to, but if he wishes to respond then Dr Bennett, of course, is absolutely free to do so. I will not set a time limit because provided we get to it in the course of the Closing Submissions and provided it is responsive then we do not see any particular urgency and we would rather Dr Bennett had, as it were, more time rather than less given that it is not completely straightforward work and the CMA has done an excellent job in the time we gave them.

MR O'DONOGHUE: Sir, we will update the court as soon as we --

THE PRESIDENT: I am very grateful. The second point is something I think we have raised, but we are going to have to really work out how the pricing in this market worked, how the tariff worked, and I think it is fair to say that we have a general sense but not a very granular

sense, and one of the things that will be quite high on the agenda when we draft our decision is to unpack exactly what is in play and how it works.

It is pretty likely that we are going to be asking the parties for further help on this, ideally to identify where in the record the data exists. But it may be that in fact the questions we will be asking are not in the record but will require further digging.

Now, of course these questions will be coming after the record has closed but I want to put, I think, on the record that at the moment we think it is going to be quite important for us to work out how the market works in the terms of price setting, and we would be disinclined to entertain objections that the record had closed to the producing of further detail in relation to this factual point.

So I just want to flag up that at the moment we see this as something of some importance. We have not worked out whether all the material is there for us to piece together. We expect it will be, but we just want the parties to be on notice that if there is a request that requires, as it were, further factual evidence we very much hope that it can be agreed between the parties and provided to us. If it cannot be agreed then we will think further, but I suspect we will not be permitting

the argument that the record is closed to bar our request for this material to be provided.

So I say that now so that the parties know what we want. Our views may change but I put it now so that no one is thinking that one party is going to be favoured or not. We have no idea where this point goes; we just know that we need an answer to it. So that was the second point of housekeeping. Mr Brealey, sorry.

MR BREALEY: Sir, if it is possible some time later this week on Friday, if the Tribunal gave us a few questions, and I am sure then we can try and agree what the response would be.

THE PRESIDENT: That is an excellent idea. We will give that some thought and frame exactly what we are interested in.

MR BREALEY: We should be able to do it.

THE PRESIDENT: I am quite sure you can. It is the sort of thing that is granular and potentially important and -- thank you, that is very helpful.

MR BREALEY: It is something I am sure we can all agree.

THE PRESIDENT: That is very helpful, Mr Brealey. Ms Ford.

Closing Submissions by MS FORD

MS FORD: Sir, thank you. My submissions are going to follow the order of our grounds of appeal, and rather than engage in any lengthy introductions I propose to

just jump straight in and deal with them in that order.

Our first to fourth grounds of appeal are concerned with the CMA's excessive pricing case, and the first ground of appeal is concerned with the CMA's approach to market definition in the Decision.

Can we start by looking at this Tribunal's summary of the applicable legal principles governing market definition, *Aberdeen Journals*. This is {M/25/28}, please. The Tribunal has in this case conducted a review of the relevant case law, and if we look at paragraph 96 we can see its summary of the applicable principles.

It explains that the relevant product market is to be defined by reference to the facts in any given case taking into account the whole economic context, and then it identifies five factors which may be taken into account:

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

It makes the point in 97 that:

"Each case will depend on its own facts, and it is necessary to examine the particular circumstances ..."

I would like to focus on points (i) and (ii) in the list that the Tribunal has identified. The first is the objective characteristics of the products and this, in my submission, is referring to functional substitutability. It is asking: do the products have materially the same objective characteristics?

The second is then concerned with substitutability in terms of relative price. At paragraph 98, if we could go to that, please, what we see is that the Tribunal explains the relationship between these first two criteria.

What it says is:

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

So it is first dealing with this first criterion. It is saying it is going to be quite straightforward insofar as products have similar objective characteristics, and it gives an example: bananas from different Caribbean islands all form part of the same market for bananas.

If the question is more complex, so you are seeking to determine whether or not products which do not have the same, or completely the same objective characteristics are nevertheless substitutable for each other, and in this case the Tribunal gives an example of moving from bananas to other fresh fruit, then you move on to the second criterion and you ask whether or not they are nevertheless substitutable in terms of price.

At 99 {M/25/29} you see the Tribunal recognising that one possible economic technique for doing that is to apply a SSNIP test. But then if we go on to 102 {M/25/30}, we can see the Tribunal recognising that in some circumstances techniques such as the SSNIP test may be of limited value, perhaps because the conditions of competition are atypical or because there may be insufficient data for such a process to be reliable.

So those are the classic and familiar principles that govern market definition, but the case law tells us that particular considerations then apply when these classic principles are being applied in the context of pharmaceutical markets.

Can we look then, please, at *AstraZeneca*, it is at {M/43/86}. We see the heading, "Specific features of competition in the pharmaceutical sector." I am going to focus on two of those. The first one is about four

lines down where it says:

"One specific feature of the pharmaceutical market is the existence of a classification system in which products, ie medicines, are grouped according to their functional interchangeability, ie therapeutic indications."

In my submission what the Commission is referring to here is the same as the first criterion that was identified by the Tribunal in *Aberdeen Journals*. It is the objective characteristics of the products, and what it is saying is that in the context of pharmaceuticals there is already an established system of classification which does the exercise of identifying whether these products have relatively similar objective characteristics.

It gives more information about that at paragraph 371 on page 88 {M/43/88}. The Commission here is explaining the anatomical therapeutic chemical classification system, according to which:

"... medicines are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties."

It explains:

"Both the World Health Organisation ... and the

European Pharmaceutical Market Research Association ... maintain systems that classify medicines according to their therapeutic indications. Medicines are classified into groups at five different levels. The fourth ATC level normally takes into consideration the mode of action and the narrowest classes (individual active substances) are defined at the fifth ATC level. The third ATC level allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use."

It says:

"This level is generally used as the starting point for enquiring about market definition in competition cases. 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 what is being said by the Commission there is that medicines which have been grouped at the third ATC level, because they are functionally interchangeable, could be expected to exhibit sufficiently similar -- sufficiently strong competitive constraints on each

other and so to fall within the same market, and that is because if they are functionally interchangeable they will in principle be substitutable for each other for the purposes of market definition. So it says the third ATC level is generally recognised as the starting point in terms of market definition.

If we go back to paragraph 362 on page 86 {M/43/86}, the second feature that we see that the Commission identifies as being distinctive in pharmaceutical markets is the modified role of price, and it says here, "A key feature relating to the demand side" -- this is probably about two-thirds of the way down:

"A key feature relating to the demand side is that in their choice of medicines prescribing doctors are the main determinant of demand in pharmaceutical prescription markets."

and it says:

"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 by their price."

It goes on in paragraph 363 to say:

"... since neither the key decision-makers on the demand side (the doctors) nor the ultimate consumers

(the patients) bear the bulk of the cost for prescription medicines with the EEA, the public authorities have, by various mechanisms instituted a high degree of price control."

So it is in some respects explaining the extent of regulation in this market, but it is also making the point that the underlying reason is that demand is peculiarly divorced from price in these sorts of markets.

When this matter was appealed to the General Court that point was made as well. If we look at {M/79/70}, paragraph 183, please. This is the General Court saying 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. In the pharmaceutical sector, competitive relationships respond to mechanisms which differ from those determining competitive interactions normally present in markets which are not so heavily regulated."

So those two particular features of the markets that I have identified have then featured in other cases. If we start, please, with *Servier* in the General Court, it

is {M/154/1}. This is a case where the General Court found that the Commission had gone wrong in defining the market very narrowly at the level of a single active ingredient, perindopril. If we start, please, at page 159 {M/154/159}.

If the Tribunal looks at paragraphs 1426 and 1427, what we see there is the General Court describing the ATC classification system in terms that are consistent with the way it was explained in *AstraZeneca*.

At 1428-1429 we can see the General Court explaining:

"In the present case, the Commission did not end its analysis at the third level of the ATC classification, but defined the relevant market at the fifth level of that classification, namely the perindopril compound, the active ingredient of Coversyl. Although the definition of the relevant market at the fifth level of the ATC classification is not open to criticism in itself, it should be noted that all ACE inhibitors, of which there are 16, are grouped together both at the third level of the ATC classification, corresponding to therapeutic indications, and at the fourth level of that classification, corresponding to the mode of action, in the same group called 'ACE inhibitors, plain'.

Thus, the ATC classification system does not permit

a distinction of any kind between perindopril and other ACE inhibitors with respect to therapeutic use. It confirms ... that there are no differences between ACE inhibitors in terms of indications and mode of action."

So the General Court clearly considers it is relevant that these products are all functionally substitutable according to the ATC classification.

It then went on to criticise the Commission for placing excessive weight on price in that context. If we look at page 181, please, {M/154/181}. Paragraph 1576 the General Court says:

"Where, for the treatment of the same condition, prescribers have a choice between medicinal products of which none is recognised or perceived as superior to the others, in particular because their mode of action is the same or because their therapeutic benefits or their adverse or side effects do not make it possible to distinguish between them, the analysis of the competition between these medicinal products also relies, in large part, on a qualitative comparison. In general, the practitioner's choice depends primarily not on the respective cost of those treatments, but on the degree to which they differ therapeutically, on their suitability to the profile of patients, on the doctor's knowledge of the various medicinal products or

even on his personal experience and that of his patients."

So the General Court is saying what is driving prescribing practices in these cases is not price.

THE PRESIDENT: You will probably be coming to it, but just to flag our interest in it: the distinction between full label and skinny label presents a certain difficulty in how one analyses it because one has functional interchangeability, and on that level I think everyone is agreed they are the same thing. Yet one has a distinction which arises out of the number of indications that they can be used for, which on one side you could say, well, it is totally artificial and should be disregarded; on the other side that would be to disregard what is clearly thought out, and thought out regulation is there, one would expect, for a reason.

So one has, as it were, a distinction which does exist which is a bit like the classification regime but rather different in the way it operates. I wondered if there is any law on that aspect of pharmaceutical regulation. I am sure you will take us to it, but we would certainly want to know how we should deal with that aspect as a matter of market definition.

MS FORD: Sir, I certainly propose to come to that in the context of one of my other grounds of appeal. In fact

our ground of appeal on market definition does not focus so much on the full label/skinny label distinction. It is actually concerned with products which are indicated for treatment of the same condition. So we are actually talking about an even narrower distinction being drawn between products, and I will develop that further.

THE PRESIDENT: Yes.

MS FORD: Obviously the Tribunal will appreciate that there is a parallel with what the General Court is saying here in terms of --

THE PRESIDENT: No, indeed. And I am afraid all of the parties are going to have to anticipate that we are going to be throwing questions at them which are not necessarily their case, I think simply because -- I mean, it may be that we decide different appeals differently, but I strongly suspect that we are going to try and have a decision that is, as it were, unified in terms of market definition and all of the other common questions. So I think you can all expect that the questions that are troubling us, even if they are not arising out of your case, will be put to you because I think you can take it that we will be striving for -- we may not achieve it, but we will be striving for a degree of consistency in all of the appeals.

MS FORD: Sir, we can certainly see that would be desirable.

We are happy to chime in insofar as we are able.

THE PRESIDENT: No, indeed.

MS FORD: If we look at what the General Court says at paragraph 1581. It says:

"It is apparent from the documents in the file that the price factor played, in the Commission's analysis, a decisive role ..."

What it did, it excluded other ACE inhibitors from the relevant market, and the reason it did that, if we look over the page {M/154/182}, is because of its econometric analysis by which it thought to ascertain whether or not the fall in the price of certain medicinal products had an effect on the sales of perindopril.

It relied on the absence of price constraints that had been revealed by an analysis of natural events, and it concluded from that that no other product exerted a significant constraint. It did that in circumstances where prescription practices were not being driven by price.

If we look at 1584, it says:

"By attaching decisive importance to the results of its analysis of natural events, which is essentially based on the impact of price changes, the Commission has not fully taken into account the specific context of the

pharmaceutical sector and has not paid sufficient attention to evidence supporting the existence of qualitative or non-price competitive pressures."

So that is really the General Court's concern. Then at 1585 it says in those circumstances it is appropriate to uphold *Servier*'s appeal:

"The Commission could not infer from the analysis of natural events and the low sensitivity of perindopril to changes in the price of other ACE inhibitors that *Servier* was not subject to any kind of competitive constraints from other products, except for the constraints exerted by generic perindopril."

That was the General Court's take on it. It is fair to say, as we flagged up in our written submissions, that the Advocate General was somewhat critical on this aspect of the General Court's judgment. Of course, the Advocate General's opinion is not binding and so it may not be followed by the Court of Justice. But in any event, what particularly concerned the Advocate General was the particular factual scenario that was in issue in this case, the fact that there were natural events and they had caused the prices of other ACE inhibitors to fall and they had not affected the price of perindopril.

I am going to come on to address the specific circumstances of this case, but suffice it to say we say

they are very different. We say on any view it is clear that a great deal of care has to be taken when placing reliance on pricing factors in the context of pharmaceuticals.

The CMA was criticised by this Tribunal for making a similar error in *Paroxetine*. Can we have a quick look at that, it is {M/183/27}. Starting at 81, we can see that in the Decision the CMA defined the market as being confined to paroxetine, and it explains:

"The Decision reached that conclusion after conducting a qualitative analysis, which it found was of only theoretical value and inconclusive, and a quantitative analysis which found that other SSRIs constrained the price of paroxetine to a much lesser degree than generic paroxetine once that entered the market."

So again we have this tension - on the one hand, qualitative evaluation, and on the other hand, pricing factors.

Paragraph 82, the Tribunal says:

"In our judgment, we held that the qualitative evidence [so non-pricing factors] was not inconclusive but showed that there were no significant therapeutic distinctions between paroxetine and other SSRIs; and that the fact that patented paroxetine faced little

competitive constraint from other drugs in matters of price is not decisive when demand for such prescription medicines was not price-sensitive ..."

If we look at 84 {M/183/28}, the Tribunal was there saying that it was:

"... attracted by the opinion of [the CMA's economist in that case, that was] Professor Shapiro, that the definition of the relevant market may depend on the conduct under scrutiny: the relevant market may therefore be different when considering exclusionary conduct from a case concerning another form of abuse, such as a product tie ..."

I am going to come back to this point that the Tribunal makes, because we do say that it is important to have well in mind in this case the fact that the relevant market is being determined for a particular purpose, and it is to try and ascertain whether a product has been priced excessively and we say that that is quite an important point that the Tribunal has to bear in mind when doing the market definition exercise.

At 85 you can see that the Tribunal in this case decided that there was an independent reason on the evidence for finding that paroxetine was the relevant market, and it was not the reason given by the CMA; it

was the competitive constraint imposed by parallel imports.

If you look at 90 you can see, over the page, please {M/183/30}, that the Tribunal did ultimately find that the relevant market was comprised of paroxetine but it was on the basis of the parallel imports' role rather than the reasoning of the CMA. So it does not detract from the fact that it expressed a lot of scepticism of methods which place emphasis on price to the exclusion of the qualitative elements which feed into market definition.

Turning to what we say about this case, we have identified a series of inter-related errors of law in the CMA's approach to market definition, and we say that they are each illustrative of an overarching error in approach, and that is to wrongly prioritise price and economic considerations over other considerations in the circumstances of this case.

The CMA has defined the relevant market as immediate release Hydrocortisone tablets, and it is important to underline just how narrow that is by way of market definition. It is not even ATC level 5, the molecule level, because it excludes Plenadren, which is also a Hydrocortisone tablet. So it is even narrower than ATC level 5.

I have shown you that in both *AstraZeneca* and in *Servier* the case law suggests that ATC level 3 should be at least the starting point for market definition, and what we see in the Decision is that the CMA pays lip service to that obligation but it does not really follow it in practice.

If we start, please, with {A/12/307}. If we go down to 4.32. Under the heading "The CMA's assessment of market definition".

The CMA says:

"The CMA has defined the relevant market in this Decision by reference to the specific facts of this case. In accordance with the legal framework ... the CMA has assessed a range of qualitative evidence on non-price and price parameters of competition as well as quantitative evidence on actual consumption patterns in response to price changes and the entry of other hydrocortisone tablet suppliers."

So there is an air of something of a familiar formula in terms of what we have looked at -- both quantitative and qualitative factors.

4.33 {A/12/308} then moves straight into the CMA's reliance on the pricing side of the equation, and you see them saying:

"... the CMA has reviewed evidence on the effects of

Auden/Actavis's actual price increases over the relevant period and the impact of the entry of other hydrocortisone tablet suppliers to assess whether other products competed sufficiently with full label hydrocortisone tablets to warrant inclusion within the relevant product market."

4.34 is making the point that the CMA took into account various submissions, and 4.35 is summarising the conclusion that the relevant market is 10mg and 20mg Hydrocortisone tablets.

If we go over the page, please {A/12/309}, we can see at subparagraph (a) one of the factors that the CMA has taken into account is that:

"There are few alternatives therapeutically so almost all patients for adrenal insufficiency are treated with hydrocortisone tablets as the first line treatment of choice. Consistent with this, there is little evidence of switching away from hydrocortisone tablets despite significant price rises, or switching to hydrocortisone tablets when prices were falling, indicating that the constraints from other medicines were not sufficient to warrant their inclusion in the same relevant market."

So again, we see a very prominent emphasis on role of price and switching in this analysis.

The CMA does expressly consider the ATC classification system, if we look at page 312, 4.43 {A/12/312}. We see the CMA recording there that:

"The Commission, the General Court and the CMA have noted in previous cases that a starting point for defining the relevant product market in the case of pharmaceutical products is the Anatomical Therapeutic Chemical ... classification system."

The way in which that applies in this case is at 4.45 in this case, three lines from the bottom:

"... the classification system indicates that hydrocortisone tablets belong to the third level category, 'Corticosteroids for systemic use, plain'. The fourth level class 'Glucocorticoids' includes a set of 16 medicines including Hydrocortisone, Prednisolene, Dexamethasone and various other corticosteroids."

In our submission if ATC level 3 or even ATC level 4 were being genuinely used as a starting point as is directed by the case law, what you would expect to see is the CMA looking at each of the 16 molecules that are identified in this paragraph alongside Hydrocortisone that are listed in ATC level 4 and engaging in the sort of exercise we saw discussed in *AstraZeneca* and *Servier*. So an analysis of the extent of their functional substitutability, taking into account

similarities or difference in factors such as side effects or effectiveness.

In our submission you do not see that exercise being conducted in the Decision at all, and in fact the CMA expressly tells us why not. If we look at the bottom of page 313 {A/12/313}, footnote 1177:

"Auden/Actavis submitted that the CMA should place weight on ATC classifications as a starting point and analyse differences (such as side effects and effectiveness) between hydrocortisone and other products at ATC level 4 ... The CMA has considered ATC classifications as a starting point."

This, in my submission, is why we say that there is paying lip service to this exercise, but you then get this:

"However, each market definition will depend on its own facts, and there is no obligation to follow any particular analytical approach ..."

and they quote there paragraph 97 of Aberdeen Journals, which I have shown you.

They say:

"The CMA's quantitative analysis implicitly takes account of all other medicines in the treatment area because to the extent that there was switching away from hydrocortisone tablets in response to Auden/Actavis's

price increases, this would be evident in the volume data ..."

Then you see:

"... other medicines not recommended as a first line treatment for adrenal insufficiency in adults, and as such, are unlikely to be therapeutic substitutes for hydrocortisone tablets."

So we get the assertion that the CMA has considered the ATC system as a starting point, but beyond that there is no real dispute that it has not engaged in the analysis that we suggested it should do based on *AstraZeneca* and *Servier*.

You get two reasons why not: the first is because the CMA says its analysis of price means that the exercise of analysing functional substitutability becomes unnecessary, and in our submission that is falling into exactly the same trap as in *Servier* because the case law specifically tells us that this is a market where price is not determinative, and yet the CMA is saying: we do not have to look at functional substitutability precisely because we have decided to look at price instead.

Then the second reason they have given for not doing this is a factual assertion, and it is the assertion that other medicines are not recommend as a first line

treatment for adrenal insufficiency in adults, and our submission will be that that is an error of factual assessment, and I am going to come on to address that in the context of two particular products.

We have focused our appeal on the circumstances of two of the products which are listed at ATC level 4. The first is Plenadren, and the Tribunal has heard a lot about Plenadren over the last few weeks. It contains the same active ingredient as Auden/Actavis's hydrocortisone tablets; it is in tablet form, the same as Auden/Actavis's hydrocortisone tablets; and it is indicated for the treatment of adrenal insufficiency in adults, like Auden/Actavis's hydrocortisone tablets. So it is a direct clinical substitute for Auden/Actavis's hydrocortisone tablets.

One might expect it, presumptively, to be in the same market. If we recall the analogy that the Tribunal drew in *Aberdeen Journals* about bananas, Plenadren is essentially a banana from a different Caribbean island. It is of different origin but it is functionally the same.

Why does the CMA say that it is nevertheless not in the same market? If we look at {A/12/314}, please, paragraph 4.52. This is a paragraph which makes three, essentially three points as to why Plenadren is not in

the same market. First it say:

"Plenadren is not routinely or commonly prescribed as it is not NICE recommended or recommended by the specialist CRG for endocrinology. Instead, prescribing restrictions are imposed locally by individual CCGs [clinical commissioning groups]."

So the first point to emphasise is the medicines that doctors are permitted to prescribe are constrained by the clinical commissioning groups.

We then see the CMA saying:

"Plenadren is much more expensive than hydrocortisone tablets. The combination of high prices for Plenadren and the lack of data on its efficacy has led many CCGs not to recommend Plenadren for the treatment of adults with adrenal insufficiency, which explains the very low volumes of Plenadren being prescribed and dispensed in the UK ...

So the second point is because Plenadren is more expensive than hydrocortisone, than Auden/Actavis's product, for no concrete additional therapeutic benefit, CCGs do not include it in their formularies and so doctors cannot prescribe it and pharmacies do not dispense it.

Then the final point in this paragraph {A/12/315}:

"This indicates that CCGs do not consider

hydrocortisone tablets and Plenadren to be interchangeable and, by not including it in their formularies, they are limiting further interchangeability between the two products for prescribers using those formularies."

This, in my submission, is then express recognition of the fact that excluding Plenadren from the formularies because it is too expensive prevents switching between Plenadren and Auden/Actavis's product.

So if we just step back from this and if you ask the key question that the CMA focuses on for the purposes of market definition: is there switching between Auden/Actavis's product and Plenadren? The answer is of course there is not. Of course there is not, because Plenadren is not included on the CCGs' formularies and it is not available for the doctors to prescribe because it is too expensive.

In our submission this is one of those scenarios where the absence of switching is simply uninformative for the purposes of market definition, because the possibility of switching has been ruled out by the prior decision of the CCGs not to include Plenadren on the formulary at all. The reason for that is because it is poor value compared to Auden/Actavis's hydrocortisone.

The President, during the course of the evidence,

canvassed with Mr Bennett how one might go about trying to assess market definition in a command economy, and as we understand it the purpose of that thought experiment was trying to get to what you do in a scenario where you have no price data at all. In many ways, in our submission, there is a parallel with the present situation because here the utility of the data about the extent of switching is completely undermined, because Plenadren was not included in the formularies and so, by definition, there is no switching.

In those circumstances, in our submission, the exercise of market definition cannot be driven mechanistically by asking what is the extent of the switching? You have to stop and ask, well, why is there no switching? Is it because these two products are not properly interchangeable, or is it because they are functionally interchangeable but actually Auden/Actavis's product is better value?

We say there is another reason why one has to be suspicious of the psuedo-SSNIP analysis that is driving the process. We have heard from the economists a lot about the fallacies of -- the perils of the cellophane fallacy and how one has to be sure that one is starting with competitive prices in order for that exercise to be an informative one. On the CMA's case not only are

Auden/Actavis's prices not effectively competitive but also the prices they are comparing them with, Plenadren on the CMA's case are not effectively competitive because they say the prices for Plenadren are not set in conditions of effective competition either, and when we come to look on for the comparators for the purposes of the excessive pricing case we will see that that is the reason the CMA gives for saying, we are not going to look at Plenadren.

So if both of the products you are comparing, on the CMA's case, are not set in circumstances of effective competition then the exercise of price comparison that the CMA has purported to do and that is driving this entire exercise is doubly suspect.

In our submission, what the case law tells us is in these circumstances functional substitutability ought to be enough and Plenadren ought to be in the same market.

This is where it becomes important, in our submission, to ask what is the purpose of the market definition exercise, as the Tribunal indicated in *Paroxetine*? The purpose here is to assess whether Auden/Actavis's product is excessively priced. If that is the exercise you are trying to do, in our submission, it makes no sense at all to exclude from that consideration a competitor product because it is more

expensive. That, in our submission, makes no sense when you are asking: is Auden/Actavis's product excessively priced?

THE PRESIDENT: So what you are saying there is that first of all a price-driven market definition test does not work for various reasons which you have gone into, but you are also saying that market definition as a concept is context-sensitive, i.e. it is a tool which is used in mergers, in abuse of dominant position, in collusion cases, but it is coloured by the use you are putting to it, and in this case you are saying that that context particularly matters because it is -- one ought to be very cautious where the abuse alleged is excessive pricing when one has something which may or may not be in the same market, who knows what the test is, but one ought to be quite cautious about excluding a potential substitute when it is at a higher price.

MS FORD: Sir, you have the point. One has to be cautious about excluding a substitute because it is higher priced, and particularly when that substitute is functionally substitutable. It has the same objective characteristics, it has the same active ingredient, it has the same indications, it has the same pharmaceutical form. So we are not picking something which is very remote and saying look, it is higher priced and so you

ought to have included it. This is a functionally substitutable product which has been excluded because it is too expensive, and that in our submission makes no sense when the exercise you are trying to do is to ask whether Auden/Actavis's product is too expensive.

THE PRESIDENT: You would have less of a problem if, hypothetically speaking, Plenadren was cheaper than Auden/Actavis's product?

MS FORD: Well, certainly.

THE PRESIDENT: In other words, your context sensitivity is particularly fine because if it is at a higher price then that is somewhat damaging to an abuse that is based upon excessive pricing.

MS FORD: It is certainly damaging to the CMA's case --

THE PRESIDENT: Well, yes, that is what I am --

MS FORD: -- and no doubt that is why it is at pains to not treat Plenadren as a comparator, because if one does treat it as a comparator one sees that it is price higher and therefore the Auden/Actavis price point should not be subject to criticism. I am going to come on to that in the context of the comparator analysis.

Obviously this is the prior step, and this is asking really, well, what is within the market definition? It does have relevance because one of the reasons why the CMA says it does not want to look at Plenadren is

because it says it is not priced in conditions of effective competition. Of course, if it were within the market on the basis that it is a constraint on hydrocortisone then that objection falls away.

But certainly one must apply an element of common sense to this exercise, and if the purpose is to try and ask whether something is excessively priced excluding a potential competitor product because it is too expensive makes no sense at all, in our submission.

So that is the position with Plenadren. The second group of medicines in ATC level 4 that we rely on is other corticosteroids, and in particular prednisolone, and the exclusion of these from the market is based on the CMA's factual findings.

If we look at {A/12/315}, please. Paragraph 4.54, you see a finding:

"Other corticosteroids such as prednisolone and dexamethasone are not generally viewed as clinical substitutes for hydrocortisone tablets ..."

and then at 4.55:

"... other corticosteroids are only recommended as a second line treatment for adrenal insufficiency in exceptional circumstances when hydrocortisone tablets are not well tolerated by patients ..."

Those are the factual findings that caused the CMA

to exclude these products from the market, and we say that these amount to an error of factual appreciation. We say that at least some clinicians did recommend the use of prednisolone as a first line of treatment or as a prominent alternative to immediate release hydrocortisone tablets, not just in exceptional circumstances.

To show the Tribunal some examples of that, if we look, please, at {H/564/1}. This is an article published in the British Medical Journal and the authors are from Imperial College London Centre for Endocrinology. If we just look at the conclusion on page 2 {H/564/2} and the final paragraph, second sentence, they say:

"At present, however, there is no evidence of any difference between the three replacement options ..."

and the three replacement options are hydrocortisone, Plenadren and prednisolone:

"... so it is logical to use the most cost effective, which is prednisolone. Plenadren is the least cost effective and hence has no current place in the treatment of adrenal insufficiency."

Just pausing there, that is entirely consistent with what we saw earlier, that it is too expensive to be included:

"Hydrocortisone was the most effective option until 2008, when its price increased 60-fold, but prednisolone should now be the first line option for glucocorticoid replacement therapy."

So that is those authors' view.

If we look at {H/915/1}, please. This is the Society for Endocrinology's response to the CMA's request for information on hydrocortisone, it is dated July 2016. If we look at the response to the second question:

"Please estimate the proportion of patients that are children and those are that are adults, for both 10mg and 20mg hydrocortisone tablets."

We see:

"Based on the adult population of patients ... we estimate 95% are on Hydrocortisone (the remaining 5% are either on prednisolone, dexamethasone and <1% are on Plenadren)."

Then in response to question 3, if we look at the second bullet under question 3:

"What treatments/medicines are considered, if any (including other corticosteroids or modified release hydrocortisone tablets)?"

You see there prednisolone mentioned.

If we go on to {H/900/1}, please. This is

a response to the CMA from a consultant and a professor of endocrinology at Oxford, and he comments in paragraph 3, second sentence:

"Occasionally prednisolone tablets are used but they cannot be monitored so accurately whereas hydrocortisone can be measure in the blood.

As above, no alternatives are used. Very rarely modified release hydrocortisone tablets are used but these are very much more expensive."

If we go on over the page to paragraph 9 {H/900/2}:

"Patients are usually not switched from hydrocortisone. They may occasionally use prednisolone."

Then {H/998/1}, please. This is the NICE clinical knowledge summary on Addison's disease and it is dated March 2016. If we go within this to page 13, please {H/998/13}. You see there "Glucocorticoid replacement", the second bullet:

"Hydrocortisone is usually used, but longer-acting glucocorticoids, such as prednisolone and dexamethasone, are sometimes used to avoid the peaks and troughs which may occur with hydrocortisone."

Then {H/816/1}, please. These are the Endocrine Society's 2016 clinical practice guidelines for the diagnosis and treatment of primary adrenal

insufficiency. If we go then to page 2 {H/816/2}, paragraph 3.3 on the right under the heading "Glucocorticoid replacement regimen", you see:

"As an alternative to hydrocortisone, we suggest using prednisolone ... administered orally once or twice daily, especially with patients with reduced compliance."

So in our submission the CMA was wrong to dismiss prednisolone in the blanket terms that it did. We say it is not right to suggest that it is not viewed as a clinical substitute or only used as a second line treatment. Of course, it is important to remember that the test for these purposes is not absolute bioequivalents, it is interchangeability, and if a medicine is capable of being prescribed to treat the same condition, even if it is not as a first line choice, then it is plainly capable of imposing some competitive constraint on Auden/Actavis's immediate release hydrocortisone tablets, and, in our submission, ought on that basis to have been included within the relevant market.

Finally, we say that the oddity in the CMA's approach to market definition really is brought home when it defines a single market for 10 and 20mg hydrocortisone tablets before competitive entry but two

separate markets after competitive entry.

Nothing has changed about the products' functional characteristics after generic entry. The only thing that changes are price and economic factors. In our submission, what that shows is that what is driving the market definition exercise here is price and economic factors rather than anything else.

We say that given that the position in the case law is that this is a market where you really have to be very careful in focusing on price factors, that is an error of law.

We say it becomes particularly dangerous in excessive pricing cases. The reason is because market definition, if you are not careful, can become an answer to the entire enquiry. So if we assume that the CMA identifies a product which it thinks is excessively priced, so for example, it does a basic cost plus analysis and it finds a product which it says is excessively priced, it points to that high price and it infers from the high price that other products are not exercising a competitive constraint on its focal product.

Then it excludes from the relevant market other products even if they are functionally substitutable for its focal product, because they are higher priced and so

they represent less value for money, and so it defines the market in a way which is extremely narrow at the level of a single product.

Then as a consequence of the narrow market definition it finds that the originator is dominant, and then as a consequence of excluding from the market products which are higher priced, and then relatedly concluding that such products are not valid comparators because they are not set in conditions of effective competition, it finds that the product it has identified is abusively highly priced.

In our submission, there is a real risk that this market definition exercise drives the outcome of the entire process from the outset. In our submission, the focus on price in this way is an error of law.

Unless I can assist the Tribunal further on market definition I am moving on to deal with our second ground of appeal, which is dominance and countervailing buyer power.

THE PRESIDENT: No, thank you.

MS FORD: So, the Tribunal will be familiar with the applicable principles and we have cited the relevant authorities in our written submissions. An undertaking is dominant if it has the power to behave independently of, amongst others, its customers and even an

undertaking with a very high market share may not be able to act independently of its customers if its customers have sufficient bargaining power. Countervailing buyer power will be of sufficient magnitude if it may deter or defeat an attempt by the undertaking profitably to increase prices.

In our case we say that the entity that is able to excerpt countervailing buying power is the Department of Health and Social Care. The Department of Health is, we say, a monopsony purchaser. It acts on behalf of the NHS and on behalf of clinical commissioning groups who ultimately pay for hydrocortisone tablets, and it has the power to limit the prices charged for those medicines. Those powers mean that as a purchaser it has the means to defeat an attempt by a manufacturer or supplier of medicines to increase prices. So we say that this is a purchaser which is able to exert countervailing buyer power.

There are two relevant statutory powers. The first is in section 262 of the NHS Act 2006, this is at {M/52/423}, please. This is the power that is relevant to Auden/Actavis. Auden/Actavis was not a member of any voluntary scheme, and so until 31 August 2015 the applicable power is the one in section 262(1), which says:

"The Secretary of State may, after consultation with the industry body --

(a) limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine ..."

With effect from 1 September 2015, Auden/Actavis's immediate release hydrocortisone tablets passed to Actavis.

THE PRESIDENT: Just pausing there. How often is this power exercised, just generally speaking?

MS FORD: We have seen evidence in the *Paroxetine* case which I will show the Tribunal in a minute -- *Phenytoin*, sorry, which I will show the tribunal, where the Department of Health essentially deployed the power in the sense of threatening to use it if matters were not changed to its satisfaction. I will show the Tribunal that. That is the only example that we are aware of it being practically used. But, as I will come on to develop in our submission, there has been a failure to investigate on the part of the CMA as to what reasons lay behind the fact that it was not used more often and we say that it is not permissible, in circumstances where it has not properly been investigated, to draw any inference as to why that might be the case.

THE PRESIDENT: The reason I ask is because I would

anticipate that the Secretary of State's exercise of power would be judicially reviewable. I mean, one would think that by reference to 262(1) but do feel free to correct any of these assertions because they are made from a position of ignorance rather than strength. But it would be helpful, I think, to have had case law on this because it obviously would inform the extent to which this is a buyer constraint or buyer power not operating on an otherwise dominant supplier. Because I mean, if it was the case that the Secretary of State could simply arbitrarily put a price limit, then your point would be a very strong one. If, on the other hand, there are significant constraints on how the Secretary of State may limit price, then the point becomes more attenuated.

But we are going to have to, this is right, work it out for ourselves, because there is no law in this area as to precisely what 262 enables the Secretary of State to do.

MS FORD: Sir, I think that is right. I do not dissent in principle from the assumption that these would be judicially reviewable powers. Subject to one case I am going to show you which relates to the other power that we are concerned with, we are not aware of any case law exploring this area.

THE PRESIDENT: Ms Ford, if after the event you identify an area of helpful law i.e. something that sheds light on this, then do feel free to put it in a note to us. I think it is something that again, we ought to understand how it works or how it should work.

MS FORD: Sir, we certainly will. I would observe insofar as it is a judicially reviewable power, it will be subject to the usual constraints on public powers and so, for example, it would not be -- I think you, sir, just used the word "arbitrarily.

THE PRESIDENT: Yes, well clearly you could not do that.

MS FORD: One could not do that. It would be subject to rationality controls. It would be subject to the usual constraints on public power. But, subject to that, one has here a clear and undisputable power to take steps to limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine. It is a very clear --

THE PRESIDENT: Yes, I mean, in a sense the ability to judicially review is in some senses entirely irrelevant. I mean, if you looked at a procedural challenge to the exercise of the power, frankly who cares. It is the substantive limits, which you are absolutely right will operate in an attenuated way in a JR, that would matter.

But one can see potentially quite interesting

questions of the purpose with which the Secretary of State is acting arising in this context.

Suppose one had a Secretary of State taking the view that one ought to have a kind of species of windfall tax operating on pharma manufacturers such that they can never charge more than the prescription price for their products no matter how much the cost of production. One could see a quite potent challenge on the basis that one was using a power for an improper purpose.

Now, that is begging a question as to what the purpose of this thing is, but you see the point. If the limit to 262 powers are that they are only to be used to constrain abusive prices, abusive being defined as an infringement of competition law, then one gets into a rather curious circular position where you are saying actually the power should not have been exercised because there is no abuse here.

So actually the way this provision operates could be quite important to determining whether it is, as you say, a buyer power constraint.

MS FORD: Sir, this does rather bring into sharp focus the fact that the Department of Health's perception as to any constraints that there may be on what is, on its face, a very clear and untrammeled power has not been properly investigated by the CMA. Insofar as one relies

on any such potential constraints as saying that is the reason why this power, which ostensibly is a form of countervailing buyer power, actually would not operate as such, it is for the CMA to investigate and establish that.

THE PRESIDENT: That is an entirely fair point. You are saying actually it is a double-barreled argument you are running: first of all, you say there is this power which exists on the buyer side, but secondly, even if the power does not exist you say frankly it should have been looked into to see whether it is or is not a power that should have been taken into account in the decision, and so there is a failure, you say, on the part of the CMA to understand the terrain in which these pharmaceuticals were priced.

MS FORD: Sir, I say it is very clearly a power that does exist --

THE PRESIDENT: No, no, indeed.

MS FORD: -- there is no scope for any argument to say that actually it does not. It is a clear power, and my submission is, insofar as there is any attempted reliance or doubts as to its scope or the manner in which it can be exercised, that is a matter which ought to have been investigated and so one cannot dismiss this power on the basis of any inferences or assumptions in

circumstances where the proper investigation has not taken place.

THE PRESIDENT: Yes.

MS FORD: Sir, I am told that Hansard says, and I have no doubt we can substantiate this with a note, Hansard says:

"Section 262 is about unreasonably high-priced unbranded generic medicines."

That may give some insight as to the --

THE PRESIDENT: That certainly would be the purpose I would have attributed to this section, but I think it just underlines that we are keen to proceed with as much data on this as we can. What we make of it, again, is going to be a different matter, but I would rather exclude material that we have than write a judgment wishing we had more data on points that are essentially uncontroversial.

MS FORD: Sir, yes, I am sure we can draw attention to where that has been located.

So that is the power which is applicable for the period until 1 September 2015. Then with effect from 1 September 2015 Auden/Actavis's immediate release hydrocortisone tablets business passed to Actavis, and Actavis was a member of Scheme M and so the consequence of that is that the power is no longer available to the

Department of Health under section 262(2) because it is then covered by a voluntary scheme.

The relevant power then is section 261, which is in the same document at page 422 {M/52/422}. The Tribunal will see:

"The power under this section may be exercised where there is in existence a scheme (referred to ... as a 'voluntary scheme') made by the Secretary of State and the industry body ..."

Then under subparagraph (a), one of the purposes:

"Limiting the prices which may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines ..."

If we look at subparagraph (4) one can see:

"If any acts or omissions of any manufacturer or supplier to whom a voluntary scheme applies ... have shown that, in the scheme member's case, the scheme is ineffective for any of the purposes mentioned in subsection (1), the Secretary of State may by a written notice given to the scheme member determine that the scheme does not apply to him."

and if that were to happen and the scheme no longer applies, then one would fall back into the following power, 262, which is the power which applies where there is no voluntary scheme. We will see that mentioned in

the actual terms of the scheme as well.

If we look at subparagraph (8) we can see:

"The Secretary of State may --

(a) prohibit any manufacturer or supplier to whom a voluntary scheme applies from increasing any price charged by him for the supply of any health service medicine covered by the scheme without the approval of the Secretary of State"

Then (b):

"provide for any amount representing any increase in contravention of that prohibition in the sums charged by that person for that medicine, so far as the increase is attributable to supplies to the health service, to be paid to the Secretary of State within a specified period."

If we go, please, to {M/77/1}. These are the terms of Scheme M which applied and to which Actavis agreed. If we start, please, on page 5 {M/77/5}. Paragraph 14 there, there is the statutory provision in that it says:

"Any company that fails to comply with the Scheme or fails to provide information required under the terms of the Scheme membership, or in any other way acts in a manner that would breach the Scheme, will be required to leave the Scheme. That company shall then not be exempt from the terms of any relevant statutory scheme."

So the effect there is that one then falls back into the 262 provision.

If we go on to page 7 {M/77/7}, paragraph 27 under the heading, "Pricing and submission of Information".

It says:

"The scheme allows freedom of pricing subject to the following provisions:"

Under the first bullet point one can see:

"Any Scheme member supplying a generic medicine to the NHS may set or alter the price at which that medicine is sold to wholesalers or dispensing contractors without any prior requirement to discuss such prices with the Department of Health. This freedom is allowed on the condition that, if requested to do so, a Scheme member shall provide the Department of Health with information sufficient to satisfy the Department of the reasonableness of prices ..."

Then if we go on to page 8 {M/77/8} under "Determining the reasonableness of company prices", you can see the intention is to:

"... allow changes in market prices to be influenced by existing market mechanisms. This means that, where there is effective competition in respect of any given generic medicine, then the Department will not interfere in the operation of the market for that medicine.

However, should the Department identify any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure, then the Department may intervene to ensure that the NHS pays a reasonable price for the medicine(s) concerned."

Paragraph 31 is setting out the information that the Department of Health can require to be included -- to be provided, and it is, the first bullet is essentially information as to manufacturing costs and the second bullet is information about profit margins.

Then finally under paragraph 42 {M/77/10}:

"Under the [NHS] Act 2006, the Secretary of State for Health may serve notice on a Scheme member that the Scheme is no longer to apply to that company."

This is, again, reflecting the provisions of the statutory power:

"He or she may do this where, for example, any acts or omissions of the Scheme member have shown that in the Scheme member's case, the Scheme is ineffective either for the purpose of limiting prices for the supply of NHS generic medicines or where there is evidence that a Scheme member has manipulated the information provided under the scheme in a way that may be disadvantageous to the NHS."

Again, if the Secretary of State were to do that then the consequence would be that they fall back under the default provision, essentially.

THE PRESIDENT: Yes.

MS FORD: In terms of the legal effect of Scheme M, it is a voluntary scheme but it does create legal obligations of a binding nature and, that has been held to be the case in a case called *GlaxoSmithKline v Department of Health*. It is at {M/56/1}. This is an appeal from the reasoned opinion of the PPRS Arbitration Panel, and in the context of the appeal there was a challenge of the jurisdiction of the court to hear the appeal, and the basis of the challenge was that the PPRS was a voluntary agreement and not a contract. That was rejected by the court. If we look, please, at page 8 {M/56/8}. Paragraph 10, please. The court is here commenting on the extent to which it is permissible to look at Hansard, but it says about two-thirds of the way down:

"Schemes are 'voluntary', in the sense that there is a choice whether or not to enter into them. There is nothing in the Act which suggests that a voluntary scheme is a non-binding scheme once entered into, although a pharmaceutical company or the Minister can in certain circumstances bring it to an end as between

1 themselves."
2 If we go on to paragraph 12 on the next page,
3 {M/56/9} the court is there setting out the statutory
4 provisions which:
5 "... give the Secretary of State power to require
6 information to be given, to prohibit price increases and
7 to provide for payment of any amount representing
8 an increase made in contravention of the prohibition."
9 Then in 13 it says:
10 "It is clear therefore that there are mandatory
11 provisions which operate within the framework of the
12 voluntary scheme. The wording ... denotes obligations
13 of a binding nature."
14 Then the conclusion in paragraph 20 on page 10,
15 please {M/56/10}. The court says:
16 "In these circumstances I hold that the PPRS does
17 constitute a commercial contract ..."
18 So these are concrete enforceable powers to control
19 prices, and the simple point that we make is that the
20 Department of Health is a monopsony purchaser, and as
21 a purchaser it has the power to control prices, and that
22 amounts to countervailing buying power which is
23 sufficient to negate dominance.
24 This is a point that the CMA did grapple with in the
25 decision, and it makes two points in response. I am

reminded that it might be, before I go on to that, a good moment for the shorthand writer break if that suits the Tribunal.

THE PRESIDENT: Yes, indeed. We will rise until five to midday for ten minutes, thank you.

(11.46 am)

(A short break)

(11.56 am)

THE PRESIDENT: Ms Ford.

MS FORD: Sir, I was about to move on to deal with what the CMA says about countervailing buyer power, and it is at {A/12/416}, please. The CMA essentially makes two points in response. The first is at 4.333, and this is a point of law. What it says is that:

> "... the CAT, the Court of Appeal, the European Commission and the European Courts have consistently held, in the pharmaceutical sector and in other sectors, that the prospect of 'regulatory' intervention does not negate the possibility of dominance."

If we go down to the footnote, 1488, we can see the authorities which are cited for that proposition. In summary, what we say about all of those is that they are all concerned with the possibility of intervention by an extraneous third-party regulator. They are not

concerned with the situation that is before this Tribunal, which is not about extraneous third-party regulation but it is about the ability of the Department of Health, as a purchaser active on the relevant market, to resist the market power of the supplier on a market. We say that that is the relevant distinction, and for the purposes of making that good I am going to go through the authorities that the CMA cites in support of its proposition.

The first is *Hutchison 3G v Ofcom*. It is {M/46/1}. This is a case about whether a mobile operator, H3G, had significant market power in the market for wholesale for determination on its own network on which it had 100% market share.

If we look at page 43, please {M/46/43}, and down to paragraph 88. H3G's case was that:

"... in assessing whether an entity has SMP, at least in a case like this where power over price is an essential element of the regulator's decision, it is relevant, if not important, to consider the effect of regulation or possible regulation on the entity in question."

So H3G was arguing that you have to take into account the effect of an extraneous intervention by a third-party regulator, not a constraint on its prices

exerted by a counterparty in the market.

If we go on to page 51, please, paragraph 98 {M/46/51}. The Tribunal has cited a Commission decision and the proposition that derives from it:

"... a potentially regulated person cannot claim that it does not have SMP because regulation has procured a situation in which it no longer has it. So long as it is regulation which is bringing about competitive outcomes, the markets are not competitive independently of that regulation. It follows that the potentially regulated person cannot say that it does not have SMP because the threat of regulation means that it does not have the necessary power. That would be circular and illogical. Ofcom relied on this reasoning."

The conclusion of the Tribunal in 99, consistent with that, is that:

"... the possibility of [extraneous third-party] regulation being brought to bear on H3G ... cannot be prayed in aid by H3G as militating against its having [significant market power].

It reached the same conclusion in relation to dispute resolution by the regulator. If we look at page 75 {M/46/75}. Under subparagraph (b) it is talking about the nature of a dispute resolution clause. It

says:

"The regulator's powers are conferred and constrained by statute, and while Ofcom's are extensive they do not include the power to be a third party arbitrator. In truth clause 13 does not invoke the latter sort of status. The sort of dispute that clause 13 contemplates is a form of interconnection dispute, which Ofcom would resolve as a regulator, not as a third party dispute resolver. Its intervention would therefore be as a regulator, and would be a form of regulation. It therefore falls to be disregarded as a matter of principle, just as Ofcom's general presence as a regulator with a potential effect on the conduct of the putatively regulated person falls to be disregarded, for the reasons given above."

So again, in our submission it is very clear that what is being disregarded is extraneous third-party intervention in the market.

So the matter was then remitted to Ofcom to reconsider, on a separate point, specifically whether or not the counterparty in the market, BT, had countervailing buyer power, and there was then an appeal against Ofcom's subsequent decision, and that is at {M/59/1}. So, this is the appeal against the decision which arose out of the remittal. If we go to page 52

{M/59/52} we see that the Tribunal again finds that:

"... the dispute resolution powers of Ofcom ... should be disregarded under the application of the modified greenfield approach. The exercise of Ofcom's dispute resolution powers is a form of regulation which has the effect of curbing H3G's exercise of market power even though that may not be its sole or even main aim."

Again, the Tribunal has the point that what is being left out of account here is extraneous third-party regulation. In our submission that comes through particularly clearly from what is said by the Court of Appeal when this decision was then appealed up. It is at {M/74/26}. The quote at the top of the page is paragraph 122 of the Tribunal's judgment that we just looked at. Then paragraph 60, the Court of Appeal's judgment, we see the final sentence:

"The possibility or probability of ex post regulation (such as fixing a reasonable price by dispute resolution) may in fact operate as a constraint on the freedom of an undertaking which has a large market share, but it is not relevant to a decision as to whether that undertaking as SMP.

61. A question as to how an undertaking would operate on a market cannot be answered, in this context, by saying that it would behave in a way that would

comply with the regulatory controls that might be imposed on it if it did not. That would result in a regulatory system being self-defeating. Its existence would mean that the mischief which it exists to deal with would be found not to be present because of the very existence of the system, thereby negating, in theory, the conditions for the application of regulatory control but leaving it open to the undertaking, in practice, to operate (for a time at least) uncontrolled by regulation."

So that is the concern, the degree of circularity that arises if the answer is given by extraneous third-party regulation.

If we look at 66 {M/74/27}, in my submission this is a passage which is particularly clear in drawing a distinction between external regulation and the parties that are actually active on the market. So the relevant enquiry is whether the undertaking in question is able to act independently of its customers, and you see the court saying:

"A regulatory provision which, if used, would have an effect on the freedom of an operator to act independently of its customers cannot be allowed to provide an a priori answer to the question whether that operator does or does not have SMP. It does not seem to

me to matter whether the provision is one which affects, directly, the operator in question or a third party dealing with it, such as BT in the present case, the extent of whose [countervailing buyer power] is in issue and would affect the operator's freedom in relation to its customers. Accordingly it does not seem to me helpful or relevant to consider whether the dispute resolution powers are to be seen, in this context, as affecting BT or H3G or both. Either way ... if it were taken into account in the way [counsel] submitted is correct, it would provide an automatic answer to the question, and would not allow a finding of SMP in any such case. That cannot be a correct application of the legislation."

In my submission you have the Court of Appeal here referring to three separate elements. You have H3G, which is active in the market; you have got H3G's counterparty which is BT; and you have the regulator, and it is very clearly drawing a distinction between each of those three. What is to be excluded from consideration is the extraneous intervention of the regulator. This is not, in my submission, authority for the proposition that one does not look at any ability by a party active in the market to resist the power of their counterparty.

Just moving on to the next authority that the CMA cites, it is at {M/69/32}. They rely on paragraph 80, where you have the Tribunal saying:

"We do not consider that the existence of the price cap in this case negates the existence of market power."

Again, the short point is that the price cap is imposed by a third-party regulator. It is not concerned with the ability of a market participant to restrain market power.

The CMA then cites *Napp*, it is at {M/24/43}. What *Napp* was considering was whether the PPRS was sufficient to negate dominance. What comes through very clearly from the Tribunal's perception of the way in which the PPRS operated is that it is not the same as the powers in issue in the present case. If we look at 154 we see the Tribunal recording the submission by the director:

"... that *Napp* is dominant by virtue of its market shares alone, which are in excess of 90 per cent. That dominance is reinforced by the barriers to entry referred to in the Decision. The PPRS does not go to rebut dominance at all. That scheme controls the overall profit that a supplier of branded pharmaceuticals may earn from the NHS but is not directed at anti-competitive abuse."

If we look at 155 you see that the Tribunal accepted that submission.

If we go over to the next page, paragraph 161 {M/24/44}, the Tribunal says:

"As regards the PPRS, that scheme regulates by voluntary agreement the maximum profits to be made by any scheme member in respect of branded licensed medicines sold so to the National Health Service, and in some case the maximum prices that may be charged for medicines covered by the scheme ...

162. ... the essential feature of the PPRS is that it imposes a limit on the rate of return ... that a company can earn on its sales of branded prescription medicines to the NHS. That profit limit is applied across all the products that a company sells to NHS and is not applied to each ... individually."

Paragraph 164 on the next page {M/24/45}, the Tribunal says:

"In our view the case law on the existence of a dominant position, cited above, directs our attention to the competitive situation in the market place, and in particular to whether the allegedly dominant undertaking is able to 'prevent effective competition being maintained on the relevant market'."

That is, in our submission, quite right and it is

consistent with the point that we make, that the focus is on the dynamic between the undertaking operating in the market and its customers.

Then you see the Tribunal's perception as to the powers that it was being asked to assess:

"As seen from the foregoing, the PPRS does not have a direct effect on *Napp*'s freedom to conduct itself as it wishes in the market for oral sustained release morphine. As regards the issue of dominance, the effects of the PPRS are at most remote and indirect, in that the scheme might in some circumstances constrain *Napp* from increasing the price of MST (an issue not relevant here) and may similarly constrain *Napp*'s profits on its range of NHS branded medicines taken as a whole, as distinct from MST in particular. In our view neither of those indirect effects go to the threshold question of whether *Napp* has the degree of power in the market place necessary to bring the Chapter II prohibition potentially into play."

In our submission this is not even authority for the proposition that one should not take into account regulation, because that is not really what the Tribunal is saying. It is not saying, do not take into account. It is making a finding of fact that in the context of the problems it was looking at this scheme had limited

and indirect effects. It was too remote, it was not having the relevant effect to constrain the exercise of market power.

That, in our submission, is very different from the circumstances of the present case.

Just to -- I think it is fair to say that the authorities that the CMA cites in its footnote become of increasingly peripheral relevance as one goes down the list, but just to tick them off very briefly. There is a citation of the footnote in the Perindopril Servier decision. This is at {M/105/657}, right at the bottom of the page. Do you see, footnote 3356:

"Servier argues that both the prices of patent protected products and of generics are regulated and consequently cannot be relied upon to establish a dominant position."

If you just go over to the next page {M/105/658}:

"The Commission disagrees with *Servier*'s reasoning. Dominance is an objective notion. A source of market power may be important in explaining how that market power came into being but is immaterial as to the question of its presence or absence. The Commission wants to point out an analogy to the General Court's judgment in the *AstraZeneca* case, where it was found that the fact that competitive constraints are

absent ... due to the regulatory framework does not affect the very finding of the absence (or insignificance) of competitive constraints ..."

In our submission what is being discussed there, again, is the extraneous regulatory framework. There is no assessment here of the extent to which a particular operator in the market has the ability to constrain an undertaking's market power.

Then *Deutsche Telekom*, {M/80/41}. The CMA has cited first paragraph 87. This is making the point:

"... the appellant ... underlines the encouragement provided by RegTP's intervention, and states, in particular, that RegTP itself considered and approved the margin squeeze at issue in the light both of national and European Union telecommunications law ..."

This is not really even concerned with the situation of whether you do take into account regulation or not. What it is saying is that you cannot really point to the fact that your price was not hauled up as demonstrating that there is an absence of an abuse.

Then in {M/80/43}, this is the other paragraph, paragraph 92 that was cited.

"The same applies to the appellant's claim that the purpose of RegTP's regulation is to open the relevant markets up to competition. It is common ground that

regulation did not in any way deny the appellant the possibility of adjusting its retail prices for end-user access services or, therefore, of engaging in autonomous conduct that is subject to Article 82 ... since the competition rules laid down by the EC Treaty supplement in that regard, by an ex-post review, the legislative framework ..."

Again, that is essentially a factual finding that the regulation did not in any way deny the appellant the possibility of adjusting its resale prices. It is not really, in our submission, on point. It is to the question whether you take it into consideration for the purposes of countervailing buyer power.

So in our submission nothing in the authorities that the CMA has cited in its Decision precludes the Tribunal from taking into account the ability of a purchaser which is active on the market to exercise powers available to it to constrain the price of goods supplied to it by whatever means it might have available and simply say that there is no barrier to that being taken into account on the face of the case law.

The Tribunal may have noticed a degree of inconsistency in the CMA's stance in this respect, because we have spent a lot of time debating the extent to which the drug tariff exerts a competitive

constraint. Obviously we have seen another note come through on that point this morning.

THE PRESIDENT: Yes.

MS FORD: Nobody appears to be claiming that this Tribunal should disregard the drug tariff altogether in assessing the state of competition in the relevant market, and obviously to do so would be adopting an approach which would be divorced from the realities of the market.

Yet, when it comes to the Department of Health's powers to intervene and control prices, the Tribunal is essentially being asked to close its eyes and pretend that those powers do not exist. That, in our submission, makes no sense and it is an outcome which we say is not required as a matter of law by the authorities that the CMA has cited. So that was the CMA's first answer to this point.

If we go back to {A/12/416}, please. Paragraphs 4.335 and then also over the page to 4.338 {A/12/417}. These paragraphs are providing the second answer, which is to say that what is required is a constraint in practice and it claims that a constraint in practice, an effective constraint, is not present on the circumstances of this case. That, in our submission, is misconceived and we say there is here a concrete and undisputed legal power to control prices

and that cannot be dismissed as merely a theoretical matter. We say that the existence of such a power clearly constitutes a constraint in practice in that it is valid and exercisable, and it cannot be the case that unless and until that power is actually deployed it can be discounted altogether.

We say there is no reason to assume in that context that the Department of Health is anything other than well resourced and well advised and well capable of exercising the powers that it has should it see fit to do so, and so, in our submission, the starting point has to be that these undisputed powers are effective, and as I foreshadowed earlier in an exchange with the Tribunal, to the extent that it is being suggested that they are anything other than effective then the burden is on the CMA to convince the Tribunal otherwise. The Tribunal has my point that we say that is particularly true in the circumstances where the CMA has not chosen to seek evidence from the Department of Health as to why it did not exercise its powers.

We say the CMA could have approached the Department of Health and invited it to explain, for example, the extent of its knowledge of the price increases, its perception of its own powers to address those price increases, the approach it takes to exercising those

powers and its rationale for not intervening in the circumstances of the present case.

None of that information is properly before this Tribunal, and so we do say that the CMA is not entitled to benefit from some sort of presumption or inference that these powers are not in some way practicable where it has not troubled to seek evidence as to why they were not exercised.

In response to our criticisms the CMA has, in its Written Opening Submissions, said that it did indeed speak with Department of Health and Social Care officials to clarify its understanding of the position and received an account that was consistent with the CMA's own interpretation of the relevant powers. The document that it has cited is at {IR-H/1060/1}.

This is a note which is two pages long. It is not a formal interview note, it is not formal minutes of a meeting. It is certainly not in the form of a witness statement. We do not know which officials the CMA spoke with, we do not know what questions were asked, we do not know what process was followed. I mean, it is dated July 2017. We do not know if it was a face-to-face meeting, a call, did it take one day, did it take multiple days? In our submission as evidence of a proper investigation of these matters this note is

frankly unsatisfactory.

The CMA has also sought to derive some support from what was said by this Tribunal in *Phenytoin* concerning the Department of Health's powers. It is {M/150/30}. You see at paragraph 80 the Tribunal recording:

"The CMA did not put forward any factual evidence in these appeals. This was the subject of some criticisms by the Appellants, in particular as regards the absence of any direct evidence from the [Department of Health].

81. The [Department of Health] played a significant part in the facts leading to these proceedings. What the [Department of Health] did, or did not do, at various points in time in relation to the pricing of tablets and capsules, as well as the extent of its statutory powers, and the view it took of those powers, are matters that featured in the cases advanced by all parties about which the parties have diverging views."

If we go down to paragraph 82, we can see the Department of Health was represented at a hearing of an application for interim relief but:

"... it chose not to intervene in the main proceedings. Nor did any [Department of Health] official provide witness evidence as part of the CMA's defence."

Can we see the rest of paragraph 82, please. The

key point the Tribunal is making is probably towards the end of this paragraph {M/150/31}. They say:

"Whilst we appreciate that the [Department of Health] carefully considered its position in relation to these appeals, including the obvious interest in limiting the cost of the appeals to the taxpayer, given the undoubted relevance of the [Department of Health]'s role to the matters in issue, we consider that our task would have been easier had there been direct evidence before the Tribunal from the [Department of Health]."

So these are really quite pointed observations by the Tribunal that it would have been assisted by evidence from the Department of Health, and in those circumstances the CMA's decision not to approach the Department of Health for evidence of a properly probative nature in relation to these sorts of issues again is, in our submission, quite striking.

In any event, we say there is an important distinction, a factual distinction between the circumstances of that case, *Phenytoin*, and the circumstances of this case. If we look at {M/150/69}, paragraph 207, you see the Tribunal is saying:

"We agree with the CMA in this respect and do not consider that it is necessary for us to decide the precise extent of the [Department of Health]'s powers as

a question of statutory interpretation or otherwise. The question is whether the DH was, as a matter of fact, able to exercise buyer power in the form of regulatory power materially to influence Pfizer and Flynn's pricing. With regard to the extent of the [Department of Health]'s legal powers, and without deciding the point, we simply observe that Pfizer itself acknowledged in its skeleton argument that the [Department of Health] was unclear about the scope of its powers, and that the amendment to the NHS Act 2006 introduced by the 2017 Act suggests to us that the [Department of Health] considered it did not already have the necessary powers in this area."

In our submission it is important to realise that there was a marked lack of clarity about the extent of the Department of Health's powers in that case, such that one of the appellants acknowledged that the Department of Health was unclear about the scope of its powers. In circumstances where there might be a marked lack of clarity, one can see why it might be necessary to enquire into the extent to which those powers were actually exercised, because they might -- the exercise of the powers might inform their existence and scope.

In our submission, there is no lack of clarity about the powers that I have shown the Tribunal on the face of

the statute and under Scheme M.

The CMA has sought to rely in the Decision on the fact that permission to appeal from this finding in paragraph 207 was refused. If we look at {A/12/417}, paragraph 4.336, you can see that what the CMA is citing is what the Court of Appeal said in refusing permission, and it cites an excerpt:

"[It] was clearly entitled to conclude that it did not need to decide the precise extent of the Department of Health's powers and to find that the Department had no effective means to limiting the appellants' prices."

Now, we, in our written submissions at paragraph 79, have quoted the Practice Direction which tells you that applications for permission to appeal cannot be cited unless they purport to establish a new principle or extend the present law. They are not permissible authority, essentially. Our understanding from the passage that has been quoted is that the Court of Appeal is not purporting to establish a new principle or extend the present law, although we are somewhat limited in our ability to address it because that document has not actually been provided. It is not a public document. (Pause) I am told it is in the bundle.

But in any event, we make two points about it. The first is that it is not admissible authority, and the

second is that it is common ground that the situation in that case was that the existence of the powers was unclear, and when you have this lack of clarity one can see why it makes sense to look at whether or not they have been exercised in practice. But we do say there is no such lack of clarity in relation to these powers. There is no doubt about the existence of the powers in question, and so there is no basis, in our submission, to dismiss these powers as being merely theoretical.

The final point that one gets out of this authority is that it is clear that the Department of Health has been ready to exercise these powers in relation to other drugs, and this is the point I alluded to earlier when the Tribunal asked about instances where they might have been exercised. This is at page 69 {A/12/16}. Sorry, it is {M/150/69}, going back to the *Phenytoin* authority. There is a heading there "Teva's 2007 meeting with the DH".

What is going on here is that the Tribunal is setting out evidence that Mr Beighton gave in these proceedings -- in the *Phenytoin* proceedings, about the Department of Health's meeting with Teva in the context of *Phenytoin* tablets. If the Tribunal looks in particular at subparagraph (6), he is saying:

"I attended that meeting and recall that we were

told that the DH wanted the price of the tablets to be reduced. The DH also told us that if Teva did not cooperate they had the power to bring the price down itself but would prefer to do it with our cooperation."

So that is, as I indicated, an example not of exercising the powers of such but as in threatening to do so if matters are not resolved by way of cooperation.

This is evidence which was also repeated in the *Liothyronine* trial and we understand, having corresponded about it, that it is not factually contested by the CMA, although they do not accept that it is indication of countervailing buyer power, they do not take issue with the factual matters which are set out in this evidence.

In our submission what it shows is that the Department of Health is well capable of deploying these powers if it sees fit and so, again, one cannot simply dismiss them as theoretical.

Given that the Department of Health has this power to require Auden/Actavis to reduce their prices, we say they cannot act independently of the Department of Health and so they cannot be deemed to be dominant.

That brings me to the end of the second ground of appeal. I am moving on to ground 2B which concerns the duration of dominance unless the Tribunal can be

assisted further on that particular point.

THE PRESIDENT: No, I do not think so, thank you.

MS FORD: Ground 2B is concerned with the duration of any dominance which might be found to exist. What we say is that the CMA should have concluded that any dominance on the part of Auden/Actavis ended once competitive entry began to occur and there was downward pressure on prices. The Tribunal is now well familiar with the picture that is painted in some of the figures in the Decision on this. So, for example, if we look at {IR-A/12.1/2}.

This is obviously a familiar chart showing what happened to prices on competitive entry. In our submission from the point where there is a downward pressure on prices Auden/Actavis can no longer be said to be acting independently of its competitors and so can no longer be said to be dominant.

The Tribunal has already heard in the evidence that there is an inconsistency in the CMA's Decision in this respect between the position it has taken in relation to market definition and the position it has taken in relation to dominance.

In the context of market definition the CMA finds that Auden/Actavis clearly faced competitive constraints from skinny label suppliers with the entry of skinny

label tablets supplies precipitating falls in prices.

For example, if one looks at {A/12/302}, paragraph 4.12, you see the CMA is saying:

"Taken together, the evidence demonstrates that Auden/Actavis clearly faced competitive constraints from skinny label suppliers with the entry of skinny label tablet suppliers precipitating falls in prices, effectively halting and then starting to reverse the price rises of the previous seven years."

That is what is said in the context of market definition. One then compares what is said is in the context of dominance. If we look, for example, at 4.244. So this is {A/12/385}. In tension with what it says in the market definition context we see:

"... price reductions and the loss of a certain amount of market share do not in themselves indicate the absence or loss of dominance. In this case, the evidence shows that notwithstanding a decline in its market shares and prices ... Actavis retained the ability to act on appreciable extent independently of its competitors, customers and ultimately consumers. This is demonstrated by Actavis's retention of significant market shares despite the entry of competitors and its ability to charge a premium for its product, at a time when the competitors' prices were

falling at a faster rate."

The CMA seeks to reconcile those two positions which are at the very least in tension with each other on the basis of a finding of fact and the finding of fact is that following competitive entry Auden/Actavis had an assured customer base because a significant proportion of the market had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets. This is obviously a matter that has been explored to some extent in the evidence.

If, for example, we look at {A/12/404}, paragraph 4.288, if we just go over the page, 405, the final sentence in this paragraph:

"The CMA has concluded that the orphan designation granted in respect of Plenadren was a key factor contributing to this ability because it formed a barrier to expansion and provided Actavis with an assured customer base."

Then similarly, if we look at 4.291 you see these findings: .

"... that Plenadren meant that a significant proportion of the market had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets ..."

The Tribunal will appreciate that these factual

findings have been made in very absolute terms. Words "no choice", "were not able to switch" and the Tribunal will recall that Professor Valletti when he was giving evidence felt unable to support findings expressed in such absolute terms. He commented that the use of terms such as "totally captive" and "no choice" were "highly charged". That was his term. What he preferred to say was that there were essentially two segments in the market. One which is more inclined to be price sensitive and one which is more price insensitive.

His evidence was that in economic terms if one looks at customers like Boots they had to make a trade off and their demand was not perfectly inelastic and at some point their view would change if the price differential changed sufficiently, so it was not accurate to say that they had no choice.

Indeed, that was exactly how it was put by the CMA when they were cross-examining Mr Holt. So it was put to him that evidence showed that some of the regulatory focused pharmacies could have changed their approach if the price differential became too marked.

Our submission is that the CMA had no adequate factual basis to make the very categorical findings that it did and we say that while pharmacists had preferences they were not absolute and had the price differential

between full and skinny label been greater their decisions might well have been different.

The Tribunal will appreciate there is a significant overlap in this respect between our ground of appeal, Auden/Actavis's ground of appeal, and Intas's apeal and Mr Palmer has cross-examined on some detail on these issues. Intas are obviously running the point for their period but in my submission insofar as the CMA is factually wrong to find that customers had no choice, that is a finding which impugns their finding of dominance in respect of the Auden/Actavis period as well as the Intas period.

If anything, from Auden/Actavis's perspective there was even greater uncertainty in their period because in the early days of competitor entry they were seeing customers switching, they are seeing prices falling. They would not have had any confidence that they had an assured customer base.

So in our submission the answer to this factual question will be the same in the Auden/Actavis period as in the Intas period and in those circumstances in order to avoid duplication what I propose to do is to defer to Mr Palmer to develop this factual point further, but we do say that insofar as the Tribunal is persuaded that there is an error of factual appreciation here that is

one that applies to our period as well.

We do see in the Written Closing Submissions the CMA taking refuge in market shares as saying that dominance persisted post-entry and that appears to be an attempt to move away from this factual finding. But we know that market shares are no more than a starting point. We say that there can be no presumption arising out of market shares in circumstances where the competitive process is in the course of bringing down prices and reducing market shares whether by volume or by value, and ultimately the CMA must defend its reasoning as set out in the Decision.

It has described the assured customer base point as a key factor in its reasoning, as I showed you, and we say if that reasoning is flawed, then the finding of ongoing dominance is itself misconceived.

That is our ground 2B. Moving on to deal with ground 3, excessive pricing. As the Tribunal is aware, the leading authority on this is the judgment of the Court of Appeal in *Flynn pharma*. It is at {M/170/1}. If we start, please, at page 17 {M/170/17} and paragraph 56. This is in Lord Justice Green's judgment. This is where he is setting out the classic test for unfair pricing in *United brands* and he has quoted the relevant paragraphs.

"The imposition by an undertaking in a dominant position directly or indirectly of unfair purchase or selling price is an abuse to which exception can be taken under Article 86 of the treaty.

"It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominance position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.

"In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse."

He says at 251:

"This excess could inter alia be determined objectively if it were possible for it to be calculated by making a comparison between the selling price of the product in question and its cost of production, which would disclose the amount of the profit margin."

It goes on to point out that it had not been done in the case of *United brands*.

If we go over the page, please. 252 is really the core paragraph which sets out the two limb test:

"The questions therefore to be determined are whether the difference between the costs actually

incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products."

So if a price is found to be excessive and it is necessary to proceed to consider whether it is also unfair. There are two ways of determining whether a price is unfair and they are whether it is unfair in itself or when compared to competing products.

The Tribunal will be aware that the CMA's position before the Court of Appeal was that those two tests for unfairness were strict alternatives in the sense that if it had established sufficient evidence on a cost-plus basis to prove abuse relying on the "in itself" test for unfairness then the CMA said it was not under any obligation to either assess or rely on any other sorts of evidence such as comparables under the competing products test.

That argument was rejected by the Court of Appeal and we see that first of all in paragraph 57, final line where Lord Justice Green says:

"For the reasons set out below I conclude that the reading of the test in *United brands* by the CMA is unduly rigid and literal and invests far too much

significance in the distinction 'or' in para 252."

If we go on to paragraph 97 on page 29. {M/170/29}. This is where the Court of Appeal, having reviewed all the relevant authorities, then summarises its general conclusions. I do not propose to read all of it, but if we look in particular at (vii) on page 30, {M/170/30} you see the proposition:

"If a competition authority chooses one method (eg cost-plus) and one body of evidence and the defendant undertaking does not adduce other methods or evidence, the competition authority may proceed to a conclusion upon the basis of that method and evidence alone. If an undertaking relies, in its defence, upon other methods or types of evidence to that relied upon by the competition authority then the authority must fairly evaluate it."

He goes on to elaborate on into further on in his judgment. So, for example, page 35. {M/170/35}. Paragraph 113. We see the Court of Appeal saying:

"At base the CMA has a duty to conduct a fair evaluation of all the evidence before it."

Then paragraph 117 on the following page. {M/170/36}. You can see the Court of Appeal describes the core question, this is the third line:

"... the core question arising concerned the

correctness of the position adopted by the CMA to the effect that the 'in itself' and 'competing products' tests were 'true alternatives', in the sense that if the CMA relied upon one alternative to find abuse then it had no obligation in law to evaluate other prima facie evidence that prices were fair adduced by a defendant undertaking. On this basis, I accept that the Tribunal was right to say that the 'in itself' and 'competing products' tests were not strict alternatives. I therefore disagree with the CMA on this central issue."

Then going on to page 40. {M/170/40}. Paragraph 127. This is where he is essentially referring to the application of the principle of the facts to the case and he says:

"There was an obligation upon the CMA properly and fairly to evaluate the comparator evidence because it was adduced by the undertakings as part of their defences. It was not therefore open to the CMA to ignore that evidence simply because it had, in its judgment, conducted a sufficient analysis."

So that is what Lord Justice Green had to say about the CMA's duty to evaluate comparators and he also in his judgment makes some observations about the concept of economic value. If we go to page 48, please.

{M/170/48}. 154:

"The concept of economic value is not defined. In broad terms the economic value of a good or service is what a consumer is willing to pay for it. But this cannot serve as an adequate definition in an abuse case since otherwise true value would be defined as anything that an exploitative and abusive dominant undertaking could get away with."

So you see him saying in 155:

"The simple fact that a consumer will or must pay the price that a dominant undertaking demands is not therefore an indication it reflects a reasonable relationship with economic value. But a proxy might be what consumers are prepared to pay for the good or service in an effectively competitive market ..."

If we go on to page 152.

EPE OPERATOR: It only goes up to page 75.

MS FORD: Sorry. It should be paragraph 171. {M/170/52}. He is here commenting again on the concept of economic value, and he says:

"The Tribunal observed that this was clearly a legal test. The categorisation of this as a 'legal' concept seemingly led the Tribunal to treat economic value as a discrete component of the test in law to be applied. It is 'legal' in the strictly limited sense that it has

been ascribed a meaning in a court judgment, but, at base, it is an economic concept which describes what it is that users and customers value and will reasonably pay for [it]..."

THE PRESIDENT: I am not sure the economists who gave evidence before us today or on this hearing could agree with that.

MS FORD: They certainly struggled to define it.

THE PRESIDENT: That is true, but I think they -- it was Dr Bennett and Professor Valletti who struggled and that is not a criticism, but I think certainly Dr Bennett took the view that it was not actually his job to define it.

MR O'DONOGHUE: I do not think, sir, it was Dr Bennett. He did not deal with it.

THE PRESIDENT: Right, I am mis-remembering.

MR HOLMES: You may mean Mr Bishop, sir.

THE PRESIDENT: My error. But Mr Bishop did the highlighter pen. That was -- yes, and Professor Valletti I think --

MS FORD: He simply found it a challenging concept.

THE PRESIDENT: Yes, but I think, although he was much too polite to say so -- I think he found it as a challenging concept for us not for him. Anyway, I mean be that as it may --

MS FORD: Certainly I think one can get two points out of

what the Court of Appeal is saying. The first is that the unfair pricing test has to look at both sides of the relationship, so it looks both at the supply side in terms of the costs to the supplier but it is also saying you do have to properly look at the demand side of the relationship and that is the concept of economic value, the value the consumer ascribes to the good or service. The demand side is a proper part of the exercise.

Then he is saying difficult though it may be -- and this is in particular in 172 -- the economic value is part of the overall descriptor of the abuse. It is not the test. But he does say:

"... the test should when properly applied be capable of evaluating economic value. Insofar as an issue of fact arises which can be categorised as an aspect of economic value it needs to be measured and it can be evaluated in various parts of the test."

So he is saying very clearly this is part of the test and you need to take it into account in some particular way.

So that was Lord Justice Green's judgment. Turning on to the Chancellor's judgment. He had some additional observations, in particular, as the extent of the obligation to evaluate comparators.

If we look at page 70, please. {M/170/70}.

Paragraph 257. This is the Chancellor saying:

"The CAT acknowledged at para 366 that it was clear from [the authority that it cites] that the two tests of unfairness in para 252 are alternatives in the sense that an authority can, as a matter of law, establish a breach of Article 102 under either alternative 1 or 2 and does not need to succeed under both."

We will see when we look at the Decision that this is a paragraph that the CMA likes and so it cites it quite repeatedly in the Decision.

If we look at paragraph 259 on page 71. {M/170/71}. You see:

"The CAT was wrong to say that the CMA was obliged to consider the second alternative of the unfairness test having decided that it was appropriate in all the circumstances to adopt the first alternative. As has been repeatedly said, the tests are alternatives. But I do agree with the CAT when it said at para 367 that the CMA could not simply ignore a prima facie valid argument that a price is fair, whichever alternative it chose to adopt."

Then at 260. He says:

"The question of whether the choice between the two limbs of the unfairness test adumbrated in *United brands* is a binary one, is an academic and

irrelevant one. As will appear in issue 3 below, I take the view that the competition authority will always need, at least as part of its duty of good administration, to give some consideration to prima facie valid comparators advanced evidently by the undertakings. That is so whether or not the CMA chooses to proceed eventually under the unfair in itself or alternative of the unfairness test. Even in that situation, the fact that comparators are expressly mentioned under the second alternative does not absolve the CMA from giving whatever proper attention is required to comparators raised by the undertakings. In these circumstances I am in substantive agreement with Green LJ's conclusions on this point."

Then if we look to page 73, paragraph 270. {M/170/73}. You see the final sentence of this paragraph, essentially a warning from the Chancellor:

"If it rejects the comparators wrongly or without giving appropriate reasons, its infringement decision will be more vulnerable, if and when the matter comes before the can CAT on appeal."

Similarly, paragraph 273, you see again towards the end of that paragraph:

"If the CMA wrongly ignores evidence of comparators, and those comparators turn out to be relevant or

important, their analysis will fail at the CAT."

So that in our submission provides two key insights into the nature of the unfair pricing test. We place particular emphasis on the obligation to conduct a fair analysis of comparators and particular emphasis on the role of economic value. In our Notice of Appeal we have identified two contextual factors which we say make it particularly important in this case that the CMA supplements a basic cost-plus analysis by a fair analysis of the potential comparators.

Those two factors are first of all, the economic value of hydrocortisone as a life-saving drug and secondly, the fact that the pricing of the portfolio as a whole would be loss-making if the CMA's cost-plus approach to hydrocortisone were to be adopted.

So taking those in turn. First, hydrocortisone is described by the CMA as a life-saving drug and it would not have been available at all had Auden/Actavis not taken over the licence in 2008. The basis on which I make that submission is at {H/916/1}. This is the response to the CMA from the original marketing authorisation holder for hydrocortisone, MSD, and it is a response to a section 26 notice dated 22 June 2016.

If we look down to page 2, the response to question 5, {H/916/2} and the question is:

"the CMA understand that MSD sold its UK business for hydrocortisone tablets -- including intellectual property rights, marketing authorisations and product -- to Auden/Actavis McKenzie in April 2008. Please provide details, including contemporaneous documents, of how MSD valued this business. Please confirm, amend and/or supplement the following information regarding this transaction."

To which the response is:

"We have no contemporaneous documents relating to how MSD valued this business. However, the CMA should note that the valuation would have been arrived at on the basis that the company was going to delete the product in any event and therefore the sum would typically pay [for] the MSD's internal costs of disposal and would not have been intended to be an accurate valuation of the market for hydrocortisone tablets."

If we go to page 3, please. {H/916/3}. The response to question 6 which is asking about MSD's rationale for selling its hydrocortisone business to Auden/Actavis. What we see there is:

"MSD's business model is based on the sale of patented, ethical pharmaceuticals. Historically the profitability of products after loss of exclusivity of patent protection falls substantially which makes the

ongoing manufacture, marketing and sale of those products, generally, unattractive."

In the context of the question about the rationale for selling hydrocortisone it is saying such off-patent products are generally unattractive.

The CMA has said in its Defence that there is no evidence that MSD would have discontinued the product but for the sale to Auden/Actavis as opposed to selling the marketing authorisation to another willing purchaser. But in our submission that is a failure of evaluation of the evidence. MSD has clearly indicated that it had an indication to discontinue this product and the suggestion there might have been another willing purchaser is in our submission speculative in circumstances where there is no evidence of any other such purchaser and, as MSD has pointed out, the market was generally unattractive.

Of course, there is no evidence before this Tribunal suggesting that the CMA sought to investigate whether MSD would have sought an alternative purchaser or indeed did seek an alternative purchaser had Auden/Actavis not stepped in.

So, in our submission, Auden/Actavis's decision to take over and market this drug, which inevitably entails price rises because, as MSD have explained, it was

unattractive to market in its hands at the price that it was marketing it, had the effect of retaining a life-saving drug on the market. Had it not done so, hydrocortisone tablets would have likely ceased to be readily available in the UK at all during the period 2008-2012.

Then even once Plenadren was launched in 2012, as we have seen, Auden/Actavis's product was consistently cheaper and that in our submission is economic value which ought properly to be reflected in the CMA's pricing assessment.

This point in particular may be relevant to the question that the Tribunal raised on Friday concerning the explanation for the pattern of pricing that is shown on the pricing graph in respect of this product. Clearly at the price at which it was priced by MSD it was described as unattractive, so unattractive that they were going to delete it and they were going to bear the cost of disposal and so price rises would have been inevitable from that point.

The CMA then says, well, retaining a product on the market doesn't justify the extent of the price rises. But in our submission that just begs the question because what the CMA needs to do is assess the extent to which the price was justified by the economic value and

in our submission that exercise has not properly been done.

It has been canvassed to some extent with the economists to the extent to which it is very difficult to ascribe a concrete economic value without falling into the trap of willingness to pay but we have in our submissions pointed to contemporaneous evidence which we say assists with that. There are contemporaneous documents from CCGs who considered the costs of hydrocortisone and compared them with the costs of Plenadren.

So, for example, if we look at {H/1108/1}, this is a document dated July 2013 from the Lancashire Medicines Management Group. You can see the conclusion at the top:

"Plenadren is not recommended for the treatment of adults with adrenal insufficiency. Robust evidence of a clear therapeutic advantage to justify the significantly greater acquisition costs compared with immediate release hydrocortisone is currently lacking."

If we go to page 5 of this document. {H/1108/5}. We can see that this Medicines Management Group conducted a comparison of the unit costs between Plenadren -- perhaps we can scroll down so we can see the -- thank you. The comparison is between Plenadren

on the one hand and Auden/Actavis's hydrocortisone on the other hand and this is done at a point when Auden/Actavis's prices were approximately £35.50 per pack and so the estimated total costs per patient per year for immediate release hydrocortisone tablets were calculated to be between £621 and £1,225. That is depending on the assumptions you make about the relevant dosage.

THE PRESIDENT: Yes.

MS FORD: That was a calculation in 2013. Even at the peak of the drug tariff prices for hydrocortisone, if one applies the same methodology, you get a cost of between £1,099, and £2,461 per patient per year as compared to approximately £2,920 or up to £6,461 per year for Plenadren.

So that is the price per year of a product that the CMA considers to be both essential and life saving.

As to how one converts that into economic value, the National Institute for Health of Care Excellence tells us that medicines that cost less than £20,000 per quality adjusted life year are considered to be good value. The Tribunal have the point that, even at its peak, hydrocortisone cost a fraction of that.

The CMA has sought to dismiss that point on the basis that the quality adjusted life year's approach is

used to make recommendations for new and innovative treatments rather than existing treatments.

But in our submission that is really immaterial because what we are trying to get at is the economic value to the recipient of a life saving treatment and the beneficiary of the treatment is not going to be drawing distinctions between a new treatment and an existing treatment.

Even if it were to be accepted that you have to take into account to some extent the novelty value or the absence of novelty value, Auden/Actavis's prices even at their highest point represented an 87.7% discount on the price that the NICE guidelines considered to represent good value.

In our submission that is concrete evidence of economic value which ought to be taken into account in assessing those prices.

Sir, I see the time. I do not know if that is a good moment for a break.

THE PRESIDENT: No, indeed. Just two questions which I will leave you with to think about over the short adjournment.

First of all, MSD clearly felt they could not raise prices, whereas Auden/Actavis clearly did. Is that simply because MSD mis-evaluated the market or because

of some characteristic that Auden/Actavis has that MSD did not? Because I mean, it is slightly odd to see MSD saying, well, we cannot make this drug pay, we are going to therefore sell it for £190,000 which is not the value of the drug, it is the fact that we want to get it off our books, and then Auden/Actavis clearly can do something which well, MSD either could not do or did not think of doing. That is the first question.

MS FORD: Sir, I can give you my immediate response to that.

THE PRESIDENT: Please.

MS FORD: My understanding is that what enabled the price to be increased was that the product was debranded so it was taken out of the constraints applicable to branded drugs.

THE PRESIDENT: Right. But could not MSD have done that?

MS FORD: One presumes it could but it did not appear to have any inclination to do so.

THE PRESIDENT: So, yes, I mean, -- well, that is an answer. It seems to me an incomplete answer.

MS FORD: I can certainly take instructions as to whether there is anything else we can contribute to that.

THE PRESIDENT: I just want to understand that.

Secondly, and relatedly, is there any law relating to what actually is a comparator? I infer from what the Court of Appeal are saying and indeed what

United brands say is that a comparator is a comparator product. But is there any law that suggests that one can have, as it were, a temporal comparator? In other words, one looks at the diagram we have all before talking about, the graph we have all been talking about where one sees the price of the same product over time and one can infer that something is happening from price changes in relation to the same product. So in one sense it is not a comparator because it is the same product but in another sense it is a comparator because of the history of that product. That I think would be of assistance.

Finally, you referred to the NICE evaluation of quality adjusted life years. If you could just give us a reference to that material, I think it is something that I have not looked at and perhaps we ought to.

MS FORD: Certainly, yes.

THE PRESIDENT: Thank you. We will resume at 2 o'clock.

(1.06 pm)

(Luncheon Adjournment)

(2.00 pm)

MS FORD: Sir, before the short adjournment the Tribunal asked me three questions. The first was why MSD felt that it could not itself raise its prices, and obviously in some respects the party that is in the best position

to comment on that would have been MSD itself, but I can offer a couple of additional points.

The first is that MSD was a member of the PPRS, whereas Auden/Actavis was not a member of the PPRS, and the way in which the PPRS operates is one of the matters that is dealt with in the ambulatory draft at paragraph 62. It is {IR-L1A/1/78}.

THE PRESIDENT: Yes, I think for the avoidance of doubt do not worry about the confidentiality because everyone in this room is cleared to see it. So thank you for raising it, but the default is do not worry and we will screech if something happens that is a problem.

MS FORD: So the relevant paragraph is 62, and it is just explaining that:

"From 2014 the PPRS effected this profit control via a system of payments based on a percentage of branded medicine sales, which implemented a limit on growth in the overall cost of the branded medicines purchased by the NHS from members of the scheme."

It does mean that different considerations would have applied to MSD as a member of the PPRS as compared to Auden/Actavis which was not a member, and Auden/Actavis's -- essentially their focus was on generics rather than branded drugs, and that is essentially the second point that I would draw out, that

MSD was an originator and so its business is selling, or was, selling branded products and it entails different strategies and different approaches and different considerations when one debrands a product.

THE PRESIDENT: What, I think, the implication of paragraph 62 is, is that it is not a no-cost option simply to move from branded to debranded items. You cannot, as it were, migrate a single product across from branded to debranded.

MS FORD: It has all sorts of implications. I hesitate to --

THE PRESIDENT: Indeed. I think what you are saying is it is rather more complicated than simply shunting the branded product to the debranded product, which is what I was putting to you before the short adjournment. I mean, I am sure there are other complexities as well and it may be we will ask more about that, but I am very grateful for the explanation.

MS FORD: Sir, that was the first point. The second point concerned the extent to which there is law on comparators over time. Insofar as we have been able to gather over the short adjournment we are not aware of any authority which specifically deals with comparators over time, but we are aware that there are authorities on what constitutes an appropriate comparator generally.

In particular, the *Latvian Copyright* case is concerned with comparison of prices between member states, and there is a summary of what is said about that in the Tribunal's judgment in *Phenytoin*. It is paragraphs 297-300, and for the Tribunal's reference it is {M/150/97}.

THE PRESIDENT: Thank you.

MS FORD: What is said there broadly is that when one is choosing comparators one needs to use objective, appropriate and verifiable criteria and the comparisons must be made on a consistent basis, which would seem to accord with common sense.

THE PRESIDENT: Yes.

MS FORD: Then the third point concerned the guidelines on quality-adjusted life years, and we will make sure a copy of that is provided to the Tribunal and uploaded to Opus.

THE PRESIDENT: I am grateful, thank you. When we were discussing your point regarding Plenadren and its higher price, it struck us that we did not know the answer to this particular question and it may be that we ought to think about it.

We quite take your point that in a highly regulated market a SSNIP may not be possible at all and one needs to think about things other than functional equivalents,

so we have that point. But what we were exploring was how, in a less regulated market, a more usual market without the quirks or oddities that exist here, how one applies the SSNIP when one is testing for potential substitutes that are more expensive than the focal product.

It arose when we were asking questions of Professor Valletti, where we were talking about could one work out whether a Rolls-Royce was a substitute for a much cheaper Mini.

Now, my understanding of how a SSNIP is applied is that you do not adjust for price differentials and that you simply work out what happens if you apply a SSNIP to the focal product -- here, the Mini. If that is right, then the Rolls-Royce will never be in the same market as the Mini unless something is very strange is going on with consumer preferences, because if you increase the price of the Mini at £5,000 by 5 to 10%, it is not going to incentivise anyone to buy a Rolls-Royce at 500,000.

So Professor Valletti was saying the SSNIP was generally applicable where one had substitutes that were at an equivalent price. I understood that point.

But what I think he should have said is he should have gone further and said actually, the way one applies

the SSNIP means that the more expensive product, if it is significantly more expensive, will always be in a different market, and that struck me as a slightly strange outcome if that was the consequence of a SSNIP.

Now, it may not matter but it occurred to me that it is something that we ought to have an answer to, given the point that you have just made about Plenadren being more expensive than hydrocortisone. I appreciate, of course, it is not the way you are submitting we should approach market definition. You are taking a functional approach. But again, in the spirit of wanting to know the answers to everything, that is something which surprisingly, I think, we did not think there was a clear-cut answer. Again, that is something you do not have to respond to now because --

MS FORD: I may take that lifeline and indicate that we will give some thought to whether there is anything further that we can offer in relation to that. But I would just re-emphasise, of course, that the particular oddity of Plenadren is that because it is more expensive it is not even available to be prescribed, and so one does not even encounter the point that you, sir, are making about the SSNIP because you just do not have the opportunity for it to be substituted whatever the price differential is.

THE PRESIDENT: We accept that. I mean, I think there is an awful lot of -- I am going to have to find a better word for this, but an awful lot of oddities in this market that we are going to have to unpack before we get on to how we define markets and what tests we use, and that is certainly one of them. So, yes, that point we have.

But I think what was troubling me was that I did not have the answer to an altogether simpler market, how one approached the market definition exercise there, because it seems to me slightly counterintuitive to say that on significantly increased price alone one is kicking out a potentially substitute product just for that reason alone.

It may well be in a different market, but it seems to me to be asking a little bit more by way of probing questions rather than simply by saying, well, it is an order of magnitude more expensive and so it is in a different market.

MS FORD: Yes, I certainly see the force of the point that has been made and I will give it thought.

THE PRESIDENT: By the way, it is an open invitation. So anyone who has an answer to that I would be very grateful to hear.

MS FORD: Sir, before the lunchtime adjournment we were talking about one of the two factors that we have

identified that we say mean that it is particularly important for the CMA not to just rely on a cost-plus type analysis and to properly consider comparators, and that was the economic value to be attributed to hydrocortisone as a life-saving medicine.

The second factor that we have made in -- that we have identified in this context is the practice of portfolio pricing. Portfolio pricing means setting your prices in such a way that the portfolio as a whole is profitable, and it is a common industry practice and it is a practice which is beneficial to the NHS because it means that generic companies are able to make a wide range of products available at low cost, not just those that are produced in sufficient volumes or are capable of being independently profitable.

This is what Auden/Actavis were doing, they were pricing their products, including immediate release hydrocortisone tablets, on a portfolio basis and if the CMA's approach to cost pricing of hydrocortisone were to be adopted then the consequence of that would be that Auden/Actavis's portfolio as a whole would have been loss-making for a number of years over the relevant period. It hardly need be emphasised that a loss-making price is self-evidently not an excessive price.

The CMA's answer to this, and one finds it in the

Decision at paragraph 5.278 {A/12/498}, is to say that an undertaking cannot be permitted to prop up an otherwise unprofitable business by charging excessive and unfair prices on a product which holds a dominant position.

THE PRESIDENT: In a sense that begs the question of what is an excessive price, does it not?

MS FORD: Sir, it very much does. That is absolutely what we say about it. We say we are seeking to establish whether this is an excessive and unfair price, and when you are assessing fairness it is necessary to take into account the commercial reality of pricing practices in this industry.

THE PRESIDENT: I will say this so that the parties know what I am thinking about, because there are two instances where I think this sort of phenomenon has been considered. One was in the *Sainsbury's* decision that I did with Sir Gerald Barling in 2016 where we actually had evidence on this, and it was quite clear that all the supermarkets did not price by reference to cost, they priced by reference to what attracted customers in and by what their competitors were doing, but there was no necessary correlation between the cost of a banana and the price it was sold at. It was very much like a portfolio pricing system. They were keen to

make a profit overall but they looked at all of their costs, they looked at all of their revenue and they adjusted prices in a way that maximised that but not in any way relative to cost.

The other thing I am thinking of is the water bed that one gets in price controls where you say that one of the problems of controlling a product in a multi-product portfolio is if you push down product A the price of product B goes up, rather like the water bed. Really all I am doing is I am articulating that the notion of prices being interrelated between products is something that is quite familiar in economic thinking, and if someone is going to want to say that it should not be then that ought to be, sort of, pushed back on quite firmly. I know you are not going to say that, but it may be that others will.

MS FORD: It does relate to another point that the CMA makes because they say, ah, well, your portfolio is not necessarily loss-making because you could have charged more for other products in the portfolio and in that way addressed the concern that you are reducing the hydrocortisone price.

Again, that engages an important point of principle about what is meant by fairness in this context, particularly because what is being said to us is, you

could have priced your other products higher but obviously in the factual we did not in fact. So you are left with an artificial ex post facto counterfactual which says, well, you could have avoided being loss-making and that disregards the commercial realities of the situation.

So, in sum, what we say is that there does not appear to be any dispute that this is a common business practice, the way in which the portfolios are priced, and we say that is a factor which ought properly to be taken into account when one is assessing whether a price is fair or unfair.

We say that these two factors that we have identified together mean that it is particularly important that the CMA supplements its cost price analysis with a fair consideration of comparators.

Those are the two that we have identified in our Notice of Appeal. There is a third element of economic value which has rather come out of the evidence that the Tribunal has heard, and that is the fact that Auden/Actavis's product was full label rather than skinny label. It has come through very clearly, in my submission, that customers perceived a benefit to having a full label product over a skinny label product and that was something that Professor Valletti drew

attention to in his evidence. Again, we would say that is a factor that needs to be properly taken into account when you come to assess, essentially, the fairness of the pricing.

If we turn to --

THE PRESIDENT: Are you really saying that the *United brands* test is absolutely fine as a starting point but actually one needs to be extremely careful how one applies it, in that you have all kinds of other factors which may inform what is an excessive price. You have identified one, which is the portfolio of products which may affect what you regard as an excessive price. Another thing is, I think, the point made by the Advocate General in the *Latvian* case where what was said was cost can be a rather difficult thing to keep track of, particularly with intangible products. I mean, I know we are not really talking about intangible products here but if you are talking about, for instance, the price of a pharmaceutical you may have all kinds of R&D questions. I appreciate it does not arise here, but all kinds of R&D costs which in some way need to be taken into account.

Equally, is the question of failed R&D, the drugs that fail in the market, a relevant factor to take into account when one is working out what is a non-excessive

price, in that you have to have an industry which is sustainable in general terms. These are all sort of variants on your portfolio point.

So really what I am saying is, do we need to be very careful about what we are -- what we are pricing actually when applying this test?

MS FORD: Certainly we would say that it is always the case that one needs to be extremely careful when applying the test. The test is, in our submission, capable of accommodating these sorts of factors if applied correctly. The concepts of unfairness are capable of taking into account these sorts of elements.

The concern we have about the approach that the CMA took is that it has sought to reduce the test to little more than a cost-plus exercise without additional factors that then enable you to take into account all these contextual and important points.

One way in which you do try and get at those is by looking at comparator products because they do cast a light on what might otherwise be reasonable pricing, and that is why in our submission the Court of Appeal was very clear that insofar as the defendants raise comparative products it is important for them to be fairly evaluated. In our submission that has not occurred in the circumstances of this case.

I was going to come on to show the Tribunal what was done. If we start off at {A/12/441} you can see the heading "Auden/Actavis's prices were excessive", and if we look at 5.76 you can see the CMA is recording that it conducted a cost-plus analysis, and it concluded that Auden/Actavis's prices were excessive by reference to cost-plus. As we have seen, that is the first stage of the *United brands* test.

If we then go on to {A/12/503}, paragraph 5.293, we can see that the CMA chooses to rely on the unfair in itself limb of *United brands* and it finds that Auden/Actavis's prices were unfair in themselves.

But in our submission if we look at the factors which are relied upon to show, supposedly, unfairness in itself they are in reality a recycling of the CMA's cost-plus analysis and they add limited, if any, additional analytical content to the CMA's reasoning.

So they are summarised in paragraph 5.296 towards the bottom of the page, and you see:

"The CMA has concluded that Auden/Actavis's prices were unfair in themselves ..."

So this is what is supposed to be adding more beyond the cost-plus:

"... for the following reasons:

(a) the substantial disparities between

Auden/Actavis's prices and Cost Plus ..."

Well, self-evidently that adds nothing to the cost-plus exercise. You then have in (b) the assertion that prices:

"... were not justified by any features of hydrocortisone tablets ..."

If you go over the page you can see that what is being talked about there is things like innovation costs, production improvement and that sort of thing. Those are the things that could be factored into a cost-plus analysis to the extent that they are present, and so in our submission pointing out the absence of those things really does not add anything to a cost-plus analysis.

At (c) {A/12/504} you have reference to "the features of the relevant market(s)", and what is going on there is that it is essentially a recycling of the factors relied on to say that Auden/Actavis enjoyed substantial market power. So it is really, before you even get to cost-plus that is the prior requirement.

At (d) you see reference to "the scale and significance of Auden/Actavis's price increases".

That, in my submission, is a repetition of cost-plus and also a repetition of the first point about the disparities between prices and cost-plus. It really

does not add much else.

You then have at (e) the alleged adverse effects of price increases. That, in my submission, is circular reasoning because of course if the prices were deemed to be fair then adverse effects could not be attributed to them. So simply asserting that they had adverse effects does not take matters any further. Finally, at (f) you see the purported lack of any independent or objective justification for the prices, and again in our submission that is repetitive and it is conclusory reasoning. It really does not add anything at all. So, in terms of concrete analysis, we have a basic cost-plus exercise and very, very little else.

If we go back to 5.294, please {A/12/503}. You see the CMA saying:

"The Unfair Limb is an alternative rather than a cumulative test."

That is the paragraphs of the judgment in Flynn Pharma that I have shown you. You see:

"The CMA's finding that Auden/Actavis's prices were unfair in themselves is sufficient for a finding of unfairness in law."

Again, references to *Flynn pharma*.

Then:

"However, in this case the CMA also finds, secondly,

that Auden/Actavis's prices were unfair when compared to competing products ..."

If we go to {A/12/523}, please. Paragraph 5.36 -- 5.336. It may be a wrong reference, we are on 523. Can we go towards the bottom of the page, please. Yes, so 5.366, sorry. We see again this formula that comes from *Flynn pharma*, about:

"The Unfair Limb is an alternative rather than a cumulative test. Accordingly, it is sufficient to demonstrate that one of the unfairness alternatives ('unfair in itself' or 'unfair when compared to competing products') is satisfied to establish an infringement."

In my submission the repeated use of this mantra does tend to suggest that the CMA would prefer to base its findings solely on limb 1 of the test, the cost-plus analysis plus unfair in itself, but of course what the Court of Appeal has emphasised is that that does not absolve the CMA from actually considering appropriate comparators even if it has chosen to proceed on to the unfairness limb of the test, and so far as it has failed to do so its reasoning will be vulnerable on appeal.

What we then see at 5.367 {A/12/524} is that although the CMA has found that Auden/Actavis's prices were unfair in themselves, and that finding is

a sufficient basis for a finding of unfairness in law, it says:

"... in the specific circumstances of this case, the CMA has also concluded that Auden/Actavis's prices were unfair when compared to competing products, namely the current prices of competing hydrocortisone tablets."

If we go down to 5.375, so this is on page 525 {A/12/525}, you can see:

"The CMA has considered whether there are further products which are sufficiently similar to Auden/Actavis's hydrocortisone tablets to allow for a meaningful comparison between their prices and Auden/Actavis's prices and has concluded there are no such products ..."

So, again, it is important to realise just how limited this exercise of supposedly considering comparator products is. The CMA has concluded that the only relevant comparator to immediate release hydrocortisone tablets is immediate release hydrocortisone tablets, and it has disregarded every other relevant comparator.

So although this has been put forward as an alternative, a different way of assessing and engaging with the second limb of *United brands*, in reality the content of it is extraordinarily limited.

We have identified two comparators that we say the CMA should have considered: the first is Plenadren and the second is a product called Hydrocortistab. Plenadren is an obvious comparator for all the reasons that we have already canvassed in the context of market definition. It is a tablet product, it contains the same active substance and it is similarly indicated for treating adrenal insufficiency in adults, and it is precisely because of the similarity between Plenadren and immediate release hydrocortisone tablets that Auden/Actavis was a beneficiary of the orphan designation for Plenadren. That really does underline the similarity between the two.

If we look at {A/12/535}, please. This is the section where the CMA purports to have considered but ultimately dismissed Plenadren as a comparator for pricing purposes. It seeks to distinguish it on two bases. The first is at 5.406, and you can see the bold text, the CMA says that:

"... there are significant qualitative differences between Plenadren and hydrocortisone tablets."

Obviously this is between two products which are so similar that Auden/Actavis benefited from Plenadren's orphan drug designation, but what the CMA says is, well, there are nevertheless significant qualitative

differences.

If we work through them, 5.407-5.408, you have the point that Auden/Actavis's products were an old product, whereas Plenadren is a relatively new and innovative product.

In our submission the mere fact that one product has been on the market for a long time and the other has not cannot be the determining factor for the purposes of trying to get at the economic value attributed by the user of the product. The value of a medicinal product must be dependent on its clinical outcomes and not the novelty of the treatment. So in our submission, in relying on this as a reason for dismissing Plenadren the CMA has taken into account an irrelevant consideration.

5.409 makes the point that:

"Plenadren was specifically developed for a niche use."

Of course, that is true insofar as it goes but it hardly means that it can be dismissed altogether as a comparator. We have pointed out in our written submissions that the Defence has overstated matters when it says that Plenadren was developed for adults who suffer from adrenal insufficiency and who cannot take immediate release hydrocortisone tablets. That is -- for the Tribunal's reference that is Defence

paragraph 284(b). We say that is factually incorrect. It is not the case that there is a group of patients who cannot take these tablets, and the response to the CMA provided by Shire, which is the Plenadren manufacturer, has been cited by the Decision in support of this point. All that says is that there is a segment of patients who do not do well on immediate relief hydrocortisone.

Paragraphs 5.409-12, these are making the point that Plenadren was granted orphan designation, and what the CMA is trying to infer from that is that Plenadren provides a significant benefit over immediate release hydrocortisone tablets. But it is important to be clear that that is not a finding that is made on the evidence, that is essentially a citation of the legal requirement under EU law governing orphan designation.

If we look at the CMA's own findings elsewhere in the Decision, some of which we have already seen in other contexts, we see that it flatly contradicts any suggestion that Plenadren provides a significant benefit over immediate release hydrocortisone tablets.

So, for example, if we look at {A/12/78}, paragraph 3.133(a), towards the bottom of the page:

"Notwithstanding the orphan designation recognising the innovation of Plenadren's modified release formulation ... there are in practice few clinical

advantages associated with taking Plenadren instead of hydrocortisone tablets other than for those patients that Plenadren is targeted at (i.e. those who have severe compliance problems) as the biological rhythm can be obtained by taking immediate-release hydrocortisone tablets two to three times a day."

Going down to 3.133(c), this is citing evidence from clinical commissioning groups and it is saying in the last sentence:

"... Plenadren was generally not included in formularies ... [because] the limited potential benefits of Plenadren are not significant enough to justify the considerable extra cost associated with prescribing Plenadren."

I have shown the Tribunal one of those already. That was the Lancashire Medicines Management Group document that was comparing the unit cost of Plenadren and those for immediate release hydrocortisone.

Just to show you two other documents along the same lines, if we look at {H/1015/1}. This is a response to the CMA's section 26 notice to CCGs by Coastal West Sussex CCG. If we go down to page 2, the response to question 8 {H/1015/2}. You can see it start:

"Coastal West Sussex CCG does not recommend the use of Plenadren modified release tablets for the treatment

of adrenal insufficiency in adults."

Then four lines from the bottom:

"Hydrocortisone immediate release has remained the cost-effective treatment of choice as the very limited potential benefits of Plenadren (potentially increased compliance from once daily dosing although no evidence) are not considered significant enough to justify the considerable extra cost."

Then {H/1098/1}, please. This is the Dorset Medicines Advisory Group commissioning statement on the use of modified release hydrocortisone for the treatment of adrenal insufficiency. If we go to page 2 of this, please {H/1098/2}. There should be a line here, "Assessment of cost implications". There it is. You can see based on May 2017 drug tariff prices, one month's supply of Plenadren there cost £224 as compared to £94 for an equivalent dose of immediate release hydrocortisone tablets.

If we go to {H/1090/1}, please. This is a note of a call with a professor of endocrinology at Oxford University. If we go to page 3 {H/1090/3}. Response to question 4:

"Plenadren: The CMA understands that Plenadren is much more expensive than Hydrocortisone Tablets and is not widely prescribed in the UK. In your responses on

behalf of the Society for Endocrinology and Royal College of Physicians to CMA's section 26 notices ... you note that Plenadren is very rarely prescribed as a result of its high price.

(a) How important is the drug's price for prescriber's decision?"

It says:

"PW confirmed that the drug's price is essential for prescribers' decisions. Plenadren's very high price has been the very primary reason for not prescribing Plenadren more widely. There is not enough data on the efficacy of Plenadren to justify a significant price premium."

You can see in response to question (b) there:

"PW said that the very high price of Plenadren is the reason for not having Plenadren in formularies."

Finally, in the context of market definition I have already shown you the British Medical Journal article which was commenting that there was no evidence of any difference between hydrocortisone, prednisolone and Plenadren and so the most cost-effective option should be selected.

What we see in all these documents, in my submission, is that the CCGs and the prescribers are actively comparing the price and the efficacy of

Plenadren and Auden/Actavis's hydrocortisone and they are concluding that there is no evidence that Plenadren provides a significant clinical benefit over hydrocortisone tablets.

So, in our submission, there is simply no reason to exclude it as a comparator on that basis.

PROFESSOR HOLMES: May I seek a clarification on that. I think I am right in saying that you are not questioning that the test for granting of the orphan designation is that it needs to provide a significant benefit, nor do I think you are questioning the validity of it in terms of the authorities having got that wrong. What you are saying is that for present purposes the significant -- the benefit was not sufficiently significant as to justify it not being considered as a comparator.

MS FORD: Sir, that is absolutely right. What we see the CMA doing is pointing to that test in a fairly formalistic way and saying there must be a significant benefit otherwise it would not have been granted orphan status, and in our submission, there is an inconsistency between that and the factual information which is before the CMA and before the Tribunal. Actually there is insufficient relevant difference to justify disregarding it as a comparator altogether.

PROFESSOR HOLMES: Thank you.

MS FORD: If we go back, please, to {A/12/536}, 5.413. You can see that the final point the CMA makes as to why it has tried to disregard Plenadren is that it is barely prescribed in the UK and its sales volumes are very low when compared to hydrocortisone immediate release tablets.

But we know the reason for that through everything that we have just seen. It is because of the similarity, the very similarity between Plenadren and immediate release hydrocortisone tablets in circumstances where Plenadren was much more expensive.

So we really make, essentially, the same point again in the context of comparators. It is simply perverse to exclude a comparator from consideration for the purposes of excessive pricing on the basis that it is too expensive.

The other point that the CMA advances purporting to disregard Plenadren altogether, and we can see this at 5.417 on page 537 {A/12/537}. You see:

"In addition to these material differences between the products, Plenadren's suitability as a potential comparator for determining the fairness of Auden/Actavis's prices is further and substantially undermined by the fact that there is no evidence that

its price is set in conditions of effective competition."

So, a number of points on that. The first is that if we are right about market definition then this point has to fall away, because on that basis Plenadren will be in the same market as immediate release hydrocortisone tablets and subject to effective competitive constraint on that basis.

Even if we are not right about market definition, that would be because the Tribunal is satisfied that Plenadren does not exert sufficient constraint on hydrocortisone tablets, immediate release hydrocortisone tablets. But in my submission it is very clear from all the documents we have just seen that immediate release hydrocortisone tablets do exert a competitive constraint on Plenadren. That is exactly the process that we have seen at work in these documents. The CCGs are actively comparing these two products, and hydrocortisone is being selected over Plenadren because it is better value for money.

So we would say even if we are wrong about market definition Plenadren is subject to effective competition.

But in any event, as a matter of law we do not accept that there is any basis for this bright line rule

that seems to be being applied here that if there is no evidence that prices were set in conditions of effective competition then they are not meaningful comparators and you do not have to look at them any further.

The CMA has cited certain authorities in its Decision. It is essentially the *Albion Water* authorities from this Tribunal, and we have addressed them in our written submissions but we say in essence what is going on there is that the Tribunal was rejecting the utility of certain comparators in that case based on the circumstances of that case.

We say similarly, in this case the Tribunal has to assess the utility of Plenadren as a comparator in the circumstances of the case before it, and we say it is clearly a useful and informative comparator.

It is particularly problematic, in our submission, for the CMA to be using this mantra that there is no evidence that it was priced in conditions of effective competition, that is the phrase that one sees in the Decision. The reason why one sees it is that the CMA has adopted wording that was used by the Tribunal in *Albion water* I in respect of a particular comparator in that case, so that the Tribunal said there is no evidence and so the CMA uses the formula of no evidence as though what has been articulated is

essentially a legal test.

But the effect is to reverse the burden of proof in relation to the suitability of Plenadren as a comparator, in circumstances where the CMA itself has not engaged with the Department of Health at all about the basis on which Plenadren is priced.

We say that the consequence is that you dismiss an obvious comparator on the basis that there is no evidence that it was priced in conditions of effective competition without actually properly having investigated the point at all.

We do, of course, accept that Shire is the only supplier of Plenadren and it is subject to Category C of the drug tariff. But it would be a very dangerous precedent, in our submission, in the context of pharmaceuticals to have this blanket rule that essentially single supplier products are not suitable comparators. It is not at all uncommon for pharmaceutical products to have single suppliers and it would exclude a large swathe of otherwise informative comparators if they can simply be dismissed on the basis that there is no evidence that their prices were set in conditions of effective competition.

We have highlighted in our written submissions that both Auden/Actavis and Shire independently told the CMA

that their respective products were pricing comparators. I am going to show the Tribunal the relevant documents where that happened, and as I do so I am going to pick up the references to Hydrocortistab at the same time, because we will be coming back to those in the context of the second product that we rely on.

Starting with {H/969/3}, please. This is a transcript of the CMA's interview with Alan Barnard, who was the head of sales and marketing at Auden/Actavis. If we look starting at line 4 you can see him explaining:

"We would have looked at products in the markets to see what competitors were doing with similar molecules and pricings. I know when I first joined the company we had a discussion about Hydrocortistab, which was a similar make, albeit an injection rather than a solid dose tablet and Amit had pointed out that the equivalent price for Hydrocortistab compared to Hydrocortisone; I think it was a lot higher based on the reimbursement for the injection and that he was comfortable that we were in the right ball park with our pricing in fact as long as we were under sort of £2 a tablet then we were happy to price hydrocortisone accordingly given ... the current market obviously, other people would have gone to market which may have changed our situation."

Then the question is posed:

"So, you're saying that, so you were effectively benchmarking then, you were looking at Hydrocortistab when you're pricing?"

To which he says:

"Yeah, that was the first one I became aware of, then there was a product not long after, I think it was in the beginning of 2012, Plenadren, came on the market as well which had been granted a trade price again multiple times higher than what we were selling our tablets, albeit theirs was an MR tablet but was effectively the same, the same product, so we sort of benchmarked against those other products in the market."

So that is his evidence on the point.

If we then look at {H/965/3}, please. This is the witness statement that the CMA obtained from Mr Patel. Paragraph 1.7 is dealing with Hydrocortistab, and he says:

"I took some advice from a practising pharmacist to try to understand the right benchmark, because our cost of goods were above the market price. I was advised that there was a product, Hydrocortistab, which is an injection used in emergencies for adrenocortical insufficiency. Hydrocortistab is the same molecule as our hydrocortisone tablet product, so it was a benchmark

for us, and I recall it was priced in the region of between £5 and £6 per unit. The manufacturing of an injectable product is simpler but the dosage form could be more expensive to make. So we took the decision, if Hydrocortistab is priced between £5 and £6 per unit, our hydrocortisone tablets should not be above £1 or £2 per unit (i.e. per tablet) and that was our logic for setting our price."

He then goes on in 1.8 to address Plenadren. He says:

"In terms of the original pricing, we benchmarked our prices against Hydrocortistab. Further down the line, however, the UK Government approved the price of Plenadren, which was five or six times higher for exactly the same molecule and covering the same indications. However, these higher parameters never motivated us actually to go to that level and we stayed within the price that we thought was correct. We considered, and still do, that the actions taken by us were appropriate and correct and, as we were within the statutory scheme, it was open the Department of Health to approach us to discuss if they felt anything was wrong."

We then have {H/1194/14}, please. This is the transcript of Jonathan Wilson of Actavis starting at

line 18 towards the bottom of the page. He says:

"We would have had a kind of understanding of the price of hydrocortisone versus other comparator products in the market. There was no competition at the time as you are aware but Plenadren was the other product available for the, with the same indications, which was significantly higher priced."

Then if we look at what Shire was doing in the market at the time, if we look at {H/993/1}. This is a Shire promotional advertisement which is comparing the relevant merits and costs of Plenadren with immediate release hydrocortisone.

If we look down to figure 2, please. What figure 2 is doing is illustrating the cost of the daily treatment with the Plenadren versus immediate release hydrocortisone. If we then go over the page to page 2, please {H/993/2}. We can see the conclusion of this advertorial, the final line is saying:

"A total daily dose of Plenadren 20mg costs as little as £2.77 per day above [instant release hydrocortisone therapy] ..."

and it is referring back to figure 2, which -- sorry, I should say immediate release, it is referring back to figure 2 which is the comparison of the two products.

If we then go to {H/932/1}. This is Shire's response to the CMA's section 26 notice dated 20 June 2016. If we go within this to page 3, please at the top of the page {H/932/3}. This is Shire telling the CMA:

"A patient with Adrenal Insufficiency can in principle be treated with any of [immediate release hydrocortisone], Prednisolone, Dexamethasone and Plenadren. However, IRHC, Prednisolone and Dexamethasone, as the products that have traditionally been used in patients with chronic adrenal insufficiency that require glucocorticoids, are now being substituted with Plenadren as a new treatment alternative with clinical advantages, as well as the ease of use of a once daily administration that can support patient adherence and compliance. At any given time the physician and/or patient can decide to switch back to the original therapy, and therefore substitute Plenadren for the conventional glucocorticoids."

If we go to page 4 in this document, please {H/932/4}. The third paragraph down in this document is setting out a comparison of the pricing of Plenadren compared to immediate release hydrocortisone tablets. You can see what Shire is telling the CMA at the bottom of that paragraph:

"As a result of this, Plenadren faces severe market access restrictions, primarily due to not (yet) being included in primary and secondary care formularies."

There is then a further response by Shire to the CMA dated 2021, this is at {H/1254/1}. If we go, please, to page 3., question 5 {H/1254/3}. Question 5 is saying:

"In relation to sale of Plenadren in Member States of the European Union, please identify all Member States in which Plenadren accounts for more than 10% of sales of hydrocortisone tablets sales. In your response, please order these by volume and indicate the price of Plenadren in each Member State identified."

Now, the annex in which this information is set out has been described as confidential so I do not propose to read it out, but it is at {IR-H/1300/1}. The Tribunal will see the number of member states that are mentioned there in which Plenadren accounts for more than 10% of sales of hydrocortisone tablets.

The CMA has made the point in their Defence that other countries may be subject to different market conditions and different regulatory frameworks, which of course is true, but in our submission it does not detract from the point that Plenadren is obviously a pertinent competitor to look at for the purposes of pricing of hydrocortisone immediate release tablets.

We have seen that we have the evidence of Auden/Actavis personnel provided to the CMA in interview which are consistent with each other, and then you have that evidence being corroborated by documents and evidence coming from Shire, which has no particular axe to grind in this but it is saying, look, we are essentially benchmarking against Auden/Actavis's product.

So we say in all the circumstances the complete dismissal of Plenadren as a comparator for these purposes is extraordinary and it is unsustainable, in our submission.

PROFESSOR MASON: Ms Ford, could I ask a clarification question, please. As I understand it, but correct me if I have misunderstood, all of the numbers that you have just discussed are prices rather than measures of production cost?

MS FORD: Yes. I think that is correct, yes.

PROFESSOR MASON: Have you presented us with any numbers that correspond to production costs or are they all market prices?

MS FORD: The CMA has done its cost-plus analysis which factors that in. I had not proposed to make any further submissions on the point, but that is picked up in that exercise.

PROFESSOR MASON: Okay, thank you.

MS FORD: I may have misunderstood your question. Are you asking about Auden/Actavis's product or Plenadren?

PROFESSOR MASON: Plenadren.

MS FORD: I apologise. I misunderstood. Plenadren, I do not think we have that information.

PROFESSOR MASON: Thank you.

MS FORD: So I have addressed Plenadren. We say that really ought to have been taken into account as a comparator. I am moving on to deal with Hydrocortistab. As the Tribunal have already seen, it is an injectable hydrocortisone product. I have shown you that it was specifically mentioned by Mr Patel and Mr Barnard in their interviews as a product that they benchmarked against, and in my submission that alone means that it merits proper investigation by the CMA, applying the test that I have shown you in the Court of Appeal in *Flynn pharma*.

The extent of the CMA's treatment of this product is a single footnote in the Decision. It is footnote 1842 to paragraph 5.402 (b) of the Decision, if we look at {A/12/533}. The paragraph itself, 5.402(b) is referring to soluble hydrocortisone tablets. But the footnote to that, if we go back to the bottom of the page, is addressing hydrocortisone. This is 1842, and you can

see the CMA says:

"Auden/Actavis also stated that Auden/Actavis had priced by reference to injectable hydrocortisone (Hydrocortistab) ... However, it provided no evidence for this statement."

Pausing there. The evidence, as I have shown you, is what was said in contemporaneous interviews with the CMA at the time of their investigation, and of course since it is clear from this document that we raised this point in our defence that ought, in my submission, to engage the duty to investigate that was identified by the Court of Appeal in *Flynn pharma*.

The point that the CMA is making in this footnote is that what was said in interview with the CMA is not contemporaneous evidence, but in our submission interview testimony is clearly valid evidence, and that is particularly the case given the passage of time since the relevant events and the consequential difficulties in identifying contemporaneous documentation from the relevant period.

Other companies have also identified Hydrocortistab as a potential comparator. If we look at {H/1246/1}, this is a response to the CMA from Zentiva, which is a supplier of hydrocortisone soluble tablets. If we go to page 4, please {H/1246/4}. Go towards question 9,

please. Zentiva is here being asked to identify its competitors and it gives a fairly long answer, but if we go over the page {H/1246/5}, you see at the end of that it says says:

"... but also manufacturers of intravenous forms ..."

So it is identifying injectable Hydrocortistab as a potential competitor, and we have flagged up in our written submissions that Waymade, when it was developing its hydrocortisone tablets, it sought to identify them with the Hydrocortistab product. It was actually referring to them and was calling its product Hydrocortistab tablets.

If we go back to how the CMA is dealing with this, it is {A/12/533}. It is the footnote. What the CMA is saying is that in its view Auden/Actavis:

"... has not therefore discharged the evidential burden on it to adduce evidence that Hydrocortistab is a prima facie valid comparator, such that the CMA's duty fairly to consider that evidence is engaged ..."

and it cites the relevant paragraphs of the Court of Appeal's judgment in *Phenytoin*.

In my submission it is applying an excessively high threshold to even trigger a duty to investigate, to say that the evidence that has been adduced is insufficient,

and it renders this duty that the Court of Appeal has identified to look at comparators raised by the parties, it renders it completely ineffectual if the CMA can simply say: well, we see what you say about that, we see what was said in interview about it, but in our view that does not get over the evidential threshold and so we do not consider our duty to investigate even to be engaged.

Towards the end of this footnote you then see the CMA saying that:

"For the avoidance of ... doubt, Hydrocortistab would not [be] a meaningful comparator ..."

and it advances various factors. It says:

"It is a different product (an injection) with a different active ingredient (hydrocortisone acetate), which is not used to treat long-term adrenal insufficiency but primarily for certain arthritic conditions or, exceptionally, where oral medication is not appropriate ... or tolerated ..."

You see again this mantra:

"There is no evidence that its price is set in conditions of [effective] competition; it is a single-supplier product and, like Plenadren, is in Category C of the Drug Tariff, the category used when there is no competition for supply of the product.

There is no evidence to suggest that there is any competitive interaction between hydrocortisone tablets and Hydrocortistab."

We have explained in our Notice of Appeal that the CMA is not right to say that Hydrocortistab is a different active ingredient. Hydrocortisone acetate is a precursor for hydrocortisone and the actual molecule that brings about the therapeutic effect is still hydrocortisone. We say the point that the World Health Organisation does not draw any distinction between hydrocortisone and hydrocortisone acetate and it does not recognise hydrocortisone acetate as a separate active ingredient. So, for example, only hydrocortisone is included within the relevant ATC 4 class for glucocorticoids and both hydrocortisone and hydrocortisone acetate carry the same ATC 5 classification. So we say it is simply wrong to say that it is a different active ingredient.

We say the other factors that the CMA is flagging up here are equally irrelevant: different indications, different delivery method, absence of competitive interaction. They might well be relevant if you are trying to see whether Hydrocortistab is in the same market, but that is not the exercise we are doing here. We are saying, is it a sufficiently close comparator

that its pricing is informative for the purpose of assessing excessive pricing, and we say it clearly is. The CMA should at the very least have fairly investigated this point.

In our submission, the failure to fairly and properly investigate both Plenadren and Hydrocortistab alone is sufficient to annul the CMA's Decision, but had the CMA done the requisite analysis it would have concluded that Auden/Actavis's prices were fair when compared to Plenadren and Hydrocortistab. The basis on which we see that is the comparison that we have included in the ambulatory draft. It is table 3.1 of annex 5 to ambulatory draft 3, which is {IR-L1A/26/5}. The Tribunal can see at line 2, table 3.1, "Pricing comparison". If we go over to page 6 {IR-L1A/26/6}, please: this table includes two price points for Hydrocortistab, 2008 and 2016, and the right-hand column is the price per mg, and in 2008 it was 0.20 and 2016, 0.27. There are also two prices for Plenadren, Plenadren 5mg and Plenadren 10mg, and the price per mg there is 0.97 and 0.40 in the right-hand column.

Then prices for Auden/Actavis hydrocortisone 10mg, Actavis hydrocortisone 10mg and Actavis hydrocortisone 20mg at those dates. You can see the respective prices per mg these are 0.10, 0.27 and 0.17 per mg.

The Tribunal will have seen that the CMA has included a series of criticisms of these figures in the right-hand column of this document, but in our submission it lies ill in their mouth to criticise this exercise in circumstances where they have not conducted a proper analysis of these matters in the Decision.

So for these reasons we say that the CMA's findings of excessive pricing are vitiated by fundamental errors and cannot stand.

I am moving on to ground 4 which concerns the duration of excessive pricing. We say that even if there was excessive pricing it came to an end by the time Actavis acquired Auden at the end of May 2015. This is a point which derives from the case law on what amounts to excessive pricing, and in particular the Tribunal's judgment in *Napp*. It is at {M/24/107}.

If we look at 390 at the bottom of the page, please. The Tribunal is setting out what was the Director's case in *Napp* about what constitutes an excessive price. If we go over the page we can see the Director's case was that:

"... price is excessive ...:

'if it is above that which would exist in a competitive market and where it is clear that high profits will not stimulate successful new entry within

a reasonable period. Therefore, to show that prices are excessive, it must be demonstrated that (i) prices are higher than would be expected in a competitive market, and (ii) there is no effective competitive pressure to bring them down to competitive levels, nor is there likely to be.'"

You can see at 391 {M/24/108} the Tribunal says:

"While there may well be other ways of approaching the issue of unfair prices under section 18(2)(a) of the Act, the Director's starting point ... seems to us to be soundly based in the circumstances of the present case."

If we go on to page 111 {M/24/111}, paragraph 403 what we see is the Tribunal then applying that test that it has approved to Napp's prices. It says:

"... in our view the above facts demonstrate (i) that, during the period of the infringement, Napp's prices in the community segment were significantly higher than would be expected in a competitive market; and (ii) that, during the period of the infringement, there was no significant competitive pressure to bring them down to competitive levels, nor was there likely to be over any reasonable timescale."

This is a formulation which was cited by the Court of Appeal in *Flynn pharma*. Just to show the Tribunal that very briefly. It is {M/170/27}, please.

Paragraph 91. You can see there that the Court of Appeal is citing and not disagreeing with the approach taken in *Napp*.

In my submission this focus that you see in this test on whether high profits will stimulate successful entry and whether there is likely to be effective competition within a reasonable timescale makes a lot of sense and it is similar in my submission to the point that has been canvassed quite a few times now about what happened with masks and Covid.

The president made the point that demand for masks initially shot through the roof and then those that produced them were initially able to gain monopoly rents essentially and then what happened was competitive entry was prompt and prices immediately came down, and that is an example of competition working.

What is being said in my submission in these authorities is that in order for prices to be considered excessive it has to be demonstrated that there is an absence of such a corrective mechanism. That is what they are saying. It is part of what you look for in characterising a price as excessive.

Insofar as a corrective mechanism is shown to be present, because competitive entry can be anticipated within a reasonable period, then the conditions for

excessive pricing will not be satisfied.

In the present case Actavis expected competitive entry from the date of its acquisition of Auden. Competitive entry did in fact begin to occur from July 2015. The Tribunal has already been shown one of the key documents where you get that from. It is {IR-H/646/1}. This is the Project Apple slide deck that has been canvassed with one or two of the witnesses.

If we look at page 2, {IR-H/646/2}, we see the fifth bullet point:

"Hydrocortisone tablets comprise 40% of sales today due to a unique orphan drug exclusively -- expected to erode in the near term; hydrocortisone erosion is factored into current Bid."

Consequently you see it being described as a "near term cash-cow".

Then page 6. {IR-H/646/6}. Heading, "Hydrocortisone background". Then the last two bullet points:

"Actavis has modelled competitors entering into 2015 without indication for adrenal insufficiency and being launched and dispensed off label.

"Modelled share erosion of 60% and price erosion of 90% over 3 years."

The CMA has made factual findings to this effect

based, one presumes, on this document in the Decision. So, for example, {A/12/73}. Paragraph 3.113. You see:

"In January 2015, Actavis labeled hydrocortisone tablets a 'near term cash-cow'. This status was 'near term' because Actavis and its analysts expected competitors to enter the market soon and erode its margins through the process of price competition."

Then Decision 3.627. Unhappily I have not got a reference for that but I will read out what is said there:

"Hydrocortisone tablets comprise 40% of sales today due to a unique orphan drug exclusivity -- expected to erode in the near term."

And

"Near term cash-cow with the remainder of the business growing with a significant pipeline."

So again, quoting from that document, Decision 3.627.

So, in my submission, the CMA has made factual findings to the effect that the requisite corrective mechanism, the anticipated market entry is present from the point of acquisition of Auden by Actavis.

So our short point is from that point onwards in those circumstances the test for excessive pricing as set out in the case law is no longer satisfied because

that corrective mechanism has been shown to be present.

THE PRESIDENT: Ms Ford, you will recall the exchange we had with Professor Valletti regarding exactly this point and we asked about, as it were, the gradient by which one moved from a position of to a position of dominance to a position of non-dominance by virtue of the sort of corrective I think you are talking about.

I will ask you the same question that we asked Professor Valletti. Is your position that, provided the corrective mechanism is in place, there is no dominant position even if one is, as the dominant or formerly dominant undertaking, actually trying to maintain the market position to the best one can? In other words, is that factor irrelevant? What matters is that even if you try very, very hard you cannot preserve your market position because of the corrective.

MS FORD: I think we have to draw a distinction between the test for a dominant position and the test for excessive pricing.

THE PRESIDENT: Fair enough.

MS FORD: The point that I derive out of these authorities relates to excessive pricing, and that essentially tells you that the presence of the corrective mechanism means that the test for excessive pricing is no longer satisfied because there is an imminent prospect that the

competitive process will correct any excessive pricing.

THE PRESIDENT: But suppose the process, the corrective process is one that can be prolonged by the undertaking, in other words, it does not happen from one day to the next, it happens over the space of a certain period of time, is that length of time relevant to the question of excessive pricing? In other words, there is a corrective mechanism in place throughout the period, it is just that it takes time to have an effect.

MS FORD: The test that has been endorsed in *Napp* refers to successful new entry within a reasonable period.

THE PRESIDENT: Yes.

MS FORD: The tribunal when it applied the test it said "nor was there likely to be any reasonable timescale". So there is a concept of reasonableness which one must apply.

When one is looking at dominance rather than excessive pricing the test is a slightly different one because one is asking, well, is this undertaking able to act to a significant extent independently? That is the test that one is applying. If anything, when an undertaking is faced with reducing market shares and reducing prices, in my submission the test for dominance is not satisfied in that circumstance, notwithstanding

that one might have a period of time over which the market gradually corrects itself.

THE PRESIDENT: Yes. I think the point goes to both, though it may be that the test is different.

MS FORD: I think that must be right, sir, yes.

THE PRESIDENT: Yes.

MS FORD: The point that I am reminded of is that of course what Actavis was predicting in its document is share erosion of 60% and price erosion of 90% over three years, and in our submission on any view that is within a reasonable timescale for these sorts of matters. So that would suffice to meet the test.

Sir, I am about to move on to our ground of appeal concerning the grounds, plural, concerning the 10mg agreement. So that might be a convenient moment if that suits the Tribunal.

THE PRESIDENT: Very good, Ms Ford. We will rise for ten minutes and resume at 25 past. Thank you.

(3.15 pm)

(A short break)

(3.25 pm)

MS FORD: Sir, our fifth, sixth and seventh grounds of appeal are concerned with the 10mg agreement. In our submission, the CMA faces a major hurdle in making out its case on the 10mg agreement which was not a feature

of any of the previous leading pay-for-delay cases.

We have summarised the previous case law at paragraph 187 of our Written Closing Submissions and without going back over the detail, in the leading cases the key terms which were considered to be problematic were evident on the face of the written agreements, and the debate before the Tribunal or before the European Courts was essentially about whether or not those terms disclosed a sufficient degree of harm to competition to qualify as infringements by object under Article 101.

In this case the Tribunal has been shown the contents of the two written supply agreements, and they are essentially in the form of standard supply agreements. There is nothing whatsoever problematic on the face of the agreements themselves. Their terms are unobjectionable and the CMA has not suggested otherwise.

The Tribunal will recall they even expressly permit entry by AMCo with its own product. That is 3.2 of the first written agreement and 2.2 of the second written agreement.

So before we get into any sort of debate about objective infringements there is a prior fundamental question, which is: has the CMA discharged its burden to show that there was some sort of additional common understanding between the parties which goes beyond and

is in fact inconsistent with the express terms of the written supply agreement?

That is, in my submission, a significant hurdle to overcome because it is seeking to invite this Tribunal to infer the existence of an anti-competitive agreement despite the fact that no such agreement appears on the face of the documents and it is actually positively inconsistent with them.

It is only if the CMA can establish that there was any such understanding, as opposed to two parties unilaterally pursuing their own commercial self interest, that it even gets to the starting point of previous pay-for-delay cases, namely whether the terms that have been shown to exist actually suffice to show an infringement by object.

What must the CMA show? In our submission it is important to be clear what it is that the CMA must establish in order to bring itself within the scope of the Chapter I prohibition. Can we start, please, by looking at *ICI v Commission*. It is {M/3/40}. If we look at paragraph 118. This is a case where the Court of Justice is articulating a distinction between parallel conduct between competitors, which is permissible under Article 101, and a concerted practice between competitors which is impermissible.

What it says is that:

"Although every producer is free to change his prices, taking into account in so doing the present or foreseeable conduct of his competitors, nevertheless it is contrary to the rules on competition contained in the Treaty for a producer to cooperate with his competitors, in any way whatsoever, in order to determine a coordinated course of action relating to a price increase and to ensure its success by prior elimination of all uncertainty as to each other's conduct regarding the essential elements of that action, such as the amount, subject-matter, date and place of the increases."

In our submission this is an important passage of this judgment because what it tells you is what is not enough to contravene Article 101, and it is not enough for an undertaking to change its prices taking into account the present or foreseeable conduct of his competitors.

So it is not enough to change your prices in anticipation that that might cause your competitors to respond in a particular way. What is required is a coordinated course of action where any uncertainty as to the way in which your competitors will respond is eliminated.

The Tribunal will appreciate the relevance of this, because it is the CMA's case that prices charged by Auden/Actavis to Waymade fell overnight, and that once Waymade obtained its marketing authorisation to become a potential competitor, that is when it all changed.

But, in my submission, it is clear from this passage that it is not enough that Auden/Actavis changed its prices, taking into account in doing so that it was now competing with Aesica to supply Waymade, and that offering a lower price might make independent entry less commercially attractive. It is not enough for Auden/Actavis to take into account anticipated conduct in that way; there must be a coordinated course of action as between Auden/Actavis and Waymade such that any uncertainty as to whether Waymade would enter the market was eliminated in advance. There has to be that commitment not to enter.

The Tribunal also sees the reference in this passage to the elimination of uncertainty, but it is not the elimination or reduction of any uncertainty that suffices. It has to be elimination of uncertainty as to each other's conduct on the market.

So, again, it is not enough that entering into a supply agreement might reduce elements of commercial uncertainty for Auden/Actavis, for example, as to

whether it might be able to maintain its manufacturing volumes or not, and it is not enough that a supply agreement might reduce commercial uncertainty for Waymade or AMCo as to whether their Aesica product is compliant or whether it will be able to compete with a skinny label product. Those are all unilateral commercial considerations, and what has to be shown is that there was some common understanding that removes uncertainty as to each other's respective conduct on the market.

If we look at *Bayer* v Commission. This is {M/19/23}, paragraph 69. This is the General Court explaining the concept of an agreement within the meaning of what is now Article 101, and it says:

"It follows that the concept of an agreement within the meaning of Article 85 (1) of the Treaty, as interpreted by the case law, centres around the existence of a concurrence of wills between at least two parties, the form in which it is manifested being unimportant so long as it constitutes the faithful expression of the parties' intention."

That is then built upon by the Court of Justice on appeal, if we look at {M/30/42}, starting at paragraph 100, please. The Court of Justice there says:

"Concerning the appellants' argument that the Court

of First Instance should have acknowledged that the manifestation of Bayer's intention to restrict parallel imports could constitute the basis of an agreement prohibited by Article 85 (1) of the Treaty, it is true that the existence of an agreement within the meaning of that provision can be deduced from the conduct of the parties concerned.

101. However, such an agreement cannot be based on what is only the expression of a unilateral policy of one of the contracting parties, which can be put into effect without the assistance of others. To hold that an agreement prohibited by Article 85 (1) of the Treaty may be established simply on the basis of the expression of a unilateral policy aimed at preventing parallel imports would have the effect of confusing the scope of that provision with that of Article 86 of the Treaty.

102. For an agreement within the meaning of 85 (1) of the Treaty to be capable of being regarded as having been concluded by tacit acceptance, it is necessary that the manifestation of the wish of one of the contracting parties to achieve an anti-competitive goal constitute an invitation to the other party, whether express or implied, to fulfil that goal jointly, and that applies all the more where, as in this case, such an agreement is not at first sight in the interests of the other

party, namely the wholesalers.

103. Therefore, the Court at First Instance was right to examine whether *Bayer*'s conduct supported the conclusion that latter had required of the wholesalers, as a condition of their future contractual relations, that they should comply with its new commercial policy."

Again, what comes out in my submission very, very clearly from that is that unilateral conduct is not enough, there has to be something that crosses the line in terms of an invitation to act jointly, and that can itself be express or implied and that can then be accepted tacitly, but it is not enough that they independently reach a view as to what in is in their commercial best interests and those views happen to coincide. There has to be something which crosses the line.

Finally, by way of authority, *Hitachi v Commission*, this is {M/83/17}, please. Starting at paragraph 141. What is going on here is that General Court is commenting on the evidence that was before it in that case as to whether there was an existence of a common understanding.

It says:

"Mr M confirmed that he was not present when the common understanding was concluded, which, he believes,

took place prior to the signing ... Similarly, when asked whether the issue of the common understanding had been raised at meetings which we he had attended, Mr M responded that it was not necessary to refer to it since the common understanding went without saying. However, this does not call into question the probative value of Mr M's witness statement."

It goes on to say he was:

"... perfectly able to furnish evidence of a long-standing phenomenon even if he was not present ... Second, although Mr M stated that the issue of the common understanding had not been referred to explicitly at the meetings which he had attended, it is apparent from his witness statement that, in his view, this was so because the content of the common understanding was understood, accepted and implemented by the participants of the cartel without the need for an explicit discussion."

If you see, what the court there is describing is a factual position, namely that in that case there was a common understanding which was so obvious as to go without saying.

The particular factual circumstance in that case was that home markets would be respected and the participants would not contest other markets. We would

say that that is a very different situation from an understanding not to launch a product which you have invested in developing, which we would say is not so obvious as goes without saying. But in any event it is a factual question and one which must be established, whether or not the undertaking -- the understanding in question is so obvious as goes without saying.

We see {M/83/31}. Paragraph 269. This is the General Court then referring back to the evidence that it has before it and commenting on the test, and it says:

"... it is apparent from the various items of evidence ... and in particular [the statements and witness statements] that the European and Japanese producers mutually agreed not to enter the domestic markets of the other group. The existence of a mutual agreement necessarily implies the existence of a meeting of minds, even if there is no evidence which makes it possible to determine with precision the exact point in time that meeting of minds was manifested or which formalised its expression. In addition, it is apparent from paragraph 141 above [which is the one we just read] that Mr M considered that it was not necessary to refer to the common understanding during the discussions in which he participated, since the content of that

understanding was understood, accepted and implemented by all participants to the cartel without the need for any specific discussion on it."

So two points, really. Very clear that the existence of a mutual agreement necessarily implies a meeting of minds, again, unilateral conduct is not enough, and the factual circumstances of this particular case on the basis of which the General Court was satisfied that there was a meeting of minds were evidence that the understanding was so obvious as it goes without saying, that was essentially the evidence that was before it and why it was satisfied.

In terms of what the CMA accepts it must show, it does accept that it has to show that there was a commitment not to enter the market. So if we look at {A/12/654}, please. Paragraph 6.355. We see there:

"The key factor is whether, in return for the payment, the potential entrant gave a commitment not to enter the market."

And it goes on to make the point that:

"As is the case for any agreement ... such a commitment need not be explicit, but can be a common understanding between the parties."

So when we see references to a common understanding, this in my submission is what the CMA means by it. It

means a commitment, it is still a commitment but it is not an explicit commitment. It does not need to be explicit. That, in my submission, is what it is saying in this paragraph.

We do not disagree with that as a statement but in other places, in our submission, it is less clear that the CMA is properly applying its mind to what it needs to show in terms of the state of mind of the parties. So if, for example, we go to {A/12/986}, at the bottom of the page, please. What I am looking at is the -- essentially the last, the statement right at the bottom of the page which goes over the page:

"As with the 20mg Agreement, the explanation for the payments is therefore that they were in exchange for Waymade not entering the market with its own 10mg hydrocortisone tablets, and Auden/Actavis knew or should have known this."

Now, in our submission it is not enough to show the requisite meeting of minds that Auden/Actavis should have known. That is simply not enough. To be fair to the CMA, one explanation for the choice of words in this particular paragraph is that this is in the section to do with fines, and so it may be that what the CMA is doing here is using terminology which is relevant to intention or negligence for the purposes of proposing

a fine. But in other respects that does not make any sense because in order to get the place where you are imposing a fine you have to have established liability, and in order to establish liability you have to show more than that Auden/Actavis should have known, you have to show there was a conscious meeting of minds.

If we look at the position as set out in the Defence this is {A/6/37}. The heading "Legal principles", and:

"The legal principles are uncontroversial. An 'agreement' for the purposes of section 2(1) of the Act does not have to be a formal or legally binding agreement. The litmus test is a 'concurrence of wills' or 'common understanding' between the parties as to their conduct."

They then cite in the footnote the paragraphs we saw of in *Hitachi* for the proposition that an understanding need not be written down or given voice as between the parties.

You have my point that that is true insofar as you are satisfied that the agreement is so obvious as it goes without saying, but we say it is for the CMA to prove and it is far from evident in this case that any agreement not to enter the market with a competing generic is so obvious as it goes without saying.

Then paragraph 94. The CMA is here talking about

the position in respect of AMCo, and it says:

"... the CMA did not impose any test of, or threshold for, the degree of effort required by AMCo to achieve independent entry -- nor condemn it for failure to make a sufficient effort. It simply considered whether the evidence of AMCo's conduct was consistent with AMCo agreeing to forego independent entry in return for the payments by Auden/Actavis, and found that it was."

It is not enough, in my submission, to find that any conduct is consistent with any agreement. The CMA has to discharge the burden to show that there was such an agreement. It has to show that there was a meeting of minds or a concurrence of wills not just unilateral conduct, and we say it has not done that.

In our submission it is important always to keep in mind when evaluating the CMA's case the threshold that it needs to meet. It must establish a meeting of minds, not unilateral conduct.

So with that by way of introduction I am moving on to ground 5B of our Notice of Appeal, which is that the CMA's inferences as to the existence of a common understanding are unsupported by a proper examination of the real conditions of the functioning and structure of the market.

THE PRESIDENT: I mean, just -- I do not think what you have been saying about the need for an agreement as opposed to a coincidence of conduct is going to be seriously disputed by the CMA. We will see, but is the real law that helps us in this area not actually the law in relation to sham transactions?

MS FORD: Certainly the law in relation to sham transactions puts an extremely high threshold of when you dismiss the contents of a written agreement and say, this is a sham. That is very true, but in a way that is essentially emphasising the hurdle of what the CMA has to overcome. It is not telling you what it is that the CMA has to prove.

THE PRESIDENT: No, I entirely agree. I think what I am trying to do is articulate the nature of the burden that exists on the CMA but also the difficulties in framing what the sham agreement was, if there was a sham agreement. So to unpack that a little bit. You are absolutely right, the presumption is that parties are honest and what they say in their agreement, whilst it may be ambiguous, is what they have agreed and subject to things like implied terms that is it.

So, yes, it is a high hurdle to say, well, what you have put together is in fact intended to deceive. I think we need to be very clear that that is the delta

that we are faced with. As Mr Sully put it in one of his witness statements, this is a career-ending state of affairs if we find that there was indeed a sham.

So just to articulate our present agreement with your point about the seriousness of the matter, well, that is where I think sham agreements do assist.

But secondly, it is in the nature of a sham agreement that you cannot actually articulate with the usual sort of precision what actually has been agreed. First of all, because there is something inevitably illicit about it and the parties are unlikely, if they have gone to the trouble of creating a facade, to create an easily detectable real agreement. It rather defeats the object.

So we entirely accept that you have to be incredibly careful about finding a sham agreement, but if there is such a finding then I think a certain woolliness in what actually was agreed is perhaps understandable and one must be very careful though to avoid allowing, as it were, the woolliness to override the seriousness of having to find that the written agreement was not in itself proper.

That is what I am deriving from the sort of *Snook* line of authorities. With that in mind, is what we ought to be doing about the alleged sham

agreements working out in what ways they are inexplicably odd? In other words, to identify and see if there is an explanation for certain aspects of the written agreements that just do not make particular sense.

I have a list of, I think, five oddities which I will throw at you because you will want to push back on them. So, the first one is what was picked up by both Mr Sully and Mr Beighton. It is the strange pricing, the fact that AMCo was effectively benefitting to the tune of a large amount of money, being the margin over the very low cost price. The question there is whether the -- I mean, I think one of the reasons articulated for the deal is the preservation of volumes by Auden/Actavis, but given the low cost of the production of the additional volumes you are talking at best something like £12,000 if you price each packet at £1 a packet cost. You are talking about £12,000 per year in order to pay AMCo -- is it 12,000 per month, sorry, do I have it wrong? It does not much matter because we are talking about the mismatch between the profit that you are gifting to AMCo and the cost of preserving the volumes. That is the first oddity. Professor Mason is absolutely right, it was 12,000 a month, not a year.

The second oddity is that the 12,000 a month and the 6,000 and the 2,000 that pre-dated it is expressed in the agreements as a minimum, when in fact it was quite clearly a maximum. So the agreement is not quite saying what one would expect it to say in these circumstances.

Similarly, there is the branding in AMCo's, as it were, colours that was never followed through on. Now, if you were really interested in entering the market and establishing yourself, you would think that you would make use of those provisions to brand yourself differentially from Auden/Actavis rather than sell effectively the -- well, sell an undifferentiated product.

Then equally, but in the same tone, there is the obligation to sell when actually an obligation was not required, it was something that AMCo very much wanted rather than were being obliged to do.

So there are certain parts of the agreement which are a little bit odd. But just to throw another point which I anticipate you will be in agreement with, but I throw it out there because it will assist the CMA in articulating their case on this: the question that one does ask oneself is, what actually were Auden/Actavis paying for given that for a large period of time there was no ability for AMCo actually to enter the market?

So either one has a situation where they are paying effectively bargain basement prices to keep AMCo out, which does not strike me as particularly rational, or there was some kind of assessment by both sides as to the risk of AMCo entering into the market, and they were being paid off according to the level of risk that they would get into the market.

So when there is very low risk to come in you offer 2,000. When that risk increases it goes up to 6, then 12. The nature of the agreement would be when AMCo actually can enter into the market they will stabilise at 50/50. Now, that is not quite the way in which I think the CMA have packaged the agreement, but it does seem to me that we need to get clarity on what exactly was being paid for if -- and I underline the "if" -- if there was a sham at all.

So that last point is one where I think we would welcome assistance on how, if one was drafting it out, which of course would not happen, how if one was drafting it out the sham would actually appear -- sorry, the real agreement hiding behind the sham would actually appear if one was articulating very crisply that which you say was never articulated at all and which for very good reason, even if there was a sham, would not be articulated. That is not a very clear way of putting

it, but you see what I mean.

MS FORD: I do. Of course, the Tribunal has well in mind that we do not accept for one moment there was a sham.

THE PRESIDENT: Of course. That was why I said I underline the "if". We quite take the point that you are saying there was no such thing, but it must help your case if one cannot actually articulate with precision the benefit that each side were getting from the sham agreement. In other words, you are assisted, which is why I am articulating the point on which we would welcome the CMA's submissions, if you cannot actually articulate what it is that each side are getting out of it then that is an indicator that actually it is not a sham at all, that it is in fact just an oddly drafted agreement.

MS FORD: I think that must be right, and it is equally right if it is possible to point to an alternative explanation as to what each side are getting out of it which is consistent with unilateral conduct as opposed to a common understanding not to enter.

THE PRESIDENT: Well, no, that I absolutely accept, and the reason I have listed what I call the oddities is because I do not want our thoughts, no matter how wrong they might be, if we are thinking them then I think you have a right to pushback on them so that we can reach a view

in light of your submissions.

So these are things which struck us about the agreements. Of course you are absolutely right, they can be explained, no doubt you will explain them, as not being so odd at all or not being odd at all. That is the point of articulating them.

MS FORD: I am grateful. I will endeavour to pick those up --

THE PRESIDENT: Yes, I do not want to take you out of your order.

MS FORD: -- as I go through them.

The structure, the way in which we have structured our particular ground of appeal on this is that we have identified two factors that we say ought properly to have been taken into account, which do provide an explanation and which undermine any inference that what was going on here was a common understanding as opposed to unilateral conduct.

The first point that we have made is that it is commonplace for generic companies to enter the market by seeking supply from CMOs rather than entering with their own supply. It is true that there are specialist CMOs, such as Auden/Actavis's CMO Tiofarma or AMCo's CMO Aesica. It is true that there are companies which are essentially specialists in that respect. But it is also

common for generic companies to supply other generic companies.

Both Mr Beighton and Mr Sully addressed this in their evidence, and they explained that a manufacturer might offer to act as a CMO in order to keep its own costs of goods down, and they made the point that higher manufacturing volumes means a better price from your CMO.

That proposition as such, that general proposition as I understand it was not challenged by the CMA. What was challenged, what the CMA challenges about this as an explanation is, it is said this cannot explain Auden/Actavis's conduct and the reason why it is said it cannot explain Auden/Actavis's conduct is because Auden/Actavis was supplying the whole market anyway and so it had no need to keep its volumes up. That is the case that is put.

But it is also said at the same time that if AMCo were to enter with its own product then Auden/Actavis's volumes would decrease. So there is a scenario where Auden/Actavis would perceive a risk that its manufacturing volumes might fall. It cannot assume that it is supplying the whole market and it will continue to supply the whole market; there is a plausible scenario where its volumes might fall.

In that scenario Auden/Actavis has a choice. It can either lose those volumes altogether or it can compete for those volumes on a CMO basis. That is actually the rationale that Dr Bennett raised in his evidence.

The way in which this point is challenged is to say, oh, well, it must have been evident -- for example, it was put to Mr Beighton: it must have been evident to you that Auden/Actavis were only willing to offer you a deal on these terms because you have managed to get your own marketing authorisation. So the marketing authorisation is what changes everything.

What the CMA seeks to infer from that is that the only explanation is that these terms are being offered as a sort of quid pro quo for a commitment not to enter the market now you have your marketing authorisation.

But the fact that Waymade or AMCo now have their marketing authorisation is equally consistent with a situation where Auden/Actavis recognises that that is a scenario where its volumes could fall. It is a situation where if it offers Waymade, AMCo, a lower price acting entirely unilaterally then it is competing to maintain its own manufacturing volumes on a CMO basis.

So all this inference that is sought to be drawn about the fact that things all changed because

a marketing authorisation is granted, is equally consistent with a scenario where Auden/Actavis seeks to compete for those volumes on a CMO basis, and it does not provide any basis to infer that they must have been paying AMCo to stay out of the market.

All the evidence we heard from Advanz, from its witnesses, about how they would not have told -- of course they would not have told Auden/Actavis about the difficulty they were having with Aesica or their reservations about how they might compete with a skinny label product, all of that, they were saying of course they would not have told Auden/Actavis that, and so that is all genuinely consistent with Auden/Actavis perceiving that there was a likelihood that it was not going to maintain its volumes and so rather than simply abandon those volumes it makes sense for it to compete with them on a CMO basis, to compete with Aesica on the terms of its supply.

That is why there can be no assumption that there is actually a value transfer going on here. It is important, if we look at where does the CMO say the value transfer is coming from? It says Auden/Actavis could have sold these products at the market price and instead it sold them at a low price and the difference is a value transfer that it is handing over to AMCo.

But if Auden/Actavis anticipates that it is going to lose those volumes and it is trying to compete for those volumes with Aesica on a CMO basis, then there is no value transfer because the assumption is we either lose those volumes altogether or we retain them at a very much lower price. There is not an option where you say, I would have had this amount of money but I am going to transfer it to you, AMCo. So in my submission --

THE PRESIDENT: So what you are saying is that the relevant prices are £1.78 versus zero?

MS FORD: That is what Auden/Actavis is faced with once you acknowledge -- and that is the premise of the CMA's case, that it perceived there could be entry that would cause its volumes to be reduced. So it is wrong, in our submission, to focus on or to claim that Auden/Actavis is trading off the possibility of selling at a full price and thereby transferring value to AMCo. It is saying, well, I am perceiving the possibility I now face competition. I can now either abandon these volumes altogether or I can compete with Aesica to supply on a CMO basis.

Once that is the alternative that it is looking at there is no basis to infer any sort of value transfer here.

That addresses, in my submission, the first point

that you, sir, raised, the oddity of the pricing and you were comparing the 12,000 per month with the assumption that but for the agreement Auden/Actavis could have sold at a full price.

THE PRESIDENT: Yes.

MS FORD: But what Auden/Actavis is perceiving is the fact that it is now competing with Aesica for supply and so it is not comparing with the full price supply, it is comparing with losing the volumes altogether.

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

MS FORD: That also, in my submission, addresses point 5, the query about what was Auden/Actavis paying for, because of course implicit in that proposition is that Auden/Actavis was, by entering into this agreement, facilitating a value transfer whereas in my submission one cannot make that assumption if what it was doing was simply trying to retain these volumes, faced with the prospect that it might lose them altogether.

THE PRESIDENT: I mean, of course we are talking perception of risks here, but looking at it in terms of what one gains and what one loses if one gives up, as it were, 12,000-monthly units at a low price, so taking the unit price at £1.78 which I think was roughly it, it does not --

MS FORD: -- under the second agreement.

THE PRESIDENT: Under the second agreement. So let us take £1.78, which is the highest price, and 12,000. That means you are getting revenue per month of £21,360.

MS FORD: I defer to your maths.

THE PRESIDENT: I am afraid I have been deferring to my iPhone's maths, so that is -- but if you look at the gain that you get if you think you are going to retain the 12,000, then you are talking per month of £432,000, assuming a price of about £36, which is quite conservative.

So when you are juggling, as it were, the cost-benefit analysis you have to be pretty confident that you are going to lose those 12,000 in order to enter into the deal. Otherwise you had better -- you would be better off taking the risk of not losing some or all of them because you will get per month £432,000 in.

So does it -- is it implicit in your argument that Auden/Actavis's thinking must have been these are -- if we can cap our lost sales at 12,000 then that is a very good deal?

MS FORD: We know from the evidence of the Advanz witnesses that that is what Auden/Actavis was being told. We heard that -- the word "bluff" was used. We have heard that is what they were doing. They were saying, we are

going to come into this market. But importantly, this is the CMA's case. The CMA's case is to say that Auden/Actavis perceived that there was a very genuine risk that Waymade/AMCo were going to enter, and that's why -- their case is that that is how you infer that there was some sort of agreement that they would not enter. But it is equally consistent with that, that because they perceived that risk they decided to address it by competing for those volumes on a CMO basis.

So this is the case that is being advanced against us, but our point is: it does not get you to any basis to infer a common understanding that AMCo would not enter.

THE PRESIDENT: We probably ought at this point to mention Ms Lifton's evidence, because I think one of the lines of attack that the CMA was running was that there had been a deliberate go-slow on the part of AMCo which -- I mean, it is only supportive, it is by no means conclusive of the sham arguments, but there was a go-slow which supports the idea of paying to stay out of the market.

Now, Ms Lifton was pretty clear in her evidence that -- well, two things, really, she said with some degree of force. One was that to the extent that it went slowly it was her company's fault, but secondly,

that so far as she was concerned AMCo were not going slow, they were pressing in a manner that was entirely consistent with someone who wanted to bring their drug to market.

So that is something I am sure Mr Holmes or Ms Demetriou will address us on, how far the loss of, as it were, the "AMCo going slow" point is relevant. But -- and of course you may want to address us on that as well or not, I do not know. But in a sense, would not one expect a rival who was being paid to stay out of the market actually to want to move as quickly as possible to a state where they could enter the market, so as to leverage up the 12,000 to something closer to 50%? I mean, I am obviously hypothesising an extremely naughty agreement here, one where the price is calibrated by reference to the risk of entry, and one would imagine that this illicit agreement would stabilise at 50/50 once AMCo had got the wherewithal to actually enter the market, which is a point we never really got to because of the independent entry of another generic.

That is something which, again, has been running through our minds and so again, I put it out there so that the parties can address it, that in a way Ms Lifton's evidence may not be quite as damaging to the

CMA's case as one might think. But this is the problem with hypothetical sham agreements, one does not really know what actually has been agreed because it is not written down.

MS FORD: Sir, yes, in my submission the difficulty the CMA faces is that whichever way the evidence goes it is equally consistent with a unilateral attempt by AMCo to be in a position to enter the market which is perfectly legitimate and a scenario where you hypothesise that actually it was trying to leverage an unlawful agreement. There is no basis to infer that that is the explanation given that it is equally consistent with a scenario where they were seeking to enter the market.

Of course, I leave it to those on the Advanz and Cinven side to comment from Advanz and Cinven's perspective. From Auden/Actavis's perspective what it was being told essentially was that it was likely to lose its volumes because independent entry was coming and in the same way the way in which Auden/Actavis responds by competing for those volumes by offering a price which competes with Aesica is a unilateral legitimate response to that information.

So the CMA cannot point to the fact that Auden/Actavis anticipated entry and say that gives you a good basis to infer that there was some sort of common

understanding here because there is an equal and unilateral explanation for why it responded in the way it did.

THE PRESIDENT: Just to go back to where we started. I mean, you have been saying "equal". That, I am sure, must be right. That if there are two equally plausible explanations, then a Tribunal ought to go down the route of the honest explanation rather than the dishonest one.

MS FORD: Absolutely, yes.

THE PRESIDENT: But I think it goes a little bit further than that because even if it is more plausible that it is naughty than honest, the threshold for proving a sham is sufficiently high that even if it is not equal but, say -- one does not want to get into percentages but I will -- if it is 45/55 in favour of the dishonest explanation, nevertheless one probably ought to still opt for the honest explanation because one ought not to infer dishonest conduct lightly. I am not articulating a sort of percentage test but what I am trying to do is convey what I think *Snook* tells us and the sham agreements law tells us about not wandering lightly into dishonest ground.

I am very happy for you to carry on saying "equally consistent" but I think we ought to put out there our present view as to how one weighs these things up and

one has to prove naughtiness to the civil standard but to the sort of higher civil standard that we have got all these *Re H* cases where they say it is the probability of, what is it, zebras in Hyde Park. That sort of test.

MS FORD: Sir, yes, it is absolutely right as a question on the case law on sham agreements. It is equally absolutely right as a question of the case law on the burden of proof being on the CMA and the appellants benefitting from the presumption of innocence, so it follows from that as well.

So in our submission the test is whether there is any plausible alternative explanation. If there is a plausible alternative explanation without getting into a question of assigning percentages to it or anything of that nature, if there is a plausible alternative explanation for this conduct, then in my submission the CMA has not made out its case.

THE PRESIDENT: Yes.

MS FORD: I have been explaining why the notion of operating akin to a CMO undermine the assumptions that there is any sort of understanding here or any sort of value transfer here. It is important to appreciate that this is not just speculation. This is an explanation that was given to the CMA consistently by Mr Barnard and

Mr Patel for Auden/Actavis and equally, and independently, by Mr McEwan and Mr Vijay Patel for Waymade.

So Mr Barnard first of all, {H/968/2}, please. Can we look down to line 22. So the question being asked is:

"You're basically saying, you have Tiofarma supplying Auden McKenzie and Waymade could either have found an equivalent to Tiofarma or it could be supplied by Auden McKenzie with Auden McKenzie in effect being almost a CMO at least to Waymade for all intents and purposes."

Over the page:

"Yes.

"Is that a fair summary?"

"Yep".

Then: "Ok."

So the question is then:

"I just want to understand, so just going back and just to understand this fully, you're saying that from you want, that from Auden McKenzie's perspective they wanted to maintain volumes within its own manufacture, Tiofarma and it is just selling volumes of hydrocortisone and it is doing that on a monthly basis and it is receiving those volumes from Tiofarma.

Waymade comes to you and says we want some volumes from you and you say yes we'll give you some volumes, and you want to maintain your volumes and so the only way that you can do that is by giving them this lower supply price because if you don't it will mean they can source somewhere else from their own CMO."

And he agrees with that: "Yes."

That is what Mr Barnard said.

Then Mr Patel, {H/944/2}. If we look down to line 17. This is Mr Patel saying:

"So initially we had supplied Waymade with some product, because they had approached us to say that, you know, they would like supply and our view on that is you know that is fine, you know they're our competitors, that is absolutely fine. I had, as mentioned earlier ... it is on, it is on our manufacturing contract and we worked on the same principles, especially for low volume product which are steroids which are difficult to make, it was important that, you know, it was good to maintain our volume with our CMO. So if we could supply a product, and even if the margins were far lower, if we could supply, that that is fine, we will supply. I remember internally a discussion saying that, you know, it is they're our competitors and as long as we supply them and they have the full ability to compete

with us wherever they can compete, you know, there is no restrictions on them as to where, who and it is given to them as a price where they can fully compete with us and that is something that we did at that point, in terms of our CMO volumes."

Then {H/943/7}. Lines 3-6 you have him there saying:

"In 2012, at that point it was, as I said, with our manufacturing volumes, we wanted to protect the volumes that we have at the manufacturing. We supply them at a price which would fully allow them to compete with us, at any price point in the market."

Then {H/945/4}. You see him being asked: .

"The agreement with Waymade was one way of keeping your volumes?" To which he says:

"That's right."

If we go down to 22, and he is saying in response to what he is being asked about the 10mg agreement, he says:

"And our volumes would be again are maintained at the CMO."

So that was what Mr Patel said to the CMA.

Then Mr McEwan of Waymade. If we look at {H/950/10}. He is saying:

"Until you've got the marketing authorisation, you

don't have the choice as to ... to place an order on your own contract manufacturer or to source it elsewhere."

He is then asked:

"And why is there that difference? Why, if you have a marketing authorisation, are you not just another customer for Auden/Actavis?"

To which he says:

"Because we asked Auden/Actavis, effectively, to behave as a contract manufacturer."

Then the same document, page 14 {H/950/14}. Going down to line 18. He is talking about, he is saying:

"... in requesting whether they would supply or not I would say, you know, 'I have a licence for this product. I'm ... looking to come to the market with it. Would you be interested in supplying us?'"

He says at the bottom, 26:

"... maybe the inference from me is that, you know, he can supply me or I will get someone else to supply me. And if he wants to retain the manufacturing volumes, then he might agree to supply me ..."

Then he goes on to say {H/950/14}:

"... we were lucky that he did, because that's before we even got to the indications."

That is Mr McEwan's explanation to the CMA.

Then Mr Vijay Patel is at {H/1148/139}. Line 23, and the question he is being asked is why would you drop the price, why would he drop the price? If you go over the page {H/1148/140} and then the suggestion that is has been put to him is that:

"They are expecting something in return ..."

He says:

"Yes, his volumes would go down, then, eventually. His volumes would start dropping once we fight him in the market ..."

He is then putting again:

"... they are giving you a benefit."

Then Mr Patel is saying:

"He is still making a margin, don't forget, he is making a margin."

Then at 14:

"As soon as we come in the market, his volumes will start diminishing so his costs will start going up, and that's how the market works ... it is common in our business, in generics ... one manufacturer will be supplying half a dozen companies on their own label ... so everyone has the stock, and this is the normal market practice."

In my submission what comes through from these interviews is a consistent alternative legitimate

explanation for a reduction in price which is being offered unilaterally when Waymade obtains its marketing authorisation. It is accepted at paragraph 103(f) of the CMA's Closing that if another plausible explanation exists then no anti-competitive practice can be inferred. In our submission there is such an alternative plausible explanation.

That was the first feature of the market that we identified in our Notice of Appeal. The second feature of the market that we identified was essentially looking at it from the other side of the table, the perspective of the generic, and saying the risk and complexity of the environment in which the generic companies operate and the fact that a generic company has to supply safe stable products which are compliant with its marketing authorisation and the fact that it runs reputational and regulatory risks if it does not do so.

The points we made there derived support from what was said by Mr Sully of Advanz, because he was giving evidence as to the importance to AMCo of security of supply, and he mentioned its policy of dual sourcing and he commented that AMCo had been severely criticised by the Department of Health in that context.

Obviously we heard a lot of evidence about the difficulties that AMCo was facing with Aesica, and while

they would not have been known to Auden/Actavis they explain why a supply deal might well have made sense from AMCo's perspective as well. Both Mr Sully and Mr Beighton gave evidence of their subjective perception about the obstacles that might arise from their skinny label product, and the Tribunal has my submissions in the context of Auden/Actavis's dominance that in some respects those obstacles are overstated, but certainly their evidence was of their subjective perception and in those circumstances one can see why, faced with a choice whether to take the supply of a skinny label product from Aesica or a full label product from Auden/Actavis, it might well make commercial sense on a completely unilateral basis to take supply from Auden/Actavis.

Again, we say that what the Tribunal heard by way of evidence lends support to the point that we have made in our Notice of Appeal.

Finally for today, the final point that came through fairly clearly from the oral evidence of the Advanz witnesses was that they speculated at the time, AMCo speculated at the time that the supply of hydrocortisone was a quid pro quo for the supply of Carbimazole. It is fair to say that that possibility is unexplored in the Decision. In circumstances in which the CMA is asking the Tribunal to infer that the only possible explanation

for the arrangements between Auden/Actavis and Waymade is some implicit common understanding, the absence of any detailed analysis of the Carbimazole position is, in my submission, a striking omission.

So I am at that point coming to the end of the first limb of our ground of appeal on 10mg, so if it is a convenient moment for the Tribunal.

THE PRESIDENT: Well, yes, thank you, Ms Ford. How are you doing for time?

MS FORD: I am doing well for time. I have -- I would hope to be finished before the end of the day tomorrow. It is difficult to say how much before.

THE PRESIDENT: No, that is fine. I would not -- what I do not want is for you to be under pressure in terms of rushing your submissions. I get the sense you are getting nicely through them --

MS FORD: Absolutely, yes.

THE PRESIDENT: -- and you are not rushing us, because we want to understand every word. Good. That is not in any way an invitation to go faster.

Just in terms of points which I suspect you are going to address because they are in your written submissions, but you are going to come to what inferences, if any, we should be drawing and against whom in relation to the non-calling of Auden/Actavis

witnesses?

MS FORD: Absolutely, and just to give the Tribunal an idea of when I was planning to do that. I was going to do that at the end of our grounds of appeal on the liability issues, because at that point the Tribunal will then have heard how we put it and that will inform what we say about the inferences.

THE PRESIDENT: That is very helpful. I just want to make sure that they're coming. Then equally, what inferences, if any, one can draw from the 20mg agreement which is not appealed. Again, I am sure you are coming to it.

MS FORD: Yes, I am.

THE PRESIDENT: But I just want to express the hope that you will. Very good. We will resume then at 10.30 tomorrow. Very good. 10.30 tomorrow. Thank you very much.

(4.30 pm)

(The hearing adjourned until Wednesday, 14 December at 10.30 am)