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)

Thursday, 22 December 2022

(10.00 am)

Closing Submissions by MR HOLMES (continued)

THE PRESIDENT: Mr Holmes, good morning. Before I forget, there are simply a few factual queries that I will throw out there to be answered at some point.

First of all, is Plenadren under patent and what are the details of its patent protection, if it is?

Secondly, where do we find, amongst all the various very helpful graphs and diagrams, a pricing schedule for Plenadren itself? I am sure it is somewhere there, but we cannot work out where it is.

MR HOLMES: Certainly, sir, we will attend to that and get back to you as soon as we can.

THE PRESIDENT: There is no rush, but they are just two thoughts that occurred to us overnight.

MR HOLMES: I am grateful.

If I might just briefly tie up the question of timetabling, sir, it will only take a moment.

THE PRESIDENT: Of course.

MR HOLMES: First, we have discussed on our side and we are very content with the appellants' helpful proposal that there should be two further hearing days instead of three, if that meets with the Tribunal's approval. We are very grateful, I should say, to the Tribunal for its

willingness to accommodate the extra sitting days. We know that you are very busy people and we are very much appreciate your careful consideration of the case.

Secondly, can I give you our suggested path to Christmas?

THE PRESIDENT: Of course.

MR HOLMES: We propose to cover three matters today and tomorrow. First, I will deal with as much of dominance as I can. Secondly, Ms Demetriou will address you briefly this afternoon on the Oxera report for ten minutes. Thirdly, Mr Bailey will tackle penalty and the Allergan point, more likely tomorrow than today.

He is hopeful that he can conclude in time for the Tribunal's suggestion of an early finish, if that meets with your approval.

THE PRESIDENT: That certainly does. I am very grateful to all the parties for diffusing the situation. Thank you.

MR HOLMES: We plan to use our day in the new year then primarily for submissions on the topic of abuse, but there may be some overspill from dominance.

THE PRESIDENT: They are connected, are not they?

MR HOLMES: They are indeed, sir, yes.

Can I pick up then two points arising from yesterday. First, there was some discussion of the CMA's margin of appreciation in its economic assessment

of the market and it was the point you canvassed with me yesterday afternoon, sir. It is something on which the appellants are likely to return in reply, so could I just give you some references to sketch out our position.

The long and the short of it, sir, is that we respectfully endorse the position you set out in the *Meerkats* judgment in paragraph 105 as a helpful and succinct summation of the correct position in law. I do not think we need to turn to it. You are well familiar with it.

The second reference is to the *Aberdeen Journals* case from 2003. {M/27/47} at paragraph 125. Again, we do not need to go there, but it simply shows this is a longstanding aspect of the Tribunal's practice.

It is also to be found in the *Genzyme* judgment from 2004 at {M/31/52} at paragraph 150. Again, not one that we need to visit now. That case indicates that the same point applies to economic assessment in the context of dominance.

Then the final authority is the one that you mentioned, sir, during the course of discussion, which is the Court of Appeal's judgment in *Phenytoin*. I will return to that to look at it carefully in the context of abuse, given what is said there about unfair pricing.

But can I just pick up one point on the relationship between the margin of appreciation and the Tribunal's task at the appellate stage. If we could go to that one, please, it is at {M/170/42}.

You see the heading in the middle of the page:

"The distinction between the CMA's margin of manoeuvre or appreciation and the supervisory jurisdiction of the Tribunal".

In paragraph 135 Lord Justice Green distinguishes between the judgment calls that competition authorities must make under the Chapter II prohibition and the powers of courts and Tribunals called upon to supervise the decisions of such authorities.

He accepts that the CMA has a margin of manoeuvre or appreciation or discretion and the legal test is broadbrush and necessarily confers a significant latitude upon a competition authority as to the methods and evidence bases that it resorts to.

He then says that this is different in principle in paragraph 136 to the question of whether the Tribunal must pay deference to the CMA's exercise of judgment. The Tribunal has a merits jurisdiction. It is not bound to defer to the judgment call of the authority and it is empowered to come to its own conclusions.

I should say immediately, we accept of course the

distinction drawn by Lord Justice Green and the merits standard before this Tribunal.

There is then a consideration of the case law, noting the quasi-criminal nature of competition law and at page 44 at paragraph 140, you see the conclusions drawn from the case law and they include in the final four lines a recognition of the margin of discretion, but the qualification that this does not dispense with the requirement for an in-depth review of the law and of the fact by the supervising judicial authority, here of course the Tribunal.

In my submission, that is consistent with the approach that you will see was taken in *Napp* and *Genzyme*, a margin of appreciation, but a need to consider whether the CMA has established the underlying facts, where they are under challenge, and a need for the Tribunal to be satisfied that the CMA's analysis is robust and soundly based with the correct legal conclusions drawn.

But Lord Justice Green does not stop there. You see the heading below paragraph 140, "The limits of the appellate jurisdiction" and he here points to the limits of the Tribunal's task on appeal.

At paragraph 141 you have the point that Ms Demetriou referred to, the Decision is the starting

middle and endpoint, and it stands except to the extent that the appellant has shown error, for example some error of fact.

At paragraph 142 the Tribunal can hear evidence, including fresh evidence.

But at 143 the point that a material error needs to be shown, the one you referred to in the *Meerkats* judgment. There is then a discussion of what is meant by materiality, which I know, sir, you will be well familiar with and I do not need to dwell on it now, save to make two points. The first is that the concept of materiality shows that the CMA may arrive at a decision which is right in terms of its overall conclusion, though its reasoning or analysis may be in some respect flawed. In those circumstances, the error may not be material.

You will recall that Ms Ford showed you one such example in the context of market definition from this Tribunal's judgment in the *Paroxetine* case. You have my submission on why the full versus skinny market definition point would not be material to the CMA's overall findings, if you were to consider it materially mistaken -- sorry -- even if you were to consider it mistaken, not materially so.

The second point on materiality appears on page 45

at paragraph 146 and you see that Lord Justice Green himself qualifies this as an important point and he says there that it is consistent with a merits appeal for the Tribunal, having heard the evidence, to conclude that the approach taken by the CMA and its resulting findings are reasonable in all the circumstances and to refrain from interfering on that basis. If the Tribunal considers that the findings of the CMA are reasonable, it might be difficult to say that any findings that it arrives at, which differ from those of the CMA, are material.

So, sir, this I think closes the belt. It shows that if the CMA reaches conclusions within its margin of appreciation and they are reasonable ones, it may then be difficult for the Tribunal to identify any material error, even were you to form a different view.

The upshot, we say, is crisply and correctly captured in the *Meerkats* judgment.

So that is the first point from yesterday. I hope that was useful. I suspect it is all quite familiar ground.

THE PRESIDENT: It is. I think it is useful really to provide a target for the appellants, because, to be clear, what we expressly were trying to do in *BGL* in the *Meerkats* was follow Lord Justice Green's approach and to

the extent that we, as articulated, have got that approach wrong or there are points which bring it outside that approach, well, I mean, it would be helpful from the appellants' point of view to articulate that. But the battle lines are, at least, clear on your side.

MR HOLMES: Yes, I am grateful.

The second point to pick up from yesterday is the question put by Professor Mason in relation to market definition. The question was whether a change in the valuation of a QALY might have caused a shift up in demand. It is a good question, if I might say so, and we are glad that you have raised it.

The first point is that despite Ms Ford's reliance on the QALY, that was entirely ex-post. There is no evidence that such a QALY assessment has in fact taken place in this case and no one has provided evidence of such an assessment having been conducted or that it affected demand for the product. Moreover, the evidence as to market outcomes is consistent with there being no such assessment or impact. The treatment guidelines that I took you to yesterday showed that hydrocortisone tablets were the recommended first line treatment for adrenal insufficiency and that did not change.

The graph of prices and volumes that I showed you at figure 4.3 of the Decision, demonstrates that there was

no change in prescribing practices. Despite the massive increase in price, the volume of prescriptions for hydrocortisone tablets continued to slowly rise in line with the increase in patient numbers.

To relate this to the unusual demand curve which you posited, we say that the evidence suggests we are at the point where demand is vertical at the quantity determined by the number of patients requiring treatment. I hope that addresses the point that you were putting.

PROFESSOR MASON: 95% but let us just close it off completely and, to be clear, it was me entering into the spirit of the exercise that you were conducting, which is stepping through different factors that might be considered to explain the Matterhorn, I think you called it.

Just to finish off on that, yes, I agree that one way of viewing this is that step-shaped step function for demand and the vertical section corresponding to the total number of patients in the UK.

So I take your answer then to be in explaining the height of the step there is no evidence that there was an evaluation done such as whether the QALY was higher than was previously thought to be the case. No contemporaneous evidence that an exercise was undertaken

that would make us think that the size of the height of the step changed over the period.

MR HOLMES: Exactly.

PROFESSOR MASON: Is that right?

MR HOLMES: Exactly so, sir, that puts it very well, if I might say so.

PROFESSOR MASON: Thank you very much.

MR HOLMES: Can I now turn to the second pillar of Chapter II, the dominance assessment. Despite the huge volumes of paper that have been devoted to this issue, the Tribunal, in my submission, should not lose sight of the fact that there is a bedrock of relevant and undisputed evidence in this case and we say that combines to produce a clear-cut case of dominance.

First, in the period prior to competitive entry the facts really speak for themselves. If we are right about the market definition, Auden/Actavis was a monopolist, there was no other supplier of hydrocortisone tablets and no other product in the relevant market. Auden's prices climbed inexorably throughout this period without loss of volumes and there could hardly be a clearer case of a firm which was appreciably free of competitive constraints.

The only challenge to the findings of dominance in the pre-entry period alleges that Auden's dominance was

constrained by countervailing buyer power and Auden is the key appellant in this connection, supported by Allergan.

Secondly, in the period following competitive entry, Auden/Actavis lost a proportion of its sales to skinny label suppliers and its prices fell in part due to the automatic operation of the drug tariff and Intas claims that these facts mean that Auden/Actavis no longer possess any dominant position of the kind that it held prior to competitive entry.

But it is well established that the existence of some competition does not preclude a finding of dominance and the relevant legal question is whether Auden/Actavis retained the power to behave to an appreciable extent independently of its competitors, its customers and, ultimately, of consumers. On this again, we say that the evidence is quite clear cut. Throughout the whole of the post-entry period, Auden/Actavis retained the ability to set prices very substantially above those of competing suppliers of fully bioequivalent products and it did so while retaining very high and stable market shares and it earned vast profits in doing so. This reflected a structural advantage, which it enjoyed by reason of the orphan designation and its impact on a sizeable section of

demand.

We say that these are all classic hallmarks of a dominant position. The basic underlying facts are largely undisputed. They show that although Auden/Actavis began to face some competition, it still possessed the ability to behave to an appreciable extent independently of competitive forces and that is what counts for dominance.

So that is the case just to layout my stand. I will come back to it in some detail, but that is the broad outline and I propose to begin by tackling countervailing buyer power, if I may, the key issue on the pre-entry period.

THE PRESIDENT: Can I just press you on the extent to which market definition really matters in relation to dominance. I mean, normally, you define the market in order to work out what is the terrain that you need to examine in order to see just how much of a market share you hold, because market shares are an indicator of dominance.

But suppose we decided against you on all of the four deltas that you articulated yesterday on market definition and just to trip through them. It is our non-hydrocortisone product substitutes. What about non-immediate release hydrocortisone tablets? So that

is the injectable product and the slow release product. What about the 10, 20mg differentiation and what about the full/skinny label? If, hypothetically speaking, we were to throw them all in and say, yes, they are all part of the market, they are all to a greater or lesser extent substitutes, what difference does it make to your dominance case?

MR HOLMES: As you know, sir, and as I think was alluded to during the expert evidence, there is a school of thought in competition policy and economics that the whole question of market definition is overblown and that very often one can step directly to an assessment of the underlying competitive constraints looking at competitive conditions using a range of indications.

If the Tribunal were to find that, one would obviously need to consider the basis on which that conclusion were reached, but the underlying quantitative evidence in this context, in my submission, is pretty clear and it shows that there were no significant constraints on pricing power during the pre-entry period and in the post-entry period, such constraints as there were, clearly weighed differently with Auden/Actavis by reason of this structural feature, this barrier to expansion represented by the orphan designation. They weighed differently with Auden/Actavis than they did

with other suppliers of at least the closest comparable product; namely, skinny label hydrocortisone tablets.

I do not know if that is -- it is a question I can perhaps return to as we go through the detailed discussion.

THE PRESIDENT: That would be helpful. I mean, I do not think I am putting to you quite the radical notion that if you can successfully abuse the market, then you are ipso facto dominant. That I think is something that I know is articulated in the literature, but I do not think it is a route that we are permissibly able to go down without substantially rewriting the approach.

So my question was a somewhat different one, which was: let us suppose we throw it all in and you end up with a market share which is obviously going to be lower rather than higher. You certainly will not be able to say the monopolist point, because there will be other products around and that means that the range of enquiry is going to be wider, we will have to look at other curves beyond simply the price volume curves in relation to immediate release hydrocortisone, full stroke skinny, we will need to look at, for instance, the data in relation to non-hydro products and the non-immediate release, non-tablet formulations in order to get a feel for what is going on in the market.

But taking that against you, although of course it widens the ambit of investigation in terms of the data we have to look at, does it in the end of the day make any difference, given the mountain that you articulated yesterday and how it appears not to have been affected by anything other than skinny?

MR HOLMES: I understand, sir. Yes, my submission would be that the findings of dominance would remain robust in a market which included all of the alternatives that have been posited, bearing in mind the enormous market shares that on that view would remain with hydrocortisone tablets and with the incumbent supplier of hydrocortisone tablets. We saw, for example, that Plenadren represented I think under 1% of the total demand for adrenal insufficiency treatments, 5% were represented by the other corticosteroids, so it is very hard to see how that could turn the dial on an assessment which took account of market shares which are a classic indicator of dominance, as we know, for all of Mr Palmer's able efforts to move attention away from them.

You would also be left, sir, with evidence of very high prices in the market. Now, the mountain, sir, just to take slight issue with the way in which you drew back from my original observations, may show pricing power

separate and distinct from the question of whether the prices charged are abusive. It is a separate conceptual exercise which is undertaken at the second stage or at the final stage when considering whether prices are abusive.

THE PRESIDENT: I completely agree, yes. Yes, it is a separate enquiry.

MR HOLMES: On any view, the mountain would still be relevant when assessing dominance.

Does that address your question more closely?

THE PRESIDENT: Yes, that is exactly it. I was not going down a radical rewriting of competition law. What I was really articulating was, clearly it does matter because the process matters, but one often goes through stages of enquiry and actually, having done it, you go back and say, well, actually it was not necessary.

MR HOLMES: Yes.

THE PRESIDENT: I just wanted to get a feel, again to enable the appellants to pushback on this, for where the CMA stood on this.

MR HOLMES: Yes, well you have my submission --

THE PRESIDENT: I am very grateful.

MR HOLMES: -- should I be driven to it, but my primary case is very much that the markets are correctly drawn.

THE PRESIDENT: I entirely understand.

MR HOLMES: Turning then to the countervailing buyer power question. Auden's basis for resisting dominance during the pre-entry period turns on the Department of Health's powers to intervene and to regulate price during the infringement period. Auden claims that the existence of these powers provides clear evidence of a constraint in practice which was sufficient to remove any market power that Auden would otherwise enjoy.

I think it is common ground that countervailing buyer power is a matter of degree and depends on whether market power is in fact constrained as a practical matter. One gets that from Auden's Written Closings. We should perhaps look at those briefly. {IR-L/4/21} at paragraph 59.

You see there the well-known test for dominance in *United Brands;* a position of economic strength which enables an undertaking to prevent effective competition being maintained by affording it the power to behave to an appreciable extent independently of competitors, customers and, ultimately, of consumers.

That itself is a matter of degree, as the economists accepted.

Then at paragraph 60 a summary of the approach to countervailing buyer power:

"Competitive constraints may be exerted not only by

actual or potential competitors but also by customers. Even an undertaking with a high market share may not be able to act to an appreciable extent independently of customers' size or their commercial significance for dominant undertaking, and their ability to switch quickly to competing suppliers, to promote new entry or to vertically integrate and to credibly threaten to do so. If countervailing buyer power is of sufficient magnitude, it may deter or defeat an attempt by the undertaking to profitably increase prices."

So the relevant question is whether there is a constraint on the demand side that is sufficient to deter or defeat price increases.

Two points about that. Clearly a matter of degree. Is the constraint sufficient? Sufficient to do what? Effectively to constrain market power by deterring or defeating price increases. We completely agree with that. There is no difference between us on that point.

If we turn on to page 27, {IR-L/4/27}, we see again that Auden accepts the need for some constraint that is able to restrain market power in real practical terms. You see that at the foot of the page at paragraph 80.

You see how Auden puts its case in the bottom two lines:

"The existence of a concrete and undisputed legal

power to control prices is not merely theoretical; it is clear evidence of a constraint in practice. It would be perverse to dismiss such a constraint simply on the basis that the DHSC had chosen not to deploy it for reasons best known to itself."

So there is I think an acceptance of a need to show a constraint in practice.

That is certainly how the Tribunal has previously approached this question in other cases in the pharmaceutical sector where similar arguments have been repeatedly run.

If we could go, please, to the Tribunal's judgment in the *Phenytoin* case, it is {M/150/66}. The Tribunal sees the argument that was being pressed in 199 that the CMA was incorrect to find that the DH, that is the Department of Health, did not have countervailing buyer power sufficient to constrain Pfizer's or Flynn's conduct so as to prevent them holding dominant positions on their respective markets.

Then at paragraph 200, you see the arguments relied on by the CMA. One, the structure of the NHS meant it was difficult for the NHS to exert buyer power. I will return to that point in a moment.

Secondly, the clinical commissioning groups were not able to exercise any choice of product. In other words,

once a product is prescribed, the CCGs must pay for it.

Thirdly, the Department of Health did not have material countervailing buyer power through the power to regulate prices.

It was the third point that was the focus there. You see that in the final sentence and so that is also the case here.

At 201 there is again a recognition that this is a matter of degree:

"An undertaking with significant market power may not be dominant if the customer has a sufficient degree of countervailing buyer power effectively to constrain the undertaking's conduct."

Then a reference to previous case law, including from the pharmaceutical industry, the *Genzyme* case.

Turning on to page 67 at paragraph 203, you see the Tribunal summarises the state of the law based on its consideration of the authorities:

"It is clear from this jurisprudence that to be an effective constraint on behaviour the buyer in question must not only have the theoretical capability of exercising countervailing pressure on suppliers but there has to be a real possibility that this pressure will be exercised in practice and to a sufficient extent."

At paragraph 204 the Tribunal notes that countervailing buyer power in the classic sense is not applicable in this context:

"Countervailing buyer power is not as it is normally understood in competition law terms relates to the bargaining position of the buyer, and could arise, for example, if a commercially significant buyer was able to make a credible threat to switch to a competing supplier."

But for reasons the Tribunal then records, that is not how things work in relation to the NHS. That is due to the way the NHS is organised, but also, and importantly, because continuity of supply in the fourth line from the bottom of the page:

"Affected the extent to which clinical commissioning groups could choose to purchase alternative products. Thus, the CMA found that the structure of the NHS meant that it was difficult for the NHS to excerpt buyer power over Pfizer and Flynn and that CCGs had no choice but to purchase Pfizer-Flynn ..."

Turning over the page, you see part of the CMA's reasoning was not challenged and nor is it challenged in this case. The upshot is:

"It is hard to see how it could realistically be

said that the Department of Health could, in practice, excerpt any material buyer power, as normally understood in competition law terms, such as to influence the pricing behaviour of Flynn and Pfizer."

The short and central point is once the prescription is issued, there is an obligation to pay and that significantly constrains the ability to refuse to purchase, to walk away.

THE PRESIDENT: I mean, buyer power, however big the buyer, only really works if you have got an alternative, a threat to deploy. So here depending on how the evidence as to its use pans out, Plenadren might arguably have been an alternative in that it could be used though I note what you said yesterday about it not being as good a medicine for those who could take their hydrocortisone immediate release pills three times a day, but let us park that question and assume that it is in fact a different but more or less acceptable substitute for immediate release.

Buyer power would be helpful if you had Plenadren at a cheaper price, but Plenadren was more expensive and, in fact, we see the buyer power operating in that way, in that what was said in the literature that you showed us yesterday is that CCGs and others were saying do not go for Plenadren because it is too expensive.

Now, the question which one does ask oneself is why did the supply of Plenadren price at that level, but it does not assist -- it is an interesting question -- but it does not assist in why the NHS generally did not threaten to move to Plenadren because you would immediately realise that it is a hopeless threat. The threat would operate the other way. We will buy hydrocortisone. If you reduce Plenadren's price, maybe we will use that, but that is.

MR HOLMES: Sir, you are quite right to pull me up on that. You are right of course, sir, that one of the ways in which countervailing buyer power arises is where there is a credible outside option and, as you say, sir, depending on where you come out on the clinical evidence, it is difficult to see where that option would lie on any view given the pricing of Plenadren, which is the alternative hydrocortisone form.

The point that I perhaps leapt to too quickly is that another way in which countervailing buyer power might arise in some contexts would be a refusal to purchase at all, to walk away. That is an option in ordinary commercial negotiations, but here, clearly, that is not an option.

THE PRESIDENT: Yes.

MR HOLMES: Patients with Addison's disease needed treating.

You could not leave them to suffer and to suffer the life-threatening consequences. So, therefore, and given that once a prescription is written the pharmacies have to be reimbursed, that left no way out on a classic and traditional countervailing buyer power analysis.

THE PRESIDENT: Buyer power, it comes down to no more than this: if I as an individual go to a supplier and say, unless you give me a 10% discount, I am going to walk away. Well, I am afraid in most cases, they will tell me, well walk away, be my guest, because I am not economically significant enough. On the other hand, if I represent the purchase of a vast number of units and I say, well I am going to switch my supply, well then the suppliers is going to sit up and listen, but it is no more than that.

MR HOLMES: Yes, and here there is no possibility of threatening to walk away, as of course Auden must have been aware.

For the reasons we have been debating, the real focus of debate has therefore classically been not on countervailing buyer power in the classic sense that you have just adumbrated it, but rather, as set out in paragraph 205, a rather unusual form of buyer power deriving from the Department of Health's unique position, statutory powers and non-statutory leverage.

Do you see that in the third line?

THE PRESIDENT: Yes.

MR HOLMES: As the Tribunal observes, this aspect of countervailing buyer power is better described as a form of regulatory power: so not CBP in the classic sense at all.

Notwithstanding that point, if we turn on to page 69, it is clear from paragraph 207 the Tribunal regarded the underlying nature of the enquiry as the same.

Picking it up in the third line, the Tribunal said this:

"The question is whether the Department of Health 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."

So still a matter of degree, still a question of real practical constraints, but deriving from regulation or the threat of regulation, rather than purchasing and the threat of not to purchase.

Now, Pfizer sought permission to appeal this approach, but was refused by Lord Justice Newey. The order is at {H/1173.3/1}.

THE PRESIDENT: By all means take us to it, but I have well in mind the points that Auden make that this is not

something more than in this case a statement of the reasons why permission to appeal was refused.

MR HOLMES: No, indeed, sir. We do not rely on it as formally binding upon you.

THE PRESIDENT: No.

MR HOLMES: Of course, sir. But it is interesting to see the trenchant terms in which the ground was dismissed. You see that he concludes that the Tribunal 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 of limiting the appellants' prices:

"Both the case law and common-sense show that the focus should be on whether there is an effective constraint rather than the theoretical position."

As I say, not formally binding, but it means that the Tribunal's approach stands and we commend it to you as clearly the correct approach.

The proper focus is therefore upon whether there was any effective constraint in practice.

As a first point --

THE PRESIDENT: The trouble is theoretical is not quite the right word, because these powers in the NHS Act were there.

MR HOLMES: Yes.

THE PRESIDENT: There is no reason why they could not be exercised. They were not. Are you saying that a contingent restraint, in other words one that depends upon the Secretary of State choosing to act, is not for purposes of assessing dominance a relevant thing to take into account?

MR HOLMES: It may be relevant, sir, but you need to show that it has actually operated to constrain dominance and for that to you need to engage in a practical enquiry, not just looking at the words on the page, else it would be impossible to apply this aspect of competition law at all to the pharmaceutical sector, because it is common ground that there were in theory powers. There was text in the statute. But you need to look at whether that legislation was practically operable and I will show you why we say that it was not and, for that reason, it did not in fact constrain the market power of Auden.

It did not do so either through the exercise of any price regulation. It did not do so through the threat to exercise any price regulation and it did not do so based on any evidence before this Tribunal on the basis of a perceived risk on Auden's part that it might do so.

THE PRESIDENT: These provisions are relevant at two levels, are they not? They are relevant at the dominance question, but they are also relevant to the abuse by

excessive pricing question, because I think what is said, by at least some of the appellants, is the fact that there was no intervention enables us to make some sort of inference that in fact the prices were not perceived as excessive, because if they had been excessive, there would have been an intervention. You may want to address that point separately when you come to abuse, but it does impact at both levels, does not it?

MR HOLMES: It is also I see a point that may arise in relation to abuse and I will deal with that when I come to abuse, if I may.

THE PRESIDENT: Of course.

MR HOLMES: Can I show you for now why we say for the purposes of dominance there is not any practical constraint arising from the provisions that are relied upon.

Indeed, we say that this is an unpromising ground of appeal where in fact the prices are seen to have risen relentlessly and to extraordinary levels. If this is a case where prices really were constrained by regulation or the threat of regulation, it is hard to imagine what unconstrained pricing would look like. We saw the mountain figure, the 10,000% inflation with individual prices per tablet rising from a few pence to

several pounds. That is not suggestive of a constraint in practice.

There is no dispute that the Department of Health did not in fact exercise any regulatory powers to regulate the price of hydrocortisone. Nor has Auden relied on contemporaneous documents or witness evidence in these proceedings before the Tribunal to suggest that it in fact decided to restrain its pricing because of a concern that the Department might intervene.

On careful analysis, it will be my submission that none of the powers that were theoretically available, and I take your point about theoretically the powers that were available on the face of the statute to the Department, were in fact such as to exercise an effective constraint on Auden's pricing.

To see why that is the case one needs to consider in a little bit of granular detail the regulatory position as it changed over time and I propose to turn to that now, unless the Tribunal has further questions on the framework.

THE PRESIDENT: No, thank you.

MR HOLMES: Annex B of the Decision for your note addresses this in some length. As set out there, there are three distinct periods which need to be considered reflecting shifts in the regulatory position, either as a result of

changes in the status of Auden over time following its acquisition by Actavis or as a result of amendments or changes to the regulatory framework itself.

The first period runs from the start of the infringement in October 2008 until the end of August 2015. During this period, the only potential basis on which price could be regulated is section 262(1) of the NHS Act 2006. The version in force at the time is {M/55.2/3}. If we could go there, please.

As the Tribunal sees, subsection (1) permitted the Secretary of State after consultation with the industry body to do two things. First, at (a) to limit any price which may be charged by a supplier of a pharmaceutical product and, secondly, to give useful effects to such a limit to provide for any amount charged in excess of the limit to be paid over to the Secretary of State.

Subsection (2) then confined the power to cases where the supplier was not a member of a voluntary scheme. There were two potentially relevant voluntary schemes in existence at the time in this context. The first was the PPRS, which applied to branded pharmaceuticals and the second was Scheme M which applied to generic pharmaceuticals.

As we know, Auden was not a member of either

voluntary scheme until its acquisition by Actavis on 31 August 2015 and, as a result, it is common ground that this power could, at least on paper, be used against it.

Last Tuesday you asked, sir, how often section 262(1) was used in practice by the Department. The answer, so far as the CMA is aware, is a short one: never. The provision was not used to regulate the prices of any pharmaceutical product at any point. There was never a limit imposed under section 262(1)(a).

One of the reasons for this was that the Department had no powers to gather information about the costs and pricing of products and no powers to enforce any price control imposed under section 262.

Can I consider in turn those twin gaps in an effective enforcement regime for section 262.

Starting with the power to gather information. We saw yesterday, just as a framing factual observation, that Auden repeatedly claimed that its prices were increasing during the upward march by reason of changes in its costs. It did so publicly in response to press scrutiny. You will recall Mr Patel's description of a state-of-the-art facility costing huge amounts and you will recall the emails to customers.

We saw that those claims were false. Auden bought

from a CMO at prices that remained very low throughout.

That was the kind of behaviour that the Department would need to be able to look behind and to deal with to regulate a company like Auden effectively. Without effective information gathering powers, the Department had no way of assessing the relationship between Auden's prices and its costs in order to challenge the prices. Auden was not a member of Scheme M. It did not provide data pursuant to category M and the Department did not have powers in secondary legislation to gather the information.

The NHS Act contained enabling provisions which would have allowed for information gathering and would have permitted enforcement.

If we could turn to page 4 of this document, please you see that at section 264(1) {M/55.2/4}, the statute made provision for enabling or facilitating the introduction of a limit under 262.

At subsection (2) such provision was permitted in particular to require any person to whom such a limit may apply to record and keep information and provide information to the Secretary of State.

Do you see that, sir?

THE PRESIDENT: Yes.

MR HOLMES: Such information was needed not only as

a practical matter in order to have any hope of identifying unjustified price increases in the face of dissimulation by suppliers like Auden. It was also necessary from a legal perspective in view of the requirements applicable to section 262(1) under section 266 of the Act. That is on page 5 of this document {M/55.2/5}.

As the Tribunal will see, pursuant to section 266(3) the power to impose a limit under 262(1) (a), this the putative power that is relied on here, was:

"Exercisable only with a view to limiting by reference to the prices or profits which would be reasonable in all the circumstances --

"(a) the prices which may be charged for, or

"(b) the profits which may accrue to any manufacturer or supplier in connection with, the manufacture or supply [of the product]."

At subsection (4) the Secretary of State must bear in mind two things in particular:

"The need for medicinal products to be available for the health service on reasonable terms, and

"The costs of research and development."

So the short point is this: in order to be able to decide what prices or profits would be reasonable, taking into account what terms may be reasonable and

what costs are entailed by research and development, the Department would in practice require plentiful information and that could only be obtained mandatorily with the enactment of further regulations pursuant to section 264 (2) which during the relevant period had not occurred.

So no powers to gather information.

As regards research and development, one of the matters to which regard had to be paid, the Tribunal will have well in mind the fact that Auden's owners were during this period obtaining transfer from Auden into offshore accounts on the basis of sham invoices alleging payments for research and development and the Department would need proper and searching powers to have any hope of lifting the lid in an effective manner on Auden's pricing when confronted with behaviour of this kind.

PROFESSOR HOLMES: Can I ask, I fully understand the point you are making. If supposing hypothetically the price was £5, I understand that, without enquiry, you do not know whether £5 is a low price, high price or whatever. But if the price changes dramatically from say £1 to £70, the mountain point, would that not put the Secretary of State on notice that there might be something that they would want to enquire about without having to have detailed information and costs on prices?

A related question is, even if where you do not have powers many statutory bodies have considerable influence, the CMA is an example, when it does not have statutory powers it has in practice the ability to get information without using its formal powers, in fact that is its normal modus operandis. I am slightly surprised there was not more of this going on.

MR HOLMES: Sir, one of the features, which I will come to in a moment, is the fact that the Department of Health, which has limited resources of course as every public authority does, is overseeing an enormous drugs budget with many, many different products and we will see that in the generic sector competition was relied on to try and keep prices in check and the focus was really upon blockbuster drugs. So that is part I think of the factual answer to your question, sir.

PROFESSOR HOLMES: The sort of below the radar.

MR HOLMES: Below the radar, a phrase indeed that -- one of the features of this case, of course, is that there has been another parallel case heard recently in which "below the radar" featured prominently in relation to exactly this argument with lots of contemporaneous documents suggesting that was exactly how the undertaking in question viewed matters. So there is the below the radar point and it is undoubtedly an important

aspect of the practical features at work.

But the underlying point that I am developing here, sir, is that what is said against me is that there was a real practical constraint arising from section 262(1) and the point I am making is that the statutory apparatus, the secondary legislation which would enable the kind of fine-grained enquiries that would be required, not only to identify but also then to police, to regulate prices of individual products, just was not in place during the relevant period as a result of conscious policy choices as to where to focus regulation and how to regulate different parts of the market. This was --

PROFESSOR HOLMES: Effectively, you are saying it was pretty toothless even if they had used informal influence.

MR HOLMES: You have hit the nail on the head, sir. That is exactly my submission: toothless, because there was none of the regulatory apparatus in place that could ever have given in force and that explains why there is no contemporaneous evidence suggesting the Department threatened it in this case or that any action was taken or that Auden was worried about such action being taken. It just was not realistic at all.

PROFESSOR HOLMES: Thank you.

MR HOLMES: The second gap in the Department's powers, which

gives the lie to any suggestion that 262 was effective as a constraint in practice, concerns the lack of ability to impose and enforce any regulation. As regards enforcement, section 265 similarly makes provision for secondary legislation.

If we could look, first at {M/55.2/5} at 265 (7). It defines enforcement decision in very broad terms. We will come to see the significance of enforcement decision in a moment. But it includes decisions of the kind we have just been discussing to require the provision of information. It also includes the decision actually to limit any price or profit, so the limiting decision under 262, the price regulation itself. It also includes decisions refusing to approve a price increase and it includes decisions requiring a specific manufacturer or supplier to pay any amount, which would arguably extend to the requirement to pay amounts in excess of a limit pursuant to section 262(1) (b), which is how the provision is given useful effect.

Subsection (8) provides that a limit under inter alia section 262 may only be enforced under section 265 itself and may not be relied on in any proceedings other than proceedings under this section. This is the unique enforcement route. The only way in which a limit could be imposed and then enforced is via section 265.

Turning back to page 4, one sees that enforcement is to occur pursuant to regulations. You see the title of the section, "Enforcement" and then a series of things are specified for which regulation may provide: payment of penalties under subsection (1) and (2); interest under subsection (4) and also a right of appeal under subsection (5).

So the whole statutory scheme was premised on the enactment of secondary legislation in the form of regulations empowering the imposition of price limits, the enforcement of price limits and appeals from price limits and without such a regulatory scheme, the legislation was a dead letter. But such regulations were not in fact in place at any point relevant to this case. We say that without them enforcement would not have been possible, broadly understood as including the imposition of a limit itself and the practical enforcement of such a limit.

So the regulation really was a toothless power, as you put it, sir.

This practical difficulty is explained in the Decision at Annex B, which is at {IR-A/13/27} in paragraph 9. You see with respect to generic drugs there was no enforcement regime to underpin any exercise of the reserve power -- that is section 262 -- or the

supporting power in section 264 to require the provision of information -- the point I made earlier -- which would enable the Department to determine that a current price was excessive or what a reasonable price would be. So two points.

First of all, identifying excessive, but then also working out what price to impose, given the factors to which regard had to be paid.

Section 658 stated that any price limit or requirement under sections 261 to 264(a) could only be enforced under regulations providing for a right of appeal and no regulations existed.

During the course of her oral submissions, Ms Ford handed up a supplemental note on the Department's statutory powers and that makes the point that the provisions now contained in section 262(1) of the 2006 Act were previously to be found in section 34 of the 1999 Act and that regulations were enacted pursuant to that provision.

Those were, however, revoked in May 2007 prior to the beginning of the infringement in this case. If anything, they underline how the regulatory framework had changed by the time of the infringement and why the power in section 262(1) was not, during the period relevant to this case, capable of supplying any

effective constraint in fact on Auden's pricing in the absence of further enabling legislation.

The reason why section 262(1) lacked a regulatory framework is explained in paragraph 9 (c) based on what the Department told the CMA:

"Instead of using the reserve power, the Department's policy with respect to the pricing of generic medicines was to rely on competition in the market to control prices. Where markets did not function well, the Department's policy was to have statutory or voluntary schemes in place, rather than consider one product in isolation."

At 9 (d):

"Although the DHSC was resourced to develop, operate and maintain its schemes, it did not have the resources or appropriate infrastructure and implementing framework in place to determine the fair and reasonable price of an individual generic drug."

This comes back to the point that I made in response to the question from Professor Holmes. The Tribunal will have well in mind that the NHS pays for many hundreds of drugs in many different treatment areas and even with the eye-watering price increases imposed by Auden/Actavis, hydrocortisone was still a small part of the overall drug reimbursement bill and with limited

resources and an asymmetry of information the Department could not realistically attend to individual drugs in the way proposed by Auden and the Department understandably did not attempt to do so. It would have required a really intensive forensic exercise where you see the types of practice which were in play in this case with sham research and development payments that would need to be looked behind.

Lest it be said against me that the Department could have enacted legislation to enable such an individual monitoring exercise, I should stress that it is not the job of either the CMA, or indeed this Tribunal, to second guess the Government, the choices made by the Government or the Department. This is a competition law case. It is not a public enquiry and the proper focus of the present enquiry is a consideration of a factual nature ultimately: was Auden in fact constrained by such regulation as there was or the threat of regulation? The only realistic answer to that question, in my submission, is that it was not.

So that deals with alleged countervailing buyer power in the first period, subject to any questions.

THE PRESIDENT: There is an end of the telescope question here, is there not? You say one needs to look at the effect of the legislation on the supplier and you say

well, for the reasons you have given, there was not any. I think Ms Ford would say, no, you should ask why the Department of Health did not do more to intervene, did not exercise the powers, including the ability to put in place secondary legislation in order to control precisely such abuses as these, if they existed. You say that is simply the wrong question. You have got to -- we will have to decide which end of the telescope.

MR HOLMES: Yes, the question -- I have no doubt that Ms Ford does say that and will say that, but the point is that we are only involved in a consideration of countervailing buyer or regulatory power to the extent that it qualifies dominance. The case law makes clear that that is a fact-sensitive enquiry which is a matter of degree. So this is, in my submission, rightly a consideration of how things actually panned out and whether there really was some constraint which bit such that there was no dominance here, such that dominance was circumscribed.

When you see the threshold that has to be met, as it is set out in the case law, you readily see the difficulty that Auden faces in doing so. I do, sir, very much maintain that it is not this Tribunal's task or the CMA's task to question why the legislature, primary or secondary, did not exercise its legislative

powers in a given case when assessing dominance and I also rely on the passages in the Decision which I showed in the annex, which show the position as to policy which explains that choice, which was in any event a reliance upon competition and a rolling back of regulation which is a perfectly legitimate regulatory choice.

Having done that, of course where competition is left to play out the general rules of competition law apply as a constraint to players in the market.

THE PRESIDENT: Yes, you are now addressing Ms Ford's end of the telescope, are you not? Ms Ford made the point, I think she made it, but the point has been made that there was a failure on the part of the CMA to ask the Department why it had not acted and that is very much looking at the reasoning behind the Department of Health's position.

Your answer to that is twofold. First of all, you say that is the wrong question. You have got to look at the actual effect on the market as it was and if there was no effect then it does not matter.

MR HOLMES: Yes.

THE PRESIDENT: But even if one looks at the other end, you say there is in fact a sufficient explanation as to why the Department did not act in the fragilities that you

have articulated in relation to the statutory powers.

MR HOLMES: Yes, and it was not only the Department telling the CMA in private discussion what its policy was. We will see there are plentiful indications as to the policy which applied to generic medicines at the time and the reliance on competition law and market pricing as the mechanism that would apply in relation to those products.

THE PRESIDENT: Are you going so far as to say that actually 262, because when I read it initially, without looking at the later sections, it looks rather like a standalone provision that provided the Secretary of State consults with the industry body, the Secretary of State may limit any price charged, but I think what you are saying is if one followed to the letter the provisions in 262(1), you would actually be breaching later sections of the Act, which control that power.

MR HOLMES: It has to be read, sir, in the light of the conditions that need to be met as set out in subsequent provisions of the Act.

THE PRESIDENT: Yes. Does that then provide an answer to my judicial review question, because I put to Ms Ford that if this power was exercised, it would obviously be subject to JR.

MR HOLMES: It does.

THE PRESIDENT: In fact, it is dealt with in a statutory regime --

MR HOLMES: Yes.

THE PRESIDENT: -- later on.

MR HOLMES: I am very grateful. That was a point I had intended to incorporate in my script, but I am afraid in the small hours I failed to do so. But it struck me that exactly addressed the point you were putting. One can see the considerations that are identified as relevant considerations that require to be weighed.

THE PRESIDENT: Yes, thank you.

MR HOLMES: The second period to consider is Actavis's conduct of the business following its acquisition of Auden. This period begins in September 2015 and lasts until 6 August 2017 when the legislative framework changed once more. The reason why this period requires separate consideration is of course because Actavis was a member of both the PPRS, the voluntary scheme applicable to branded products, and to Scheme M, the voluntary scheme applicable to generic suppliers.

That meant the reserve power in section 262(1) could not be used against it by reason of the limitation in section 262(1) subject to the arguments which I will now come on to address.

During this period, Auden/Actavis relies on three

potential routes to price regulation. The first is section 262 (4) of the 2006 Act and that is at {M/55.2/2}. That provides that:

"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 either of the purposes mentioned in subsection (1), the Secretary of State may ... determine that the scheme does not apply to him."

The purposes identified in subsection (1) are limiting the prices or profits of a supplier to whom the scheme relates.

So 261 (4) confers a power to eject a supplier from a voluntary scheme and, so the argument goes, the Department could have used this power to eject Actavis, thereby enabling it to exercise the power to regulate price under section 262(1), which we have already considered. So it is a two step. First you chuck them out of the voluntary schemes and then 262(1) becomes available afresh.

There are two profound difficulties with this tortuous scenario. The first is that it simply takes you back into section 262(1) and that lacked teeth for all of the reasons that we have already discussed.

The second is that the Department would arguably

have needed to take the extreme step of expelling Actavis from both the PPRS and Scheme M. This is on the basis that on one widely held view at the time the limitation in section 262(2) prevented the application of section 262(1) to generic products, whether the supplier in question belonged to the PPRS or to Scheme M. The Tribunal will recall this is the uncertain legal question which the Tribunal concluded it did not need to resolve in *Phenytoin*.

The expulsion of Actavis from the PPRS would have removed all of its branded products from the profit controls applicable under the PPRS mechanism and that would have been an obviously undesirable outcome from the Department's perspective.

THE PRESIDENT: Yes, but only because of the toothlessness of the regime that operates.

MR HOLMES: Sir, it may be that my first answer is all that one needs, but I am now developing -- the first answer being 262(1), even once you are through, faces all of the same difficulties as it did in the prior period. But I would say that there are further significant difficulties involved in the step of expulsion, which presents another hurdle to the application of section 262(1) after Actavis's acquisition.

THE PRESIDENT: No, I mean my point is a rather more brutal

one which is: why would you bother expelling someone from either scheme, given that you have got an inability to control the prices outside the scheme because you have a toothless regime?

MR HOLMES: Yes.

THE PRESIDENT: So, in effect, you have got the toothlessness extending to the threat of expulsion from the scheme.

MR HOLMES: Yes, indeed, sir, I completely agree. I only take these points because there has been a root and branch --

THE PRESIDENT: I am just trying to understand how it all works.

MR HOLMES: Yes, indeed. These are supplemental points which may be entirely unnecessary, but the first is the need to expel from both PPRS and Scheme M and it is at least doubtful whether Actavis could have been lawfully expelled from the PPRS for its pricing of a generic product which was not subject to the PPRS.

One of the curious features of the case, sir, is that we are rearguing points which have been debated several times before this Tribunal and the view that the Tribunal took in the *Genzyme* case, in respect of the equivalent power under section 33 of the Health Act 1999, was precisely that it would not be possible to

expel from the PPRS by reason of a pricing of a generic product.

We do not need to go there, but for your note the reference is paragraph 273 of the 2004 *Genzyme* judgment, which is at {M/31/84}.

So that route would have been legally very difficult and at best uncertain. Given that uncertainty, and the litigious nature of this sector of economic activity, there would be a clear risk of judicial review here too.

There is of course no evidence that it was ever contemplated or that Actavis feared that it might occur in the present case or that there was any practical constraint at all.

The second regulatory route which Ms Ford relied on during this period was the power to control price under Scheme M. The relevant version of Scheme M from March 2010 is at {M/77/1}. Starting with the preamble on page 2 {M/77/2}, you see the explanation there that:

"The Scheme is a voluntary (non-contractual) one made by the Secretary of State and the representative industry body within the meaning of section 261 of the National Health Service Act 2006."

That is the British Generics Manufacturers Association.

The general approach is that Scheme M allows freedom of pricing. You see that in paragraph 27 and it is all of a piece with this policy choice that I was discussing a moment ago. If we could go, please, to {M/77/7}, you see at paragraph 27:

"The Scheme allows freedom of pricing subject to the following provisions ..."

The first sentence of the bullet:

"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."

So no automatic regulation or control of price under Scheme M. The default was freedom of pricing.

But if we read on, the second sentence notes:

"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."

And it cross-refers to paragraphs 30-34, and paragraph 30 lies at the heart of Auden's submissions on this point, and paragraph 30 is at {M/77/8}. The existence of the powers set out here is not in dispute. But we know that the Department never in fact used or

threatened to use the power against Actavis. You see the provision provides that, first paragraph 30:

"The Department will allow changes in the market prices to be influenced by existing market mechanisms."

Where there is effective competition then the Department will not intervene.

"However, should the Department identify any significant events or trends in expenditure that indicate the normal market mechanisms have failed ... then the Department may intervene to ensure that the NHS pays a reasonable price ..."

The CMA's position is that had the Department attempted to use this power it would have gone nowhere. For example, if the Department had attempted to intervene to ensure that the NHS pays a reasonable price for the medicines, Actavis could have opted to dispute the new price under the dispute resolution provisions in paragraphs 35-41. They are on page {M/77/9}. Had Actavis done that, then the Department could not impose the disputed price and that is because disputes were to be resolved by a three person panel consisting of a chair, a member appointed by the Department and another by the BGMA. So it would have been out of the Department's hands.

Even then if Actavis objected to the Department's

intervention under paragraph 30 or disliked the decision of a dispute resolution panel it could simply leave the scheme as per paragraph 44 which is on page {M/77/10}.

In that scenario the Department of Health would have been left without a leg to stand on. Why do I say that? Because we would then be back in a world in which the reserve power under section 262 could not be used against Actavis because it was a member of the PPRS and we would then need to consider removing it from the PPRS and if it were removed from the PPRS there would then be the problem of lack of necessary enabling provisions. So it is a real thicket.

The third route on which Ms Ford may have sought to place reliance during this period was section 261(8). That is in {M/55.2/2} at the bottom of the page. The Tribunal sees that it empowers the Secretary of State, so looking at the foot of the page to:

"... 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."

And:

"... to provide for any amount representing any increase ... to be paid over to the Secretary of State."

But as Auden noted in its supplemental note

section 261(8) was not in fact in force during the second period. Enabling legislation was only introduced as part of the August 2017 changes, which I will come to in a moment.

For the period I am currently considering it was not available and could not possibly have exerted any countervailing constraint on Auden/Actavis. So in my submission it is a complete red herring. It required enabling legislation and there was none.

PROFESSOR MASON: Mr Holmes, can I just check with you then that I understand the exact argument. One interpretation of what you have just said is that all those dispute resolution provisions and three person panels and so on are not actually worth the paper they are written on because, as you have described it, there is no scenario in which they would be effective. Is that a general statement or are you particularising it to this case?

MR HOLMES: Again, to our knowledge, sir, the Scheme M mechanism was never used to regulate any pharmaceutical price. It was never applied in practice.

PROFESSOR MASON: Any?

MR HOLMES: Any. I see there may be some disagreement. If anyone on the other side of the Bar can point to a case I would be interested to see it of course but I am not

aware in the materials of any evidence that it was ever used in practice to regulate the price.

MR JOWELL: If I may, so Mr Holmes knows our position. There is recorded in the original *Phenytoin* judgment what occurred in that case which is the informal intervention as against Teva for its tablets where an enormous reduction was achieved by the Department of Health by virtue of -- in the context of Scheme M.

MR HOLMES: Mr Jowell need have no concern. He can of course address you in reply as he sees fit. I will be coming to and we will deal with this rather discrete exercise.

MR JOWELL: While I am on my feet and so that this is also, as it were, so Mr Holmes can also deal with this, we are slightly concerned that there is a sort of hinting at what was going on in the Department of Health's mind. For example, it is suggested that this was all under the radar. It is suggested that --

THE PRESIDENT: I do not think you need worry about that.

MR JOWELL: Yes, but, well --

THE PRESIDENT: No, do go on.

MR JOWELL: If I may. Then it was suggested this would all be toothless because it was anticipated that Actavis would leave the scheme. We find that a very far-fetched proposition and we do not think that there is any

evidence to support it. One point that I think we have made very clear is there is a dearth of evidence from the Department of Health in this case.

THE PRESIDENT: That point has certainly been made and it is the telescope point that I made with Mr Holmes. I think we would be prepared to go so far as to understand the operation in the abstract of the legislation.

MR JOWELL: Yes.

THE PRESIDENT: To that extent it is helpful to be educated about it. But to go any further, in particular to do anything more than infer from the black and white wording of the legislation what was or might have been in the mind of the Department I think would be something that we would not be prepared to do as the evidence stands.

MR HOLMES: I am slightly concerned that Mr Jowell has now on several occasions made submissions during the course of my Closing submissions in circumstances where objection has been taken to the length of time that I am taking. At the beginning of yesterday we had further submissions on the economic literature. He can of course address --

THE PRESIDENT: No, gentlemen, the intervention was I think a helpful one and there have not been many. Let us be fair.

MR HOLMES: I am grateful, sir.

THE PRESIDENT: I will certainly shut up anyone who is taking too much time out of your time, including myself.

MR HOLMES: I appreciate, that, sir. I am conscious of the time. It may be that is a convenient moment to pause.

THE PRESIDENT: Yes, of course. We will rise for ten minutes and resume at 25 to.

(11.27 am)

(A short break)

(11.41 am)

MR HOLMES: Sir, that brings me to the third and final period, on which I think I can be quite short. This began with the legislative changes brought in on 7 August 2017 and it ended up in July 2018 at the conclusion of the infringement period.

The changes were effected by the Health Service Medical Supplies Costs Act of 2017. We do not need to go there, but for your note it is at {M/137/1}. Intas places particular reliance on these legislative changes, describing them as "enhanced powers". For your note, that is Intas Written Closings at paragraph 106.

For present purposes, the 2017 Act did two things in particular. First, section 4 amended section 262 of the National Health Service Act, "the 2006 Act", to enable the Secretary of State to require companies to reduce

the price of an unbranded generic medicine notwithstanding their membership of the PPRS. So it resolved the uncertain legal point that was identified by the Tribunal in *Phenytoin* making clear that section 262 could be used notwithstanding a membership of the PPRS.

Secondly, section 8 inserted a new section 264A into the 2006 Act that enabled the Secretary of State to obtain information about the costs of producing medicines and the upshot of the 2017 Act was that the Department of Health could now use the reserve power under section 62 in respect of Actavis's UK 10mg tablets.

But even at this point the regulatory powers were not fully operational. It was not until the 11 April 2018 that the Department was given powers to enforce directions to limit prices. That is explained in the Decision at footnote 265 and the relevant legislation is the Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018. For your note, they are at {M/145/1}.

It was not until the final month of the infringement period on 1 July 2018 that the Department was given powers to gather information on manufacturing supply and distribution costs and the relevant statutory instrument

is the Health Service Products (Provision and Disclosure of Information) Regulations 2018. For your note, they are at {M/149/1}.

My short submission in relation to these implementing powers is that they were too little too late to make any difference to the tail-end of the 10mg abuse. Moreover, and in any event, we know that the Department was not ready to use its powers under section 262 even at this time. To make that good, can we go, please, to {IR-H/1141.1/1}. This is a consultation response from the Department and the title shows that it concerns legal requirements to provide information about health service products. It's dated June 2018. It preceded the Regulations which gave the Department information gathering powers in July 2018.

If we could go, please, to annex B of the consultation, which is at page {IR-H/1141.1/34}. As you see from the heading, this is a statement on prices of unbranded generic medicines. In the first paragraph in the third line we see the Department's view that effective competition between suppliers was an effective means of cost control in most cases.

The second paragraph reiterates in the fourth line that the Department is committed to allowing freedom of

pricing for unbranded generic medicines where there is effective competition.

So that is a statement of the general position. But then in the third paragraph the Department says this:

"The CMA has several live investigations into excessive pricing of unbranded generic medicines. It has become clear that where competition is not working effectively, some manufacturers or suppliers have increased their prices to what appear to be unwarranted levels. The Department recognises that there may be legitimate reasons for price increases. However, in cases where unwarranted prices are being charged, the Department has concluded that control of those prices is necessary."

The Department then sketches out how it might identify potentially unwarranted prices when normal market mechanisms have failed to protect the NHS.

We can see the list of factors it proposed to have regard to which are listed in the bullets.

Turning over the page, the Department explains how it would intervene, starting by engagement with the company, then information gathering and using the information in discussion with the company about the price level. If necessary, you see in the sixth line, the Department explains that it may use its powers

under section 262 after consulting the BGMA. The Department also notes the possibility of referring cases to the CMA for investigation and the statement concludes:

"If the Department has not engaged with the company about the price of its unbranded generic medicine this must under no circumstance be understood as approval of that price."

So inaction should not be taken as acceptance. Finally:

"The Department will consult the relevant industry bodies, the BGMA and the HDA, about its proposed policy and procedures for limiting the price of an unbranded generic medicine under section 262."

That is where matters were left at the time of the infringements. The Department of Health said it would consult on its policy and procedure for applying section 262. That did not happen during the infringements and, in my submission, the powers were therefore not, even then, realistically at a stage where they could be deployed during the infringement.

Standing back, we say looking at the evidence before the CMA and the Tribunal, it is fanciful to suppose that Auden/Actavis was constrained by the possibility of Department of Health regulation at any point in the

history of the case. There simply was not the legal apparatus in place for the Department to regulate hydrocortisone tablet prices. It did not attempt to do so. There is nothing to suggest that anyone in control of Auden/Actavis ever feared such intervention or modified their conduct in consequence and this point comes back in the end to the mountain. In the face of the price increases that were imposed, it is hopeless to suggest that Auden or Actavis was at any point seriously constrained by countervailing regulatory power.

On the contrary, the evidence shows that someone with an eye to a lucrative opportunity acquired an old drug with inelastic demand and then pushed the price up for great gain and the loser was the National Health Service.

The final point is Auden/Actavis's passing reference to Mr Beighton's evidence about a meeting with the Department of Health to discuss Phenytoin sodium tablets, an entirely separate product, during the first *Phenytoin* appeals in 2017.

It suggests that this shows that the Department was ready to flex its muscles in relation to other drugs. Now, I would make two points about this example. First, it relates to a single meeting in 2007 in relation to a single drug in a case in which the Tribunal concluded

that the Department of Health did not have regulatory power to constrain Pfizer or Flynn. It is not evidence of the Department regularly exercising its regulatory powers in respect of generic drugs during the infringement period.

The second point is that there is no evidence that Auden and Actavis knew about this meeting with Teva at any point during the infringement. Nor has Auden/Actavis claimed that it knew about this intervention and somehow felt constrained by it. There is no document recording any such inhibition.

The reality is that this Teva meeting, in my submission, has nothing to do with the facts of this case. So those are my submissions on countervailing regulatory power or, as I would say, the obvious lack of it.

I should say Intas has an additional argument on countervailing buyer power in the Intas period of a more conventional kind based on the alleged credibility of a threat of customers to switch to rival suppliers. Now, that is obviously not an argument that is open to any of the appellants in relation to the pre-entry period, for reasons that we have canvassed, but if convenient to the Tribunal, I propose to park that point and deal with it as part of the discussion of dominance.

So I will come back to it, because it really ties in with the assured customer base.

So that brings me to the other strand of the appeals on dominance, unless there are any final questions on countervailing regulatory power. I have obviously exhausted your appetite for further discussion of that topic.

This is whether dominance was retained by Auden/Actavis in the post-entry period. On this topic, the main running was made by Intas, for obvious reasons. I will focus on the arguments which it has advanced.

Can I start by addressing two overarching points that Intas has made about the CMA's approach in this case. The first is the need, as it is said, to consider the Intas period separately. The second is the distinction that Mr Palmer drew between a legal concept of dominance and an economic concept of market power.

The first point has been a recurring theme in Intas's written materials and the second point really hove into view during Mr Palmer's oral submissions on Monday. I would submit to you that those complaints are both unfounded as criticisms of the Decision.

In relation to the alleged need to focus on the Intas period, Intas's claim is essentially that the Decision fails to consider the key developments that

have taken place by the time of the Intas period. On this, I hope I can be brief.

I should say to begin with we absolutely accept that in this case, as in case of infringement, it is necessary for the CMA to show an infringement for the entirety of the period covered in which an infringement is alleged. You need to show it applied at the beginning. You need to show that it applied throughout and you need to show that it applied at the end. So there is no dispute about that.

THE PRESIDENT: No, but in some cases it matters less. I mean, if you have got the middle locked away, you may not have very much argument about the beginning or the end because it is there. The problem I think here is that the point is sharpened by the differing ownership of, as it were, the 10mg hydrocortisone supplier and it is very much, as I put to Professor Valletti, the question that one perhaps would not normally ask arises with particular sharpness here, because one has got a particular point in time at which one needs to, or at least I am suggesting one needs to, revisit the points of dominance and indeed abuse, which are defined not causally but by virtue of the party who is paying the penalty.

MR HOLMES: Yes, so may I take it in stages. As an initial

point, I would fully accept that this case does require careful attention to be paid to the final period of the infringement because of significant changes that occurred at the point of entry and in the aftermath of entry. We do not demur at all from that proposition.

As a second point, I would accept there may be cases where at the stage of liability and the analysis of the stage of liability, a change of corporate ownership does have implications for the substantive analysis of the case. In fact, a good instance of that would be the need to factor in, in relation to Actavis's acquisition of Auden, its membership of the PPRS and of Scheme M, which is material to the discussion of countervailing buyer power and requires a differentiated analysis of the period before and after.

But on the proposition of whether a change in corporate control is in itself significant for the purposes of competition analysis, I think I may detect a difference between the way that you have canvassed matters, sir, and the position as we would see it and so it may be that I need to seek to persuade you.

THE PRESIDENT: Maybe that is right. Let us make sure that we are on different pages. I mean, Mr Palmer made very clear both in his submissions and in cross-examination that he was not suggesting any kind of causative

relationship between acquisition of an entity and competition law infringement and that is what I understood him to say and that is exactly where I am at. I am not suggesting that mere transfer of ownership is something that is necessarily relevant. It may be in some cases, but I do not think it is suggested here.

What I am saying is that it provides a peculiar sharpness to the enquiry. If one is saying to an entity that has acquired another, you are on the hook, then one needs to be more careful in assessing the infringement at that point in time than if one has simply got a single undertaking which is responsible for an undoubted infringement over 90% of the time when, frankly, you can say, well, the 5% at either end where you can argue, unless it is really material to penalty, does it matter?

MR HOLMES: Sir, I was not sure that I detected any difference between the position that Mr Palmer advanced and the position that I would adopt, which is that, as I understand it, he made clear that Intas is not contending that the change of corporate control made any difference to dominance and I think we are agreed about that, unless he indicates otherwise.

THE PRESIDENT: No, I think you are on the same page there.

MR HOLMES: As to whether a change of corporate control

might be relevant to the question of liability, I must say, sir, that applying the legal principles, as I understand them to be, I am sceptical about that proposition. Let me try to persuade you.

Obviously, the starting point is that one identifies and considers the conduct of an undertaking over a relevant period and one sees whether the undertaking has committed an infringement and one then turns to entities when one comes to the question of attribution of liability and the calculation of penalty. The principles for determining whether a parent is liable for the actions of its subsidiary are the classic principles of decisive influence, which do not turn on knowledge or, classically, have not been understood to turn on knowledge of the infringement either constructive or actual.

So for the purposes of liability, my submission would be that one approaches this at the level of the undertaking and one considers whether the undertaking can be said to have committed an infringement throughout the period and whether that is sustainable across the full sweep of time for which an infringement is found.

THE PRESIDENT: Yes, I do not think I am disagreeing with that.

MR HOLMES: Very good, sir.

THE PRESIDENT: What I am saying is that given the unfortunate, one might say for analytical purposes, the unfortunate temporal coincidence of the change in ownership and the entry of skinny label product into the market meaning that one has got a downward effect on prices because of a degree of competition, some form of competition, and the shift in parental liability, one must examine this phase with more care, simply because you have got a different parent being affected, vicariously, by the liability of that which it has acquired.

So that is why I am saying it is a point that means that if one did not have this sort of change, one could take a much lumpier approach to the infringement. Of course, you would say one has to establish the (inaudible) over the whole period: absolutely. But one is not going to be looking with the degree of scrutiny that I think one does have to do here, because of the non-causative coincidence of the two factors that I have identified and that I think is the point that Mr Palmer is making and that is the point that I am putting to you and, indeed, the one I put to Professor Valletti.

MR HOLMES: I will address you on the temporal coincidence in a moment.

THE PRESIDENT: No one is saying it is causal.

MR HOLMES: No, no. I apprehend from your question that the focus is perhaps more on questions of attribution of liability and of penalty than the analysis of dominance as such.

THE PRESIDENT: Well, no, I think the loss of dominance point is an important part of that. I mean, what Mr Palmer is saying is that you have got a situation where it is not excessive prices, it is the unreasonable maintenance of excessive prices that matters; going back to the face mask example. So you might well have a graph that looks in terms of shape exactly the same as the mountain that we are discussing here, albeit one would expect it would be of a shorter duration, which would show excessive prices, but not abusive prices because it is simply a temporary undersupply and over-demand.

MR HOLMES: Yes.

THE PRESIDENT: Now, I think what is being said is that there is something in the entry into the market of skinny label producers that meant that the end was nigh and that there was no longer a sustainable ability to maintain a dominant position and that is why I asked Professor Valletti the points about the temporal aspect or the gradient of the downward curve in that if you have a from one day to the next shift from an excessive

and abusive price to a proper price, then the dominance question obviously resolves itself alongside with the abuse question, because you have simply fallen off a cliff edge and gone down.

It is a question of the gradient and whether that degree of gradient affects the question of at what point is a dominant position or an ability to abuse a dominant position, the two questions are separate, has that occurred when you have got a slope rather than a vertical straight line?

MR HOLMES: Yes, sir. Where I think we are fully agreed is that it is necessary to show that dominance was retained by the undertaking in question throughout. But I think my submission would be in the light of what I have heard that we may part company to this extent: we say that the test for dominance is always the same and it needs to be met throughout and there is no difference of evidential threshold or of the assessment that requires to be undertaken based on changes in corporate control at least at the level of liability.

So that is the submission and the Tribunal obviously will take its view.

There is a separate point I think, regardless of any potential legal difference between us on that point, which I do need to tease out, which concerns whether in

fact there is a temporal coincidence and also, following from that, the extent to which the CMA attended to changes that were occurring in the market.

Again, I suspect that in terms of the question of principle there may be little between myself and Mr Palmer on this. He said that there is a real point of substance about the market conditions being different, dominance being lost, abuse ending and that focused, as I understand it, on whether the infringement is made out based on the extent to which dominance is found, which is a prerequisite for any finding of abuse.

Now, the short point is that the CMA in its analysis did capture market conditions throughout the post-entry period. It reflected the major change of market circumstances that occurred once the agreements with AMCo ended and competing suppliers began to enter the market.

We say that the temporal coincidence is not as exact as perhaps has been stated at times. It is striking in fact that the changes of market conditions to which Intas refers occurred before the Intas period began. So in the course of oral argument, Mr Palmer agreed with your characterisation, sir, of Intas's argument as being that there was a temporal coincidence between the change in ownership and the changes in the competitive

landscape, but we say that we do not share that view of the facts.

The competitive constraints which Intas invokes are not specific to the Intas period. We do not need to turn it up, but they are set out for your note, sir, at paragraph 93 of Intas's Written Closings. The principal constraints on which Intas relies are essentially twofold.

The first is the direct competitive constraint arising from entry by competing suppliers and Intas also relies on the indirect constraint arising from the operation of the drug tariff mechanism. But both of those constraints emerged well before the start of the Intas period. Competitive entry began in July and October 2015 and prices began to fall in April 2016 and the drug tariff mechanism kicked in in October 2016.

As I will seek to show the Tribunal and to persuade you when we go through the key findings in the Decision, the CMA fully recognised the existence of both those direct and indirect constraints and it explained why they did not result in the loss of a dominant position on the CMA's view.

But as I will also show you, by the time of the Intas period, the initial effects of competitive entry had reached a relatively stable position. We will see

that Actavis enjoyed high and stable market shares during the Intas period following the initial decline when price-sensitive independent pharmacies switched away to the skinny label suppliers.

Significantly, once this had occurred, Actavis maintained a price premium over the skinny label suppliers which increased in relative terms over the course of the Intas period.

That brings me to the second overarching complaint made by Intas, which concerned the CMA's reliance on Actavis's ability to price well above its competitors.

The way Mr Palmer framed this point was by seeking to distinguish between dominance as a legal test and dominance as an economic concept. The legal test, Mr Palmer noted, was whether the competitive constraints, which by now had been identified, are sufficiently effective to mean that the undertaking is able to behave to an appreciable degree independently of competitors, customers and consumers. We say that is uncontroversial. It is clearly correct and it is how the CMA approached matters in the Decision.

But the question is how is one to assess whether the constraints to which a firm is subject are sufficiently effective that it is not able to behave to an appreciable degree independently of competitive

pressure. We say that the orthodox way of addressing that question is that you look at market outcomes over time, market shares and prices, and broader structural features of the market, such as barriers to entry and expansion.

These matters help to determine whether a firm is able to act appreciably independently of competition and in this there is no radical disjuncture, as we see it, between law and economics and, indeed, it would be surprising if there were such a separation. Competition law should generally be consistent with economic principles in this field of endeavour.

That is of course why the Tribunal sits in the formation it does with an expert economist as well as with legal representatives.

The correct approach, we say, is to look at the evidence on the extent of competitive constraints or the lack of them, having regard to all market indicators and features, including price, and see where it takes you.

Specifically, Mr Palmer contended that it was not part of the test for dominance whether a firm is able to price appreciably above the level of its competitors. Now, as to this, there was unequivocal consensus between Professor Valletti and Intas's own expert, Mr Bishop, that the ability to price above the competitive level is

a clear marker of dominance and it might be worth just turning it up. If we could look at the joint experts' statement at {G1/2/28} and look at proposition 45 at the bottom of the page. If we could enlarge the bottom of the page.

You see there:

"Dominance is a matter of degree, it does not imply a firm is free from all competitive constraints. Question for dominance is whether competitive constraints are strong enough to prevent a firm from pricing substantially above competitive levels."

That is the proposition that the economists were addressing. If we go up the page, we see that both Professor Valletti and Mr Bishop agree with this proposition and they do so without qualification.

During the course of cross-examination, you may recall, sir, Mr Bishop's observation that the next factor he would want to consider after market shares would be prices. On Opus the relevant exchanges begin at {Day7/17:12} and Mr Bishop confirmed that he would want to look at prices on page 18 between lines 1 and 5. I do not think we need to visit that now, for reasons of time, but you can do so at your leisure.

So it is therefore curious that Intas should now seek to disavow this approach.

Moreover, the pricing trend in the market is in fact a key part of Intas's own case, which makes this more curious still, as we see it. It relies on the fact that there were downward pressures on prices from the drug tariff and from skinny label competition to show that it cannot be dominant, but we say that this focus on absolute prices falling is to look at only one part of the picture.

The pricing data from the market needs to be considered in the round and not looking only at absolute prices, but also at the substantial price differential that Actavis was able to maintain.

The key point from the perspective of dominance is that Actavis was much less vulnerable to competitive pressures than its rivals. It maintained high and stable market shares, even though its competitors' prices were falling much faster than its own prices.

In terms of the legal test, that ability to price much higher in the market whilst sustaining substantial volumes, shows that it could behave to an appreciable extent independently of its competitors and its customers. So that is the case that I will be seeking to persuade you of at a high level.

Can I turn now, with those points in mind, to show you some of the key elements of the CMA's analysis in

the Decision. I am conscious that the Tribunal will have read the relevant parts of the Decision carefully and will no doubt do so again before giving judgment and so I will not go through the dominance analysis paragraph by paragraph, but, instead, I would just like to enumerate some of the key findings on dominance. I will focus on the 10mg position, given that they constitute 96% of all volumes. Intas has focused its submissions on the 10mg position as well so that seems a fair approach.

Can I run you through a few key points from the Decision. The aim is to show you that the CMA was not guilty of the errors of approach that Mr Palmer purported to identify and that the findings are robust for the Intas period, reflecting an approach to the question of dominance that is both correct and conventional.

The first point is that the CMA directed itself correctly by reference to the uncontroversial legal test for dominance. So if we could turn to the legal framework section first at {A/12/362}, 4.17. You see there the *United Brands* test set out and at the top of the next page the equally uncontroversial point that some degree of competition does not preclude a finding of dominance and 4.174 the need for a rounded assessment

considering a combination of factors.

The second point I want to emphasise is that the Decision fully recognised and took account of the direct and indirect competitive constraints on its prices on which Intas places central reliance.

So if we could turn, please, to page {A/12/385} and look at paragraph 4.243 of the Decision, which neatly summarises the position. We see that this is right at the start of the analysis of the post-entry period, which you can see is being considered separately. The very first line of the analysis of the post-entry period recognises that:

"From July 2015 onwards, competitors began to enter the market."

Reference is then made to the detailed factual findings in section 3.E. That is the long factual section and, for your note, the detailed consideration of competitive entry begins at paragraph 3.308 on {A/12/151}.

Remaining with paragraph 4.243, the CMA goes on to recognise that:

"Following this independent entry, Actavis's market shares and prices declined ..."

So a clear recognition that competitive entry resulted in a competitive constraint that affected

Actavis's market shares and price. But we see that the CMA then says that Actavis nevertheless retained its dominant position throughout the post-entry period. I will show you the evidential basis for those findings shortly.

So Intas is incorrect when it says the CMA simply ignored this feature of the market post-entry. It did take it into account. Equally, the CMA had proper regard to the indirect constraints arising from the drug tariff, but it found that this did not provide a fully effective constraint on Actavis's pricing.

The relevant section of the Decision begins at page {A/12/402}, if we could turn that up. I do not need to go through this in detail. You have the points I think, but at paragraph 4.278 you see that:

"Although the Drug Tariff provided some constraint ... that constraint was not sufficient to prevent Actavis's 10mg hydrocortisone tablets prices from profitably remaining at levels much higher than its competitors throughout the Post-Entry Period ..."

Turning on a page to {A/12/403} to 4.282 you see the way the drug tariff was calculated limited the extent of this constraint and this was because most skinny label tablet suppliers were not members of Scheme M and their prices and sales data did not contribute to working out

the drug tariff price.

The Department of Health has subsequently revised the method it uses and does take account of all suppliers' prices, but that happened only after the period of the CMA's findings on abuse of dominance.

So those findings about the limitations of the drug tariff are not contested in these proceedings.

That brings me to the third element of the CMA's analysis of dominance and this is the finding that throughout the post-entry period Actavis's market shares in absolute terms not only remained high, but also stabilised following an initial decline when a chunk of demand switched to the skinny label suppliers. Importantly, they had stabilised by the time of the Intas period.

To see this, can we please go to page {A/12/390} of the Decision and look at paragraph 4.249.

The CMA here finds that at every point during the post-entry period, Actavis's value market share for both tablet strengths remained above the 50% level at which dominance can be presumed.

Looking down at footnote 120, you see that reference is made to the Tribunal's judgment in *Aberdeen Journals* and we see a quotation from the judgment:

"In our view the Director is correct to conclude

that market shares of this order [78% by value/67% by volume; and 73% by value/63% by volume] suffice to establish that *Aberdeen Journals* was dominant unless exceptional circumstances are shown."

If we can then look at paragraph (a), you see there the point that:

"Actavis's value share of the supply of 10mg and 20mg hydrocortisone tablets remained around 60% or above (for much of the Post-Entry Period, substantially above) despite independent entry."

Then subparagraph (b):

"For 10mg tablets: after declining until March-May 2016, Actavis's value share stabilised above 70%. In July 2018 (the last month of the abuse) Actavis's value share was 86%."

So it is important to know note this was not a case of inexorable decline in market shares with a decision to be made somewhere on the downward slope. It is a case in which there is an initial loss of market share, essentially reflecting the fact that a lot of independent pharmacies switched away to the cheaper skinny label suppliers, but there is then a stabilisation at above 70% from the middle of 2016, six months before the Intas period. Moreover, there is then a recovery to around 86% by the end of the Intas

period. These clear factual findings in the Decision are again not in dispute and they suggest that Actavis was managing to increase its market shares by value to even higher levels over the course of the Intas period.

Then if we could turn on to paragraph 4.250(a), we see what the CMA says about the 10mg market share trends by volume:

"For 10mg tablets: Actavis's volume share declined until mid-2017, at which time it stabilised at around 50%. For seven months in 2017 (April to September, and December), Actavis's volume share fell below 50% (though for most of that period, it remained between 40 and 50%). During 2018 it recovered to around 50%, fluctuating slightly above and below that level and reaching 53% in July 2018 (the last month of the 10mg unfair pricing abuse)."

So again, when the CMA looks at volume-based market shares, we do not see a picture of unremitting decline. We see an initial decline and then a stabilisation at around half of the market by volume and, in this case, the stabilisation occurs during the Intas period.

The CMA recognises that there are a number of months when Intas's volume shares dip somewhat between 50%, but then finds there is then a recovery which are market shares by volume returning to above 50% by the end of

the Intas period. Again, these factual findings are not in dispute.

We see that the CMA is considering trends across the period, including across the Intas period.

The fourth key point is the finding that Actavis's market shares, when measured by value, stabilised at a level which is well above the 50% threshold referred to in the cases on market shares. I will return to the legal significance of market shares of this order of magnitude when I come to my next topic, but for now let us just look at the significance that the CMA attached to high shares in the Decision.

We see this at paragraph 4.251 on page {A/12/391} and the CMA finds that:

"Actavis's retention of a very large value market share demonstrates its continued ability to act to an appreciable extent independently of its competitors, customers and ultimately of consumers throughout the Post-Entry Period. In particular, its market share by value remained above 50%, the threshold at which the reassumption presumption of dominance applies. In these circumstances even a downward trend in these shares does not prevent the CMA from relying on this presumption."

Could we look also at footnote 1422 on the same page. You see there a reference to the decision of

General Court in *Astrazeneca* and just looking at what is said in the footnote, we see that:

"The Court considered that Astrazeneca remained dominant in Germany, observing that although the data in Germany showed 'an uninterrupted downward trend in Astrazeneca's market share, it was still very significant in 1997 (53.9%). A dominant position may be presumed from market shares above 50%.'"

So that is a very clear statement from the General Court that market shares above 50% do indeed give rise to a presumption of dominance.

That presumption is not rebutted even in a case where there was an uninterrupted downward trend. In the present case, as the CMA notes at the end of the footnote:

"The downward trend in Actavis's market share was not uninterrupted."

We have seen that its market shares by both value and volume stabilised, in the former case at around 70% and in the latter case at around 50%. Indeed, the value-based shares increased again after an initial decline.

But I would not want the Tribunal to be under the impression that the CMA relied formalistically on the presumption of dominance arising from high market

shares. We can see that is emphatically not the case if we skip ahead to paragraph 4.255. One sees here the CMA's intermediate conclusion following its consideration of Actavis's high absolute market shares post-entry:

"Given that Actavis's shares remained at high levels through the Post-Entry Periods, and in the light of the factors explained in the following sections, the decline in Actavis's market shares does not indicate that it lost the appreciable independence which is the hallmark of dominance."

I would just invite the Tribunal to note the words "in the light of the factors explained in the following sections". In my submission, they show very clearly that the CMA did not rely exclusively on Actavis's absolute market shares and we will see it relied instead on a range of other factors.

Before leaving absolute market shares, I just want to emphasise a fifth element of the Decision. This is the CMA's finding that value-based market shares are a better metric than volume-based market shares in the circumstances of this case.

We can see that in paragraph 4.253, further up to page, and the CMA says there that:

"The decline of Actavis's market share was more

significant in volume than in value terms. Although value and volume market shares are both relevant measurements for assessing market power, the differentiated nature of full and skinny label tablets means that value market shares better reflect the relative position and strength of each supplier in the Post-Entry Period."

We then see at footnote 1424 at the foot of the page there are various authorities given in support of the proposition that value-based market shares are a better metric for market power than volume-based market shares in the case of differentiated products.

Then at paragraph 4.254, the CMA starts by reiterating that Actavis's decline in market shares by volume was more extensive than it was in value terms, but then we have the key point:

"Actavis was able to maintain its market position in volume and especially in value terms at a very high level. Despite competitors taking sales volumes, Actavis's hydrocortisone tablets were able to generate revenue for Actavis at far higher levels than competitors were able to achieve from their sales (as a result of the price premium it was able to charge over competitors' prices) and is more relevant for the assessment of its market power than the fact that its

sales volumes declined."

So the point that is being made there is really a matter of common sense. What matters in a case of differentiated products sold at different price points is the value of the sales that a firm is able to generate. Sales revenues are what matters to the firm's bottom line and, hence, to its economic strength.

But the CMA is of course not saying that volume-based shares are irrelevant. On the contrary, we have seen that it has looked at those too and observed that volume shares also stabilised at a high level, at or around 50%, with some periods both above and below that level in the post-entry period.

That brings me to the sixth element of the CMA's analysis of dominance and this is the finding that Actavis's shares, measured by both value and volume, were always considerably higher than those of its competitors, often by several multiples. They were also more stable than the rival suppliers' shares.

Relative market shares are addressed at {A/12/393}. Can we look, please, at the finding at paragraph 4.256. So referring back to the absolute market shares that we have already looked at, the CMA notes that:

"[These] show not only that Actavis retained a particularly high market share but also that it

retained its preponderant market position as its market shares were much higher than those of its competitors. Actavis maintained a substantial gap by value and by volume to its nearest competitor. This is an indicator of its continued substantial market power, which was out of all comparison to that of other market players."

Where an undertaking has a preponderant market share that is significantly higher than that of its rivals, that is a highly relevant factor that it holds a dominant position.

The footnotes to this paragraph refer to two cases, *British Airways* and the *Astrazeneca* case already mentioned, which provide clear authority for that proposition. I will come back to both of those cases when I come to develop my submissions.

If we could then look at paragraph 4.257, the CMA there states that:

"The evidence demonstrates that Actavis's competitors had unstable market shares, where new entrants initially obtained a higher market share before dropping following entry of other suppliers. This is indicative of a high degree of rivalry amongst new entrants. However, the fact that these market share fluctuations were primarily among new entrants but had less impact on Actavis's more stable market shares

confirms that, as the market developed, skinny label tablet suppliers competed more meaningfully with one another for the contestable portion of the market (sales to customers who were prepared to purchase skinny label product…) rather than with Actavis."

Then at paragraph 4.258 the CMA notes that in contrast:

"The shares attained by entrants were unstable throughout the Post-Entry Period, and there was greater volatility in those shares as compared with Actavis's more stable shares."

We do not need to go there now, but we see in paragraphs 4.259 and 4.260 the CMA makes various more specific observations about competitors' relatively small and fluctuating market shares.

I should say also that the relative market shares of Actavis's competitors can be seen at a glance in figures 4.13 to 4.16 of the Decision. Remember those figures showing the different volumes over time.

The CMA, I should also say, has the underlying spreadsheets. I think the Tribunal mentioned that it might find it helpful to have the volume data as well as the graphic illustration. I am sure we can provide those in an uncontroversial form if the Tribunal would find that helpful.

THE PRESIDENT: I am sure that would be helpful.

MR HOLMES: Yes, very good. We will arrange that, sir.

You will recall there was some debate between Mr Bishop and Professor Valletti about how precisely you measure relative variability in market share. You remember the range versus coefficient of variation debate.

Mr Palmer did not address that orally and I will just therefore give the Tribunal a reference to where we address it in writing. It is in paragraphs 276-279 of the CMA's Written Closings.

But leaving that debate to one side, the important point is there is no dispute about the factual findings we have just seen concerning the relative size of the competitors' market shares and the fact that the rival suppliers were competing more closely with one another than they were with Actavis.

In my submission, these findings, on any view, provide an important indicator of Auden/Actavis's economic strength.

As Professor Valletti observed, when you just look at the price trends, you see that the competitors follow in lockstep. They are really very closely aligned and that is just not true of the Auden/Actavis trend. That shows intense competition amongst a fringe of much

smaller competitors with shares fluctuating sharply among them, but Auden/Actavis able to retain a larger and more stable share of the market and, as we will see, that is attributable to the structural characteristics of the market which the CMA identified.

The seventh point is that whilst Actavis's prices fell during the post-entry period, Actavis nevertheless throughout retained the ability to price significantly above its competitors' average prices. In fact, that price premium increased in relative terms over the course of the post-entry period in relation to 10mg. We can see this from figure 4.19 on page {A/12/398} of the Decision.

This shows the difference between Actavis's 10mg prices and its competitors' average prices. You can see the absolute price differential through the combination of the Y axis on the left-hand side and the solid red line and you can see there is a significant absolute price difference throughout the period, getting as high as £35 in December 2016.

We see that the absolute price difference was still in excess of £15 per pack at the end of the Intas period in July 2018.

Then the pink line --

PROFESSOR MASON: I am sorry, could we just zoom out ever so

slightly so we can see the legend. There we go. That is perfect. Thank you.

MR HOLMES: Very good.

PROFESSOR MASON: I just wanted to see --

MR HOLMES: Yes, of course.

PROFESSOR MASON: Because I forget which one is red and pink.

MR HOLMES: Not at all. Pink --

PROFESSOR MASON: Is relative.

MR HOLMES: Exactly so, sir.

PROFESSOR MASON: The right-hand Y axis.

MR HOLMES: Showing the percentage, yes.

You will see that the pink line shows the relative price difference and we say that it is a particularly important observation in this case. It provides important context for the appellants' submission that the post-entry period was characterised by effective competition which constrained any market power that Actavis may have possessed. It shows a clear upward trend in the relative difference between Actavis's prices and its competitors' average prices. In other words, the gap between Actavis's prices and its competitors' prices was growing larger in percentage terms throughout the post-entry period. Or put the other way round, Actavis's prices were falling

considerably more slowly than its competitors' prices were.

We see the relative differential goes from around 150% at the start of 2017 to around 500% by the end of the Intas period, so 5 times the price of its rivals.

Turning on a page at 4.272, the CMA gives some more concrete detail in relation to the 10mg market. We see the following two findings, both key in my submission (a):

"Although Actavis's price started to decrease following entry by further supply ... its competitors' prices decreased at a faster rate.

"(b) As a result, the premium Actavis charged over its competitors' prices increased substantially, speaking at £34.75 in December 2016 and remaining very large (£16.60) even at the end of the Post-Entry Period in July 2018."

So large absolute differences.

Then at (c):

"These significant absolute differences between Actavis's prices and its competitors' prices, particularly in the context of declining prices overall, meant that the relative price difference was growing throughout the period. Actavis charged a premium of, on average, 145% of its competitors' average prices during

the Post-Entry Period, and its price had reached ... over five times its competitors' average prices [at the end of the infringement in July 2018 which is also the end of the Intas period]."

Paragraph 4.273 then describes the position in relation to 20mg tablets. I will not read that out, but, again, the picture is one of a growing relative price differential.

If we move on to paragraph 4.275, we see a further highly relevant finding. This is the point that:

"As the number of entrants increased and competition intensified ... Actavis's price premium increased relative to its competitors. This is not the pattern that would be expected if competitors were able to appreciably constrain Actavis's conduct: instead, it would be expected that as more competitors entered, competition would become more intense between all suppliers and erode Actavis's ability to charge a premium over its competitors' prices. The increasing premium in the face of entry therefore demonstrates Actavis's ability to act appreciably independently of its competitors."

So the CMA is there making an intuitive point. If entry by rival suppliers in increasing numbers had given rise to effective competitive constraints on Actavis,

its ability to command a premium over its rivals would reduce and not increase.

But we see precisely the opposite here.

The eighth key element from the Decision is the related finding that Actavis was able to maintain this price premium for a sustained period without losing market shares.

We see this at paragraph 4.274 of the Decision, slightly up. This makes the important point that the observed price trends need to be considered in the context of the market share findings made earlier in the Decision. Picking it up at the end of the second line it explains that:

"Actavis's market share declined initially at a time when the absolute and relative premium between its price and that of its competitors was growing (particularly for 10mg hydrocortisone tablets). However, Actavis's market shares then stabilised, at a time when its competitors' prices continued falling faster than its own prices. This direct evidence that Actavis was not losing any market share despite its competitors' tablets becoming relatively cheaper in relation to its own, and provides a strong demonstration that Actavis retained an ability to price above competitive levels, thereby demonstrating its market power."

So the point the CMA is making is again an intuitive one. If your rivals are reducing their prices, but they are not taking market share away from you, that is a pretty compelling indicator that you possess market power. All of these factual findings in relation to pricing levels are uncontested. They show that the CMA did not inflexibly rely on the mere fact that Actavis was pricing above the competition. The CMA relied on the scale of the price premium and also the fact that the relative price differential increased across time during a period in which more competitors were entering the market and that Actavis was, nevertheless, able to retain high and stable market shares.

Pausing there, I would suggest that Intas has essentially skated over this detail about relative pricing that we see in the Decision and has instead presented what might perhaps harshly be described as a caricature of the CMA's approach. You remember Mr Palmer talked about a freeze-frame or snapshot of whether the prices are above a competitive level. That is not at all the analyses that we have just been looking at.

I would submit that Intas has skated over the relevant findings because it has no good explanation for the trends that are shown across time and the comments

that are made in relation to them in the Decision, other than that they are reflective of market power.

The closest we got to an answer to the point about relative price differential increasing was what Mr Palmer said on Monday. He said that all it shows is that prices generally were reaching lower levels, meaning the same or even lower absolute differentials were translated into higher relative differentials. The reference for that is transcript {Day15/137:1-12}.

But if the prices of two products X and Y are falling while the difference between their prices increases in relative terms, that means that the price of X is not falling as quickly as the price of product Y. It is simply a logical proposition. It is telling that Mr Palmer gives an example here in the transcript where the higher price product declines to a level that is twice that of the lower price product. In fact, as we have seen, Actavis's price was still five times greater than its rivals' average prices at the end of the Intas period.

So in my submission, the CMA's point on the increasing relative price differential is a good one and it is all the stronger when allied with the evidence that Actavis's market shares remained stable, despite the price premium.

We are nearly through the Decision, sir. There are two more points to note. The ninth finding in the Decision that I would emphasise is the point that Actavis earned extremely large profits on hydrocortisone tablets and did so right up until the end of the Intas period.

We see at paragraph 4.276 the CMA remarks on Actavis's ability to persistently earn an excessive rate of profit in the post-entry period and the CMA says that when combined the points just made about the price premium that Actavis commanded, this shows the durability of Actavis's substantial market power.

At paragraph 4.277, the CMA refers to Actavis earning supra-normal profits and it says that these profits:

"Did not represent a return on previous innovation, since Auden acquired the hydrocortisone tablet MAs rather than invented the drug, nor did it make any investments in hydrocortisone tablets".

Again, these findings about the lack of innovation and investment are not contested.

Then at subparagraphs (a) and (b), we see some more details about the profits. At (a) we learn that Actavis earned profits in excess of costs, including a reasonable rate of return, in percentage terms of

between approximately 1,000% and 3,000% for 10mg hydrocortisone tablets and between approximately 1,250% and 2,500% for 20mg tablets.

In each case, it did so throughout the post-entry period.

Then at (b) the CMA explains what this amounts to in terms of real term profits. I think the figures may be confidential, so I will not read them out, but you see the enormous profits earnt on 10mg hydrocortisone tablets in the post-entry period. So that is the concrete reality of the near-term cash-cow that was anticipated in the document at the time of the Actavis acquisition.

In the final sentence, the CMA properly recognised here that profits declined as a result of the price falls following entry, but makes the point that they remained very high.

Then over the page at (c), we see the scale of Actavis's gross margins during the post-entry period and, again, I will not read the figure out, but it is strikingly high.

Those points about profitability received little or no attention in Intas's written materials or indeed in the limited submissions that Auden and Allergan have made on post-entry dominance. It was touched on briefly

in Mr Palmer's oral submissions on Monday.

Can we look at what he said, please, at {Day15/138:7}. Just looking at line 7, if we may. Mr Palmer suggests here that profitability is not really a separate point, because it is just a reflection of the increased differential, given that the costs in each case were not significantly different. So that is the submission.

It is certainly correct to say that profitability partly reflects Actavis's ability to charge higher prices than its rivals whilst costs remained constant, but it also, obviously, reflects Actavis's ability to retain high sales while doing so.

That is what generates the very large profits, not just profit margins that we observe in the Decision.

This is a point that we saw emphasised by Professor Valletti as being material to the assessment of market power. As I will come to a little later, the General Court placed heavy reliance on points of this nature concerning relative pricing and market shares when considering dominance in the *Astrazeneca* case. Again, in my submission, Intas has no good answer to it.

The tenth and final point from the Decision is the findings concerning the assured customer base. The key point can be seen in the final sentence of

paragraph 4.288 on {A/12/405} of the Decision. You see there that the CMA finds that:

"The orphan designation granted in respect of Plenadren was a key factor contributing to this ability [by which is meant Actavis's market power] because it formed a barrier to expansion and provided Actavis with an assured customer base."

I will come back to some of the more specific findings on the assured customer base later when dealing with Intas's specific arguments on that point, but, for present purposes, I would just observe that this shows very clearly that the CMA was not solely looking at market outcomes, let alone focusing on a freeze-frame of what prices were being charged at particular points in time. The CMA was here analysing a specific structural feature; namely, the barrier to expansion created by Actavis's privileged position as the only fully-licensed supplier of 10mg tablets.

Taking that feature together with all of the evidence of market outcomes, the absolute and relative market shares and the large price differential, my submission is that it provides a sound and orthodox foundation for the CMA's finding of dominance.

Sir, that is the Decision. Can I now turn to the submissions that are made, the specific challenges that

Intas has advanced in respect of the CMA's analysis of dominance during the Intas period.

I am going to split these into three headings: market shares, price and assured customer base.

I will deal with matters in that order, focusing principally on the points which Mr Palmer emphasised in his oral submissions for Intas on Monday.

Sir, on market shares, there are three main points of contention. The first concerns the significance to be attached to high absolute market shares. The second concerns the significance of relative market shares and the third concerns whether value or volume is the most appropriate measure.

I would like to begin, if I may, with the question of high absolute shares. I have shown you the undisputed facts: high market shares well above 50% in value terms and around 50% at the end of the period in volume terms sustained at a stable level throughout the post-entry period following an initial decline.

The weight concerns the legal significance of those facts and the question whether they give rise to a rebuttable presumption of dominance.

As Mr Palmer says, this is an argument that could easily occupy a day or more of court time, but I will endeavour to be as brief as possible. The first point

to note is that while the CMA referred in the Decision to the fact that Actavis's absolute market shares were an order of magnitude above the levels that gave rise to a presumption of dominance, it did not stop there. As I have shown the Tribunal at some length, it went on to consider a range of other factors.

It follows from that that the debate as to the precise legal significance of high absolute market shares is an interesting one, but it is arguably academic in the circumstances of this case. It is one that the Tribunal may very well not need to embark upon, if it is satisfied that the CMA's overall assessment of dominance is well founded.

Insofar as it is necessary to determine the point, the position in law is not as Intas would have it. In my submission, the special legal significance that attaches to market shares in excess of 50% is almost a matter of textbook EU competition law and it reflects the economic intuition that the most likely explanation for very high market shares, enduring across time, is the existence of market power, although that is obviously not always the case.

There are many cases that attach particular significance to market shares being in excess of 50%. As I will come to in a moment, the case law shows that

very high market shares are capable in themselves of proving the existence of a dominant position absent exceptional circumstances. Indeed, the market shares above 50% give rise to a rebuttable presumption that it is for the putatively dominant firm to displace.

Mr Palmer's position described this as a legal nonsense and divorced from economic reality. He sought to support that arresting submission by reference to the scepticism about the reliability of market shares as an indicator of dominance that is expressed in Faull and Nikpay and Bellamy & Child.

In my submission it is quite striking that he should found his oral submissions on this point on academic commentary. We will see in a moment that cases are very clear on this point, but given Mr Palmer's approach I would just invite the Tribunal to look at what the other main practitioner texts, Whish & Bailey, has to say on this point and Intas refer to Whish & Bailey in their Written Closing submissions but not the extract that I am about to show you.

The relevant extract appears at {M/186.02/2}. We see under little (viii), second bullet that market shares can provide important information about the state of existing competition within the market, but they cannot, in themselves, be determinative of the existence

of market power.

So the authors are obviously here referring to the economic concept of market power. It is obviously correct that market shares alone cannot tell you whether a firm possesses market power as a matter of economics. But then look at what the authors say under the heading "A final reflection on market shares". They repeat the point that market shares alone do not in themselves determine whether an undertaking has market power. But they then note there are a large range of situations in which the EU and UK competition law emphasises market shares. Reference is made to table 1.1 which sets out a series of market share thresholds that should be embedded in the mind of hypothetical in-house counsel.

Then look at what is said over the page about the threshold of 50%. If we could go on to the next page, please. You see at the 50% point:

"There is a rebuttable presumption that you hold a dominant position if your market share is 50% or more of the market other than in exceptional circumstances ..."

Then reference is made in footnote 32 to the Court of Justice's 1991 judgment in *Akzo* where the 50% threshold was first adopted by the court.

So in view of these authors in a leading text market

shares above 50% do indeed give rise to a rebuttable presumption of dominance. And I will turn after the short adjournment, if that is a convenient moment, to consider what the case law says about that question.

THE PRESIDENT: Thank you very much, Mr Holmes. How are you doing time-wise?

MR HOLMES: Well, sir.

THE PRESIDENT: Would it assist if we started at quarter to?

MR HOLMES: It will not be necessary.

THE PRESIDENT: Very well.

MR HOLMES: Also I have in mind that it might be convenient to fit Ms Demetriou, given her other commitments, in at 2 o'clock when she is due to arrive at the Tribunal.

THE PRESIDENT: Very well. We will look forward to seeing her at 2 o'clock. Until 2 o'clock. Thank you very much.

(12.58 pm)

(Luncheon adjournment)

(2.00 pm)

Further Closing Submissions by MS DEMETRIOU

THE PRESIDENT: Ms Demetriou, welcome back.

MS DEMETRIOU: Thank you. It is a small cameo role at this stage.

The Tribunal asked me yesterday to comment on a section of a report prepared by Oxera, which is relied

on by Mr O'Donoghue and I just wanted to make some short submissions which I hope will be of assistance in relation to the CMA's position on that.

We have loaded the whole of the report on to Opus in case the Tribunal wants to look at it more broadly and you will find it at {H/0.35/1}. Perhaps if we turn it up so you can see the first page. Before turning to the passage relied on by Mr O'Donoghue, the Tribunal will see the date of the report, July 2001. So it was prepared a long time ago and, obviously, before any of the pay for delay cases, so before that case law.

Of course Oxera, the Tribunal may know, gave evidence in the *Paroxetine* case to the effect that the pay for delay agreements in that case were not anti-competitive.

Now, going to page 94, if we could, please, {H/0.35/94}, which is where the passage relied on by Mr O'Donoghue is located. (Pause).

Thank you very much. So the appellants rely on the statement here that cross-supply agreements, cross-supply arrangements were common in the industry at the time and that the ability to self-supply a drug is an effective and credible threat with which to negotiate supply from another manufacturer.

You see there the sentence that is relied on.

Sorry, I am not seeing it. I just wonder if it is --

THE PRESIDENT: Further down I think.

MS DEMETRIOU: Yes, can we perhaps scroll down. (Pause) {H/0.35/94}. So we see the paragraph "Manufacturers confirmed" and then we see there:

"Ownership of a licence for a particular drug increases the leverage for that manufacturer in negotiating the price for supply from a rival manufacturer. The ability to self-supply a drug is the most effective and credible threat with which to negotiate supply terms from another manufacturer."

Then we see a reference in the immediately next paragraph to the prevalence of these cross-supply arrangements.

We say, even on its own terms, this is a single statement really in the context of a very lengthy report and Oxera does not say that this practice is legitimate or lawful and nor would an economic consultancy, we say, be qualified to give that view.

If the Tribunal were inclined to place any weight on this statement, we respectfully submit it should be read in the full context of the report, which, as I say, we have uploaded. These statements were made in the context of a discussion of practices in the sector that are negatively affecting competition: in other words,

companies holding on to or hoarding their licences in order to use them as leverage rather than transferring them to others who could use them to actually enter the market to compete.

The Tribunal will also see that this is a statement, a statement about leverage, that is made in the abstract divorced from any factual context. The CMA does not dispute the view of the economists at Oxera that the threat of self-supply, so meaning in other words the threat of independent entry, may very well amount in fact to an effective and credible negotiating tactic in securing more favourable supply terms. We can well see that. Indeed, that is wholly consistent with the CMA's case in this appeal.

However, there is no discussion here of any of the surrounding facts, so there is no discussion of whether the companies concerned were in fact potential competitors to those already on the market.

If they were potential competitors, the CMA's position is of course that it would be anti-competitive for a potential competitor to leverage its marketing authorisation to secure supply if the evidence showed that this was on the basis of a common understanding that in exchange it would not enter the market itself.

So that would have to be decided on the evidence of

any individual case and the Tribunal of course has our submissions on this case, which I am not going to repeat. But our primary submission is that this statement by a firm of economists, a very long time ago, before the pay for delay case law, divorced from any factual context, should be given very little, indeed, no weight, we say, by the Tribunal in carrying out its task of determining whether there is an infringement on the facts before you.

Sir, that is what I wanted to say about that.

I want to just for a moment return to one question where I felt we were at cross-purposes a bit yesterday and that relates to the question of dishonesty, because as the Tribunal pointed out yesterday, this arises potentially at two stages.

In my submissions, in my main submissions, I have been addressing the first stage, which is that the CMA did not allege dishonesty at the time that the agreement was formed. So there is no allegation of dishonesty in the Decision, in the CMA's Decision.

But then I apprehend that the question you were putting to me, sir, yesterday was a bit different to that.

THE PRESIDENT: It was, but it also was not. I mean, I am putting to you that both stages are at least potentially

engaged here and that is certainly, I think, how a number of the appellants view that. I mean, I entirely take on board your point that it is not a necessary part of establishing a competition law infringement to show dishonesty or anything like that. Of course that is right. But the probability, or otherwise, of an agreement that is infringing competition law is informed by, as you say, all the facts.

If one has a state of affairs where one has not got the inadvertent breach of competition law, where, for instance, one has got a Mastercard or Visa type MIF, which is there for all the world to see, no one is denying the agreement was made. The argument is is there or is there not an infringement? The questions of dishonesty of course do not arise. The point here is that we have got something, on the CMA's case, which is hidden behind the written agreement and not incorporated, for whatever reason.

So, obviously, one's antennae are twitching as to why it is that this sub silentio or unwritten agreement exists.

Of course, it may be, as you were submitting yesterday, that there is a tacit understanding which Mr Beighton slipped in and he is in innocent breach of.

Maybe that is right. All I am saying is that given where we are at, and certainly given the point that the appellants are making, you cannot exclude this as an outcome and, certainly, I am not doing so. We are going to look at the facts in the round and at the moment, I see this as potentially a dishonesty case at both stages.

Now, where we end up, who knows, but that is the way we are looking at this. I do not think we have got any choice about that. Wherever we end up, it is an outcome that is on the cards and that is why we had this debate with a number of people, but Ms Ford in particular, about the extent to which there is a burden of proof, which is to the civil standard, but involving the Hyde Park variant of something which is improbable, not because competition law is requiring of dishonesty, but because that is the most likely fact constellation, if there is an infringement.

MS DEMETRIOU: Sir, that is extremely helpful. Can I make two short points in the light of what you have just said. The first point relates to the first stage, if I can put it that way. I think we both understand what I mean by that. You make the point that the appellants say, and of course they do say, that there is necessary -- their case is, and one can understand

forensically why they put it that way, that this is a case of dishonesty and so there is an elevated standard of proof in some way.

Now, in relation to that, we say two things. One is that just on the case law, and I am not going to go into that because you know the *Napp* case law that there is no intermediate standard of proof, that this is a question on the balance of probabilities.

THE PRESIDENT: Yes.

MS DEMETRIOU: But, secondly, of course in any case -- I understand the distinction you make between a MIF type of case and many other types of competition infringement, but of course in most types of competition infringement, leaving aside the MIF type of case or vertical agreements, which might stray the wrong side of the line and so on, take a pricing-fixing cartel or a market-sharing cartel, you have the same position, but in none of those cases has any elevated standard of proof applied.

The second point I make -- because those are not inadvertent cases. Those are cases where the parties have colluded to achieve an anti-competitive objective and yet you do not see in any of that case law any elevated standard of proof or necessary finding of dishonesty on the part of the participants.

The second point we make is this --

THE PRESIDENT: Ms Demetriou, I mean, all I am doing is referring to the, I think pretty well-established case law, that the civil standard operates to a variable level in that the more improbable the matter that you are alleging, the more difficult it is to meet the same civil standard. That is what the House of Lords and the Supreme Court have said many times.

MS DEMETRIOU: Of course, I do not dispute that.

THE PRESIDENT: Right, that is all I am saying.

MS DEMETRIOU: No, that is fine. The appellants I think, some of them at least, put it a little bit more highly than that and we say that would not be right.

The second point, the other aspect of the point I was making in relation to the first stage is that of course it is not the CMA's case that there was some -- and I hope I made that clear -- that there was some illicit side agreement or some conspiracy to hide the true facts.

Our case is that the premise on which the parties entered into the written agreement was the premise that AMCo would not enter the market, which is a bit different to saying that they approached the written agreement in a conspiratorial manner so as to hide the true state of affairs.

THE PRESIDENT: You have to be quite careful here, Ms Demetriou, because you quite emphatically have not made a case that this is simply an implied term arising out of the express agreement. If that was your case, then we would have a different debate altogether.

MS DEMETRIOU: No, I have not made that case.

THE PRESIDENT: No, it was, I think, attempted to be made and then moved away from, in the statement of objections I mean.

MS DEMETRIOU: I see in the statement of objections there was a case based on the wording of the agreement.

THE PRESIDENT: You have been quite consistent in this appeal. Do not get me wrong.

MS DEMETRIOU: Yes.

THE PRESIDENT: But if you are going beyond an implied promise, then there has to be something which is done or said or commonly understood. I appreciate you have got a case on tacit understanding. All of these things we have got well in mind.

MS DEMETRIOU: Yes.

THE PRESIDENT: But all I am saying is that we are going to look at the totality of the facts and, at the moment, it does not seem to me that your tacit agreement that is not dishonest, if it occurred, is highest in the order of probability in terms of what we are looking at.

MS DEMETRIOU: Sir, the only point I am making is this: the way that the appellants have sought to characterise the CMA's case is, and I dealt with all of this, I am not going to repeat myself, but it is a sham agreement, there is a side agreement that was covered up, and that simply is not the CMA's case.

Now, of course we say there was a crossing of the line, a shared understanding, a common understanding, but that operated by way of premise. That was what everybody knew the deal was, so there has to be an agreement, but we are not saying, and the CMA has never suggested, that there was some dishonest attempt to cover it up by not recording it in the written agreement. That is the only point I am making.

That is relevant to the House of Lords authorities you are talking about where -- obviously, if we were saying there was some cover up, then that is less probable and so one would look more carefully at the facts. That is really the only point I am making there.

Sir, the point I wanted to make about the second stage is that of course -- I think that of course we do say that various things said by the witnesses in their evidence to the Tribunal were factually wrong and we have gone through those in our written submissions and I picked some of them up orally. But there are various

potential reasons why that might be, as in any piece of civil litigation, and the Tribunal will be very well familiar, for example, with the frailty of memory, particularly when things occurred a long time ago, particularly under the pressure of litigation, and that is why it is generally not necessary for litigants to allege, or indeed for courts to find, that a witness has been dishonest just because his evidence is wrong.

That is really the point that -- the simple point I wanted to make in relation to the second stage, dishonesty at the second stage.

THE PRESIDENT: Ms Demetriou, let me set your mind at rest. This is not a Tribunal that if it disbelieves a witness automatically proceeds to say that the witness is dishonest. We do not want to find people dishonest.

MS DEMETRIOU: No, of course, but I just wanted to make that rather obvious proposition, because I think that in my submissions I had been focusing on dishonesty at the first stage, because that is what the appellants had focused on and then I appreciated yesterday you were addressing actually a different thing, which is dishonesty at the second stage.

THE PRESIDENT: As I say, I think both aspects are in play. Where we end up, who knows.

MS DEMETRIOU: Of course.

THE PRESIDENT: But that is the present thinking and it may be that that is where we do not end up, in which case the standard of proof moves to the ordinary unadjusted civil standard. But if one is looking at an outcome that is along the lines of stage one dishonesty, then one has to be pretty sure of one's ground in making such findings.

Clearly, if we find that it is something in the middle, that there is an infringement but it is an innocent one, then the improbability becomes less so.

MS DEMETRIOU: Sir, and I do not disagree with any of that. The only point I make is that the CMA's case in the Decision is not at the higher end, as it were, of your dishonesty scale at all, because it is the understood premise for this agreement, for this supply arrangement, was that AMCo would not enter.

Of course, as I have said now, I will not repeat myself, but we do -- of course we agree that there has to be a crossing of the line and I have made my submissions on that already.

Sir, I am extremely grateful for letting me -- interpose.

THE PRESIDENT: Not at all.

MS DEMETRIOU: -- for a short time.

THE PRESIDENT: Thank you very much.

MS DEMETRIOU: I intend no discourtesy, but I think I will now leave, if that is all right, and let Mr Holmes carry on with his submissions.

THE PRESIDENT: Thank you very much.

MR O'DONOGHUE: Mr Brealey and I will join Ms Demetriou in the exodus. Can I just give you one reference?

THE PRESIDENT: I am sure Mr Holmes will not take it amiss.

MR O'DONOGHUE: He is secretly delighted. Can I give you one reference before I leave. It is {IR-E3/4/8}, please. These are the Commission's horizontal merger guidelines. If we look at paragraph 65 and you will see in the middle:

"This would be the case if the buyer could immediately switch to other suppliers, credibly threaten to vertically integrate into the upstream market or to sponsor ... entry."

So Oxera is not a flash in the pan. In virtually every vertical merger context, one question would be: can the customers discipline the seller by threatening to potentially enter the market? So this is not some flash in the pan. This is normal and normally is pro-competitive.

THE PRESIDENT: Thank you very much, Mr O'Donoghue.

Mr O'Donoghue, you are not coming back, are you?

MR O'DONOGHUE: Sir, for gluttony we are back for penalty.

MR BREALEY: We are definitely here, yes.

THE PRESIDENT: I was just going to say should I wish you a merry Christmas or not, but not quite yet. You will be back. Very good. Thank you very much.

Closing Submissions by MR HOLMES (continued)

MR HOLMES: I should however warn Mr O'Donoghue and Mr Brealey there is a chance that penalty will commence this afternoon. It is only so they were aware.

I should put immediately on the record that it is never my secret delight when Mr O'Donoghue leaves. On the contrary, it is always my pleasure to see him so he will be missed.

Sir, before I resume, can I just very quickly pick up the query you raised with me at the beginning in relation to Plenadren. Those behind me have done some digging and the position is as follows: first, Plenadren was and is the subject of a Europe-wide product patent, which was filed in April 2005. We are seeking to obtain a copy for the Tribunal. Normally of course that would have a 25-year term, which means that it remains valid and in force.

The second point concerned Plenadren pricing data. The relevant documents were I believe on the case file, but they have not been uploaded for the purposes of the bundle. So we are going to do that and we will give you

the reference in due course.

You saw in the BMJ editorial, which Ms Ford took you to and which I returned to, that Plenadren was at a much higher price point than hydrocortisone tablets.

THE PRESIDENT: Yes, we knew the general. We did not know the specific. If there is any objection to material being uploaded, then you can deal with it behind the scenes and we will resolve it if necessary, but I would not want something to be uploaded that was from the case file but not the Decision without everyone else being happy.

MR HOLMES: Of course, we will liaise, sir, to make sure that there are no objections.

THE PRESIDENT: Yes, thank you very much.

MR HOLMES: I should begin by saying before the short adjournment there were some quite dense submissions by reference to the Decision and I should perhaps immediately give the Tribunal an opportunity to raise any questions which occurred during the short adjournment, because it was rather a spiel on my part and that may not be conducive to assisting the Tribunal so if there is anything that arose out of what I said which you would like to raise with me immediately then I should pause.

THE PRESIDENT: It may not quite be arising out of what you

said, but it certainly was informative or triggering of our discussion over the short adjournment, and it is this: I appreciate of course that *Napp*, or the passage in *Napp* that I am going to cite, is to do with excessive pricing not dominance, but we will all recall the double-barrelled test that to show that prices are excessive it must be demonstrated, one, that prices are higher than would be expected in a competitive market and, two, that there is no effective competitive pressure to bring them down to competitive levels and I am sure we will be coming back to that next year.

MR HOLMES: Yes.

THE PRESIDENT: My question is: how far is this a test that is also informative of the question of dominance. Professor Mason over the short adjournment put the analogy rather nicely since we have been talking about mountains and hills. If one assumes a particularly smooth contoured mountain and you put a marble at the top of the mountain so it has been crawling up and that is where the position is, as it were, in a case say to dominance, but the marble then rolls down the hill and if it rolls down very, very, very, very fast so that you move to a competitive price extremely quickly, is that not merely an indicator that the (ii) *Napp* test is not met, i.e. there is effective competitive pressure, but

is it also an indicator that there is no dominance or diminishing dominance to an extent that one can no longer say that there is dominance? Whereas if one has a very gradual decline, so the marble rolls down very, very slowly, so that one can maintain one's prices for longer, is that a situation where you have an easier run on dominance?

MR HOLMES: Yes, I should say to begin with that it is a helpful and illuminating analogy and a useful one.

The first point in relation to *Napp* is that it will be my submission in due course that what was set out in *Napp* in relation to excessive pricing was merely one way of approaching matters and that I think appears in the immediately following paragraph and indeed it is set out in Lord Justice Green's judgment.

THE PRESIDENT: Indeed.

MR HOLMES: It does not have authoritative force as a part of the test for pricing that is excessive and unfair, but that is to anticipate a submission that will come.

A second submission, and again anticipating what I will be saying in relation to unfair and excessive pricing, is that insofar as it is suggested that excessive pricing ceases in circumstances where entry is anticipated, it produces the perverse outcome, in a case such as this, that for the very period when prices are

pushed to their pinnacle they see the steepest and most extreme increases and the highest level of supra-competitive profits, the most exploitative behaviour, you cease to find an infringement.

We say that that as a proposition cannot be right. It would be --

THE PRESIDENT: The darkest hour comes before the dawn is your point.

MR HOLMES: Yes, exactly, so, sir. But that is a point that perhaps I could leave over.

To give an immediate reaction in relation to the dominance question, what is distinctive in this case is not just the speed at which the Auden marble rolls down the hill, and I am sure that the Tribunal has this point, but the fact that it is rolling down the hill at a significantly lighter gradient than the other marbles, the prices of the other players in the market, and that, on my submission, meets the test for dominance. It is a sign, a clear indication, particularly when combined with the high market shares which are retained, and there the explanatory factor identified in the structural feature of this market which insulates Auden against competition that Auden continues to enjoy significant market power in the post-entry period.

There is another point that I think is worth teasing

out, which may be relevant to excessive pricing as well as to dominance. The marble analogy suggests that this is an entirely predestined path and there was a flavour of this in Mr Palmer's submission to you as well, that Auden/Actavis during the post-entry period was stuck on an ineluctable path where it had no choice. In my submission, that is not the correct analysis of the situation in which Auden/Actavis found itself in.

It is true that to an extent it was constrained. There is no doubt about that. It is accepted and it is agreed on all sides and that prevented it from keeping its prices up or raising them further. It constrained the extent to which it could maintain the very high prices that it had put in place. It was not as constrained as anyone else in the market and we say that that is sufficient to meet the test for dominance, both of the experts agreeing that a hallmark of dominance from an economic perspective is the ability to price appreciably above the competitive level.

But Auden always had the choice to bring its exploitative and unfair pricing to an end. The price has been marched up the hill. It has been ramped up to an extraordinary level. It is coming down the hill. It is coming down much more slowly for Auden/Actavis than it is for the new entrants, but imagine how different

the conditions in this market would have been if Auden/Actavis had reduced its prices to levels that are more reflective of its costs and it had ceased to milk the cash-cow and had instead corrected its prices, instead of pricing up to the highest level that it could, given the constraints that were imposed upon it by the drug tariff and by the existing but limited competitive constraints resulting from the skinny label suppliers.

But this is really, I think, to anticipate a submission that will need to be developed in the context of excessive pricing. It is simply that the marble analogy really suggests a flaw represented by the gradient of the ground down which the marble is rolling and I am just gently pushing back on that proposition. If you accept that there is abuse in the post-entry period, then it would not be correct to say that there is only one gradient that the marble could follow.

Auden/Actavis could bring an end to its excessive pricing by reducing its pricing more sharply, and that would of course benefit consumers, the demand side in this market, not only by removing the exploitative supercompetitive prices that Auden/Actavis was itself charging, but it would have prevented others in the market from benefitting under the umbrella of that

conduct because, as Mr Palmer observed, everyone in this market was pricing at very profitable levels during the post-entry period as prices came down.

THE PRESIDENT: I mean, does it amount to this, Mr Holmes: that obviously one must look at things in the round and we will be looking when evaluating all this at the entire picture, but that at a certain point in our analysis we ought to try to forget the past and just look at the pricing point and other metrics at a given point in time, forget that it has fallen in terms of price or volumes sold, however you want to look at it, forget about that and simply look at the point without reference to the past and say, look, at this point in time, assuming no prior knowledge, would one be saying that there is dominance at this point in time? I am not saying it is the only test, but as a means of being not seduced by falls in price volume share so that you see things in perspective.

So look at them in the round of course, but also take a step back and just forget about the overall shape and look at the moment in time.

MR HOLMES: So certainly, sir, I think one needs to look at each period over time separately and in the light of the circumstances during that period. I think my submission would be that there is an inherently dynamic element to

the assessment of dominance and were Mr Palmer correct that the CMA or Professor Valletti had adopted a kind of snapshot and had simply observed the delta between two price points at a single moment in time, that would not be the correct approach.

One needs to see the flux, the dynamic, and how various factors in the market are evolving in conjunction with one another: in particular, the very telling combination of price differentials and maintenance of volumes.

So I would not want to accept a proposition that one freezes the frame, but I think the underlying proposition that you advance that one should look at each period on its own terms is one that I would very much adopt and endorse.

Does that address your question?

THE PRESIDENT: Yes, it does.

MR HOLMES: I am grateful.

Before the short adjournment, I was discussing the legal consequences of very high market shares. You have my point that this is, in our submission, a somewhat academic point, given that the CMA did consider a range of other factors besides market share and certainly did not fall back unthinkingly on high market shares and say: there, got you. That was not any part of the

analysis.

I should say as well, in order to avoid any risk of misunderstanding, that we also fully accept that the CMA as the authority needs to consider all of the circumstances relevant and it needs to consider all of the evidence which is brought forward by analogy with the approach that one sees in *Intel*. That is part of the duty of fair evaluation which is described by the Court of Appeal in *Phenytoin*.

The question is, what are the legal consequences at this stage of the process when evaluating whether there is error in the CMA's assessment? The only point that I am making is that there is clear guidance in the case law in support, I will submit, of a rebuttable presumption or, in any event, in support of the proposition that high market shares must carry significant weight. They are a very important indicator. They are not just one indicator amongst others. They are a factor to which significant weight needs to be afforded.

That is for sound reasons of economic principle because market shares -- but there may be other explanations for consistent market shares over a long period, but where one undertaking in the market manages to command a significant share above all of the others,

for a sustained period of time, that is in itself indicative of market power.

Can I just show where we say the case law lies by reference to a couple of decisions, one European and one domestic.

The European case is the Court of Justice's decision in *Astrazeneca*. It is at {M/92/1}. This is the Court of Justice's judgment in that case. We looked earlier at the General Court decision in the context of market definition and, indeed, I will return to that judgment on the question of price.

But for present purposes, I just want to look at the clear statement of principle from the Court of Justice on the significance of market shares.

If we could turn, please, to page 31 of the judgment {M/92/31} and look at paragraph 176. You see there the statement that:

"The Court has already clarified that, although the importance of the market shares may vary from one market to another, the possession, over a long period, of a very large market share constitutes in itself, save in exceptional circumstances, proof of the existence of a dominant position, and that market shares of more than 50% constitute very large market shares ..."

So we say that is a pretty clear statement from the

EU's highest court that market shares above 50% are probative of dominance, absent exceptional circumstances.

We did note that Intas did not refer in its detailed excursus of the case law on market shares to that decision of the Court of Justice in *Astrazeneca*.

In relation to the domestic position, I showed you a footnote in --

MR PALMER: Would you mind reading the next paragraph as well?

MR HOLMES: Certainly. At paragraph 177 it continues:

"As the General Court pointed out ... it is common ground that AZ, during the reference period and on all the geographical markets in question, held very large market shares that were well above those of its competitors, its position on those markets sometimes being even overwhelmingly strong. The General Court was therefore fully entitled to hold ... that the Commission, in its detailed analysis of the competitive conditions which took into account a range of factors, [as of course was the case here] could rely specifically on AZ's generally very large market shares as an indicator of its market power, which was out of all comparison to those of the other market players."

Now, in relation to the domestic position, I have

shown you already the Decision and the reference there to *Aberdeen Journals* and we do not need to turn it up, but we saw that the Tribunal there held that market shares in the order of 70 to 80% by value and 60 to 70% by volume sufficed to establish dominance, absent exceptional circumstances.

For your note, that is at paragraph 310 of the judgment in *Aberdeen Journals* which is at {M/27/98}.

Instead, can I show you a more recent authority from this Tribunal which shows that the domestic position remains aligned with the approach of the Court of Justice and that is the *Churchill Gowns* judgment from earlier this year, which is at {M/190.1/1}. This was an abuse of dominance case brought against Ede & Ravenscroft and Mr Justice Zacaroli was in the chair. Somewhat disappointingly, it is not a case about barristers' wigs and gowns, but rather about Ede & Ravenscroft's other main line of business, which is the supply of academic garb for student graduation ceremonies.

If we could pick it up at page 20, we see that the Tribunal is considering dominance {M/190.1/20}. So you see there the statement at paragraph 55, please:

"While market share is not determinative, a share in excess of 50% is prima facie evidence of a dominant

position. In this case, as already noted, E&R have a market share of between 70-80%. Moreover, they had enjoyed a market share of this magnitude for at least five years prior to the claim period. It accordingly falls to E&R to displace the prima facie inference that they are dominant."

So the position adopted by the Tribunal in *Churchill Gowns* is again that sustained high market shares prima facie support an inference of dominance and, moreover, it is for the putatively dominant firm to displace that inference.

Given the need to make progress, I will not show the Tribunal this now, but in the Tribunal's consideration of whether the prima facie inference of dominance was displaced on the facts of Ede & Ravenscroft, I would invite you, sir, to read at your leisure paragraph 63-67 of the judgment. They show that Ede & Ravenscroft had adduced evidence that there was active competition in the relevant market and that its prices had fallen throughout the relevant period and, indeed, that they were comparable to those charged by competing suppliers.

The court did not call any of that evidence into question, but it held that it was insufficient to displace the presumption, especially in the absence of analysis of whether the prices being charged by

Ede & Ravenscroft and its rivals were competitive prices, but it does show a situation in which prices were falling, but the conclusion of dominance was robust.

Mr Palmer did not address *Churchill Gowns* in his oral Closings. There was a suggestion at footnote 60 of the Intas Written Closings that *Churchill* may be different because it is a private damages case, but we could not see, for our part, why that should make any difference to the legal analysis on this point.

The *Astrazeneca* case was an appeal from a Commission Decision and yet we saw that it took the same approach in substance.

Mr Palmer said that if there is any presumption, it is weak and is evidential in nature only. But despite quite an extensive tour of the cases in its Written Closings, Intas did not identify any case in which an undertaking that enjoys sustained market shares of 50% or above has been found to be non-dominant and, on our side, despite the prodigious talents of Professor Bailey, who as we all know is a walking encyclopedia on matters of competition law, we are not aware of any such case either.

It is not just a jury point, sir, that I am making here. It reflects the intuitive economic point that the

best explanation for very high market shares is likely to be, absent exceptional circumstances or an explanation, that a firm enjoys market power.

Sir, we say that the legal position is actually very clear. Of course, it does not, as I have said, detract at all from the fact that the CMA always has to, and did in this case, properly consider other factors which are relevant to dominance, including relevant arguments and evidence that Intas put forward.

But given the array of other evidence pointing to dominance, extending right through the Intas period, we say the presumption certainly has not been displaced here.

Even if we take Intas's case at its highest and assume this is really a legal nonsense to say that the high market shares give rise to a presumption in law, the fact remains that it is, on any view, highly relevant to look at market shares as an indicator of dominance. The two expert economists in this case agreed with that and it would be frankly perverse to suggest otherwise, given the plethora of cases that consider market shares.

Mr Palmer appeared to suggest at one stage that market shares may not even be relevant. He said that market shares, taken alone, tell you nothing about

dominance, but if he intended to submit that market shares are an irrelevant consideration in this case, which I am sure is not the case, it was plainly wrong. There is a recent judgment of the General Court that makes this extremely clear. It is the judgment in the *Baltic Rail* case from November 2020 and it is at {M/177.05/51}.

So just looking at paragraph 345 of the judgment, if we can go down the page. The General Court is here considering the question of whether the applicant acted intentionally or negligently in committing an abuse of dominance and, in that context, the General Court makes the following observation about market shares. It says that:

"It is clear ..."

This is picking it up -- I am so sorry. It is paragraph 346. That is why I could not find my place:

"It is clear from the case-law that a prudent economic operator is in no doubt that, although the possession of large market shares is not necessarily and in every case the only factor establishing the existence of a dominant position, it has, however, a considerable significance which must of necessity be taken into consideration in relation to his or her possible conduct on the market."

The reference to the case law, we say, can only be a reference to the case law confirming that market shares above 50% are sufficient to prove dominance, absent exceptional circumstances.

Just to preempt the inevitable response from Mr Palmer on this case, we recognise, sir, that this was a case about a statutory monopoly, but the court's reference to the position in the case law is not confined to monopolies. You see on its face it refers to large market shares and it confirms that, at the very least, they have considerable significance and that they must necessarily be taken into account.

Sir, as a matter of law, they are not just an initial consideration or a filter. They are always, we say, a highly relevant indicator of dominance.

There is a further point from Intas's Written Closings submissions that I should briefly address in this connection, although I do not think it was developed orally. Can we look at Intas's Written Closings at {L/5.1/24}.

At paragraph 45 you see that Intas advances an alternative submission. It says that even if there is a presumption, it only applies if rivals with smaller shares are unable to meet rapidly the demand from those who would like to break away from the undertaking which

has the largest market share.

This is a proposition that Intas seeks to derive from the *Hoffmann-La Roche* case.

The first point to make is there is no suggestion in the much more recent Court of Justice decision in *Astrazeneca*, or in the domestic case I showed you, that the presumption only arises if you can also demonstrate that smaller rivals would be unable to rapidly meet demand from the dominant firm's customers if they wished to switch away.

Given the time, I will not go to *Hoffmann-La Roche*, but I would respectfully invite the Tribunal in its own time to read the court's analysis of dominance in the various vitamin markets which begin at paragraph 50 at {M/5/62}. In my submission, that analysis provides no support for the idea that the presumption of dominance only arises on the satisfaction of a freestanding requirement to show that rivals could not rapidly meet demand from the dominant firm's customers.

To the contrary, the court plainly considers that high market shares in themselves provide strong evidence of a dominant position in the various vitamin markets. Other relevant factors are certainly considered, but it is clear that market shares are, at the very least, a highly significant factor in the assessment.

The second issue related to market shares concerns the significance of relative shares. This was not a point that Mr Palmer developed orally so, again, I will be brief.

The point appears at paragraph 35 of the Intas Written Closings at {L/5.1/17}. So if we could go to that, please. You see that Intas here records that the evidence of Actavis's relative market share is not in dispute. Intas notes that, individually, skinny label producers did not gain market shares as large as Actavis. That is a mastery of understatement. The Tribunal may recall figure 4.13 of the Decision with the large expanse of blue showing how large Actavis's market shares were in relation to its nearest rival at all times during the infringement.

Intas then makes the point that in aggregate skinny label suppliers gained around 50% of the market by volume.

That of course reduces the assessment of relative market shares to an assessment of absolute market shares. It just lumps together the whole of the rest of the market.

At paragraph 36, we see reference to a dispute about whether individual or aggregate market shares are relevant. Looking just below halfway down the page, you

see that Intas notes that:

"A large number of competitors..."

It is about two-thirds down the screen:

"A large number of competitors in the market with a substantial volume of sales in aggregate would have (and in this case did have) the same effect on Accord-UK's prices as a single competitor with that same market share."

The point that Intas appears to be making here is that it is somehow i*Napp*ropriate for the CMA to have relied on the fact that Intas's market shares were much higher than its rivals' individual shares and that the CMA should instead have focused on the aggregate constraint.

The first point to make is that the CMA obviously did consider the question of whether Actavis's pricing was constrained by its competitors generally, including through the operation of the drug tariff and I have shown you the key findings about that.

The second point to make is that there are many cases in which the courts have relied on the fact that a dominant firm has much higher shares than its next biggest rival as a strong indicator of dominance. This is not a formal or legalistic point. The reason why relative market shares are relevant is, with respect,

obvious. It is a clear indicator of comparative economic strength in the market. That is particularly the case where, as here, rivals' shares are also more volatile.

Can I show you just one example of this point being emphasised in the case law. It is the *British Airways* case, which you saw cited in the decision at {M/29.1/48}. I do not need to trouble the Tribunal with the background facts. The relevant point for present purposes is that BA was seeking to rely on a decline in its market shares as demonstrating that it was not dominant.

We see this from BA's argument recorded at 183. BA's market share fell from 47.7 to 39.7.

The General Court here emphasises at paragraph 210 on {M/29.1/53} that:

"Account must be taken of the highly significant indicator which is the fact that the undertaking in question holds large shares of the market and of the ratio between the market-share held by the undertaking [concerned] and that of its nearest rivals ..."

We also see that rivals' shares are significantly below the levels that *British Airways* held of 46.3, and 39.7% which I think is set out in paragraph 211. If we could go to the next page, please, to paragraph 211, you

see there the shares shown.

As the court puts it in the paragraph above the table:

"BA's market shares are to be regarded as large and they invariably constitute a multiple of the market shares of each of its five main competitors ..."

Even though those shares are below 50%.

Now, we say what can be inferred from these figures is that the aggregate market shares of the competing suppliers exceed 50% at all times and, yet, the court is never, nevertheless, placing significant emphasis on the fact that BA's shares are a multiple of its rivals' individual shares. The point emerges even more clearly at paragraph 224 on page {M/29/57}:

"The reduction in BA's market share cannot, in itself, constitute proof that there is no dominant position. The position which BA still occupies ... remains very largely preponderant. A substantial gap remained, during the whole of the period of the infringement found by the Commission, between, on the one hand, BA's market share, and on the other, both the market share of its closest rival and the cumulative shares of its five main competitors ..."

Then look at paragraph 225, the court holds that:

"The Commission was therefore right to hold that BA

held a dominant position ..."

So here we say there is an authoritative statement from the General Court that an undertaking to market share relative to the market shares of its nearest rivals is a highly relevant indicator of dominance and we say the CMA was right to have regard to it in this case.

The third issue on market shares concerns whether value or volume is the most appropriate measure. The CMA's position is that value-based shares are more informative in a differentiated product market with different price points. Firms are ultimately competing to maximise their profits and where prices differ between products, a value-based measure shows in clear terms who is winning in that process of rivalry.

As we saw earlier on, the Decision cites a number of cases, including pharmaceutical cases, in which this basic proposition has been emphasised.

Now, Mr Palmer dealt with it on the transcript for {Day15/130:15} if we could go there, please, and look at line 15. So he was here in the course of answering the question from the bench about whether cases generally favour a volume- or value-based approach and at line 16 Mr Palmer makes the point:

"In differentiated markets value would be more

helpful."

But he says:

"Value-based shares are less helpful when the products are exactly the same."

I must say we found that slightly perplexing. An important part of Mr Palmer's case on both dominance and abuse is that Actavis's product is differentiated from other products in the market by reason of the orphan designation and the CMA found as much in its Decision as well, that there was this differentiation in the product.

While the CMA disagrees with the relevance Intas attaches to product differentiation when it comes to both dominance and abuse, it agrees this is a differentiated product market. This is exactly why, consistently with other cases, the CMA observed in the Decision that it placed more weight on the value-based measure.

With that said, we see that Mr Palmer goes on to make clear, at this point in the transcript, that value-based shares are not irrelevant.

You may recall that Professor Valletti said in his oral evidence that both metrics are relevant. The Decision, as we have seen, looked at both and it is clear that, on any view, Intas held a commanding

position, maintaining very large shares of the market by both value and volume at levels from which dominance may safely be inferred.

In terms of value, we saw Intas's market share was very considerably above the level at which dominance is usually inferred. They are in the mid 80%, 80th percentile by the end of the Intas period. In terms of volume, it is the case there were some months during the Intas period when Actavis's market share dipped below 50%, but the key point, in our submission, is that they stabilised at around that level and were above 50% at the end of the period.

On both metrics they were not only large in absolute terms, but were always preponderant. They were several times bigger than any competitors' market shares and that preponderance is the factor that the General Court in *British Airways* described as a highly relevant indicator of dominance.

We say on this, as one of the other aspects of the analysis relating to market share, the approach taken in the Decision was unimpeachable, both as a matter of law and of common sense.

I am going to deal now, sir, with price, unless there are any questions on market share.

What I propose to do in relation to assured customer

base is to park that topic, because we think that it is closely bound up with the analysis of abuse. As you pointed out this morning, sir, abuse and dominance really go hand in glove and one does need to consider them together and we think we will have enough time on our day in the new year to address both. So with the Tribunal's permission, I will leave those aspects of the case, both abuse and the assured customer base, for the new year. That will also ensure that Professor Bailey can commence today and will be in good shape to finish by lunch tomorrow.

Let me just briefly give you some points on price and then, if I may, I will cede to my learned friend Professor Bailey.

THE PRESIDENT: Of course.

MR HOLMES: So on price, I can take this quite briskly, as I have already shown you the key factual material. The appellants focus on the fact that prices were falling due to the direct and indirect constraints that were operative on Actavis during the post-entry period.

They say that where an undertaking is compelled to reduce its prices by the fact that competitors are lowering their prices, this shows that it was not able to behave to an appreciable extent independently of competitors or customers.

They derive that proposition from *Hoffmann-La Roche* at paragraph 71. We do not need to turn that up, but in my submission it is clear that the court was not there laying down any principle that where an undertaking is driven to reduce its absolute prices, as a result of competition, this means that it is not dominance.

On the face of the relevant paragraph of the judgment, the court was at most making a general observation. I referred you to the discussion of price in the *Churchill Gowns* case and the Tribunal there observed that you cannot simply equate a decline in absolute price levels with the absence of dominance. You also need to consider what competitive price levels are and a dominant firm's price may fall as it starts to face some competitive pressure, but still remain well above the competitive level in a manner that indicates its ability to act appreciably independently of competitive forces.

There may of course be other factors, other indicators, that point towards dominance, despite declines in absolute price levels.

So that is why Intas's and Auden's focus on what happened to Actavis's absolute price levels is, we say, too simplistic.

I have already shown you the key uncontested

findings in the Decision. They show that Actavis at all material times remained able to price very considerably above its competitors' prices. I have also shown you what Professor Valletti and Mr Bishop thought about that. They were ad idem in thinking this was a highly material indicator of dominance.

Intas's answer to this is that price differentiation on its own tells you nothing in a differentiated market. That is how Mr Palmer put it in {Day15/19:3}.

The CMA would respectfully agree if that was all there was. But of course in this case the answer is that the CMA did not rely on the mere fact that there was a price differential between Actavis's prices and its competitors' average prices.

First, the CMA relies on the sheer magnitude of the price differentials. We saw from the Decision that even at the end of the Intas period Actavis was charging nearly £17 more for a pack of 10mg tablets than its competitors' average prices.

Just on a commonsense basis, product differentiation alone cannot explain price differentials on this scale.

We must bear in mind of course that while these products are somewhat differentiated, they are entirely bioequivalent. In terms of the costs, what they are, the nature of the product, they are the same. They are

commodities that do exactly the same thing.

Secondly, we have seen that the CMA relies on the fact that the relative price differential between Actavis and its rivals' prices increased during the post-entry period. By the end of the post-entry period, as we have seen, Actavis was charging five times more than its rivals and product differentiation cannot explain this trend, unless it is supposed that the products become more differentiated as time progressed. But that is not Intas's case and there is no evidence to support the suggestion. The products did not in fact change.

Thirdly, and perhaps most significantly of all, there is the fact that Actavis not only maintained a price differential vis-à-vis its rivals, but that it did so whilst still retaining very high market shares. We say that is a compelling indicator of dominance.

The fourth point is that differentiation can itself confer dominance. Here, the differentiation was as a result of a regulatory happenstance that conferred a unique advantage on Auden/Actavis. None of its competitors could hope through competitive effort in the market to match that and influence demand conditions in ways I will develop in the new year, but that in itself may be a factor which creates dominance. You can have

dominance in differentiated markets and, here, that is the only factor which explains the differentiated position of Auden/Actavis by comparison with its competitors.

Now, I would like, if I may, to show you an authority that places particular emphasis on the combination of high relative prices and the retention of high market shares as evidence of dominance. That is the General Court's decision in the *Astrazeneca* case. We saw the Court of Justice's judgment and I showed you the decision referred to the General Court's findings in relation to the German market. The case concerned abuses of dominance in various European markets for medicines treating heartburn and indigestion.

Astrazeneca was found to have engaged in an exclusionary strategy relating to its dealings with patent authorities. So it was not an excessive pricing case, but the findings on dominance are, nonetheless, highly germane.

The General Court's decision is at {M/79/1}. It is a very long judgment, but, for present purposes, can we pick it up at {M/79/84} under the heading "Dominance". Can we look first at paragraph 224 where we see what EFPIA, the European Federation of Pharmaceutical Industries and Associations was arguing in support of

Astrazeneca's appeal.

{M/79/83}. It says:

"In the abscess of a thorough analysis of competitive conditions on the market in question, high market shares are not sufficient to conclude that there is dominance. That is particularly the case in the pharmaceutical sector, which is characterised by strong competition by innovation, where substantial market shares are noticeably less meaningful than in other industry sectors."

So that is what was being said: market shares not determinative.

At paragraph 225, we see that the applicants submitted that the Commission relied excessively on factors relating to prices and market shares and suggested:

"That pharmaceutical companies cannot exercise market power in respect of price, even if they have high market shares".

Various further arguments are then recorded.

Can we see what the General Court makes of it all. If we could go to page {M/79/93} and pick it up at 255. So the court there records that EFPIA were disputing that the higher prices charged by AZ for Losec, its PPI product, amounted to evidence of the existence of AZ's

market power. And as we will see, the court dismissed this argument.

If we could turn on to page {M/79/95} at paragraph 261 you see that the court states that:

"As the Commission claimed ... the fact that AZ was able to maintain a much higher market share than those of its competitors while charging prices higher than those charged for other PPIs is a relevant factor showing that AZ's behaviour was not, to an appreciable extent, subject to competitive constraints from its competitors, its customers and ultimately, consumers."

If we turn on to page 97, could I ask the Tribunal just to read to itself paragraphs 264-266. {M/79/97}. Perhaps when the Tribunal is ready we can scroll down at that point. (Pause).

THE PRESIDENT: Next page please. (Pause).

MR HOLMES: So in my submission those paragraphs are highly germane to the present indicates. The court is not focusing simplistically on what was happening in terms of absolute price levels. Indeed it was not looking at absolute price trends at all. Rather the court was focusing on what could be inferred from the combination of high market shares and the charging of higher prices than rivals.

The court finds that this very combination of

factors shows that *Astrazeneca* possesses the ability to act to an appreciable extent independently of competitors, customers, consumers.

It is saying that this is the case, notwithstanding arguments about the market being heavily regulated. We have seen that this is exactly the combination of factors to be observed in this case.

Now, during his oral submissions Mr Palmer sought to contend that these observations in *Astrazeneca* are to be explained by the fact that this was not a differentiated product market in contrast to the present case. For your note he said that at page 136, lines 4-14 of the day 15 transcript. {Day15/136:4-14} There are two points to note about this.

The first point is that the paragraphs of *Astrazeneca* we have seen do not rely on the fact that the relevant products were undifferentiated. That forms no part of the reasoning we have just seen. The second point to make is that Mr Palmer suggested that the General Court in *Astrazeneca* had specifically rejected the argument that the relevant product market was differentiated and in support of this he referred to two paragraphs, paragraphs 73 and 220. I need to show you them because they do not support the point that was being made.

Paragraph 73 is at page {M/79/29}. We see that the court records the conclusion that the commission was right to find that there was a relevant product market comprising PPIs only. The court here rejected *Astrazeneca*'s argument that the relevant product market also included an alternative treatment with a different type of active ingredient and a different therapeutic mode of action, H2 blockers.

But it simply does not follow that there was no product differentiation within the relevant product market that the Commission had Identified being *Astrazeneca*'s Losec drug and other competing PPIs with different varients on the same active ingredient.

Then let us look at paragraph 220 which is the other paragraph that Mr Palmer relied on. That is on page {M/79/82}. We see here that the court is upholding the Commission's conclusion that H2 blockers did not exercise a significant competitive constraint over PPIs during a given period.

That is again a point about market definition. But it does not show that there was no product differentiation as between different PPIs. On the contrary, as we have seen, prices for different PPIs varied and on its face that suggests that there was some degree of differentiation at work.

So we say that *Astrazeneca* is a relevant authority and that it tends to endorse the approach taken by the CMA in the present case in confirming as a relevant indicator of dominance that a combination of market shares, high market shares and -- the high relative prices and retention of high market shares is a highly relevant factor in assessing dominance.

So, sir, those are my submissions on price. What I propose now to do is have perhaps an intermission, if that is convenient, and we will resume with Professor Bailey at a convenient point.

THE PRESIDENT: Very good. I see it is quarter past. We will resume at 25 past with Mr Bailey. Thank you very much.

(3.17 pm)

(A short break)

(3.30 pm)

Closing Submissions by MR BAILEY

THE PRESIDENT: Mr Bailey, good afternoon.

MR BAILEY: May it please the Tribunal. Sir, this afternoon I am going to address you on Allergan's third ground of appeal. Sir, last week you indicated you were very keen to understand the route by which the CMA attributed liability to Allergan Plc. To assist the Tribunal and to save some time at the hearing, we prepared a short

note, which I hope has now made its way to you.

THE PRESIDENT: It has, thank you.

MR BAILEY: That was served on the parties earlier today.

I understand from my learned friend for Allergan that the note, in terms of the legal principles, is agreed. Those are not in dispute. So what I would propose to do is to invite the Tribunal, perhaps if I may, to read the note this evening and of course if you have any questions that arise from it, I would be very happy to answer them tomorrow morning.

THE PRESIDENT: Yes.

MR BAILEY: But just to give you a couple of highlights, if I may. I am not going to talk you through the note, but just say that the CMA attributed liability to Allergan Plc, because it formed part of the same undertaking as the subsidiaries, AM Pharma and Actavis-UK, which were found to infringe the competition rules.

The test we applied was the decisive influence test and that is set out at paragraph 9.117 of the Decision at {IR-A/12/870}. No need to turn it up.

In any my submission, therefore, the CMA did not need to make a finding of vicarious liability for the actions or knowledge of [redacted] or Mr Stewart and that is because, we say, the domestic rules of

attribution do not apply in this context.

As the Tribunal noted, and in my submission correctly, at paragraph 363(20) of its judgment in *Sainsbury's* -- and it might be worth just to turn that judgment up. I am sure, sir, you will recall it. It is at {M/122/225}, please.

The Tribunal is saying in this subparagraph that, conceptually, the questions of the existence of an undertaking, on the one hand, and attribution of liability to companies within an undertaking are distinct. But the Tribunal went on to observe, and in my respectful submission correctly, that in fact they are very closely related and, indeed, the European case law very often does conflate them as two sides of the same coin.

So if I may just ask the Opus system to move down to subparagraph (22), please, there is a pithy, and in my submission correct, summary of the circumstances in which a legal person may be liable for a breach of competition law and we say at (ii) that is the legal approach to be taken in deciding whether or not Allergan is liable: did it exercise a decisive influence over AM Pharma and Actavis UK who have participated in the infringement?

Sir, actually last week, I do not need to take you

to it, but at {Day13/47:1} you had an exchange with leading counsel for Allergan and sir, if I may say so, you put your finger on it, when you said:

"The question is simply is there or is there not decisive influence over the subsidiary?"

That is the question I am going to focus on.

Sir, you also indicated last week that you had not yet seen a crisp articulation of the battle line between the CMA and Allergan on the hold-separate point. So in light of that, I am going to structure my submissions in five parts.

First, I will identify the battle line. It is a short but important point. Second, I will make a couple of observations on the legal principles. Third, what I propose to do is look at the hold-separate period from different perspectives. So, third, I will start with Allergan and what it did before and during the hold-separate period. Fourth, I will look at the hold-separate manager and what her role was and the point being that she was responsible for the day-to-day running of the business, but we say in line with the existing business plan and budget. Then, fifth and finally, I will turn to the monitoring trustee and what its role was in all of this.

So in terms of the battle line, sir, we identified

that at paragraph 260 of our opening written submissions. That is at {L/6/73}. It is this: it is whether Allergan has rebutted the presumption that it actually exercised decisive influence over Actavis UK during the period 10 March 2016 to 1 August 2016.

In case it is helpful that is, I hope, common ground, because the parties before the hearing prepared an agreed list of facts and issues and at paragraph 19 (b) {IR/L1A/32/8} that is exactly the way the issue is framed.

Now, on one side of the battle line, you have Allergan and they say the presumption is rebutted and they refer particularly to the commitments to which I am going to come. They say they could not exercise decisive influence over Actavis UK.

On the other side, you have the CMA and we say that Allergan has not rebutted the presumption, because Actavis continued to implement the strategy that had been set under Allergan's decisive influence.

Last week, my learned friend referred to this as the drag forward theory at {Day13/55:1}. I think for our part the way we would characterise this is that what the commitments did, as I will seek to show you, was to cement the status quo ante. That is the wording of paragraph 9.186 of the Decision at {IR-A/12/891}.

So what we say occurred was that Allergan had overseen the business strategy during its ownership before the commitments came into force and then that was carried through. As Mr Stewart accepted, it was business as usual during that period.

If I could turn then, please, to the legal principles and, happily, there is much common ground between the parties on that. We summarise them at paragraphs 345-351 of our Defence and that is at {A/6/129}. Today, if I may, I would like to highlight two points that I hope will inform the Tribunal's consideration of this ground.

The first is that decisive influence does not have to be manifested in the giving of instructions to the subsidiary. The second is that decisive influence does not have to be exercised over the infringing conduct.

To make good those two propositions, I would like just to take you to one authority of this Tribunal and that is a judgment of Vivien Rose, now Lady Rose, in the *Durkan* case. That is at {M/81.1/1}. I would like to go to that, please.

At page 5 at paragraph 10, the Tribunal is describing the issue in that case. In essence, it was whether the shareholders, the parent companies, Durkan Holdings Limited, exercised a decisive influence over

the infringing subsidiaries, in that case involving cover pricing.

If I may, I would commend paragraphs 13-22 of this judgment as a helpful and authoritative overview of attributing liability for an undertaking.

But the Tribunal pulls the threads together at paragraph 22 and that is what I would like to address you on. That is to be found at {M/81.1/11}. The first thing you will see in the opening part of paragraph 22 is that, perhaps unhelpfully, but maybe understandably, the courts over the years have expressed the test in a number of different ways. There is no sort of one uniform way of putting the point.

But then the Tribunal helpfully in my submission distills four propositions. The first at subparagraph (a) is really the point in issue between the CMA and Allergan. It is the rebuttable *Akzo* presumption. My learned friend took you to the *Akzo* case at paragraph 60, which is the authority for that point.

But it is the proposition at subparagraph (b) that I say is also important, because it makes in fact two points. The first is it says that the exercise of influence can be indirect and that, in particular, the parent does not need to interfere with the day-to-day

business of the subsidiary. That is a point I am going to come back to in explaining the role of the hold-separate manager.

The other thing that one sees here is the Tribunal says:

"The influence is not reflected in instructions or guidelines emanating from the parent to the subsidiary."

Now, a number of times last week it was said by counsel for Allergan that there was no way it could give instructions to Actavis UK during the hold-separate period and that it was said, well, case closed.

I would respectfully differ about that, because that is not the litmus test for decisive influence.

I accept of course, as paragraph 22 makes clear, one does see reference to this idea of instructions, but it is only one formulation. In my submission, like the *United Brands* test, one must be careful not to read it too literally or, as the Chancellor of the High Court said in *Phenytoin* "as if it were a deed", and instead take note of 22 (b) which makes clear that instructions are not a mandatory requirement in all cases. So I am saying that instructions can be an indicator of decisive influence in some cases, but it is not a sine qua non. It is not a mandatory requirement in all cases.

The third proposition in paragraph (c) is that the

test is not whether the parent actually exercised influence over the infringement. Sir, you may recall last week, this is {Day13/41:1} you were looking at paragraph 9.186 of the Decision. It perhaps would be helpful to turn that up. It is at {IR-A/12/891}, please.

My learned friend for Allergan, very fairly, took you to this paragraph and said this is where the CMA's case is being made and one of the points that you raised, sir, was when it says in the second sentence "The commercial strategy of Accord-UK was set under Allergan's decisive influence" in the period May 2015 to March 2016, you asked "Should the word 'unlawful' be read in or inserted to that passage?"

Counsel for Allergan very fairly said, well, that is a question you will have to put to the CMA and so I would like to answer it and our answer is: no, you do not need to insert that word and the reason being is that, as *Durkan* shows, we do not need to show decisive influence over the infringing conduct.

If there were any doubt about that, I will just simply give you the reference. Page 9 of the judgment in *Durkan* there is a quote to the Advocate General's opinion in *Akzo* to which my learned friend took you and at paragraph 90 she points out that it is not required

for the parent to know about or be involved in the infringement.

So with that introduction, I would like to turn, if I may, to start with Allergan. It bought Auden and AM Pharma at the end of May 2015 after detailed due diligence. That is summarised at paragraphs 9.138-9.158 of the Decision, which is {IR-A/12/875-882}.

The Tribunal will recall that the PwC report -- my learned friend Mr Holmes showed that to you yesterday and of course I also canvassed it with Mr Stewart.

I do not think we need to turn it up. I can just simply make three points about that report.

The first is the Tribunal will recall that PwC said that Auden was a highly cash-generative company selling niche high margin drugs of which hydrocortisone was one and it drew attention to the significant price increases of the product and also its highest absolute gross margin.

That is at {IR-H/639/8}, {IR-H/639/18} and {IR-H/639/23}.

The other point that Mr Stewart fairly confirmed was that Allergan knew that Auden's strategy was similar to its own. One can see that if we briefly look at one of the Project Apple presentations. That is at {IR-H/922/4}, please.

The reference is {IR-H/922/4}, but I can probably make the point without even going to the document. The point is simply that is a document that records -- here we are. If we look at the fourth bullet. It talks about:

"The Auden portfolio and pipeline is well aligned with our existing GX strategy -- specialised, niche, low competition products."

And we can see the internal message, second row, first bullet:

"Auden McKenzie has a solid business that is highly profitable -- 70% plus EBITDA margin driven by exclusive, semi-exclusive products and low cost structure."

Mr Stewart fairly accepted that hydrocortisone was one of those products.

So Allergan clearly had a good understanding and appreciation of Auden McKenzie's strategy and the importance of hydrocortisone. But on the other side of the ledger what these due diligence materials also show is that Allergan was modelling what might happen when entry occurred, because that affected the bottom line, it affected how much it wanted to pay for the business.

Counsel for Allergan emphasised last week the prediction that there would be a 90% price erosion over

a three-year period. In relation to that, I would invite the Tribunal just to bear in mind two points.

The first is that the model itself predicted that most of that price drop would not occur until two years after entry occurred. We can see that in this document if we go to page 15 {IR-H/922/15}. Entry was predicted to occur at that time in the second quarter of 2015. We can see that the market share and the prices and the price changes and everything looks rosy, if I may say so, between 2012 and 2015 and then things do change when entry is predicted to occur. One has to accept that. There is no impact on price in 2015, but there is some indeed in 2016, essentially reversing the price increase of 2014.

But my point is that the business was not expecting there to be a significant price drop until 2017. That is some two years after entry was predicted to occur. So that is just the first point.

The second point is that we know that that model turned out to be wrong and we saw that in Allergan's own 2015 update and 2016 budget, which was presented to Mr Stewart. He accepted that at {Day10/174:1}.

What we did in our Written Closings was to try and summarise some of the highlights of that document at paragraph 322. That is {L/7/138}. But the submission

I would make in relation to that presentation, I do not think we need to turn it up as such, is that it shows Allergan keeping a close eye on the performance of hydrocortisone, flagging the significant contribution to the profitability of the generics business, and making a prediction that there would be high net sales and high net margins in 2016. Just to give the Tribunal the reference, that is at {IR-H/790/39}.

So all of this is to say by way of context that Allergan clearly reviewed and must have been taken to approve the performance, the profitability and the projections for hydrocortisone in the UK before the 10 March 2016.

But of course my learned friend rightly then says, well, things changed. At the point of the 10 March the commitments entered into force. So I do need to address you on that change.

Before I do so, I just must pick up one point that seems to have crept into Allergan's written submissions. There was a reference to 4 March being the relevant date. That was the date on which the commitments were signed, but I hope that it is common ground that they only came into force when the European Commission adopted its Decision and that was on 10 March 2016. Just for your note, members of the Tribunal, at

{H/986/19}, that is the commitments themselves, one can see that where it says in terms the commitments come into effect on 10 March. So I say that is the relevant date.

MR JOWELL: Just to clarify, that is absolutely correct.

MR BAILEY: I am very grateful. So if we can turn then to the commitments and I would like to go through those, if I may, with you.

They are to begin at {IR-H/986/4}. I begin with commitment 1, simply for the proposition as to which commitments bound Allergan, because not all of them actually applied to Allergan and it is right to acknowledge that.

You can see there 30 to 41, I am going to come to some of those; 72 and 73, and I am going to come to 73. That deals with the derogation.

If we could then move in numerical terms to commitment 36 at {IR-H/986/8}, please. Now, this required, relevant for our purposes, Allergan until the completion of the divestiture to preserve and procure the preservation of the viability, the marketability and the competitiveness of the divestment businesses, in accordance with good business practice.

Pausing there just to see what does that positive obligation mean? We would invite the Tribunal to have

regard to what the Commission says about this interim preservation of the divestment businesses at paragraph 110 of its notice on remedies. So if I may just take you to that so you can read it for yourselves. It is at {M/62/23}, please. If I could ask the Tribunal, please, to read paragraph 110. My learned friend did take you to that, but I would be grateful if you could refresh your memory of it.

THE PRESIDENT: Yes. (Pause). Yes, thank you.

MR BAILEY: I am grateful. Sir, the point that I take from this is particularly in the last sentence:

"The parties must maintain the business in the same conditions as before the concentration [that is the legal word for 'merger'], in particular provide sufficient resources, such as capital or a line of credit, on the basis and continuation of existing business plans."

That is going to be a theme of my submissions and something I am going to come back to.

But what I say that this is doing is that this is requiring the parties to preserve the business so that it is in as good a state before the merger at the point at which the remedy is implemented. The Commission very helpfully at paragraph 108, on the previous page, please, explains why this is so important under the

heading "Interim preservation of the divested business" and paragraph 108 explains that the parties have a responsibility essentially not to allow the businesses to be run down or neglected, but then the last sentence:

"Only such commitments [we can see they are talking about essentially commitment 36] will allow the Commission to conclude with the requisite degree of certainty that the divestiture of the business will be implemented in the way as proposed by the parties in the commitments."

Now, in my submission, what that is doing is saying when the Commission takes a Decision to clear a concentration on condition of certain remedies, here a divestiture package, it needs to be confident that when it takes that decision in March of 2016 that when that remedy takes effect in -- in fact it goes to Teva in August, but actually it takes effect in January 2017. I am going to come on to explain Teva's position in a moment if I may -- it needs to be confident that that business is going to be as effective, as promising, have the competitive potential, the viability, so that when it reaches independent hands, in this instance in Intas's hands, that that will address the significant impediment of effective competition that the Commission was concerned about.

Otherwise, if one thinks about it, if there were to be material changes of direction, products being withdrawn from the market, perhaps new products being launched, there would be a degree of uncertainty that the Commission could not be confident that the package of assets to be sold are going to be the ones that actually fix the competition problem that it has identified.

So what the Commission is keen to do, and it says that in its notice, is it wants to preserve the businesses to be divested in this interim period, by which is meant the period from the date of the decision to the date of the completion of the transaction and it is all about sort of holding the ring and ensuring that there are no material changes.

So we then say it is important to see some of the specific obligations that are imposed on the parties.

I acknowledge some of those are favourable to the CMA's case and some of those are challenging and so one has to look at, I think, the commitments as a whole.

If we can go back to them, please, it is at {IR-H/986/8}. Please could we go down the page. I would like to go through each of the subparagraphs. The first one is clearly a restriction on Allergan. It says so in terms it cannot take action that may have an

"adverse impact on the value, management and competitiveness of the Divestment Businesses." In my submission, that is all of a piece of: you must preserve the business prior to completion of the sale. But I absolutely acknowledge it goes on to say:

"That might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Businesses."

So this clearly is stopping Allergan from altering the industrial commercial strategy. It says so. Subject only to a proviso that if Allergan pulled out of the deal, of course the commitments fall away. But if we just deal for the moment with the commitments for what they say. If I may borrow a metaphor, and I hope it is one that is fitting with the wintery conditions, we say that what the commitments are doing here is effectively putting the divestment businesses in a sort of permafrost. They are going to be run in the ordinary course in line with existing business plans and they only thaw at the point at which the business is then sold to a suitable purchaser.

Now, of course I need to make that good and I am going to try and do so by reference both to some of the other commitments and also the protagonists and how they understood these commitments were to be applied and, in

particular, Actavis UK, Allergan's lawyers and the hold-separate manager herself.

Before I do, if I may just continue with going through commitment 36 and move to commitment 36 (b). Of course the CMA does attach importance to this, because this is the one that says that the parties, so Allergan prior to completion, must:

"Make available, or procure to make available, sufficient resources for the development of the Divestment Businesses, on the basis and continuation of the existing business plans."

Now, pausing there. It does not say that the divestment businesses are autonomous and they already have all their resources. If that were the case, you would not need this commitment. Nor does it say that Allergan must provide any resource that the hold-separate manager considers in her business opinion that she needs for the business. Instead, we say it means what it says. That the expectation is that the divestment businesses will be developed on the basis and continuation of existing business plans.

I am going to come on to develop that is how Allergan's lawyers understood it, that is how the hold-separate manager understood it and, indeed, that is how Actavis UK understood it.

But before I do that, I think it is right to acknowledge that there are other commitments that indeed limit Allergan's involvement still further. I have to address those. Those are at page 9 and my learned friend showed you these last week. It is commitment 37 and commitment 40. I assure you I am going to come on to commitment 38 as well in a moment.

But commitment 37. That is the restriction on Allergan's staff. They are not to be involved in the running of the divestment businesses. Commitment 40 is the one that ring-fenced confidential information.

So as to those, we say that meant that Allergan's staff could not be and should not be involved in the day-to-day running of the business. We are going to see in a moment that was the job of the hold-separate manager. The corollary of that of course was that Allergan could not and should not receive flows of confidential information about the divestment businesses. So, in my submission, what those things are doing is they are taking Allergan out of the day-to-day running of the business.

The reason why that is so important is because that is what the hold-separate manager is there to achieve.

Now, one of the things that my learned friend said last week was that, well, where do the commitments say

that the hold-separate manager must slavishly follow the existing business plans? I have two answers to that.

The first is commitment 36 (b), which we have seen, which is consistent with what the Commission says at paragraph 110 of its remedies notice: that you have to continue on the basis of the existing business plans.

But the second is actually about the role of the hold-separate manager and something that you have not yet seen, but I think is important to show you.

That is at page 3 of the commitments and this is in section A, which are the definitions of the various terms and one of them is the definition of the hold-separate manager. The relevant one for our purposes is that "IE [so that is Ireland] - UK Hold-Separate Manager". You can see that the definition is:

"The person(s) appointed by the Parties for the IE-UK Divestment Businesses to manage the day-to-day business under the supervision of the Monitoring Trustee."

In my submission, there is a distinction here that needs to be drawn between day-to-day business, on the one hand, and strategic control on the other hand.

I will explain the distinction and then give you the authority that supports the distinction.

The distinction we say in running the business day-to-day, that is keep the lights on, produce and sell the products, deal with the customers, deal with the staff in the ordinary course of business. The strategy on the other hand, that is the business plan, the budget, the making of major investments, the launch of new products and this distinction was in fact recognised by the Tribunal itself in the *Durkan* judgment.

THE PRESIDENT: Just pausing there --

MR BAILEY: Of course, sir.

THE PRESIDENT: Just to make good one sort of point which relates to what you are saying. Could you go back to provision, I think it is, 30, where there is an obligation to adequately resource the ring-fenced entity. It was page {IR-H/986/8}.

MR BAILEY: Is it 36, sir?

THE PRESIDENT: Yes. 36 (b). That obligation which of course you have taken us to.

MR BAILEY: Yes.

THE PRESIDENT: It is not something which is informed by anyone in the ring-fenced entity itself. This obliges Allergan to itself consider what is necessary to enable the continuation of the existing business plans, what is necessary to be made available or procured made available, and it is their judgment that is central

here, because it is their obligation.

MR BAILEY: In my submission, sir, respectfully, that is absolutely right. This commitment is addressed to the parties. So it is right to say it is addressed to Teva after the transaction and Allergan beforehand, but you are quite right, sir. One can see that at the end of 36 and in particular "the parties undertake" and that is defined by reference to Allergan and Teva and so this is not part of the clean team, for example, that Mr Stewart described in his witness statement. This is absolutely an obligation on the parties.

It is the part of the commitments that we say is the basis upon which the existing business plan and budget were carried forward. More particularly, we say as a matter of fact that is what indeed happened on the ground. I think that is important, because the appellant is inviting you to see that the presumption is rebutted of actual exercise of decisive influence and so I think it is important to see what the actors did.

I hope I gave the Tribunal the reference, but it was paragraph 58 of the *Durkan* judgment which is at {M/81.1/22}. It occurs to me on my feet that there is also a reference in a document that is not in the bundles, but of course we can provide it to the Tribunal at paragraph 67 of the European Commission's

Consolidated Jurisdictional Notice, which Professor Holmes can no doubt recall from his days in private practice. That also deals with this distinction and of course I am sure the CMA would be happy to provide a copy of that to the parties and to Tribunal.

Could I move then perhaps to the hold-separate manager, because she really is at the heart of this. I have shown you the definition of her role and I think I now need to deal squarely with commitment 38, because that really is the centre piece of Allergan's ground 3.

So, if I may, could I ask to go to page {IR-H/986/9}. The opening sentences just simply talk about the appointment of [redacted]. But the key sentence that is relied upon and that I need to address is the one that says:

"The IE-UK Hold Separate Manager shall manage the Divestment Businesses independently and in the best interest of the business with a view to ensuring its continued economic viability, marketability, and competitiveness and [of course] its independence from the businesses retained by the Parties."

So that is what it says on paper. But in my submission what one has to do is to say, okay, how was that interpreted and applied in practice.

I am going to try and show you that by looking at

how it was understood by her employer, Actavis UK, then look at it from Allergan Plc's external lawyers, highly regarded and experienced firm in competition law, Cleary Gottlieb, and then finally look at [redacted] herself, her actions and what she was doing at the time on the ground.

So if we could start with her employer, Actavis UK. Its understanding of the commitments is set out, in my submission, in her amended contract of employment and that is at {IR-H/858/2}. Could I ask the Tribunal, please, to read the second paragraph. You are welcome to read the whole thing, but it is the second paragraph that I think is the bit that I would like to.

THE PRESIDENT: Beginning "Under Commitments"?

MR BAILEY: Yes, please, sir. (Pause).

THE PRESIDENT: Yes.

MR BAILEY: So you can see that they were referring to the commitments, so they obviously have those before them. If we could just scroll up, please, just to see the date of this or maybe scroll down to the next page, I apologise. Yes, it is dated 18 April 2016.

So they have the commitments when they are amending this contract of employment. The simple point that we make is that this is saying in terms: you need to go out and promote and commercialise, sell essentially, the

divestment business products, which of course include hydrocortisone and that your efforts are to remain substantially unaltered. That is why we used the permafrost analogy.

But of course Actavis UK is not alone in having this understanding. We can also see a similar point being made by Cleary Gottlieb. You recall, sir, we took those to Mr Stewart during evidence and I just want to take you to a couple of passages, if I may. It is at {IR-C1/2/6}. This of course was, as we discussed during the cross-examination, a draft memorandum of legal advice. I do not think we know of a final version, so I just have to accept that. But it does come from a very eminent law firm experienced in anti-trust and here they are providing granular guidelines on the hold-separate regime in the EU.

So if I can just take you to paragraph 7, if we can scroll down please, where they have a summary. We can see first of all that bullet and that first bullet, what that is doing is essentially summarising commitment 38. That's the gist that is being put there. But then it is important to see what is then said in the second bullet:

"The hold-separate managers must run [so it is being very clear and mandatory] the relevant divestment businesses in the ordinary course of business [business

as usual] based on existing business plans and budgets."

We can see an echo. I mean lawyers repeat themselves, just I guess to drive the point home, in paragraph 8 after business as usual. If we can turn to page 7, please, we can see in the first bullet the:

"The CEOs of the Divestment Businesses ... "

So that would be Mr Wilson. He was the managing director of Actavis UK at the time:

"Must continue to run their operations in the ordinary course and within existing budgets/business plans, under the instructions and guidance of the hold-separate managers."

So at the moment we have got Actavis UK says you must not alter your commercial efforts. Cleary Gottlieb have told Allergan you must preserve and abide by existing business plans and budgets, but then what does the hold-separate manager, what does she do in all of this?

My learned friend showed you last week, and I am not going to go back to it, unless the Tribunal wishes me to, the first monthly monitoring trustee report. He very fairly took you to the passage that the CMA relies on at {IR-C1/3/18}. That was the bit that explained how she had had meetings with management and then they had cascaded the message down that you have to execute the

2016 business plan. That is section 3.5 of that report.

But the bit I wanted to show you was a bit that I had shown Mr Stewart relating to the strategies and goals for hydrocortisone. One of those was from February before the hold-separate period and one of those was from May in the middle of the hold-separate period.

Could I ask if it is possible to bring up two documents side by side please. So the first is {IR-H/815/3} and then the second is {IR-H/868/3}.

So here, rather delightfully, we have a plan on a page for hydrocortisone and there are various highlights, disappointments. The bit I want to focus on is in the bottom left-hand corner and I apologise it is now quite small to read.

THE PRESIDENT: No, not at all.

MR BAILEY: But basically what one sees if we start on the left-hand side in February, we have five strategies and goals. They are delivering NR, I believe that is net revenue -- of 37.9 million. Second, review penetration from Alissa and AMCo in the more than 18 -- I think that is in other words the adult indication part of the market.

Continue communications to pharmacy decision makers on dispensing guidance due to different licence

indications. That is a reference to Project Guardian, trying to persuade pharmacies not to dispense the skinny label product.

Increase scheme penetration following scheme launch in Q4, 2015. That, as I understand it, is a reference to a buying scheme which wholesalers are invited to join in order to get preferential terms and then you have wholesale support for the defence campaign agreed with and then various wholesalers are listed.

Now, if we look then at the right-hand side, and I am not going to read it out, but each and every one of those strategies and goals are identical, except for the final one, where there is a difference in wording. It says:

"Continue to use campaign to reinforce benefits of Actavis/Auden Hydrocortisone."

In my submission, that is all apiece with Actavis UK continuing the existing business plan in that instance to persuade stakeholders of the alleged virtues of their full label product.

So if I may, I have looked at it from the point of view of -- I am sorry.

MR JOWELL: I wonder if my learned friend could just clarify he is not alleging that the plan on the right-hand side was ever seen by Allergan. It would have gone to

monitoring trustee, I assume.

MR BAILEY: I am very happy to confirm that it is no part of the CMA's case that the document on the right-hand side in May went to Allergan, no.

The submission I am making is that this is the hold-separate manager's documents and that she is applying exactly the same strategies and goals, which it is common ground prior to 10 March both Allergan and the CMA agree that the presumption of actual exercise of decisive influence has not been rebutted. That is common ground. The point I am making, just to assuage my learned friend's concerns, is it is not that Allergan would have seen this or approved this or done anything of that kind, but rather this is a continuation of the business plan and strategy.

Now, I think it is right, particularly because Professor Holmes asked a question last week about the monitoring trustee and I think you asked leading counsel for Allergan about potentially its liability as well. I would like to address that question if I may.

But before I do so, if I could just show you again another part of the commitments you have not yet seen and that is on the monitoring trustee. Its duty, Duff & Phelps, is set out in commitment 37 and there was quite a number of them. It is at {IR-H/986/13}.

Sir, I see the time. I am optimistic, if I may, that I will be able to finish this ground in about 15 to 20 minutes, if that is acceptable to members of the Tribunal.

THE PRESIDENT: Yes, of course, do go on.

MR BAILEY: I am grateful.

So here we have commitment 57 and, as I say, please do read these at your leisure in more detail, but the one I am going to focus on just for present purposes is at (ii). If I could just ask you to read that.

(Pause).

THE PRESIDENT: Yes. I assume there is more after the second dash.

MR BAILEY: There is more to come. You will be reassured I am not going to go through each and every one of those.

THE PRESIDENT: If I could move it up then. Thank you.

(Pause).

MR BAILEY: I am grateful. So the monitoring trustees' job was essentially twofold: to oversee the ongoing management of the divestment businesses and, particularly, to ensure the commitments were complied with. We do not need to turn it up, but paragraph 112 of the remedies notice says essentially the same thing and, moreover, so does the definition of the monitoring

trustee in section A at {IR-A/986/3}.

So how does the monitoring trustee fit in? We say, first, Allergan is exercising decisive influence by virtue of having set the business plans that are applied during the hold-separate period. The hold-separate manager has been appointed to run the business day-to-day, business as usual. Then the monitoring trustee, it is there to ensure both the parties and the hold-separate manager comply with the commitments. Indeed, my learned friend showed you in the remedies notice that the monitoring trustee could issue instructions and we entirely accept that, but they are instructions to ensure that the commitments are complied with. They are not instructions to simply do whatever it so wished.

Now, to address then Professor Holmes question, could the CMA have held the monitoring trustee liable for the alleged breach of competition law? It is at {Day13/21:1}. My answer is, respectfully, no. It could not have held the monitoring trustee liable. That is because the monitoring trustee did not exercise decisive influence over the divestment businesses. Its job was to preserve the divestment businesses and, essentially, get them in the same state from the date of the Commission's decision into the hands of a third party

purchaser as quickly and as effectively as possible.

Sir, there were some exchanges last week between yourself and leading counsel for Allergan about various scenarios that did not in fact arise. They were sort of hypotheticals, but they might still be playing in your minds and so, therefore, if I may, I would like to address those scenarios before I finish.

Before I do that, one thing that you may be wondering is, well, why do we not hold Teva liable? Because of course it owned the business between 1 August 2016 until 8 January 2017 before then Intas acquired it on 9 January. I certainly asked myself that question and so you might have also.

THE PRESIDENT: Is that because of the indemnity?

MR BAILEY: It is not, sir. The answer is given -- alas, it is buried in a footnote -- at footnote 3,126. It is there. {IR-A/12/894}. But the reason I bring it up is because actually it shows or it illuminates a relevant difference between Teva and Allergan. I am sorry that the footnote runs over the page, but if I could ask you to read the footnote and then I will make the point. (Pause).

THE PRESIDENT: Next page, please. (Pause).

MR BAILEY: So, sir, the relevant difference in my submission is this: we say that Allergan did in fact

exercise decisive influence during the first sort of nine or ten months of the ownership and then that was carried through the hold-separate period. That is the cementing the status quo ante.

Of course, when Teva acquired the business, it never had that opportunity. It was already ring-fenced hands off, it is subject to the hold-separate regime from day one and so, in my submission, that means it never in fact exercised decisive influence and it would have been wrong, if I may say so, for any authority to have sought to hold Teva liable in those circumstances and so that is the distinction that we draw between them.

The scenario that was canvassed -- it came up in the hearing and it is also raised in Allergan's reply at paragraph 56 -- was, well, what would have happened if the hold-separate manager had discovered, lo and behold, that the divestment product was, say, dangerous or unsafe? What do we say would have happened? Of course, that is not a situation which actually arose, but it may be is interesting just to sort of explore how we say this regime operated.

So we say, first of all, could the hold-separate manager unilaterally have withdrawn such a product that is suspected to be unsafe? So in my submission, the answer to that is no, because that is not just

day-to-day running of the business. That is the end of that business. In fact, more than that. It would have fundamentally changed the composition of the businesses to be divested.

So what should she have done, because, clearly, I am not saying she should continue to sell a dangerous product. My suggestion is that what she should have done is raise it with the monitoring trustee, because we know that she acts under the supervision of the monitoring trustee.

The monitoring trustee then its obligation, as eyes and ears of the Commission, is to ensure the commitments are complied with. We saw commitment 36. Commitment 36 says in terms that the parties must preserve viability, marketability, competitive potential of the divestment business. Clearly, a dangerous product is going to potentially jeopardise viability and saleability and so the monitoring trustee would have told the parties: this engaged your obligation just as much as the hold-separate manager.

What should then have happened, correctly, is that the Commission needs to be told about this, because, ultimately, these commitments are given to the Commission.

If one looks at commitment 73, could we go to

{IR-H/986/16}, please. You will recall, sir, I think I went to this particular clause with Mr Stewart and we say that if a product was discovered to be dangerous, that actually is a good example of an exceptional circumstance and, moreover, that is something that no doubt the Commission would be concerned about, because if the product is dangerous and needs to be withdrawn, then we say the correct approach would have been for the parties then to request the Commission for a derogation so that it can be withdrawn. Moreover, that would allow the European Commission to be apprised of the situation, which is exactly the right approach, but also to review whether or not the remedy is still effective and appropriate, given the concerns that the commission had identified.

Now, of course that does require some fairly nimble communication between hold-separate manager, monitoring trustee, parties, European Commission. In my submission that is precisely how the hold-separate regime was supposed to work and so that is how we say that would really operate.

To conclude, if I may, I might ask a slightly different question to one I started with and look at it from the other end of the telescope. So look at it from the perspective of, well, okay, was Actavis UK an

autonomous and completely independent entity on the market? In my submission the answer to that is no. No because it was expected to continue and adhere to the existing business plans and budgets set by Allergan. No, because it relied on Allergan for sufficient resources to develop the divestment businesses, and I realise I am now saying no three times, but no, for a third time because ultimately Allergan did have the power, and I accept this is a nuclear option, but it had the power to pull out of the deal and discard the commitments and it did in its form 10K filing at {IR-H/646.2/46}. It did tell investors and the US regulator there are risks and uncertainties with this deal. It is not done and dusted.

The General Court in the Parker-Hannifin case did refer to this particular factor at paragraph 66. That is {M/123/11}. Now, just to anticipate an objection that might be raised I am not saying that this case is analogous to the facts of Parker-Hannifin. I think it has emerged from the written submissions that Allergan and the CMA agree that this is not a direct analogue.

What I am saying is when you are considering the factors as to whether or not Allergan continued to have decisive influence I would invite you, as one of the factors to bear in mind that it retained that power.

In conclusion, we say it is no part of the hold-separate manager's remit to make major investments, launch new products, open new factories, change the branding which of course are the hallmarks of an autonomous entity on the market. I mean, in fact if she had done so in my submission there would have been a real risk to the viability or the marketability and the competitive potential of the divestment businesses, and that is the very thing that Allergan was required to preserve.

So for all those reasons we say that Allergan has not rebutted the presumption of actual exercise of decisive influence in the facts of this case.

PROFESSOR HOLMES: Can I ask one question: you helpfully answered a question which I put to Mr Jowell which was to the effect that if his argument, was the corollary of his argument that if Allergan did not have decisive influence then the monitoring trustee did and that he or she might be held liable, and I think his answer was yes, it was that corollary.

Understandably you have said in answer to that question because you think that Allergan retained decisive influence that the CMA could not have held the divestment trustee liable.

Can I ask, if you were wrong on that assessment

would the logical corollary, would you agree that the logical corollary would be that the divestment trustee had decisive influence and therefore could be held liable or is there some third possibility that I have not thought of?

MR BAILEY: Sir, if we are in a world where I am wrong about the role of the monitoring trustee such that it did exercise decisive influence over the divestment businesses during the hold-separate period, then I think I would have to accept that, given the decisive influence test, that it would be part of the undertaking with the divestment businesses.

The only point I would perhaps add in answer to your question is that although there is a discretion for the authority and indeed the court to hold liable particular corporate legal entities within the undertaking, there is no obligation to do so. If it would assist the Tribunal, I can provide authority to support that proposition.

So although technically, yes, it would be part of the undertaking and in principle could be fined, I would hope that a responsible authority acting reasonably would not fine the monitoring trustee in those circumstances.

PROFESSOR HOLMES: Thank you.

THE PRESIDENT: You addressed the hypothetical that we debated earlier in these proceedings by reference to an unsafe product.

MR BAILEY: Yes.

THE PRESIDENT: Which is a different hypothetical to the one that we used but I take it that your answers would be the same if the hypothetical that we did use, namely the discovery of the unlawful conduct.

MR BAILEY: Yes, I am very happy to address you on that as well, sir. You are quite right. I used a different one I think that came from the reply, but my answer is, yes, you are right. I actually had three answers, and the third one was the one I addressed you on, dangerous products. Effectively yes, there would have to be that liaison between them.

The other two points are very short. The first is that I probably would not accept the premise of that scenario, if only because I think, as Mr Holmes said to you earlier today, there is no reason why we say that the undertaking could not have terminated the infringements well before the hold-separate period. One did not need to wait until that point. Of course that is not a complete answer because you were interested in the hold-separate period itself.

The only point that I make is of course it was

a hypothetical because she did not discover it but, yes, the short answer is my answer is the same.

THE PRESIDENT: I quite understand why you used a different example. It keeps it a little bit cleaner but I just wanted to make sure it was a transferable example if we were to use a different hypothetical.

MR BAILEY: Yes, sir, it absolutely is, a transferable example.

THE PRESIDENT: Very grateful to you, Mr Bailey. What time tomorrow? Mr Jowell.

MR JOWELL: May I just clarify one point for Mr Holmes because I just want to be clear what is our position is on the hold-separate manager.

Two points. First of all, we entirely agree with Mr Bailey, we are not seeking to suggest that somehow the monitoring trustee should have been held liable. There is absolutely a discretion and one would not seriously expect one regulator to hold another person in a quasi-regulatory position liable for an infringement.

But secondly, also just to be absolutely clear, whilst we do say that the correct analysis is actually if you ask yourself, who was exercising decisive influence in that period, it would be the monitoring trustee or perhaps even ultimately the European Commission for whom they are the eyes and ears.

Nevertheless, we do not say that is, if you like, a necessary corollary of our argument. It is perfectly possible to conclude that Allergan did not have decisive influence without also concluding that someone else did. I mean, because, if you like, it is ultimately a negative test, did we have and anyone can have subsidiaries that are effectively just purely autonomous.

THE PRESIDENT: Yes, it is quite possible that the decisive influence was dissipated as it were, in the morass of involved parties.

MR JOWELL: Indeed, and there is nobody up the chain.

PROFESSOR HOLMES: Thank you.

THE PRESIDENT: Thank you very much, Mr Jowell. Mr Bailey.

MR BAILEY: Tomorrow morning I will be addressing you on penalties and I would be grateful if the Tribunal would be willing to start at, say, 10 o'clock and then I would do my level best to be done by lunchtime.

THE PRESIDENT: Very good. We will start at 10 o'clock and we will adjourn until then. Thank you very much.

(4.34 pm)

(The hearing adjourned until Friday, 23 December at 10.00 am)