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)

Monday, 19 December 2022

(10.00 am)

Closing submissions by MR O'DONOGHUE (continued)

THE PRESIDENT: Mr O'Donoghue, good morning.

MR O'DONOGHUE: Sir, good morning. Sir, I was going to move on to my penultimate ground on object.

THE PRESIDENT: Thank you.

MR O'DONOGHUE: On the law we gratefully adopt what Ms Ford set out in her oral submissions. I want to add three supplemental points, if I may. First, of course Ms Ford took you through very ably, as one would expect, the case law on object, but we say it is important to underscore the direction of travel here. The critical insight we say one gets from *Carte Bancaire* and Budapest Bank is that the concept of object is to be interpreted restrictively.

The importance of *Carte Bancaire*, we submit, was in a sense that it was a backlash against an expansionist phase in object, something of course which fundamentally jars with the single biggest trend in competition over the last couple of decades, which is a shift to an effects-based approach.

In *Carte Bancaire* what the Court of Justice said in a nutshell was that the general court's approach was too simplistic. It was wrong simply to suggest the banks

coordinated collectively on fee setting. One needed to contextualise this, in particular in the context of a two-sided market where the balance between issuing and acquiring activities needed to be optimised for the system to work efficiently in the interests of intermediate and final consumers.

So we say at base, all else equal, the object box should not be expanding or, more precisely, that it would develop incrementally where it is clearly justified to do so.

My second point is the question of economic experience. If we can quickly go to *Budeapest Bank* at {M/171/13}, please. So this is the Court of Justice and it is paragraph 76. So there is a cross-reference to the AG's opinion. And they say that:

"There must be sufficiently reliable and robust experience for the view to be taken that the agreement is, by its very nature, harmful to the proper functioning of competition."

So we then quickly go to the cross-references they pick up on. It is at {M/162/11}, please, and we can start at 63. So he says:

"Next, particularly in view of the complexity of the factual circumstances at issue in the main proceedings, I would have expected the parties arguing in favour of a

restriction by object to put forward a reliable and robust wealth of experience showing that the agreements such as the MIF Agreement are commonly regarded as being inherently anticompetitive. Is there a relatively widespread and consistent practice of the European competition authorities and/or the courts of the Member States supporting the view that agreements such as that at issue are generally harmful to competition?"

So 65 at the bottom of the page.

So there is a reference to commission practice and he says:

"I would question whether that amounts to a robust and reliable wealth of experience required to support a finding that a given form of conduct is patently and generally anticompetitive."

If we then skip forward to 68, so there is a synopsis of the decision on practice such as it was and he says at 68:

"I would be cautious about coming to the conclusion that a handful of administration decisions (especially when issued by a single authority and evolving over time), which concerned familiar forms of coordination are a sufficient basis for holding that any comparable agreement can be presumed unlawful."

And then finally at 72, please, the next page:

"I am somewhat surprised that, in the submission of the parties that argue for restriction 'by object', there is no trace of studies or reports prepared by independent authors and based on methods, principles and standards recognised by the international economic community supporting their view. Indeed, whether there is a sufficient consensus among economists that agreements such as the one at issue are inherently anticompetitive would seem to me of the utmost importance. The concept of restriction of competition is, after all, mainly an economic concept."

Now, in this case we say the CMA does not rely on any body of economic evidence or experience with agreements of this type in the decision. Indeed, what we saw on cross-examination is that there was a profound disagreement between the economists. As Ms Ford pointed out, one could be forgiven for thinking the cross-examination that we were in the realms of an effects restriction given the depth and scale of the cross-examination.

Certainly Professor Valletti does not refer to any articles of empirical work in this area. Dr Bennett of course does; the *Edgeworth* papers from over a century ago. I will come back to the economic evidence in more detail.

So we say that on the critical issue under the case law as to whether there is a robust body of economic experience showing the agreement should be placed in the object box, that is sorely lacking in this case.

Now, this leads me to my final point of law, which the CMA picks up at 159 of its closing. So their fundamental point on the law is that there is a pay for delay paradigm and this case is either on all fours or they say close enough to that paradigm.

Indeed, they say that the analogy between pay for delay and the present case is, and I quote, "obvious".

Now, we say first of all the analogy is a bad one. Secondly and in any event, it does not take the CMA anywhere in this case. We say the concept of pay for delay is something unusual and sui generis. It concerns a reverse payment, the situation where the patent owner ends up paying the generic who claims it is infringing its patent. There is something unusual in the sense that it is a claimant paying a defendant, albeit of course it might be said that the defendant generic has a counterclaim.

So the direction of the payment in a pay for delay reverse payment case is odd and one can see why that calls for an explanation.

Now, this of course has been a vexing issue in

competition law. It ended up in the Supreme Court in *FTC v Actavis* where they found that the pay for delay is a rule of reason case. As we will see shortly in *Paroxetine* the Court of Justice took a slightly different view and they said that pay for delay may, and I emphasise may, be an object in certain circumstances. I will come back to that.

The key point in terms of economic experience and robustness is that there is a cottage industry of economic and other publications on pay for delay specifically and there is no analogue in the context of supply agreements as one sees in this case. So we do rely on the absence of this body of economic experience.

The critical point we say on pay for delay is actually quite a straightforward one. Most of these cases concern simply a lump sum cash payment and one can see why being paid to stay in bed may call for an explanation.

The other category of cases is where the predominant form of payment is a lump sum cash payment where there is a supply agreement, but the supply agreement has a contractual clause, typically a profit guarantee, which means that one does not regard it as a traditional supply agreement. There is effectively a mechanism within the contract or the settlement agreement whereby

the purchaser in a sense is also incentivised not to compete.

We say that is a crucial and fundamental distinction. One can see, for example, where there is a lump sum cash payment and a supply agreement, and a fortiori with this mechanism that I mentioned, that the existence offer the lump sum cash payment in a sense taints the supply agreement. If you are being paid a large sum of money for no obvious explanation and in parallel there is a supply agreement with a profit guarantee clause, one can see quite readily why that calls for an explanation and why the cash payment in effect may taint or call into question the supply agreement.

We do not have that in this case. There is only a supply agreement and we say the analogy breaks down.

The supply agreement is not paying someone not to compete. If anything, it is paying someone to compete, albeit we do not accept that it is properly characterised as a payment at all. We say it is the purchaser who is paying the supplier for the supply of the products in question.

The other important difference, we say, between pay for delay in the present case is that there is in contrast to the lack of robust economic experience with

supply agreements of this kind, there is publications procured by the Department of Health which say that cross-supply agreements in the generic sector of this kind are extremely common.

If I can quickly give you the reference. It is {M/21.1/1}, please. So this is a report by Oxera and you see it was on behalf of the Department of Health and it is from more than two decades ago.

If we can go to the next page, please, where it says the second point. It is towards the bottom "manufacturers confirmed" and so on. {M/21.1/2}.

So it is really the second half. So:

"... the 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. Without a product licence, the firm seeking supply would need another potential source of the product, or it would be unable to negotiate the best terms from a supplier... Cross supply arrangements of this sort between manufacturers are very common in the UK generics market."

This, as I said, was a report by an economic

consultancy to the Department of Health saying this was a very common feature of the market and, at least as I understand this passage, was pro-competitive in the sense that the credible threat to self-supply was being used as a way to leverage supply terms and supply contracts that would not otherwise have been forthcoming.

Now, this is why we say, sir, that the proposition put forward by the CMA, their so-called analogy with pay for delay, if it were accepted it would undermine commercial negotiations. Now, the CMA of course disavows all of this. One can see if that were true how toxic that would be, but we say their approach does give rise to this concern.

Their case on agreement of course is an inferential one. They say that if you use a credible threat of own entry to obtain better supply terms that can be seen as a form of payment by the supplier to keep you off the market. That is the transfer of value.

But the same, we submit, is true in the example you see before you, which is where someone is threatening to self-supply in an effort to obtain better commercial terms. What they are saying is: I will enter with my own product if you do not give me X terms and the supplier agrees to give the better terms on that

understanding.

Now, on the CMA's analysis the purchaser would be a potential competitor, because it has made a credible threat to enter with its own product. In a sense, the threat has to be credible. It if it lacked credibility, it would be an empty one. On the CMA's analysis the terms offered by the supplier in response to that threat are basically buying off that threat and ensuring that a new potential competitor does not enter the market.

So we do not accept the CMA's point that the example put forward here is fundamentally different from the present case. We say it is much closer to the example set out here than it is for the pay for delay analogy.

The final point I want to make on the law before we move on to the economic evidence and then on to penalty, is we say even within the narrow four walls of the pay for delay case law the case law is nowhere near as the prescriptive as the CMA would have you believe.

If we can go to *Paroxetine*, please, {M/168/17}. It is paragraph 84, please. If I can ask the tribunal to read that paragraph, please. (Pause).

THE PRESIDENT: Yes.

MR O'DONOGHUE: So it is the bit in the middle we say is important:

"After assessing its chances of success in the court

proceedings between it and [the originator], it may decide to abandon entry to the market concerned ... Such an agreement cannot, however, be considered, in all cases, to be a 'restriction by object'."

We say that has a strong parallel with the present case, the alleged 10mg agreement. As Mr Brealey showed you, AMCo certainly in 2014 was extremely concerned as to the existence of any viable market for its skinny label product and it was concerned about the ethical and reputational risks of supplying a product at that time.

As Mr Brealey showed you, most of the national pharmacies took a similar view which the CMA says is reasonable. That is his double standard point.

So, as I submitted on Friday, what AMCo did was decide to adopt a wait and see approach and in the meantime got supplies from Auden to keep its toe in the market.

We say this is consistent with what we see in paragraph 84, which is that AMCo is temporarily abandoning its immediate entry plans because of the unilateral threat it perceives at that stage to entering the market and that those acts do not necessarily entail an object restriction.

Indeed, we say it is quite difficult for the CMA to put forward a principle as broad as they do, because in

circumstances where they do not object to the written agreements, and in the case of the second written agreement there is a three-month notice period in the context of the existing purchase obligation, that is an agreement on their case where a potential competitor is at least subject to the notice period agreeing to not enter the market and they do not object to those written agreements and we say that is important. So even on their own case they cannot put forward a principle as expansive as one that any agreement whereby any potential competitor agrees for any period to wait and see or not enter the market for three months is an object restriction. The acceptance of the written agreement not being object rules out that possibility.

The final point I want to make on *paroxetine* before moving to the economics is at page 18, please, the next page. It is at paragraph 93. {M/168/18}:

"... has to be determined whether that net gain is sufficiently large actually to act as an incentive to the manufacturer concerned of generic medicines to refrain from entering the market concerned."

Here we make the point that Mr Beighton made which is, well, the measly volumes I was getting from Auden they were not in any material sense bearing on my decision to enter. My decision to enter was affected by

the wait and see approach, which was in turn conditioned by the lack of available market and ethical and reputational concerns as to entering that market at that stage. The fact is that certainly throughout the Cinven period AMCo did not have a skinny label product of its own and even if it did, it did not consider it to be a market, certainly an ethical market from its perspective from its customer base.

Now, this also highlights in my submission an important -- a further important difference between the pay for delay case law and the present case. In this case, depending whether one takes volume or value, it is common ground between 50 and 70% of the market was uncontestable to skinny label suppliers for a mixture of regulatory and ethical concerns.

In other words, there are important noneconomic reasons at play in this case that are simply not present in the pay for delay case law. This we say makes it all the more understandable that a supplier of skinny label might take a cautious approach to the question of entry.

In a patent case the issues are purely economic, can you enter either because the patent is invalid or the patent is valid, but not infringed by your product.

So, sir, that is all I want to say on the legal principles. If I can then move to the economic evidence

and then turn quickly to penalty.

THE PRESIDENT: Yes.

MR O'DONOGHUE: If we can start, sir, by looking at what the CMA says in its closings on the economic evidence. It is at {IR-L/7/83}, please. So it is 169 on to 187. I want to go through the points they make here.

The first point you see at 171 they say the *Paroxetine* case, which we have just seen, rejected the idea that supply agreements could create meaningful competition.

We say this is plainly wrong. The Court of Justice certainly was not saying that all supply agreements never create competition. This was of course a preliminary ruling to the Court of Justice. It was concerned with questions of law. The Court of Justice was not making any question of fact or economic appreciation that supply agreements can never generate competition. In that case, the factual matrix was very different and we say rather extreme. It was a case again involving substantial lump sum cash payments and, to the extent they were supply agreements, they were supply agreements that contained contractual mechanisms such as profit guarantee clauses, which in effect ensured the generic was disincentivised from competing. So that was the context in which the Court of

Justice said what it said, but in any event to use that as a cantilever to say well, therefore, all supply agreements of any fixed quantity can never generate competition. The Court of Justice did not say that and it would never have said that given the context. That we say does not get them anywhere.

The second point, paragraph 172, bottom of the page, and then over the page to 173, if I can ask the tribunal to read that. The basic point made here is, well, prices did not fall during the agreement. (Pause).

If we can go over the page to 173. There are a number of points we make in response. First, the point developed by Mr Brealey and Ms Ford, which is the comparison between the agreement and a situation involving a single generic entrant of a skinny label product. We say that in substance those two situations in terms of their impact on competition and prices are materially the same. This is the death spiral point, which is that a skinny label generic entrant, acting rationally without colluding, would not be strongly incentivised to engage in a race to the bottom for fear of shooting itself in the foot.

THE PRESIDENT: That would inevitably entail unilaterally limiting supply.

MR O'DONOGHUE: Yes. But the point is that that would be

rational in unilateral terms. Therefore, it adds nothing to the situation under the agreement or at least that is the submission we make.

THE PRESIDENT: No, I understand. But the only way you can avoid a race to the bottom is by trying to gauge what will prevent an aggressive cutting of prices by the incumbent.

MR O'DONOGHUE: Yes.

THE PRESIDENT: Presumably the reason it breaks down when you have got more players coming in is because it is rather harder to predict what they will do when you are setting your levels for supply and so you go for as much as you can get.

MR O'DONOGHUE: Yes, it becomes like Whac-A-Mole. The threats pop up everywhere and, therefore, you are better off getting into the spiral than standing on the sidelines and getting massacred.

THE PRESIDENT: Yes.

MR O'DONOGHUE: As Mr Brealey showed you, in a sense this is not in serious dispute, because the decision itself contrasts two phases of generic entry. The first phase where there is a single entrant who is strongly incentivised to be tethered very closely to the incumbent and they say that the intensification of competition only arises at the stage of multiple entry.

Indeed, we see this very clearly in this case. At the stage Alissa entered in early 2016, there was strong price stability and it is only when one gets into 2, 3, 4, 5, 6, 7, 8 skinny label entrants that the death spiral commences in earnest. So we say based on the decision this really ought to be common ground.

Now, just to pick up a couple of other points. There is a criticism of Dr Bennett's evidence here. Can we go our closings, please. It is at {IR-L/3.1/145}, please. It is at 258. The first point is it is a bit rich, we say, to say, well, you have not shown that the agreement caused prices to fall or at least not to rise as much as they might otherwise have done, but 85% of supplies in this market were, in the CMA's findings, wrapped up in abusive unilateral and excessive pricing and on some level one needs to disentangle that from the agreement or at least if one is making a strong criticism of the effect of the agreement on pricing, to ignore this rather large elephant in the room, we say, is not correct. That is the point made in 1.

Then the second point, this is the point I put to Professor Valletti, that his approach was to have a guillotine starting in October 2008; whereas if one even went back a short distance in terms of the pre-October 2008 data, which we say you should, because

this is before the allegedly infringing conduct, in fact, the conclusion is the opposite. I do not think -- we will see what the CMA says -- but I do not think Professor Valletti actually disagreed with that when it was put to him.

The final point is it is also incorrect, we say, to say that, certainly with a single generic entrant in the form of Alissa, that prices fell dramatically with competition. If I can just quickly give you one reference. It is {IR-H/868/3}, please. You will see, sir, in the top left "Price rise". So this is Auden/Actavis:

"Price rise Q4, 15 following tariff increase, and again Q1 2016."

So Alissa, as we know, entered in Q4 2015 and we see Auden saying here for that quarter and into early 2016 our prices are going up. So, in fact, it is not correct to say that as soon as one got even a single skinny entrant the prices went down. They went up.

The next point if we go back to the CMA's closings, please, {IR-L/7/175}, this says:

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

But we say that attacks a strawman. This is

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

The critical insight we say is that in a situation where AMCo has -- so 12,000 packs is about 16% of the total market and we say in that situation, obviously, they are incentivised to sell their quantities as much as they can and the fact that Auden is selling a bit less than it might otherwise does not tell you anything about whether there is a competition. Again, we say that AMCo has to persuade customers to switch from Auden and it has done that by offering a discount, albeit a small one.

The fourth point is at 176/177 over the page, please. This is a very basic but very compelling point:

"That it only makes sense for any sense for each party to enter into the Agreement if doing so will increase that party's profits relative to the independent entry counterfactual."

I would ask you to note the repeated reference to "counterfactual".

But we say this collapses into the point I have just been making under the third point, which is there is no material difference between a world under a supply

agreement with, say, 16% of market volume and a single skinny label entrant, such as Alissa, that equally would not wish to engage in a death spiral.

What Professor Valletti is saying implicitly is that he says there is a disconnect between volumes and prices such that more volumes does not really result in lower prices. But that disconnect, at least in law, can only exist if there is some form of coordination between Auden and AMCo. A point I repeatedly put to Professor Valletti is that he accept in the joint expert statement and when questioned that is there is no finding of explicit or tacit coordination in this case. So what Professor Valletti's very basic, but very compelling point amounts to is saying, well, unilaterally and acting rationally AMCo and/or a single skinny label entrant such as Alissa would have rational incentives to behave in a certain way and not enter into the death spiral. But that has nothing to do with the alleged 10mg agreement and, similarly, would be equally true in the case of independent entry. So we say this does not take him anywhere. It is essentially a bootstraps point. If you exclude any form of coordination, there is some sort of third way whereby AMCo is incentivised not to compete.

We say that is indistinguishable from the

independent entry scenario.

Now, we also make the points, and I put these to Professor Valletti very squarely and I do not think he fundamentally disagreed, this is Ms Ford's point, which is in a world where Auden is losing these volumes in any event, if it can make a profitable wholesale margin, that is a rational thing to do on its own terms and provides an explanation for both the supply price and why Auden would do this and in that situation consumers would benefit.

Equally, the asymmetric information point, I think Professor Valletti agreed, we will see what the CMA says, that if Auden essentially misjudges the amount that AMCo could enter with independently, it may be willing to effectively over supply under a supply agreement in the context of that asymmetric understanding.

Again, the crucial point that makes consumers better off because they get greater quantities in the factual compared to the counterfactual.

The fifth point is at 179. So the point being made here, as I understand it, well, AMCo competing is irrational once it has received what is pejoratively called a value transfer from Auden.

We say, again, that this is in a sense a sleight of

hand. If one looks at 180, it says, second line:

"If Auden does not compete over volumes then prices will remain at the monopoly level ..."

So the implicit assumption in this is that neither AMCo nor Auden are competing in any way and, in particular, that AMCo is not prepared to offer a discount to win sales from Auden.

But this is essentially a bootstraps point because there is an implicit assumption of some form of coordination when at the same time the CMA has expressly accepted that there is no explicit or tacit coordination in this case.

Again, I come back to the point, if all that is being said here is that AMCo, having received those quantities, is unilaterally not incentivised to start a death spiral, we say, well, so what? The same is true of independent entry and, in any event, that has nothing to do with the agreement.

We make two points here. This really is the answer to all of the CMA's points. Either that is not an agreement at all, and that would be my primary submission, because all they are doing is perceiving there may be unilateral incentives on the part of AMCo and that has nothing to do with the agreement, but, in any event, if the gravamen is, well, we are comparing

factual incentives versus counterfactuals incentives, we say that is clearly an effects case that it not on object analysis.

The sixth point at 182, please, the next page, {IR-L/7/85}:

"It is also important to step back and to ask why, if Auden were going to compete with AMCo over sales, the parties would have entered the Agreement in the first place."

That is a rehash of the two points we have just seen. It is an implicit assumption that the agreement is only rational if it is anti-competitive and my response to that is the same as the one I have just given.

So, sir, that is all I wanted to say on the object. If I can then move to penalty and I may have time to sweep up on a handful of shorter points.

THE PRESIDENT: Of course.

MR O'DONOGHUE: Sir, on penalty we obviously do not intend to go through every twist and turn we have set out in writing. I am also not proposing to say anything on the law of penalty. Ms Ford and Mr Jowell developed that extremely well, if I may say so, and of course the tribunal will know the law backwards on this.

In terms of context on the Cinven penalty

specifically, so the total fine is 35.1 million and, like Mr Jowell's client, the vast majority of that fine was arrived at through a substantial uplift in stage 4 on the question of specific deterrence. It was an increase of more than 300%. I think starting at 8.8 million ending up in step 4 35.1 million. So it is essentially the same point as Mr Jowell's client, albeit we can all agree that 1,000% is bigger than 300%.

Now, the second thing, again, similar to Mr Jowell and some of the other parties, Cinven has been fined solely in its capacity as a former parent of AMCo and there is one important wrinkle here. Originally in the supplement statement of objections the CMA did make a proposed finding that the Cinven parent were aware of the 10mg agreement and they resolved to bring it to an end. There was a criticism to that extent. That criticism, if it ever were criticism, does not reappear in the decision. So there is no allegation that Cinven had any direct awareness of the 10mg agreement, nor that it should have intervened to stop it and the liability is purely vicarious because of decisive influence over AMCo for the period in question.

So that is the sort of the basic context. Now, in terms of penalty there are a handful of points I want to develop today. First, on the threshold question of

intentional negligence. Obviously, if there is no intentional negligent infringement, there cannot be a penalty, but, equally, of course it is possible that an infringement was committed negligently but not intentionally and we would say that, all else equal, an infringement which is negligent as opposed to negligent and intentional is less serious than one -- is a less serious form of infringement.

The CMA does make the legal point, which is correct, well, we do not have to disentangle whether it is intention or negligence and that is true as far as it goes, but I am making a different point which is in a universe where the infringement is simply negligent, that is all else equal, unless a serious type of infringement to one which is also intentional.

THE PRESIDENT: What you are saying is that the gateway by which one triggers the penalty jurisdiction needs to be regarded differently as to the amount of the penalty that one is imposing, so you may, because the gateway is intention/negligence, say, well, it does not matter provided it is one or the other.

MR O'DONOGHUE: Yes.

THE PRESIDENT: The gateway is passed, but you are saying that may be right but --

MR O'DONOGHUE: But there is a difference.

THE PRESIDENT: But when you are looking at pounds, shillings and pence, it is a different question.

MR O'DONOGHUE: Yes, and in civil law fraud is more serious than negligence and so on.

The reason I make this point, sir, of course, as you will have apprehended, is the legal advice from Pinsent Masons. As we saw on Friday, I took you through this with some care, at all stages, well, if one winds back to 2013, there was the company-wide competition audit. They then lasered in on a number of agreements, including hydrocortisone, and we saw from Mr Sully in particular that he was at each stage obtaining prior approval, keeping Pinsents in the loop. We saw Pinsents on 6 June 2014 sitting in the room in the fulcrum of the negotiations and then final approval at each stage on the written agreements obtained from Pinsents. There was the email saying "Good to go".

This was not simply a clerical exercise. There was also specific legal advice sought on the question of would Auden and AMCo be regarded as actual or potential competitors? We saw the advice that was given was because of the orphan designation they would not be considered actual or potential competitors. So at all stages careful legal advice was sought and was followed and acted upon and we say this at the very -- we say to

say that a firm having sought that advice and acted on it was negligent, we say is a stretch. At the very least, it cannot be said that a firm that seeks such advice and follows it carefully and only enters into the agreements after having obtained the green light was acting intentionally. It knew it was infringing competition law. We say that is not fair.

Now, the CMA's response to that is essentially a legal one, which is the *Schenker* case. This is the Court of Justice judgment. I do not think we need to turn it up. It is at {M/98/1}. I can talk the tribunal through the essential difference. So the CMA's response is to say, well, in law the fact you got, as it turns out, incorrect legal advice is irrelevant to the question of intentional negligence as a threshold question for the purposes of penalty.

We say in response *Schenker* is dealing with something rather different. In that case the Austrian freight forwarders they formed a horizontal cartel and there was no doubt that it was a cartel, somewhat unusually it was a contractually agreed cartel. But the only issue in which they sought legal advice was not well, is this a cartel? The question was if this is a cartel, does it benefit from it in an exception under domestic law concerning de minimis horizontal

agreements? They did receive incorrect advice that it could be a de minimis form of horizontal agreement. That advice turned out to be wrong, not least because it disregarded completely the question of EU competition law.

So we say understandably in that context the Court of Justice said that the incorrect advice under domestic law did not have the consequence that the infringement was not committed intentionally or negligently for the purpose of penalties. In other words, we say the Court of Justice held that it was irrelevant if you wrongly categorise something that is obviously anti-competitive in nature as lawful, even if you did so on the advice of a lawyer.

The court of Justice said the only question is: did you know that what you were doing was anti-competitive in nature? Which we say plainly they did, since, again, the only question on which they sought legal advice was whether there was a get out of jail free card, not on whether there was a cartel in the first place?

In our case, we say the situation is different, because the legal advice that AMCo was seeking went precisely to the question of whether they were doing something anti-competitive in nature in the first place. That was the question that Pinsents were asked in 2013,

2014 in the context of the written agreements in particular. They were basically asked: are our supply agreements with Auden problematic from a competitive law perspective?

For those reasons we say the CMA is wrong to suggest that the legal advice in this case is irrelevant. We say it is highly relevant and it goes precisely to show that AMCo did not and indeed ought not to have known that their conduct was anti-competitive in nature.

So that is the first point on intentional negligence. Sir, you will appreciate of course even if I am wrong at the threshold level, that the question of legal advice may come back in, for example, as a mitigating circumstance. So I am hedging my bets on some of these points for reasons you will understand.

The second point we make on the threshold question is to pick up on the point that Ms Ford touched upon, which is at the very least I think we can all agree there is a high degree of novelty both about the original pay for delay infringement itself and of course we say, following on from the points I made on object, in particular whether one can have an analogy which says that the pay for delay principles apply where there is a supply agreement and nothing else. So we say that would be, at the very least, a quantum leap in the

development of the case law and certainly was not something that could have been apprehended at the time.

Of course, this also ties back to the lack -- to the legal advice because the question of what is a potential competitor was one of the questions referred to the Court of Justice in *Paroxetine* many, many years after Pinsents had given their advice and the law in my submission (a) was unclear, hence the reference, but (b) has changed in a material way. So when Pinsents were advising in 2013 and 2014 on the question of what is a potential competitor, it was under a very different matrix or context or lens than the Court of Justice subsequently clarified in *Paroxetine*.

Finally, on this threshold question, we do come back to the point I made in the context of ground 1, which is there remains a lack of clarity in the CMA's case in terms of what constitutes the offending 10mg agreement and, in particular, how it differs from the written agreements which they do not object to. But we say that is also relevant to the question of penalty and that the point we say is this: in circumstances where the CMA cannot even now explain what it is that constitutes the 10mg agreement, how can AMCo be said to have entered into that agreement intentionally or negligently?

One final point in terms of linkage between the

threshold question and step 3. As we shall see, Cinven also got an increase of I think 15% for director involvement and in circumstances where AMCo took legal advice which was then presented to the board, and sought to be transparent and inculcate a culture of competition or compliance, we say that aggravation is also unjustified and that is also relevant in if context of intention or negligence. So that is on the threshold question.

The next point is on the starting point. Step 1, as Mr Jowell showed you, the CMA went for the maximum percentage. 30% is the starting point, the highest possible one, and you have Mr Jowell's point, well, that is reserved for horizontal cartels of the most serious kind and we gratefully adopt those submissions and those of Ms Ford.

The one point I want to develop in this context is a separate one, which is the basis on which the CMA in the context of Cinven sought to justify this starting point. If we can go to the decision. It is at {IR-A/12/1027}, please, it is at 10.172. So here the CMA is setting out its assessment of the seriousness of all of the infringements and then in the subparagraphs it goes through a variety of factors that go to seriousness. We will go through them, but the reality,

as we should quickly see, that pervades all of these subparagraphs is the suggestion that the infringements have led to increased prices.

If we look, for example, under (b), third sentence, it refers to the "price increases for hydrocortisone tablets", which it says would have caused CCGs to reallocate funding and then over the page, please, at (c), {IR-A/12/1028}. So there is a reference there to the fact that Auden could not "increase and maintain prices of hydrocortisone tablets at very high levels".

Then at the bottom of the paragraph you will see:

"The agreements had the object of delaying the emergence of effective competition ... thereby enabling Auden to sustain ... abusively high prices."

And then (d) those high prices increased costs to the National Health Service and, ultimately, the taxpayer.

So it is all about price increases and harm to the NHS. That is the gravamen being said to justify the starting point of 30% in this case.

Now, the first response to that is the one I have made about ten minutes ago, which is, hang on, 85% of market volumes were Auden and the CMA found that those were priced at unlawfully high and excessive levels. So we say that is the predominant effect and one has to

look at the agreement, at least as a starting point in that context.

Second, and this is -- I keep coming back to this point, but there is no reason to think that the 10mg agreement led to higher prices when compared to a single generic entrant of skinny label product. Again, that is the death spiral point. Again, this ought to be common ground. The CMA itself finds that a single entrant will not engage in a death spiral. It is only at the multi-entry stage that one gets the death spiral.

Now, if we go back to the CMA's -- we do not need to open it. They do not fundamentally disagree with this at least at the penalty stage. Their point is a slightly different one. They say, well, there is no requirement at the penalty stage that prices must be greater in the counterfactual than in the factual and that what the appellants are trying to do here is import a sort of improper effects-based analysis through the back door. That is at paragraph 365.

That we say misunderstands the point we are making. The point is, as we have seen, it is the CMA that positively relies on the pricing impact that the 10mg agreement allegedly had in order to justify the starting point that they put forward. So that is its positive justification for imposing the highest possible starting

point.

What we are saying is that the positive justification the CMA has advanced in this case, again, based on the decisions on findings, does not actually work.

The third point is on the question of mitigation and we say in this context the CMA has made a serious error in failing to make any allowance for the fact that, even on its own findings, regulatory intervention has severely distorted the market. What I am referring of course is to the orphan designation issue and the fall out from that and how that affected the attitudes of suppliers, amongst others, in the supply chain.

The orphan designation obviously bites in two distinct a ways. First, it created a specific lengthier monopoly for Plenadren. That is the whole point of the orphan designation. Second, and in part to protect the original orphan designation grant, the orphan designation also led the MHRA to refuse to grant any new full label indications after a certain date.

Now, that of course is described in the decision as "a windfall" or "a quirk" of the regulatory system and, in a sense, we say that is not true since there was a good reason not to allow other full label MAs so as to shore up the original orphan designation. In a sense,

that was not an entirely unintended consequence of the regulatory system.

But, in any event, the bottom line we say is clear. On the CMA's own findings, between 50 and 70% of the customer base, depending on whether it is volume or value, was uncontestable to skinny label products, essentially because the national pharmacy chains basically refused to buy skinny label, except in de minimis child prescription quantities, and instead they only or overwhelmingly bought full label.

So the orphan designation, and its direct and indirect effects in the market, they have distorted competition to a very, very significant extent in this case. Indeed, this case almost certainly would never have happened, but for the orphan designation issues.

Now, we have set out in our closings there are quite a number of cases finding that where regulation distorts competition that has to be taken into account when it comes to penalty and we have given references, for example, to the *Spanish Raw Tobacco* case. There is a French beef case, but there are a quite a number of cases.

The CMA says they can be distinguished, because in those cases the regulatory framework contributed to a situation in which anti-competitive conduct occurred.

That is at, for example, 487 of their defence. We say that is a bad point. To coin the president's phrase, it is another distinction without a difference. Because, on any view, the skinny label nature of AMCo's product was a large part of the reason why it took supplies from Auden. We see time and time again they say the reason that even if we had a product, which they did not, that they could not at that stage enter the market was because of the orphan designation issues and it is Mr Beighton's point that some people may well, and some people did, take a slightly different or more less risk-averse view to these regulatory and ethical issues, but AMCo was not prepared to do that. As Mr Brealey says, well, if that is sauce for the goose, when it comes to the national pharmacies and it is reasonable in that context, why isn't that sauce for the gander when it comes to AMCo?

AMCo genuinely did not think it had customer demand for its product, which to a very substantial extent turns out to be true even today. Indeed, they subsequently exited the market.

AMCo's feedback and customer perceptions to skinny label product for many years prior to its actual entry was an important part of the story. Of course, it is only half the story. The other half being the issues we

looked at with Aesica.

So, in my submission, it is a very basic point, even if there is an object restriction, an object restriction that by definition cannot affect between 50 and 70% of the market cannot sensibly be compared to one that necessarily affects 100% of the market.

It is staggering, the decision, despite being writ large with all things orphan designation and incontestable and captive customers, when it comes to penalty takes no account of this critical factor.

Two final points on penalty. So we are now on to step 4, which is specific deterrence. As I mentioned at the outset of my penalty submissions, we are taking of appear increase of, I think, more than 300% and this is being imposed at two stages, general and specific deterrence, and I want to make two points in relation to that.

The first component of the specific deterrence increase imposed on the Cinven appellants is at the end of stage 3, so that takes the fine from 8.7 million to 14.6 million. If we go to the decision at {IR-A/12/1080}, please. It is the bottom 10.335. You see that the CMA is talking about the financial benefits generated by the undertakings involved in the infringement.

We then go over the page to the table, please, {IR-A/12/1081} 10.12. So the CMA there has estimated the financial benefit which accrued to the Cinven entities and Amdipharm companies together for the second period 2, D2. So the D2 period is the Cinven period. That was estimated 14.2 million.

Then if we scroll down to at the bottom of the page, 10.337. This is said to be the estimate of the financial benefit reflecting the amount that the CMA has found that Auden paid AMCo during that period. So that is how they have approached the question: what is the effect of payment to AMCo?

In my submission, that is a category error, because the amount paid by Auden to AMCo, as the CMA puts it, that does not represent the true financial benefit that AMCo gained by entering into the agreement. When it comes to fines, the CMA wrongly assumes that AMCo would not have entered the market with its own product, despite the entire predicate of its case on the agreement being that AMCo had agreed not to enter with what would otherwise have been a skinny label product that could have been supplied.

Now, given the CMA's primary finding that the gravamen is the agreement not to enter, in my submission, the financial benefit of the 10mg agreement

can only be assessed by comparing AMCo's actual profits to the profits that it would have made in the absence of the agreement. That, we say, is a tiny or immaterial difference and that is the point I keep making about the situation under the agreement with a single generic supplier being indistinguishable from a single independent generic entrant not willing to engage in the death spiral.

So we say that the basic comparison the CMA has made is the wrong one. They should not be looking at the payment. They should be looking at the difference between entering and not entering.

Finally, then on penalty, so this relates to the second stage of the specific deterrence uplift. So the fine goes at the end of step 3 from 14.6 million to 30.5 million at the end of step 4. That is a massive increase and, in my submission, it is wholly unwarranted and disproportionate.

The starting point I make here is very similar to the one very ably made by Mr Jowell on behalf of Allergan on Thursday in regard to their increase and he made the point, well, Allergan qua parent did not participate directly with the infringement liable on his parent and I gratefully adopt what Mr Jowell says about that.

Transposing that to Cinven situation, Cinven of course is also liable only in a parental capacity. The only conduit between AMCo as a subsidiary and the Cinven parent was of course the AMCo board. As we saw on some of the documents I showed you on Friday, the board minutes disclose no evidence that Cinven, or indeed anyone else attending the board meeting, knew or should have known that an illegal agreement was being concluded and implemented.

Indeed, they were being told the opposite consistently. They were being reassured that AMCo was seeking external legal advice on the lawfulness of the supply agreements with Auden and if it transpires the written contracts were therefore a sham, and that there was some unlawful side agreement, it certainly was not something that Cinven knew anything about.

It was being consistently informed about genuine arrangements, written contracts approved in advance by external specialist lawyers.

We say in that situation it really does not make any sense to talk about specific deterrence. If Cinven did not do anything wrong apart from own a company for a small handful of years, in what sense is the CMA seeking to deter Cinven? To borrow a public law phrase, in my submission there is no rational connection between

the objective here, specific deterrence, and the action the CMA has taken imposing a huge uplift on a company that participated only as a parent and had no direct culpability.

So that is the central point we make on specific deterrence.

We have also made the point in our written submissions the CMA we say has misdirected itself by reference to the penalty guidance. They in imposing the specific deterrence increase, and particularly on the question of benefit, they refer expressly to the 2021 penalty guidance. That of course did not apply in our case. We were applying the 2018 penalty guidance. That is in 302 and 303 of our written closings.

I have come in under budget. I might with your permission, sir, go back for ten minutes to one or two points on market definition and then I have a couple of effectively housekeeping points before I handover to Mr Palmer, but I should be done in no more than 15 minutes.

THE PRESIDENT: Very good.

MR O'DONOGHUE: Sir, on market definition, what I want to do is put my cards on the table as to where we differ from the CMA so that they can respond in their oral submissions rather than tilting at various windmills.

If we can go to the CMA's closings, please. It is {IR-L/7/99}. It is 225. Before I go to the individual reasons, so the first striking thing about the CMA's closing on the market definition is they basically only make two points. They attack the SSNIP analysis, which I will come to, and they say something about the indirect effect, which we can pick up once Dr Bennett's note I think is in today.

What they do not address in any shape or form are the detailed points I put to Professor Valletti on the cellophane fallacy, the question of one way migration of customers. So the core of the points we make has simply been glossed over in their written closings, but I want to pick up what they do say.

The first point they make at 225 is, well, we do not have to do what they call a formal SSNIP. If we can go to our closings at {IR-L/3.1/110}, we say that really attacks a rather large strawman. So it is at 203.

We say fine. In a case where you do not have pricing data, it may not be possible to do a SSNIP. We understand that. We say, well, in two-sided markets the price on one side may be free so you cannot do a SSNIP:

"But in this case, pricing data are readily available and, as noted, the CMA did conduct a SSNIP in

relation to Plenadren. Accordingly, the real issue is where a SSNIP is possible and is correctly specified, would it be correct to completely ignore the fact that a SSNIP would be profitable when it comes to market definition?"

We say the answer to that question has been an emphatic no.

We make two points. One, the CMA's own guidance says we would usually do this and, therefore, it is -- if not the gold standard at least a pretty good place to start. Then there is the *Burgess* case and the tribunal says and I quote:

"In terms of a conventional SSNIP test, even a price increase by firm A of around 10% of weighted average price increase on competitors, which yields no evidence are of switching way from firm A, would normally be regarded as a strong indication that firm A is able to exercise market power without significant competitive constraint."

We say well Professor Valletti at least in principle accepted this.

So we say the point that, well, you are not obliged in each and every case to do a formal SSNIP is no answer to the question in this case.

The second point if we go back to the CMA's

closings, please, {IR-L/7/100} 226(b). It says Professor Valletti, no one has done this assessment, let alone Dr Bennett.

So they are saying no one has done a SSNIP. With respect, that is simply wrong. As I put to Professor Valletti at some length, based on the CMA's own benchmark for competitive pricing for a 10mg product, it is clear that the SSNIP test is passed with flying colours and those were the only numbers that Dr Bennett used in his SSNIP analysis and if the CMA disputes those results, it is inevitably saying that its sole benchmark in the context of the unfair pricing case is wrong. We presume the CMA is not saying that, but if that is right, it cannot have it both ways and say, when it comes to market definition, its own benchmark for a competitive 10mg full label price is not after all a competitive benchmark at all.

For the same reason, the point made in 226(a) to the extent I even understand it does not take them anywhere.

Then, sir, under (c) you will see they say:

"The purported SSNIP assessment and critical loss analysis that was carried but Dr Bennett has been the subject of serious criticisms."

There are two points to be made here. First of all, this is not a criticism of Dr Bennett's SSNIP analysis.

It is really addressed to his second quantitative analysis which is the critical loss analysis. On the SSNIP analysis our point is the point we have just made which is that he has relied on their competitive pricing benchmarks to perform a SSNIP test and based on those benchmarks the SSNIP test has passed with flying colours. So in our submission there has been no serious criticism of his SSNIP analysis.

It is true to say there has been criticism of his critical loss analysis which is a second quantitative analysis he has done. But if one goes to his second report. It is at {IR-D3/2/4}, please, it is under paragraph 7. So here Dr Bennett in his second report is responding directly to the so-called serious criticisms. If we can go over the page, please. Sorry, if we go back to the previous page, my fault. It is at the end of paragraph 7:

"... I show that neither critique after my conclusion -- in fact, with respect to the first critique, taking Professor Valletti's implied suggestion of using later periods with relative prices greater than 1 only strengthens my conclusion."

In response to the serious criticisms Dr Bennett has a full section in his second report responding to those directly, and he says not only does this not help the

CMA but it actually strengthens my conclusion.

Dr Bennett was not cross-examined on any of this and we say it is not good enough to sidle up in closings and say, we have made these criticisms, not put them to Dr Bennett and pretended we have not responded. It is not good enough.

Then if we go back to the CMA's closings, {IR-L/7/101} 226(d), please. This is the point the CMA keeps coming back to, which is to say, what I call the John McEnroe point: you cannot be serious. They say we have had 50% switching, we have had these substantial price falls, does that not tell you everything you need to know?

Now, that has been dealt with at some length by Mr Brealey in particular, but we would make two points. One, effectively the only switching we see is at peak cellophane fallacy and the CMA has ignored that point completely in its written closings, and we will be curious to see what they say in their oral closings. You cannot just bury your head in the sand on the cellophane fallacy in a case like this.

Secondly, we say the point is quite straightforward. What one sees is initial bout of switching. Fine. But for the entirety of the post-entry period and indeed for several years after that you have essentially got

a calcification in the market that despite these enormous price differences between full and skinny label up to 500% for most of the post-entry period one still sees effectively no switching from full to skinny. We say that sticks out like a sore thumb and it really copper fastens the point that these markets were bifurcated and captivate and incontestable.

There is a very simple solution, if you were one of the national pharmacy chains who almost exclusively buys full label there is essentially no universe in which you would switch to skinny. Likewise if you were a skinny label independent pharmacy purchaser, the price of full is so many multiples above the price of skinny that it is a practical irrelevance to you. We say once those two pennies drop the idea that full is constrained by skinny is for the birds.

Those are my submissions. I have a couple of effectively housekeeping points.

THE PRESIDENT: Yes, indeed.

MR O'DONOGHUE: First of all, the response to the CMA's note on 12 December on the drug tariff and indirect constraint I think is going in as we speak to ensure the CMA has time to deal with this in closings if it wishes to.

THE PRESIDENT: That is very helpful.

MR O'DONOGHUE: We can actually hand up copies now. It is being uploaded to Opus but I have hard copies available (Handed)

The final point, this was buried in a footnote in our closings, but I want to make sure it is all above board. You may recall that Professor Valletti said in evidence that he was the subject of some online criticism or abuse, I think he said by one of the experts in this case in response to a question I posed.

THE PRESIDENT: I do not recall that. I recall the communications or tweets being put to the professor but I cannot recollect that.

MR O'DONOGHUE: He did say in response that he himself had been subject to some abuse by one of the experts in this case.

THE PRESIDENT: I see.

MR O'DONOGHUE: I do wish to make clear that was not Dr Bennett. It is obviously this is made very clear from Dr Bennett's perspective. I just want to make sure that is on the record loud and clear.

THE PRESIDENT: That is helpful. I take it it was not one of the other experts either.

MR O'DONOGHUE: I do not know.

THE PRESIDENT: We are going to proceed on the basis it was not. We are not particularly sure where it goes.

MR O'DONOGHUE: Indeed but I think Professor Valletti did say it was.

THE PRESIDENT: Did he?

MR HOLMES: Sir, I think Professor Valletti made a flippant observation about his having been described as Professor Tomato Spaghetti in jest. I do not think this goes anywhere at all, sir. I think it would be sensible to focus on the substance, rather than on any of these flimflam.

MR O'DONOGHUE: Dr Bennett has asked me to make this clarification and for his reputation and as a point of decency I think it is a clarification which he is entitled to make.

THE PRESIDENT: Of course, Mr O'Donoghue, that is absolutely right, but I had not understood Professor Valletti to be making any aspersions against any of the experts. So just so that the other counsel and the other experts are aware, we are not going to be coming close to making any statements on this subject and we will certainly not, without putting it extremely clearly to the team involved, be making any ad hominem points regarding the experts.

MR O'DONOGHUE: Sir, thank you.

THE PRESIDENT: Mr Palmer, would that be a convenient moment or?

MR PALMER: Yes.

THE PRESIDENT: We will rise then and resume in 10 minutes at five and 20 past. Thank you very much.

(11.16 am)

(A short break)

(11.25 am)

Closing submissions by MR PALMER

THE PRESIDENT: Mr Palmer, good morning.

MR PALMER: Sir, I am grateful. By way of introduction, may I say this: I adopt the submissions made by Ms Ford and Mr Jowell so far as material to Intas and I will endeavour not to repeat those points. Obviously, if there was no dominance or dominance was lost at some time before the Intas period or if there was no abuse or the abuse ceased some time before the Intas period, then the conclusion follows for the Intas period.

My submissions must proceed in the alternative, if to have any relevance at all, and so I shall assume that at least at some point before the Intas period Accord was dominant and was pricing excessively, but that is of course not an acceptance of those points or a concession and nothing that I say throughout my submissions should be taken as implicitly suggesting that. It is just that unless I adopt that premise, there is no point in my being here at all. So that is what I am going to do.

I am not going to deal with every point set out in our written closing submissions orally. I cannot. Obviously, the fact that I do not mention something orally does not mean that I do not place emphasis on it and because of the constraints on my time and the fact that that still leaves me with quite a lot to deal with, there will be times when I give you the document references without necessarily calling it up for the benefit of the transcript, but of course if I do that, and there is a document which the Tribunal would like to be reminded of or see again on the screen, you will no doubt tell me, but, otherwise, I will just give you the references so that you are able to look back at the appropriate time, should you consider that helpful.

THE PRESIDENT: Mr Palmer, you can take it that we will be reviewing the entire record when we consider what decision to hand down so references are very helpful.

MR PALMER: I am very grateful for that.

I have five main topics. The first is need to analyse the Intas period, then dominance, then abuse, then legal certainty for a brief word and then penalties. So that is the structure I am going to follow.

So starting with the significance of the Intas period and the need to analyse it separately.

As has been apparent, my focus is on the Intas period and the submission that if there was prior dominance or abuse that was no longer true by that time. It is important to identify from the outset why it is legitimate to focus on the Intas period in that way. The first is trite, if I may respectfully say so. That was your word in fact, Mr President, but critically important it is that markets can change and dominance can be lost. The case advanced is that even if it was not lost earlier, it was lost by the time of the Intas period or, alternatively, during it.

There is no need to go to *Streetmap* at paragraph 91, Mr Justice Roth's clear explanation of that fact that dominance can be lost over time. The reference, should the tribunal want it, is {M/118/25}. Equally, prices that were excessive can cease to be so as they drop or as the market context in which they are set changes.

Equally, what an undertaking knew or ought to have known about its conduct can change as the market context in which its conduct takes place changes. None of those are static concepts and this is a case where we say the relevant market did change fundamentally. Indeed, that seems now to be common ground.

THE PRESIDENT: Mr Palmer, just to put it in its absolutely most basic terms, because I think it would assist in

working out exactly where the battle lines are drawn, the implication of these changes in combination with the transitional change of ownership over time means, I think according to your case, that there is effectively a hard reset on the transition to Intas's ownership with the result that one has got to re-examine all of these questions, dominance, abuse, knowledge, including knowledge for purposes of penalty, in a manner that one would not have to do if one had the same market changes over time, but a consistent form of ownership. In other words, as I think I put to Professor Valletti, there is a -- well, one does not want do say it is completely peculiar, because changes in ownership occur, but in this case it is particularly stark because one has got what are said to be quite significant market changes, dominance and abuse, and at, unfortunately perhaps, roughly the same sort of time, some quite significant ownership changes.

Really I just want to understand that that is your starting point, that effectively the clock is reset. It is a hard reset.

MR PALMER: That is broadly right. I would add one qualification. It is no part of our submission, and never has been, despite the caricature of our points by the CMA in every response they have given so far, it is

no part of our case that the mere fact of a change of ownership in itself affects the dominance analysis.

THE PRESIDENT: No, I am not suggesting that.

MR PALMER: I do not suggest because of a change of ownership that triggers in itself a need for a new bottom up dominance assessment for that reason alone. What we do say, and this is the second limb of why it is important to focus on the Intas period separately so far as Intas's appeal is concerned, is that when it comes, and if and when it comes to penalty, it is necessary to distinguish that period, given that Intas is only responsible for the conduct of its subsidiary during that period and the principle that penalty must be specific to the offender and the offence. Those are principles laid down in this *Areva* case. I will give you the reference again. It is paragraphs 126-127. I think it is common ground, I think, to that extent. The reference is {M/104/24} and also paragraph 133 at page 25. That is a principle that the CMA ostensibly accepts, but, as I will develop later, fails to apply.

But it is because of that change in legal ownership and change of attribute of responsibility, sir, that if I have understood your point correctly, that point is crystallised in fairly hard form.

THE PRESIDENT: Yes, I mean, just to be absolutely clear,

and I am really doing it so the CMA can push back on what I understand the points to be genuinely in issue. If one had a situation where the graph was not a mountainous climb of prices, but one had basically a flat line of prices which was unequivocally excessive, and there was simply a change of ownership, the question would be extremely straightforward. You would say, let us look at what the test for excessive pricing is, there is a change of ownership, but it does not actually matter because there has been no other material change.

The point that you have got is that there is, you say, a change in the market. Now, that may be the case, that may not be. We will look at that. But you say there is a change. The gradient is going down. There is more competition. There is unrelated to that a change in ownership and the temporal coincidence of those two things is something that you say matters.

MR PALMER: Yes.

THE PRESIDENT: Yes.

MR PALMER: We say we come on to the scene after that critical change so that our period falls entirely after that event and changes the characterisation. That is going to form a centre piece of my submissions, so I will be addressing that directly.

Let me just turn to those changes and you have had

a lot of evidence about that and so I will do this in summary level, but of course you have got the detail in writing.

By the time of the Intas period, the first notable point, of course there is no alleged unlawful agreement in force. That stopped in June 2016. By the Intas period there have been six market entrants, including AMCo, a seventh with a marketing authorisation waiting in the wings. You will recall table 3.4, which is at {IR-A/12/98}. No need to turn that up again now.

All of that generating a major shift in the market, we say, by at least April 2016 when a completely different attitude at wholesaler level and pharmacy level to the acceptability of stocking a skinny product in quantities which are only consistent with off-label dispensing is apparent.

On top of that, during this period and by this period, you have the implicit regulatory endorsement from both the MHRA and NHS England, Scotland and Wales for this practice. First of all, the MHRA has made it clear that it will not intervene to prevent off-label dispensing of skinny label hydrocortisone tablets. Their only suggested action when approached repeatedly is to suggest a change to the patient information leaflet which would provide comfort to patients that

a skinny product that has been dispensed to them has been correctly dispensed to them, notwithstanding the lack of an indication for adrenal insufficiency.

In clear contrast to the MHRA's position over off-label dispensing of Pregabalin in breach of patent, has not issued any guidance to pharmacies. You will recall the letters the MHRA wrote to Auden in May 2014 and the note of the MHRA's call with the CMA. That is at {IR-H/1251/4}, at paragraph 4.1 where they considered switching from full to skinny label hydrocortisone tablets to be a commercial decision for pharmacies to take and outside of the remit of the MHRA.

Similarly, the PSNC has also refused to issue any such guidance. You will remember the guidance that was issued in respect of Pregabalin, but they have explained in 2005 that the status of hydrocortisone is not comparable to the situation with Lyrica/Pregabalin. The guidance from NHS England issued following a judgment of the High Court and the guidance we have given, they said, was issued in order to alert contractors of the risk for litigation for breach of patent law. It is {IR-H/687/1} for that reference.

The NHS, England, Scotland and Wales each independently by the time of the Intas period has gone out to the market to tender for hydrocortisone tablets

for use in hospitals. It may be a small, a relatively small part of the market. That is not my point. The point is that they do not distinguish between full and skinny for that purpose and, indeed, award all of the 10mg hydrocortisone tablets to skinny products. Again, signaling from their point of view absolutely no difficulty at all with off-label dispensing.

All of this readily ascertainable to anybody who asked, Auden did ask, AMCo did ask, and got those responses from the MHRA. If anyone else was in doubt and wanted to ask, they could do so. None of this was shrouded in mystery and, to the extent that there had been any lack of clarity in 2014/15, that clarity was provided by 2017.

Which is why all wholesalers by the Intas period are supplying increasing proportions of the skinny products, far in excess of that which can be attributed to formerly indicated uses of those products. You will remember we went through with some care that big A3 page document with the month by month figures for wholesalers and, particularly, obviously, the short-line wholesalers had gone very early on to the skinny products, but AAH and Alliance had also moved increasingly to those products in excess of the portion of patients who were children, even when including Boots and Lloyds in their

figures, but, notably, when you take those two customers out, in very large quantities indeed.

Far from prices rising during the Intas period, prices consistently and inexorably dropping by over 60% in the Intas period alone with Accord-UK unable to resist those drops, as Professor Valletti accepted, and those drops would continue afterwards equally inexorably by over 95% from their peak, driven at all times by precisely the same constraints as those which were operative in the Intas period.

By this time of course high levels of switching had occurred, 50% of volume overall, but, in fact, less than that in 10 of the 18 months which constitute the Intas period. You will remember those graphs. It fluctuates, and, indeed, sinks down to 29% at one point.

With the result that by the time of the Intas period Accord-UK cannot know how close it is to losing another customer. It lost Tesco early on. It lost Day Lewis switching in September 2016. Other supermarkets were being driven, it turns on analyses, you may recall, by their wholesalers approach. So who is next? That is what creates the direct constraint which has already started to drive down prices, even before the drug tariff kicks in, with prices beginning to fall from April 2016, continuing to fall to October 2016 when

the drug tariff effect kicks in.

But that is why there is a direct constraint, because at this point, unlike previous periods I am assuming for the purpose of my submission, Accord is looking over its shoulder and saying, what do I need to do to keep these customers and to discourage further switching? That is a point which Professor Valletti accepts. That is a point which is particularly clear from Dr Burt's witness statement; entirely unchallenged when he said "As far as I was concerned, we needed to drop our prices to keep those customers".

So that is how the direct constraint operates and it is how it continues to operate throughout the Intas period and beyond.

In particular, if Boots or Lloyds had been lost that would have meant a substantial loss of market share would follow. There is no commercial world in which Accord could have been indifferent to that prospect.

So Accord was having to drop their prices accordingly. That is Burt at paragraph 32. That is {IR-B5/1/10} and paragraph 48, which is at page 14. As I say, the CMA accepts Accord is having to respond directly to competition from skinny entry.

Then skinny purchases are already by the time of the Intas period uniquely driving the drug tariff. That

kicks in, it is common ground, with effect from October 2016. So it is three months before the Intas period begins creating a cumulative effect and we agree with Professor Valletti that after that point it is impossible to disentangle one effect from the other. They both work together.

As at October 2016 to December 2016 when the negotiations are taking place and arrangements are taking place for the compulsory divestment of the Actavis business from Teva, at the requirement of the European Commission, it becomes apparent to Accord-UK that Teva itself has registered a separate marketing authorisation in November 2016 for its own skinny label product. Although they are buying this business off them, they are going to be competing with Teva as well. Indeed, Teva then enter the market within weeks of that deal completing. The deal completes I think it is the 9 January 2017 and Teva enter a few weeks later in February.

So a major scheme is waiting in the wings to launch as soon as possible and does so within these weeks. Again, the idea that Accord can be blind to that is fanciful.

So it has been Intas's consistent position that these changes, taken together, mean that there was no

dominance or abuse by the time of the Intas period. When I say it has been its consistent position, I do not just mean in the course of this hearing, I mean right from the start its response to the first statement of objections, which was dated 18 October 2017, the response. So it is halfway through the Intas period. I will give you the reference. It is {IR-H/1074/2} at paragraph 1 and then page 3 at paragraph 4. That first response is making in effect the identical submission that I have just made to you that the factual situation in the Intas period is markedly different from the situation in earlier periods. So that point has been put in issue for the CMA to consider and evaluate right from the beginning and it was said that time was needed to have its effect on prices as market dynamics continue to unfold.

That continued to be the message to the CMA consistently, even a couple of years later when Intas was responding to the second version of the supplementary statement of objections. The response was dated 28 July 2020, so nearly three years on. Paragraph 3 of that response, the same point is made. The reference is {IR-H/1208/3}.

But despite Intas putting that point in issue from the beginning, the CMA's response to it has been,

firstly, to caricature the point and then to ignore it. So the Decision does not engage with this point that there has been a marked change in market dynamics over this period for the reasons that I have identified. So we put the point in the Notice of Appeal and the Defence did not engage with it so we put the point in the Reply and Professor Valletti agreed that he did not consider and was not asked to consider the Intas period specifically, only the infringement as a whole, which obviously includes the Intas period, but no attention to whether there had been a change in market conditions by the Intas period such as to affect the assessment of dominance.

Indeed, in the CMA's opening at paragraph 162(a) {IR-L/6/56} the CMA admits that the CMA did not separately consider the Intas period in the context of its analysis.

Why? Because the CMA says this is a single infringement. We do not have to worry about changes of ownership or do a fresh dominance assessment whenever ownership changes, which was, as I indicated earlier, not our point. It is a real point of substance about the market conditions being different, dominance being lost, abuse ending.

THE PRESIDENT: But if one were to say, contrary to your

submission, but I will articulate it now so you can push back and say why it is wrong, if one adopts the label, but I am treating it as more than a label, one says that the label single continuance infringement describes what is going on here, in other words, if one says, one looks at the market over time as a single infringement, then of course your answer that you have to bisect it almost *ex hypothesi* falls away, because you cannot partition a single continuous infringement. I raise it because that was a phrase that Professor Valletti did use in his evidence.

MR PALMER: I have no difficulty with the notion that there can be a single infringement which is then apportioned between different undertakings. My point is you have to concentrate on when that infringement actually ends and you particularly have to concentrate on that when that point has been put in issue in submissions to you from the outset and you said that is our case that by this time conditions have changed. I will come to the reasons why on the back of those developments that is so, why dominance ends in a moment, of course an important part of my submissions. But my point at this stage is the CMA have not engaged at any stage with that essential part of Intas's case.

Indeed, they make the startling assertion that the

key factors supporting a finding of dominance persisted throughout the post-entry period, including the Intas period, but without any analysis of the matters that Intas has referred to as being materially different.

So that change from the alleged ability to raise prices independently of any competitive constraints post-entry to a position where there are ineluctable price decreases which Intas is powerless to resist. A change from the initial cautious market reception post-entry to widespread adoption and regulatory clarity, all apparently so irrelevant on the CMA's case that no need to analyse separately.

Instead what it does is say, well, the infringement ends not on the basis of any analysis of the market, but when we say it ends in accordance with our administrative priorities. We are going to introduce a cut-off of £20 price as a matter of administrative priority. We are not going to investigate beyond that. That is when we are going to say the infringement ends, which of course they are entitled to do that from the basis of an issue of priority, but it is important to recognise that the end bears no relationship with any analysis of the market and the market conditions and dominance.

For the reasons which we have set out in our opening

at paragraphs 15-22, we say all of this failure to engage with the Intas period is significant and it means that the CMA have failed to discharge their burden of proof and I refer you to our annex 2 of our openings for a neat summary of the way in which they have done that in respect of the Intas period. It is at {IR-L/5/57-60}.

So with that introduction, I want to turn to the issue of dominance and the approach in law which is why we say against that background there was an end to dominance during the Intas period.

Now, it is acknowledged by Professor Valletti from the outset of his report that the legal test for dominance and the economic test for dominance are different. That might be worth having on the screen. It is at {IR-F/1/22} at paragraph 53. The difference, you see in the second sentence:

"Dominance is a legal test."

In economic terms he goes on to define it as an economist would in standard terms. But the difference between the legal test and the economic test is much commented upon in all of the standard text books and beyond that besides.

It rarely matters. It rarely matters that there is a difference between those two tests. But my central

submission to you is that in this case, in respect of the Intas period, the difference does matter. That may be a rare thing, but that occurs. The difference between the legal test and the economic test is not some kind of unhappy accident. It is a choice informed by considerations of legal policy and those are reasons both of principle and of practicality and each of those reasons, in my submission, are particularly acute when the abuse of dominance alleged is one of excessive pricings.

Let me unpack all of that. The legal test for dominance is well known to the tribunal, but it is important to go from first principles and its focus is on the ability of an undertaking to behave to an appreciable extent independently of its competitors, its customers and ultimately of its consumers; *United Brands* at 65, obviously.

That has been explained and developed in a number of different ways. Can I go to {M/5/57}, which is *Hoffmann-La Roche* at 38-39. You see at the end of 38 that same *United Brands* test and then if we can focus on 39:

"Such a position does not preclude some competition, which it does where there is a monopoly or quasi-monopoly, but enables the undertaking which

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

So, in other words, the focus of enquiry is on the effectiveness or otherwise of the competitive constraints on a particular undertaking.

That is reflected in the approach to be adopted both in the definition of the market and the assessment of dominance. I am not going to deal with any detail with market definition. That is not part of our appeal and we support the CMA's response to the case mounted by Advanz and Cinven, but, obviously, I must touch on it given the relationship between the market definition test and dominance and, in particular, the discussion of Mr Bishop's evidence.

It might be useful to go to the *Socrates* case for a useful summary of some of the key principles. That is at {M/139/40}. It just brings together some useful sources in one place, paragraph 102. This is Mr Justice Roth setting out relevant extracts from the European Commission's notice on the definition of market definition and we see there that:

"The main purpose of market definition is to

identify in a systematic way the competitive constraints that the undertakings involved face."

So right from the outset focus on competitive constraints:

"The objective of defining a market is to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behaviour and of prevents them from behaving independently of effective competitive pressure."

So you see that link with the test set out in *Hoffmann-La Roche*, *United Brands* with the very purpose of the market definition. If we go down to paragraph 105 of *Socrates*. It might be over the page, yes. Page 41. Where the tribunal records the Aberdeen Journals' approach which Ms Ford took you to last week. Then at 106 the conclusion that:

"None of this is controversial, but we think it is important to emphasise that in competition law market definition is a means to an end and not an end in itself. Here, the end is determination whether at any period the Law Society had substantial market power amounting to dominance ..."

So, again, the focus of the market definition is on identifying those constraints so it can be identified when it comes to dominance whether or not the

undertaking in question has the ability to act largely in disregard of those constraints.

Then you have Mr Brealey's points going back to paragraph 13 of the Commission notice. We need not turn it up. But you will recall that places a particular emphasis on demand substitution. So the focus is on whether competitors' products are capable of being substituted whether by reason of their functional substitution, as we see in *Aberdeen Journals* or, where it is possible to do so, by reason of price.

So then on that footing, at the dominant stage, the question is whether the competitive constraints, which by now have been identified are capable of constraining, are sufficiently effective to mean that the undertaking is able to behave to an appreciable degree independently or, to use the language of *Hoffmann-La Roche*, to act largely in disregard.

Of course this is to a large extent contrite and familiar, but in my submission it has been lost sight of by Professor Valletti's analysis as I will come on to explain.

Michelin at {M/6/43}, please. This is all language, which is not controversial, reflects the fact that competitors may very well be present. Certainly it is trite. It doesn't require a complete absence of

competition to be dominant. But see again the classic statement in *Michelin* at 48. Given all that, this is all so long as:

"As long as such competition does not affect the undertakings's ability to influence appreciably the conditions in which that competition may be excerpted or at any rate to conduct itself to a large extent without having to take account of that competition and without suffering any adverse effects as a result of its attitude."

Or it is put another way, {IR-F/1/23] which is the Commission's Enforcement Priorities Guidance, which Professor Valletti quotes for his 55. Sorry, I have gone to that quote at 55, which captures it perfectly. Three lines:

"This means that the undertaking's decisions are largely insensitive to the actions and reactions of competitors, customers and, ultimately, consumers."

Even when there is competition, it can come from a combination of factors.

So in all of these explanations or expansions or developments of that United Brand test, the focus is on the constraints and the degree to whether the undertaking concerned can act independently of them and the question is whether they can largely do so, not

completely do so.

All of that is materially different from the economic definition of dominance referred to by Professor Valletti at the top of that page, again, at his paragraph 53:

"Namely, that the undertaking has substantial market power defined in turn to mean the ability to raise prices above competitive levels over a significant period of time."

It may be a rare case that brings this difference into focus, but the difference is brought into focus, on the fact of this case with regards at least to the Intas period and the separate attribution of liability to Intas, in respect of the tail end of the alleged dominance; the run off period, as it were.

It exposes the difference in this way. Applying the economic test, as Professor Valletti does, you take any point in time or period in time that you choose, whether that be 7 January 2017 or 31 July 2018, or anywhere in between, and you ask: is the price at this point above competitive levels? Has it been so up to this point for a significant period of time? Are significant sales being made at that level notwithstanding?

That, on Professor Valletti's approach, essentially gives you the answer. If we look at his paragraph 64,

to show that is his approach {IR-F/1/26} he says -- again, this is the post-entry dominance period without specific regard to Intas, but he says:

"It remained dominant. It is evident there was a competitive constraint and this led to falling prices and loss of market shares but this does not automatically imply that Auden/Actavis was no longer dominant. The relevant question is not whether a firm faces some degree of competitive constraint but whether that constraint is strong enough to remove its ability to price substantially above competitive levels."

So in other words, if those prices are above competitive levels at that point, for him that is enough.

Let us go to paragraph 68 on page 28. {IR-F/1/28}:

"In line with my assessment of market definition, skinny label tablets did impose a degree of competitive constraint ... However, dominance does not disappear as soon as entry occurs: it disappears when there is no longer substantial market power. In this case, although [it] was constrained ... and prices began falling, [it] did not immediately lose it substantial market power. Even following the advent of competition from skinny label suppliers, Auden/Actavis remained dominant and retained the ability to profitably price at

a significant premium to skinny label rivals."

Now, the point I make is this: that is to ask and answer the wrong question. It is not the question that the tribunal must answer. The tribunal's enquiry must be directed at the legal test and that test is framed differently, because it is not concerned with the level of prices at any one moment. It is concerned with the effectiveness of the constraints which drive the process of competition over time and its focus is whether the undertaking in question is able, at any given time, to behave largely in disregard of those constraints.

This is what is explained, if we go back to *Hoffmann-La Roche*, {M/5/69}. It explains at paragraph 70 and 71. If we look at 70 first. The court recalls *United Brands* and that:

"... even the existence of lively competition on a particular market does not rule out the possibility that is a dominant position on this market since the predominant feature of such a position is the ability of the undertaking concerned to act without having to take account of this competition in its market strategy and without for that reason suffering any detrimental effects from such behaviour.

"However, the fact that an undertaking is compelled by the pressure of its competitors' price reductions to

lower its own prices is in general incompatible with that independent conduct which is the hallmark of a dominant position."

Now, in a snapshot, that is what exposes the difference between the two approaches. The question is not if we freeze the frame here, is your price above the competitive level? If it is so, that shows you are dominant. The question is: are you in the grip of competitive constraints which are leading you only in one direction and which you are unable to resist and so it cannot be said that you are able to act largely in disregard of those constraints? That is what explains paragraph 71 and I emphasise the word "compelled", because when the CMA respond to this point they omit it. Their point in response to this is to say, just because you are dropping your prices does not mean you are not dominant. I agree.

But if you are compelled to drop your prices by the pressure of your competitors' price reductions and you are in the grip of what is by this stage a run-off period, as I have called it, that gives a different answer.

That is why this legal test, as I say, is driven by policy, legal policy considerations, which I will come to unwrap a bit later on, but it is that fact which has

very significant implications in all sorts of other contexts. I will refer a bit later briefly to what happens when originator products come off patent and there is a standard glide path down as generics enter the market and that price is driven down. One can think about, sir, your example of the masks and the fact that prices may well be above the competitor level at any given period at any point in time, but the fact that there is market entry, the fact that those constraints are immediately imposed, there may be a lag before they have effect, but that does not mean that the then supplier is dominant or abusing its position. That is competition. That is effective competition. That is a position when you are powerless to ignore your competitor's prices and you are compelled to drop your own prices.

If you erode that principle by failing to distinguish between that economic test as expressed by Professor Valletti and the legal test as adopted in different terms, deliberately so, then you open a huge can of worms and this echoes what Mr Jowell drew your attention to, although that was in the context of the abuse limb, you will remember the second element of the *Napp* test to which he drew your attention and the question about whether there is going to be within

a reasonable period of time market entry to bring those prices down. It is the same rationale. Although of course we are all used to an analysing dominance first, abuse second, there are times when you have to step back and look at the abuse of dominance tort as a whole and think as a matter of legal policy what is this directed at, where are its limits, where are its boundaries?

In most cases, that will not matter, that difference. It is precisely the point that you raised, sir, with me earlier on, that that temporal coincidence of Intas only coming on the scene during that latter part when, if there is an abuse, it effectively has happened. The abuse consisted in the raising of those prices. There is then a run-off period. When does it end? Not as a matter of analysis at some arbitrary cut-off point, but when the undertaking concerned is in the grip of those competitive constraints, such that it is unable to resist them and can no longer be said to be acting largely in disregard of them.

So, once you have that legal question identified and you apply it in this case, you get a different answer, at least in respect of the Intas period. That of course is Mr Bishop's approach. You will recall from his report -- I will just bring it up. I will not spend time on it, because you have had it and you have read

it, but {IR-D5/1/9}. Just to remind you, this is the first report, paragraph 36-37 at the bottom. "Competition is a dynamic process" it is headed that section. It is fairly trite and obvious stuff at this point. He certainly was not cross-examined about that, but he is setting up right at the outset that dynamic process and the fact that competitive constraints in 37 evolve over time. That is what you need to assess.

Similarly, at page 11, {IR-D5/1/11}, paragraphs 48-49:

"Explaining why excessive pricing cases are not prevalent ... why the economic assessment of the effectiveness of the competition usually focus on the assessment of the competitive constraints ... rather than attempting to directly assess price levels.

"... the key economic question following the entry of skinny label suppliers is whether Accord-UK faced effectively competition ... as this feeds into both the legal questions of dominance and abusive pricing behaviour."

Again, it is framing it right from the outset as a focus on the constraints and the process, which runs right through his analysis, but is effectively ignored by Professor Valletti.

If we go to his second report at {IR-D5/2/7} and

I will not -- it is from paragraph 24, but this is where he explains the significance of the Intas period versus the broader post-entry period and that is a passage which runs right through to paragraph 32 over the page. I invite you to return to this report in due course rather than to spend time reading all the way through it now, but if I can just turn the page to 32. Again, he makes a point that this reassessment and focus on the end of the period of dominance is essential and the Valletti Report does not engage with it.

So that whole passage is a specific explanation of why the Intas period needs to be analysed separately. How was he cross-examined about this? Let us look at Day 7 transcript, page 11 {Day7/11:11} when he explains:

"It is not that competition only works when we get to the endpoint. It is the process, and it is about when that process starts to be implemented. I think that is a really important point, that I would argue that the entry of skinny label, particularly by the time of the beginning of the Intas period, was providing effective competitive process to take -- to erode those any monopoly profits in the market and take us towards the ultimate competitive price equilibrium."

Yes, so that is what he said. Again, that focus being correctly, in my submission, being directed at the

proper test and this was not further cross-examined by Mr Holmes, save to establish three points each aimed only at the strawman and which can be readily accepted. First of all, the change of legal ownership does not in itself affect dominance analysis. Agreed. Secondly, dominance does not necessarily cease to exist at the point of entry of rival suppliers. It is not the case that only monopolies can be dominant. Agreed. So it may take some time for outcomes to change, even if constraints are effective. Agreed, and a key point.

The question is whether the constraints are effective, not whether you have yet reached the point that outcomes have changed such as to arrive at some preordained or in fact *ex-post* analysed "competitive price" and that is the essential difference between Mr Bishop's approach and Professor Valletti.

If we go back to Bishop 2 at {IR-D5/2/11}, paragraph 44:

"In my view, it is therefore critical in any assessment to examine and understand the competitive process itself, at the relevant time. Distinguishing between a situation of dominance and one of effective competition in the case at hand requires consideration of a range of evidence that is broader than relying on market shares and ... price levels."

He gives an example at 45 making clear that on Valletti Report's approach, distinguishing between whether firms are able to retain market share after entry by responding to competitive constraints and, therefore, lowering prices, and a situation where a firm retains a high market share without responding to that entry, on Professor Valletti's approach that is irrelevant.

And over the page culminating at 46:

"Under the Valletti Report's approach, the broader context surrounding the outcomes observed would also be irrelevant. For example, the approach adopted by the Valletti Report would not view a situation where an incumbent's prices declined very significantly following entry any differently from a situation where the incumbent's prices did not change at all, provided that it retained a market share of more than 50% and its prices remained higher than those of its competitors."

Because those focus, as Professor Valletti was keen to emphasise in his cross-examination by me, was on outcomes and using that data, which from an economic point of view, as a matter of pure economic analysis, it makes some sense. But it does not square with this focus on the effectiveness of constraints, which is where Mr Bishop places his focus.

So the CMA's response to this evades this. Firstly, I will just give you the reference. I have made the point already, paragraph 152, {IR-L/6/52}, mischaracterises *Hoffmann-La Roche*, but, as I showed you, omitting the words "compelled to" and thus glossing over the point and divorcing these matters from the context that there may well be lively competition in the market, as *Hoffmann-La Roche* acknowledges. The question is what effect does that have on the undertaking in question? Does it impose a constraint which that undertaking can then ignore or largely ignore?

It explains why on the facts of this case Mr Bishop was right to contend that Professor Valletti's specific conclusions on market definition answer the question of dominance as well.

Now, let us make this clear, because the point has been consistently mischaracterised by the CMA and indeed by Professor Valletti. It is no part of my submission that the test for market definition and the test for dominance is the same. It is not. It is clear. It is no part of my submission that you can only be dominant if you have a monopoly and there is no competitors. Clear. It is no part of my submission that the moment you identify any competitors coming into the market dominance is lost. Clear. All of which Mr Bishop

accepts and indeed had always accepted.

But on the facts of this case and on the basis of Professor Valletti's specific reasoning as to what makes this market one market embracing full and skinny label, you do get the answer. I just want to analyse that now.

Professor Valletti rightly recognises that skinny label products, at least by this stage, operated as a direct constraint on the full label product and continued to do so throughout the post-entry period and then combined with a drug tariff from October 2016.

I have explained to you why he is right in principle. It is absurd to think that Accord was not looking over its shoulder and responding in its pricing to that competition and, indeed, Dr Burt unchallenged explains that they were.

But he does not simply, at his market definition stage, say that these products were therefore capable, to use the word of the notice, of constraining the full label products. He goes further. He expressly and specifically finds -- this is {IR-F/1/14}, please, his paragraph 28 -- that the result of the entry of skinny products was that the price of full label products fell from £70 to under £3. Causative. He expressly accepts -- this is his paragraph 32 on page 15 {IR-F/1/15} -- that 50% of the market share was lost as

a result and that this movement of pharmacies from full label to skinny label put downward pressure on full label tablets. That is the direct constraint.

Then of course we have got the indirect constraint, the drug tariff and then the cumulative constraint he deals with at paragraph 36 on page 16. {IR-F/1/16}. Cumulative constraint, both direct and indirect, ensures that full label products are constrained by skinny level prices.

Then at paragraph 44, page {IR-F/1/18}:

"It is quite clear... "

In the second line:

"It is quite clear that, in this case, there was a constraint from skinny label tablets that was strong enough constraint to reduce full label tablet prices from £70 to about £3. This is a decline of more than 95%!"

These are price drops that he agreed in cross-examination Accord-UK was unable to resist. The transcript reference is {Day10/34:11-14}. This all goes much further than is necessary for market definition purposes. Given those facts, it is very clear that market definition must be right, unless it is at least as wide as full and skinny label products. The tribunal have in mind Ms Ford's point that it goes wider still

and we say unreal to suggest they are not in the same market at least by the time of the Intas period.

I am conscious I am not going to get sucked into market definition points, which I know Mr Holmes is going to address, but I just drop in here of course that although the market definition changed pre-entry, post-entry between 10mg and 20mgs being together in one market and then separating out into separate markets, there was no temporal distinction made between full and skinny products. What I say about Mr Brealey's points, taking them at their highest, is that they are all directed at the pre-entry period or shortly after entry up to June 2016, so early on at post-entry. He says there was a portion of the market that was incontestable. I do not accept that is right. But if it were, that would only support a temporal distinction in the market definition. It would not support a change in the market definition so far as the Intas period is concerned and, by this period, it must be right and that is because, as the CMA accepts, there were ongoing constraints, not just a one-off shift, 50% of the market, as Mr O'Donoghue was asserting a moment ago, but continued switching, which is apparent from all those detailed figures on the A3 sheet and to which I will come back to when I address the no choice points and the

incontestable points.

But all that aside, the upshot is that at least so far as the Intas period is concerned the CMA has not erred in law, or otherwise, in failing to adopt a narrower market definition. If it had, well, then a complete re-evaluation of dominance and abuse would be required. But instead what Professor Valletti has done is go much further and reached a factual conclusion which on the application of the correct test, as applied by Mr Bishop, is only consistent with a lack of dominance, those constraints being irresistible in place and driving the price down.

The only reason he resists that conclusion and says that is not enough, they are not sufficiently strongly, is because he focuses on that set of outputs. So his focus is market share, price differential, in particular, at premium, which is maintained during the Intas period and that, he says, is inconsistent with anything other than continued dominance, but that is, as I have explained, to take the shift away from the effectiveness of those constraints, the ability of Intas/Accord to resist them and focus purely on that economic test from which there is a distinct departure in the legal test.

So he focuses on market outcomes at fixed points in

time {Day10/84:21} through to {Day10/86/24}. It is coming up on the screen. I will not take time on it now, but that was the cross-examination about that.

In his world view, on his analysis, it does not matter that all the constraints are in place and are effectively driving prices down, if as a matter of market outcome at any particular point Accord-UK is still pressing higher than cost and higher than its rivals, given its market share. That is what he explains in that passage. No matter that it is having to respond to the competition. No matter that it is unable to resist price drops. All of that on Professor Valletti's view is only informative of the market definition which is why, when I put those points to him, he said "I am bit confused. You seem to be equating market definition with dominance now". No, I am not. I am focusing on the competitive constraints and not just on the outputs and that is the difference between the approach of Mr Bishop and Professor Valletti.

The short answer to that is that on the authorities, in particular bearing in mind *Hoffmann-La Roche*, Mr Bishop's approach is the right one. So for all the reasons that I have gone through about the change of position by the time of the Intas period, it follows

that if the process was not effective at some earlier stage, for example, by the time of the Allergan period, where there remained some freedom to raise prices for a time, but as Mr Jowell said not for long, then it was certainly effective by the time of the Intas period when there was no freedom to raise prices and prices never were raised.

I said I would say something about the relevance of the originator product glide past, because that is something that Mr Bishop touched on in his evidence as well, was not asked about. Of course the CMA stresses that in a case of an originator product protected by a patent there is an ordinary drug cycle. There is a period of exclusivity which allows that originator to recover their research and development costs, but what is the analysis to be applied in that situation to the question of whether there is effective competition when the originator comes off patent, initially at least typically retains higher market share, initially at least retains a price premium over the generics who are typically entering, whilst that competitive process works through and over time that market share is worked down, over time that differential is eroded. How should that process be properly analysed?

The answer is that as soon as there is sufficient

entry to have those ineluctable effects on price, effective competition is at work. It does not matter that at any given point in the process -- during that process that market share is higher and has a price premium because the originator is already being required to respond to that competition and is not able to act independently of it.

That is why you lead to a typical glide path. I say typical, I do not mean there is a set glide path. Of course they vary enormously according to the drug, according to the market conditions, the geographic market and all sorts of things, but you will recall that Mr Bishop in his section 3.2 of his report -- that is not a paragraph. It is a whole section, but it begins at {IR-D5/1/12}. I invite your attention back to that. He was not asked about it. He made the point that what happened in this case does not look particularly different from what can typically happen and is identified by the European Commission as happening in such a case.

That is because it is the same sort of process. Yes, I accept this was not a drug that was coming off patent, but that is not the issue here. If I was wrong about dominance, we get on to questions of abuse and the fact that it was not coming off patent and had not

innovated, all those arguments which the CMA make to distinguish the position of this from an originator product, that would be relevant to that analysis in the context of abuse, but it is not relevant in the context of dominance where you are looking at what point can you say there is effective competition?

What would happen if you waited and said: no, no, you remain dominant until the point when your market share has sunk below some arbitrary level or you waited until your price premium has been eroded completely or to some small amount, what would be the effect of that? The effect of that every originator coming off patent would have to treat themselves as dominant and to behave accordingly. So do they then have to properly analyse their research and development costs that have not been recovered during the period of exclusivity and start dropping their prices bearing that in mind at that point? Must they drop to costs plus at day one? If so, there would never be any generic entry at all. There would be no incentive to enter that market or to some other comparator. If so, what? Must they analyse economic value at that point to see whether that glide path is in fact justified and potentially have to be justified to any regulator who took an interest?

If not on day one, on what timescale? All these

questions -- refer to paragraph 99 of our closings which are {IR-L/5.1/57}. Or is in fact the answer that none of that needs to be gone into, because, as a matter of legal policy, the dominance test has been framed in a way which does not require any such analysis because its focus is on whether that competitive process is underway, sufficiently underway to be established and ineluctable and that ability to be largely indifferent and largely independent of those market forces has been lost?

That is when the conditions of workable competition are observed. That is when markets are allowed to self-correct. You remember those references from Lord Justice Green in *Phenytoin* to the Advocate General Wahl and the *Latvian* copyright case about the usual position being you allow markets to self correct and that is what this is. It is a process of self-correction which can be relied upon once those constraints have been eroded even if there remains a period of time before some notional competitive equilibrium has been reached.

So all of this is wholly consistent with the language of the legal test, with Mr Bishop's analysis, with the process that was followed here, but not with Professor Valletti's approach.

Once you acknowledge that and realise the dramatic implications that adopting Professor Valletti's approach would have on the market as a whole, in my submission this is an area which needs to be trod very carefully indeed.

Now, what I have said so far concerns dominance. It goes hand-in-hand, as I have said, with what Mr Jowell said on abuse and the second limb of *Napp*. Again, for your reference, it is paragraph 403, {M/24/111}. Abuse ends not when prices have in fact sunk to some competitive level calculated *ex-post*, the question is whether there is to be significant competitive pressure to bring prices down to competitive levels either during the period of the alleged infringement or likely to be within a reasonable timescale. All of this chimes. There is no real difference here. Here to this extent questions of abuse and questions of dominance march hand-in-hand. That is because of the limits which have been adopted, as I say, as a matter of legal policy, to ensure that self correcting markets can self correct, effective competitive process can take their course, without this potentially distortive inter-regulatory intervention which could have serious consequences on generic businesses as a whole.

Against that background, I will of course turn to

look, nonetheless, at the market outcomes relied upon by Professor Valletti and the short point will be that in fact, once you have the correct legal test in mind, all of the outcomes which he identifies are in fact perfectly consistent with effective competition once that notion of effective competition is conceived of as being a process.

PROFESSOR HOLMES: Can I seek one clarification? I think the position is clear, but just linking back to the discussion we had earlier about the strawman of the change of ownership. If your argument is correct that dominance was lost before the CMA's administrative priority cut-off point of £20, I think two things would follow from that. One is that this issue would arise quite independently of any change of ownership and it is really the facts of this case that there was change of ownership that has brought this in particularly sharp focus.

Secondly, your success -- if you were successful on this point, your success would inure to the benefit of the other -- some other of the appellants, but with the extra difficulty, I think, that on your case this glide path -- we got to the point where there was no longer dominance before your client, to use your phrase, was on the scene, whereas we would still have to consider at

what point dominance was lost so far as the other appellants were concerned.

MR PALMER: Yes, you would have to.

PROFESSOR HOLMES: Have I got it right?

MR PALMER: On the latter point, yes. On that first point, the question whether this point would arise independently of a change of ownership. No, not necessarily, not in any material way, because if you had had just single ownership throughout, the abuse which is identified is abuse of raising prices at a time when you are free to do so, you are not constrained or prevented from competitive constraints from doing so and you exercise that dominance to raise prices up to a very high level and then it may very well be that they sink when competitive constraints do come in, but that does not affect the seriousness of that abuse that you have identified as a whole.

The whole episode can be attributed to one undertaking. So it does not really matter in that sense when precisely dominance was lost. What matters for identifying the fact of the abuse and assessing its seriousness for the purposes of any penalty which is imposed, what matters is there was a period of dominance, it was taken advantage of and abused with the result that prices were -- the rest is pretty academic.

In this scenario, because of the change of ownership, it is not at all academic. It is not remotely academic. It is absolutely central, because we say by the time we are on the scene, yes, dominance had been lost and that revolves around or depends upon my submission that by this point, because of the ineluctable price decreases which we were powerless to resist, you can no longer be said that to an appreciable degree or largely ignore or be insensitive to those competitive constraints. Far from it. The exact opposite. We are bound by them.

So in terms of identifying a point, which no doubt cannot be done with complete precision, but you would be looking for a point at which those prices -- at which that freedom to raise prices or to resist price drops at least was lost.

PROFESSOR HOLMES: On that argument, the dominance and the abuse would not necessarily have to co-exist at the same point in time, because the abuse would be committed when there was dominance and the abuse would continue even -- and that would be relevant on your argument even if dominance had been lost subsequent to that.

MR PALMER: You would be looking at the effects of that original abuse. You would be identifying, first of all, that there was abuse. It is a bit odd to talk about

abuse when there was no longer a dominant position, because there is no such thing in one sense, but if as a regulator you were assessing this, you would not cut off your examination of the seriousness of that abuse by saying, well, at this point, we are no longer dominant. We are not going beyond that.

PROFESSOR HOLMES: I understand.

MR PALMER: You would still look at the overall -- you would no doubt examine the overall extent of the supra-competitive gain, but you would attribute all of that to the original abuse of dominance whilst the dominance persisted. What you would not do, if someone else came on the scene, would be to say we are now going to blame you for the actions of others who came before you and attribute all of that to you when in fact what you were doing, at the time, was operating within an effectively competitive environment and you were not dominant. If you are not dominant, you cannot be blamed for the abuse, even if the effect of that abuse, that run off period, are still being felt. All that is to be attributed to those who committed the abuse in the first place by rising prices in the first place.

PROFESSOR HOLMES: Thank you. That is very clear. Thank you.

MR PALMER: The next topic, before I come to look at those

outcomes, is the question of the assured customer base, which I need to deal with and I do not propose to go through all the facts on this. I cannot possibly have time. You have heard from me many cross-examination with Professor Valletti about what we say are some of the material points.

First of all, I just want to identify what role the so-called assured customer base plays in the Decision. There is a number of places. The best encapsulation of the point that I have identified is in the Decision at 4.11. That is at {IR-A/12/301}. The tribunal will see it is a persistent theme which runs right through, but at 4.11 you can see that the central points are that the orphan designation created a barrier to expansion:

"Which created differentiated versions of hydrocortisone tablets ... and despite being bioequivalent and therefore interchangeable from a therapeutic perspective dispute with off-label dispensing expected prior to skinny label entry, full and skinny label tablets were not substitutes for all customers (as some customers had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets...) As a result, this differentiation provided Auden/Actavis with an assured base, which gave rise to substantial market power ..."

That is the encapsulation of how the point is put. As put, consistently all the way through the Decision, it is on the basis the reason why they are assured is that these customers have no choice and are not able. The key paragraph on that lack of choice is a paragraph Mr Brealey took you to, 4.311, which is at page 411 of this Decision. {IR-A/12/411}. You may recall this paragraph referring back to section 3. These customers were not able -- they had not choice but to purchase, not able to switch, no alternatives:

"That sustained ... market power because it was the only supplier of 10mg full label tablets ... the facts that the same regulatory regime applies to all customers or that dispensing is at the 'discretion' of pharmacies does not undermine this position: it is evident that pharmacies reached differing positions on whether to dispense full or skinny label tablets, but both are reasonable positions to take and, once taken, do not imply an element of choice where there is only one supplier of the type of product in question ..."

So once you make your choice as a pharmacy the implication is you have some sort of fixed position and thereafter you have no choice, and that is what creates the assured customer base.

Now, this is a critical finding in my submission for

the CMA's case given that the CMA had found that the direct and indirect constraints on the full label tablets were sufficiently effective to be responsible for 95% price drop and loss of market share. It is a finding of a hard barrier preventing switching even saying -- I will give you the reference, you have heard a lot of it from Mr O'Donoghue and Mr Brealey, 4.293. In fact, we will turn it up. It is at page {IR-A/12/406}. Even saying:

"The orphan designation rendered a significant portion of the 10mg HD market *de facto* incontestable."

That is at 4.293.

Just in passing you will note that what is actually referred to there is a significant portion. It does not say the entire customer base for full label tablets at all times as if all 50% by volume or 70% by value, as Mr O'Donoghue said, was *de facto* incontestable. That is not actually what the CMA say. They just say a significant proportion, but that is in passing.

That is how it is put in the Decision. But having heard the evidence by the time we get to the CMA's closing submissions -- it is paragraph 257 -- there has rightly been a significant retreat from this position. In their closings they abandon the language of "captive customers", they abandon the language of "no choice" and

they now say "generally unwilling". That is the new formulation. Now, it is an inevitable concession, having heard the evidence, as I will briefly remind you, but that still underplays the significance of the point. They now say that the reasons Boots, Lloyds and others continued to purchase full label tablets are not critical and the mere fact that they did continue to purchase is sufficient to confer market power on Auden/Actavis. The key point is clearly not very price sensitive.

So now we have got the mere -- it does not matter whether they had a choice or not. Just generally unwilling. The mere fact that they continued to purchase is sufficient to confer market power. Now that is an unsustainable position to take.

The moment you recognise, as Professor Valletti did, that this notion of no choice or captive customers or an assured customer base or *de facto* incontestable these were all terms which he rejected and refused to adopt. He preferred to speak only of "fairly inelastic demand". That is {Day9/197:13-21}.

"Inelastic [he said], it means that for reasonable price changes you would expect moderate changes, moderate changes in demand. But that is what it means. It does not mean that for any price change they will

never change their own views."

And he explained that this was a differentiated product market. This is {Day8/73:19-22}.

"This is a better product and they prefer to pay a higher price for the product which has better characteristics from their perspective."

You will recall that he analysed the position in terms of different trade-offs that different pharmacies would make at different times having regard to prices as they stood at any given time.

So this is not any longer about "no choice". It is about the ability to make a choice based on a product's characteristics and on the price of the product as it stood at that point.

The second point to weave in here is that the original no choice conclusion in the Decision was based on a manifestly incomplete and often materially misstated analysis of the evidence.

The decision provided the basis for both Professor Valletti's and Mr Holt's evidence on this point. You might recall this. Professor Valletti accepted that he had not been provided with the underlying documents by the CMA at all. He was not asked to look at the raw materials. He took what he saw from the decision. That is at {Day9/137:6-13}. His

expert report at paragraph 74 states that he does not review the classification between captive and non-captive customers. That is at {IR-F/1/30}. Mr Holt noted that his evidential basis was largely derived from the CMA's findings. The process was conducted by essentially through looking at the Decision and the associated documents. That is the documents cited in support of the Decision in the footnotes. Not documents which the CMA had on the case file but did not refer to.

Now, the Decision's selection of the evidence presented in my submission a wholly misleading picture. You will see this in our closings at paragraph 60 onwards for your note. For the transcript it is {IR-L/5.1/30}. I have not got anything like enough time to go through it but let me pick out some key errors which you may recall.

The first key error is that the CMA frequently froze the frame in June 2016. The only documents that they relied upon in support of their conclusion a particular pharmacist was unable to switch or had no choice depended only on documents from June 2016 or earlier, failing to acknowledge the fact that the market was moving on by the time of the Intas period and often much earlier. The result was simply erroneous and sometimes quite grievously so.

Asda they said had no choice, referring to the position in June 2016 because they left it to their wholesalers as to what they got, ignoring the documents that they had in their file for 2017 which showed that their preferred supplier was Teva and a skinny product. Ignoring that the wholesalers who were making the selection were increasingly over time moving to skinny products.

Sainsbury's, it turned out the only data they had ended in May 2016 and that they had exited the market in September 2016, and yet in table 3.8 on the Decision you had a whole column for Sainsbury's drawing attention to that 0% of their purchases in 2017 had been skinny products. It is not true because they made no purchases of any hydrocortisone tablets in 2017. They had left the market. To say therefore that they bought 0% skinny is wholly misleading and not referenced in the Decision at all.

A further flaw. Table 3.8, we might as well have it on the screen, {IR-A/12/135} is the reference, averaged away in two annual figures, one for 2016 and one for 2017, you will recall, significant trends in growth showing increasing skinny purchases over time and that was apparent only from the analysis of the monthly breakdown which was provided for the first time to the

parties during the course of this hearing.

It ignored that once you looked at those monthly figures you could see the extent to which two pharmacies, Morrisons and Superdrug, had switched back and forth in big quantities exercising their choice.

Thirdly, they suggested that there was no choice even when pharmacies such as Well actively considered changing its entire volumes to skinny label having regard to the price differential. They chose not to in the event but they went through that process. Lloyds specifically acknowledged that its position may change depending on the price differential, a point which Mr Holmes relied upon and put to Mr Holt in cross-examination. You will recall. The reference is {Day5/158:23} to {Day5/159:1-2}. He put:

"There may have been some pharmacies with regulatories concerns but for whom if the price differential became too pronounced, they may have been prepared to switch, perhaps generally or perhaps for dispensing specifically for use by children."

An absolutely right point to put on the evidence but nowhere in the Decision.

You will remember the Celesio document which indicated that our chemists, i.e. Lloyds chemists' position would depend on the price differential.

Then the other big fish, Boots, on analysis made a decision as early as December 2015 to January 2016 apparently based on its perception of regulatory risk in a leaflet which it had produced dated May 2014, and Boots never reviewed its position again after that but they could have done.

Here is the key point for a pharmacy like Boots. Accord could not proceed on the basis even that Boots was assured because Boots could review its decision at any time and it was unknown to Accord at what point the price differential would cause it to review its understanding of the market and its trade-offs. So it faced a direct constraint from them for that reason and could not act independently.

Here is the key point about being fairly price inelastic in this context. It is not my submission that at some point Boots might have said to itself, ah, to hell with regulation, we do not care about regulatory consequences, the price looks good. That is not my submission. That is exceptionally unlikely to happen. Indeed, probably impossible to happen.

What is my submission is by the time of the Intas period it would be totally open to Boots at any point to say, this price differential is too big for us, we are foregoing this profit. Let us have another look at

whether in fact it is correct that we have to buy the full label product because we need to give the full label product to adults and it is too difficult to distinguish between them at the counter and so forth. What if they re-evaluated that position? That is where the price differential is key. Because once that position is re-evaluated, certainly by the time of the Intas period, there is, if you actively turn to your mind to the question, only one answer which is there is no difference between these products. They are bioequivalent. There is no patient safety issue. There is no clinical difference. All of that accepted by the CMA. There is no intellectual property issue. All of that accepted by the MHRA. There is no professional issue. For the reasons explained by the CMA in their closings Dr Newton is wrong about that. She relies on MHRA guidance which is directed to an entirely different circumstance of dispensing off-label a product which is not indicated for a particular condition or purpose. Thereby in a sense acting some independent clinical judgment as to the appropriateness or otherwise of that drug for that condition which, as you observed the other day, sir, doctors are free to do and it is deliberately so that they are free to do that but that is as a result of a clinical judgment that for some reason which does

not apply generally that particular drug is in the best interests of that particular patient which justifies that. If they are going to make that sort of call in circumstances where it has not been generally approved for being prescribed to patients with a certain condition, then that doctor and any pharmacist who dispenses that drug if they do not question it and check it with a doctor is taking on a certain amount of risk because they are exercising that judgment and they will be answerable for that judgment.

That is what the MHRA guidance is all aimed at. The typical case of off-label dispensing. But none of that holds where you have got the identical product being prescribed and dispensed for the identical condition. At that point there is no regulatory clinical professional matter which at all calls that into question. That is not me saying that. That is the evidence of the MHRA. That is the evidence of the NHS. That is the evidence of consultant doctors and endocrinologists I think it is who were consulted by the CMA about this, and those are the findings that the CMA made.

If you turn your mind to that question, there is only one answer. So your interest if you are as in Accord-UK is keeping the price differential at such

a level that you do not give your customers a reason to go back and re-evaluate that position and actually review that position. That is the last thing you want them to do. You have got to cut your prices enough certainly to keep their margins, to respond to the competition as well, to respond to the difference between your selling price and the drug tariff. You have got to take that all into account.

So the notion that these customers were assured is entirely fictional. They were in fact precarious in those particular circumstances.

It is important to recognise that because when you do appear lies the reasons why certain customers initially chose full products and in the event stayed with them to a greater degree, like Rowlands, like Boots, in particular, like Lloyds, when you look at their reasons for doing so, as explained to the CMA, they do not engage with any of those things. They just assert the clinical difference. The clinical differences, it is said by Lloyds. So that would be against the principles of our system, of our licensing system.

It is just wrong as a matter of fact. That that was their perception but that perception was vulnerable to change and re-evaluation patently. It is just wrong as

a matter of fact to say that there is some ethical consideration independent of professional, clinical or regulatory requirements.

What is the ethical consideration? It has never been articulated by anybody. Once you have knocked down clinical, regulatory, professional obligations there is no independent ethical consideration that anyone has articulated at any time.

Once you know that, which Accord did, because they asked the MHRA, because they asked NHS and, indeed in its earlier guise, in earlier periods of ownership in 2014/2015 there is a whole suite of correspondence aimed at getting the right answer. They got the wrong answer so it knew of this vulnerability from competition from skinnies from the outset.

Just to conclude before lunch. We have provided an extensive review of the documents and the evidence in an annex to our closing submissions. If I can have it up on the screen. It is {IR-L/5.2/2}. I would not at all complain if the tribunal's collective heart sank at the sight of a 100-page document of this nature but I just want to indicate it is not as bad as it looks. I would invite your attention to it if I just provide this brief guide to it.

What it does is it goes through all of the

pharmacies in turn, then all of the wholesalers in turn and then the suppliers in turn and then the NHS. At the head of each section it has a summary of what we say in one paragraph can be drawn about the position of that particular entity.

Asda is the first one you have got on the page there. There is one paragraph on the first page above the monthly figures which have been extracted from that A3 page. You can see the point being taken.

If you go to the next page, what you then get is a review of in as a comprehensive way as we could without cherry-picking, separating each document out indicating whether it appears in the Decision or not which is it is often material, summarising what it said and then separately in the right-hand column providing a comment about it.

Now, it may well be that you do not want to work labouriously through this table looking at everything but it is a point of reference if you have a query about a -- or what was the position of Asda? What was the position of Well? What was the position of Superdrug? It is all summarised in that way.

Let me say it in this way: we have endeavoured to be as comprehensive as possible. We have not tried to leave out documents which do not suit us. We have

quoted passages as far as we can conscientiously which, if taken in isolation, might look as though they do not support our case but support the CMA's case, but we have tried to provide that in the context of all the other documents which are relevant to that pharmacy or that wholesaler so it can be seen as part of the suite.

Because one of the key flaws in the Decision, and in much of the evidence before you, is it does not fit within the chronological flow as the market develops. So you get a document plucked out, whether it be from 2015, 2016 or 2017, and dropped into the Decision without an understanding of what are the market developments around this? What is that pharmacy actually doing in terms of purchases at that point?

This provides it all in one. All the documents are arranged in chronological order. Sometimes the notes of call with the CMA are put out of chronological order because they are describing events which happened at a particular time so we have slotted them into the chronology. I hope that is a helpful guide.

The short point is that when you analyse it in the full context you do not take the selective approach that Advanz has done in annex 4. You do not take the super selective that the CMA has done in its decision. You get a different picture and you get an understanding of

1 why Professor Valletti is right to treat this all as
2 a series of trade offs which are amenable to change over
3 time at different price points as you re-evaluate
4 whether or not you can or cannot buy these products, not
5 this blunt barrier to expansion, no choice and an
6 assured customer base which formed such a centre piece
7 of the Decision.
8 That is, if I may, where I will break off for lunch.
9 THE PRESIDENT: Thank you very much, Mr Palmer. Before
10 I forget. The parties very helpfully provided us with
11 essential documents in writing in A5. We obviously do
12 have the materials electronically in a variety of forms
13 but I think it would help at least two of us if we had
14 those materials in the same format, just everyone's
15 closings including annexes.
16 MR PALMER: Yes.
17 THE PRESIDENT: It would be very helpful. Thank you very
18 much. We will resume at 2 o'clock.
19 (1.04 pm)
20 (Luncheon Adjournment)
21 (2.00 pm)
22 THE PRESIDENT: Mr Palmer, good afternoon.
23 MR PALMER: Afternoon, sir. Thank you. Just before the
24 break, I was inviting a review of the documents,
25 assisted I hope by our annex, and we say that that is

the approach that the tribunal should take in determining the facts to review the evidence, which should not come as much as a surprise.

But I note that the way the CMA has framed its case in its closing submissions from paragraphs 270 onwards {L/7/120}, is to say that it all revolves around Mr Bishop's myriad concessions, as they put it, in his cross-examination.

I simply make the observation that that whole sequence in the CMA's closing submissions on this subject takes no recognition of the point that the tribunal has itself made on several occasions during the course of the hearing, which is that it will decide the facts based on its view of the factual evidence, not on the view of an expert, that these matters were put to experts to agree the factual premise on which their opinion is then sought and given, rather than trying to get them to prove matters of fact.

So that has been made consistently clear by the tribunal as undoubtedly right, but it is telling, in my submission, that the CMA does not actually address the evidence on that basis, but does it entirely through the lens of the limited selection of documents that were put to Mr Bishop for his response.

The facts to be found are to be based on the

evidence, not on the basis of that part of the evidence that Mr Bishop was able to recall under the pressure of cross-examination and that is why we have given you a comprehensive, I cannot guarantee it is comprehensive, there may be one or two others, but as best a job we can do is what we have done.

Where that takes us is -- the tribunal may recall, we might have it back on the scene at {IR-A/12/411}, is that at least by the time of the Intas period the suggestion that it was a reasonable position to take that there was a bar to dispensing skinny label tablets is entirely unfounded. It is inconsistent with everything else in the CMA's Decision, i.e. its findings that there was no clinical difference, no IP argument that the MHRA said that there was no regulatory bar or risk and no regulatory action was taken.

All of that tells you that actually when you look at the facts that was not a reasonable position to take and it was just objectively wrong. As I submitted to you earlier, the crucial point in terms of competitive constraints and their effectiveness is that Accord could not know how close anyone was to switching and that is a reference to our closing at paragraphs 81-84, which is at {IR-L/5.1/46-50}.

By contrast, the CMA's approach is again to distort

the position. Their 263A. Can we have this on the screen. It is {IR-L/7/115} where they say at (a):

"In which is witness statement, Dr Burt ... confirms in terms that for some pharmacists it is 'important to adhere strictly to the regulatory regime, and to dispense products according to their marketing authorisation rather than stray outside them'; Dr Burt notes that this was a 'particularly important point for larger chains who in my experience are more risk-averse'."

That, as you can see from the text above that subparagraph, is said to be in tension with Mr Bishop's disagreement with the CMA's assessment of the evidence.

It is not at all of course. It is absolutely the premise of our argument that some pharmacies, for example Boots and Lloyds, appeared to be more risk-averse, but that fact does not tell you anything about their ability to reassess what the actual risk is. Once they have identified that there is no risk, the fact that they are risk-averse becomes completely irrelevant and that is why you want to offer them prices which do not cause them to raise a point on hydrocortisone tablets, amongst all the thousands, probably tens of thousands, of products that they are dealing with on a daily and weekly basis. It is that

which drives the competitive constraint.

Similarly, at the other end of the spectrum, as Mr Brealey suggests, the real distinction between these two groups of customers is on the one hand there are a group of customers who, as he put it to you in his closing the other day, do not care about regulation and regulatory risks and are not bothered by that. There is no evidence about that at all. What you have is evidence that those pharmacists took the view that they could dispense off-label and, as a matter of fact, they were right.

That tells you nothing about their aversion to regulatory risk. It simply tells you that they are more nimble, particularly independents, in spotting an opportunity to make more money consistent with their regulatory and professional and clinical obligations, which is precisely what happened.

So it tells you that those smaller independents are more nimble and fleet of foot as are, it turns out, big supermarkets like Tesco and chains like Day Lewis. Others were not so nimble and, to be honest, you can see that in practice. You will remember Morrisons switching and then switching back again and the driver for that was an account executive from Alliance emailed to say, oh, you are buying a lot of these. You do realise it is

not indicated for adult insufficiency which most of your prescriptions will be for. In that case, we had better switch. No evidence of any consideration of the point at all. Just take it from Alliance. That was an Alliance executive, I put it as being a bit cheeky during the cross-examination, as you may remember, because it was the own brand product which was being pushed. When you looked at the cascade of orders, after the own brand it actually went to a skinny before it went back to the full label Actavis product.

So these are -- it does reflect there is a difference. Yes, certain chemists are more risk-averse perhaps, particularly risk-averse, set their bar lower, but is does not tell you anything once they reassess that risk and whether you should give them a reason not to do so.

Equally, just as the last nail in the coffin of this point, there is no sense in which, and I do not think the CMA continue to suggest, it did earlier on, that Accord is in any sense an unavoidable trading partner. That has not been put forward in any point of the Decision and that would be language typical of a barrier to expansion if a certain people they were an unavoidable trading partner, but, again, there is no evidence of inability of those big pharmacies to switch

to skinny label suppliers. There is no evidence of skinny label suppliers not being able to rapidly meet that demand if they did switch.

So what this boils down to, which is going to take us on in a moment to market share, is that Accord managed to retain in particular two large customers, Boots and Lloyds, which accounted for most of their market share and they managed to retain those because those two pharmacies, however risk-averse they were, identified that there was a clinical reason why skinny products should not be dispensed to adults with adrenal insufficiency and in that they were wrong. In that they never revisited or reviewed it seems, it is a matter for them, but that misapprehension is not a source of market power for Accord-UK, because there is nothing fixed about that. Again, going back to that paragraph we had on the screen a moment ago, "once chosen" as if that is engraved in stone. No one can say: hold on a sec, we are wasting a money here. We can dispense this and let us look at this again, evaluate it. If we need to, we can ask the MHRA. We know if they had what the answer would have been.

So it is an entirely false hypothesis to say that this is an assured customer base with no choice and not able to switch. It just reflects the tradeoffs they are

making and purchasing these products indicated a desire perhaps to keep matters simple for them. They did not have to go through the hoops. They just knew, if we get the full label, that is fine for us and that is a source of value to them, as we will come back under the abuse heading. It was something they valued and were prepared to pay more for. That is an exercise of customer choice in a differentiated market, but it does not tell you that Accord were dominant.

So what it boils down to is really customers liked our product and, therefore, we had a large market share. It was pretty consistent over time, around 50%, because two or three of our customers were rather large and we retained them. But that put like that, this now comes to mean nothing more than the flip side of dominance as, sir, you put it in a question on Day 7, page 30 {Day7/20:1} as to what this language actually means and what it does mean, when you analyse it in this way, is that this limb of the Decision collapses into the limb about market shares and say, look, you simply managed to hold on to some big customers and that is highly significant, we submit.

It is true, of course, that you do not need captive customers in order to establish dominance. Of course you can have dominant undertakings who do not have

a captive customer case, but on this case, on the CMA's case, as set out in its Decision, you do need that finding to square the circle between the dominance conclusions and the market definition conclusions and the rationale that although half the market could switch to the cheaper product, and there was nothing to stop them, somehow the other half could not and that being the source of the barrier to expansion, that being the source to dominance, as I took you through.

Once you take that plank away, it is a key pillar of the Decision and it cannot stand.

So those are my submissions on that point.

On the subject of countervailing buyer power. I have done it in writing. I adopt what Ms Ford said about that. There are two sources. One is the customer negotiations, in particular with wholesalers. The other was the Department of Health powers. You also have Ms Ford's full and helpful note about the way those powers developed and were added to in fact during the Intas period.

So I will leave that otherwise in writing.

Sir, I come on to the market outcomes, on which Professor Valletti puts so much weight and the short points, as I have indicated, is that none of them dictate a different conclusion.

The first point is market share. I just want to remind you of the expert evidence that you heard as to how market share as evidence relevant to the question of dominance should be approached. Let us start by looking at the terms in which the CMA put to point to Mr Bishop. That is on {Day7/14:23}:

"Would you agree then that whether a firm ceases to be dominant is a matter of degree that will require a rounded assessment of all the evidence?"

"Answer: Yes."

Then at page 17, {Day7/17:12}, after establishing that the figures are not disputed:

"Now, I am not going to ask you about the legal issue of whether dominance is to be presumed on the basis of market share, because I appreciate that is not your domain. But as an economist you would presumably agree that if an undertaking possesses high market shares over a sustained period, however you are measuring them, that is at least a relevant consideration when coming to assessing market power?

"I would agree that it is a relevant consideration, but I do not think -- and maybe I am straying back into whether it is legal or economic -- that these are rebuttable. So if I see a firm maintaining market shares above 50%, do I immediately conclude that firm

poses significant market power? I do not. I think there is a possibility that it does, and then I would want to look at other factors, such as is it maintaining its market share through other competitive responses, for example by dropping its price? I think in those situations that would give me a very different answer to: I see a firm maintaining a 50% market share with no changes in its prices. The two situations from my economic perspective would be very different, yes.

"Question: That is very helpful."

It is not challenged further and moves on to pricing.

At page 16, lines 4 to 12 the question of market share by volume versus value is the way it is put to Mr Bishop by Mr Holmes, so just at the foot of the page:

"You say there the decision focused predominantly on market shares calculated by value. It is also important to consider market shares by volume? You are not suggesting that value shares are an irrelevant consideration for the purposes of dominance assessment, are you?"

"Answer: No."

So it is put in each case that these are relevant considerations to take into account as part of a rounded

assessment, which in my submission is faultless, absolutely faultless, which is why I put the same points to Professor Valletti in as close to the same terms as I possibly could when he gave evidence. {Day10/50/10}:

"You would presumably agree that if an undertaking possesses high market shares over a sustained period, whether measured by volume or by value, that is a relevant consideration when coming to assess market power?

"Answer: It is a relevant consideration, yes."

He agreed.

"But what is required [as he goes on at 16 through to 23] is a rounded assessment."

I put that to him:

"A matter of degree that will require a rounded assessment of all the evidence?

"Answer: Absolutely."

He wanted to move to documents, but I just intervened to say:

"You have agreed with me on, and that is on a holistic basis, that is the point?

"Answer: Yes, putting the dots together, of course."

Then at page 52, line 5:

"So given that it requires a rounded assessment, if

you see a firm maintaining market shares above 50%, just as a matter of general principle I am asking you this, one should not immediately conclude that it has significant power. You should conclude that it may do and it is necessary to look at other factors as well, such as whether it is maintaining that market share through other competitive responses?

"Answer: Yes. I will leave it to lawyers to talk whether there is a legal presumption, a rebuttable presumption, that is another point. But if I take your proposition, isolate it from the rest, I agree."

I put about the European Commission enforcement priorities and described it as being no more than a first indication.

"Answer: Yes. Yes, I agree. I want to pushback a little bit. So, market shares are still very important in the formal sense. If market shares were very small, we would not even need to be talking about this. It is like an initial filter. It is like an initial filter, because there is also ample evidence that firms with market power they command higher shares.

"Question: So we agree though, that a high market share can be consistent with effective competition. It all depends on whether a firm is having to respond to the constraints imposed by competitors and customers in

order to maintain it?

"Answer: It depends on a variety of other factors, not just whether it needs to respond or not. It depends on how strong the market power is.

"Question: You have just taken us to figure 7 on market share by value. The first thing to consider is: market share by volume and by value, they are both relevant considerations; you agree with that?

"Answer: I do.

"Question: Neither is to be prioritised over the other?

"Answer: Yes, then we agree.

"Question: This is evidence that you take into account. It is not like, well, it is the value one that really matters here?

"Answer: No, but I do not know whether I can really put my own thoughts together, but it is the two of them together."

So a complete agreement, in my submission, from both experts and which I fully accept. Obviously, when assessing dominance and coming to a dominance assessment from the outset, you are looking to conduct a rounded assessment. Market shares is, if you like, what puts you on notice at the outset as a first consideration and initial indication. If market shares are high, you are

going to look for the explanation. You are going to look to see in what conditions they are maintained as high. That could be because they are dominant, but it is not necessarily because they are dominant. It could be consistent with effective competition.

So that is the evidence before the tribunal as to the approach to be taken to market share. Contrast that with the legal submissions put forward by the CMA which bear no relationship to that approach at all. They make two allied submissions. One is their heavy reliance on a legal presumption and the other is on the supposed principle that value is more informative than volume in a differentiated market.

Both entirely at odds with the evidence that you have heard and, in my submission, not legally well founded.

They go further than that in relation to the supposed presumption. They suggest that the presumption is so strong that the burden of proof shifts to Accord to prove that it is not dominant and that in order to do so Accord must show exceptional circumstances to rebut dominance, which, they say, is a high threshold. So the high threshold point is their openings paragraph, 153 (b), {IR-L/6/53} and the reversal of the burden of proof is at 239-240 of their closings, which is at

{IR-L/7/106}. They say the relevant appellants have so far failed to grapple with the fact that they bear this burden and have not come close to discharging it.

So, in my submission, this is legal nonsense. It is as short as that. It is the divorce from the economic reality upon which all experts are agreed with principles plucked from authorities, which were determined on their own facts and their own markets and in which what was said may well have been true and appertained to that market, but bear no relationship to this market. In particular, the invitation to reverse the burden of proof is wholly misconceived. The burden of proof lies on the CMA. It brings this case and it must prove it and there is no basis to elevate the significance of market shares above all other matters.

I will come back to that and the law on that in a moment. I just want to set out the turf first.

Secondly, the description of exceptional circumstances needing to be proved and that as a high threshold is another legal error. The words where they appear in the authorities of "exceptional circumstance" indicate an expectation as to how often there will be circumstances in which an undertaking with a high market share is not in fact dominant. It does not erect a legal test or threshold of a high nature. There is no

authority to that effect, still less when there is no economic underpinning as to why on earth that should be.

In my submission, there is no such presumption in law and it is the misreading of the case law taken as a whole which gives rise to it.

Time is limited. I could spend a whole day on this point alone with the authorities we cited in our closing. I will not. We have made very full written submissions on the point, but by way of short-circuiting that and providing some framework for the tribunal to review those submissions, can I go to the commentary in *Faull v nikpay*. It is at {M/102.1/7}. Perhaps we can -- I do not know if it will end up too small, but if we do a double page, this page and the next and show the whole page. We can see how that works out and if it is too difficult to read, the tribunal will tell me. Is that legible?

THE PRESIDENT: That is legible. Thank you.

MR PALMER: It is. If it is, can I invite the tribunal's particular attention from 4.155 through to 4.163 and to indicate when you reach that point. I am just going to invite the tribunal to read those passages.

THE PRESIDENT: Yes, of course. We will indicate when we need to change page from the end of 160.

MR PALMER: Thank you. (Pause).

THE PRESIDENT: I think if we lose the left-hand page and gain the right-hand page, we can read through to the end. (Pause) Thank you.

PROFESSOR MASON: Before you start to put your point on this, just a question of clarification. As far as you understand it, in all of these paragraphs, are the market share figures being referred to by volume or value?

MR PALMER: That depends on the case.

PROFESSOR MASON: But the ones, so throughout these particular paragraphs?

MR PALMER: Are you pointing at any particular paragraph? There are a lot of cases cited.

PROFESSOR MASON: There are, but --

MR PALMER: In general --

PROFESSOR MASON: Any guidance you can give us.

MR PALMER: -- they tend to look at both and in certain differentiated markets the Commissions has preferred value to volume in certain differentiated markets. I will come back to that point in a moment, but it does depend on the market. In a non-differentiated market it is often volume which is given more attention and one can see readily the logic behind. Just to -- one of the decisions on differentiated products, for example, is in the *Gillette* razor case where the market, product

market, was for razors, but that included the cheap plastic disposable razors all up to the sort of mid-range double bladed ones, all up to what I think they referred to as "razor systems", which are the top of the range, all in one market, but clearly differentiated. If you were simply going to produce figures on volume, that would not give you the complete picture as to where the market shares really lay, because you have got the very expensive products at the top.

Another of them is concerned with bespoke computer software writing tools, which, again, very often is not products that were not made commercially available but designed for particular firm or something. Volume in that sort of market is not going to tell you very much.

That is where you get the rationale for saying, well, in differentiated markets value would be more helpful. Less helpful, I would say, is when the products are in fact exactly the same, but not irrelevant. Not irrelevant. I have not suggested it is, but not to be preferred on the basis of some psuedo-legal principle derived from Commission decision where that observation is made where it does make obvious sense.

PROFESSOR MASON: Understood. However, you haven't taken us

to these paragraphs to expand on your volume/value point.

MR PALMER: No.

PROFESSOR MASON: You are going to be making a different point than these.

MR PALMER: The point I just made. These paragraphs are not about volume/value, just about the so-called presumption, which is a misconceived idea, in my submission. As is argued here, we have set out the chapter and verse of those cases, which are referred to and others which have been referred to by the CMA in a rather extensive footnote in our closing submissions where more detail is provided and, of course, if one were to go through them all, you would have to look at precisely what market you were talking about, what the factors were that were taken into account, the role that market share played in that decision and it would take an age. So I am not going to do that.

The short points which come out of it are, firstly, despite the language which has sometimes been deployed by the court, you have to read the case law as a whole and in general it is referred to as an indication of dominance rather than the presumption of dominance and using language of indication is, economically speaking, far more accurate, at least certainly on the evidence we

have heard before this tribunal.

Even if the view were to be taken that it is a legal presumption, the authors submit it is certainly a weak one. They say in practice evidence of other factors will be adduced and a finding of dominance will rarely, if ever, be based on market shares alone.

I put the point a slightly different way. Insofar as any presumption can be referred to at all, it is just that if you in response to: you seem to have had very high market shares, tell us why, tell us how, you then have an evidential burden on you as the undertaking to explain it, to produce the evidence to show what is going on, what the constraints on you actually are, how the market is actually operating. If you did nothing, then maybe in the absence of other evidence you would infer dominance, but in practice and reality that never happens. You always adduce evidence.

So there may be an evidential burden. That is not the same thing as putting a legal burden on a party who is accused of abuse of dominance to prove that they are not dominant in circumstances where they have a market share, whether measured by volume or value, over 50% or over any other arbitrary threshold.

So too, just to show that this is not exactly an outside view, *Bellamy* & Child, {M/156/2}, at

paragraph 10.022:

"Caution about market shares".

Referring with approval to the useful first indication formulation in the Commission's guidelines, but market share should be interpreted in the light of the market and the extent to which products are differentiated. That is all the Commission:

"Possession of a very large market share is seldom, if ever, a proper substitute for a full economic analysis of an undertaking's market strength for four reasons."

There is four good reasons, but I am just going to highlight the first:

"Even if the market share figures are reliable, they provide little information about the competitive process without an understanding of the reasons for, and the pressures determining, the output and price decisions made by the firms in the market."

All of which again is consistent with the evidence you have heard in this case.

So to be fair to the CMA, they do of course say we have not just stopped at market share. We have looked at all indications and we have conducted a rounded assessment, which is the point of Mr Holmes's questions to Mr Bishop on that and that of course, we disagree

with the outturn, but as I matter of process that is of course what they have done and, to that extent, no objection.

But in their submissions to the tribunal they go further. They go further by saying the market share creates this legal presumption, shifts the burden of proof, and we have got to point to exceptional matters, high threshold, which somehow disprove that. All of which I say, on the basis of what you have read and on the basis of simple economic intuition, as well as the evidence you have heard, cannot be right as a matter of law. That is law not adding anything as a matter of policy. It is driven out of the facts of certain cases where -- there are obviously some cases where a high market share is indicative of dominance, because the reason for it, as soon as you look underneath the bonnet, is there are very high barriers to market entry. There are legal restrictions protecting the markets. There are all sorts of consideration which can come into play which explain the market share and straightaway indicate, given that is sustained over time, dominance.

But that is not the case where the market share is the result of retaining some big customers who have made a decision as to which product they wish to stock, based on their preferences, their tradeoffs at any given time

and for whom to retain you are forced to reduce your prices ineluctably. It is a different situation, as Mr Bishop explained in the answer that I read to you.

The same goes as to volume versus value. I do not dissent from how either expert put it. They are relevant factors which you must take into account, but neither should be privileged over the other and there is no legal principle to the contrary and, certainly, the Commission decisions to which the CMA refer in their openings and defence do not establish one.

So none of this, in short, can displace a proper rounded assessment. It is a starting about and, in this case, those market shares taken alone tell you nothing about the competitive process in terms of the ability of Accord-UK to act as an appreciable -- to an appreciable extent independently of competitors or customers. That is the matter that I have been through. As Mr Bishop suggests, therefore, these shares really do nothing to add to the picture.

The next topic is price differentiation. It is common ground that price differentiation on its own tells you nothing in a differentiated market. The CMA determinedly ignore differentiation in their closings on dominance. They continually refer, for example, paragraph 252-3, which is at {IR-L/7/111}, to

Accord-UK's ability to charge a price premium with no recognition in either of those paragraphs that it is their own case that the market is differentiated, which means that such a premium is to be expected.

There is some reliance on the *Astrazeneca* case. The General Court's decision is referred to. The simple point there, we will see what Mr Holmes wants to make of it, but it was not a differentiated market, so price differentials in an undifferentiated market obviously do tell you something about market power, if they are sustained over time and market share is retained.

But in *Astrazeneca* the General Court specifically rejected the argument that there was a differentiated market, paragraph 73 and 220. The references, I need not turn them up, at are {M/79/29} and {M/79/82}. There is repeated emphasis on the relative price differential rising to 500% by the end of the Intas period. There has been so much repeated emphasis that Mr O'Donoghue seem to have conceived and submitted in writing to the tribunal that the relative price differential remained at 500% throughout the post-entry period, which is not accurate. It is a figure which was reached by the end of the Intas period.

But the fact that that was at the end of the period just shows the artificiality of reliance on this

measure. In economic terms, absolute price differentials were what mattered in terms of margin to customers. What the increase in relative differentials simply reflected at the end of the period was that prices generally were reaching lower levels. So the same, or even lower, absolute differentials were translated into higher relative differentials. As Mr Bishop explained, a £10 absolute differential, when the prices are £50 and £40, will produce only a 25% differential. Bring the price down to £20 and £10 and you have got a 50% differential. So it is just a reflection of the overall absolute differentials becoming lower.

Again, that is not in itself informative of the strength of constraints in lowering full label prices in this case where what was operating on customers was how much margin they were going to get and were they getting still the same margin as they were previously getting, or at least the same as they were previously getting, and was that causing them to re-evaluate their decision to stay with full or switch to skinny or not?

I do not submit that all of these things are irrelevant. I do submit that they all have to be understood in their context as part of that rounded assessment and I also submit that these are all market

outputs, if you like, which tell you something, but do not replace the nature of the fundamental enquiry which is whether this is a result or not of Accord being able to shrug off competitive constraint and act independently. For the reasons, I have given you it was not and these outcomes, market outcomes, do not tell you anything different.

The final point, to the extent that it is a separate point at all, but I note it is stressed as a separate point in the CMA's closings. They make a separate point under the heading of "Profitability", which is really just a reflection of the increased differential given that the costs in each case were not significantly different. So there is no doubt that for all parties for a long time this was a profitable product measured over costs or cost-plus, but of course within the context of a portfolio pricing approach, which has to be remembered: see Mr Burt, at his paragraph 15 and 63-64. So it is {IR-B5/1/5} and {IR-B5/1/20}. That again tells one little more in the context of this case, which is, again, that the same competitive constraints that were operating in the Intas period brought the price down subsequently to within the costs plus bracket after the Intas period. It simply confirms that this was an effective competitive process.

So, ultimately, in the context of this case, none of these market outcomes add anything to the analysis on the effectiveness of the constraints which are sufficient to deprive Accord of the ability to act to an appreciable extent independently of its competitors and customers and Professor Valletti, in my submission, is wrong to privilege them and to say that some notion of competitive price has to be reached before dominance can be said to have ended. He is looking at everything through the wrong end of the telescope.

Those are my submissions on dominance.

So I turn to abuse. We make a number of related submissions on this, but the first is a direct consequence of the submissions I have made to you about the no choice argument, because once you remove that plank of the CMA's case that there was no choice, people were unable to switch, then it becomes very difficult to understand in what sense you can be held to be "imposing" a price. Imposing a price is something you can do either if you have a captive customer base or if, for some other structural reason of the market, although no one single consumer is captive, a portion of the market is captive, because there is not sufficient supply across the market. You become an inevitable trading partner for someone. In that case, you can

impose a price if you know that someone has to buy your product.

But that is not the position here. No one had to buy our product. There is no one whose features as a pharmacy was somehow different from another. Tesco did not have to buy our product. Sainsbury's did not have to buy our product. Morrisons did not have to buy our product. Some did. Some did not. You are offering a price to the market and it is up to the customer as to whether they want to buy. In those circumstances, it makes no sense to say you are imposing a price.

Now, this is a point we make in our opening submissions at paragraph 71 and 72. Perhaps we can just call those up. That is at {IR-L/5/1} and I now see that I failed to write down the page number, but we want paragraphs 71 and 72 to that document. {IR-L/5/29}. This is where we set out those principles. The Chapter II prohibition, as in Article 102, speaks of "directly or indirectly imposing unfair selling price", not simply "applying" but "imposing". In the following paragraph we explain that has a clear meaning. Customers had no choice but to pay it. That is what "impose" means, require to be paid or undertaken.

The language of Article 102 has the same sense in the different languages, French, Spanish, Italian

Portuguese. I won't attempt to pronounce them all:

"In the German version the sense of requirement is even clearer, using a term 'Erzwingung' which means 'enforce'."

This is not accidental language. It is an aspect of the exercise of market power, if you are able to impose a price rather than simply offer a price which a customer is free to take or not as the case may be.

Now, the CMA say this is semantics. We disagree. We do not think this is a semantic point and we set out why in our reply, if I can call that up.

THE PRESIDENT: Just to nail a potential ambiguity at the beginning of your paragraph 72, I think what you are saying is the term imposes a clear meaning: customers had no choice but to pay it if they wanted the product.

MR PALMER: That is true of any product.

THE PRESIDENT: Yes, I agree.

MR PALMER: If I want a Mars bar, I have no choice but to pay for a Mars bar.

THE PRESIDENT: Indeed.

MR PALMER: If they had no choice but to --

THE PRESIDENT: If they want the product, they pay that price.

MR PALMER: It is more than that. It goes further. You are imposing a price if they have got no choice but to buy

your product. So if they want -- if they want hydrocortisone tablets, they clearly do have a choice between full and skinny. The CMA's premise in their Decision was that certain customers had no choice but to buy full label if they wanted hydrocortisone tablets at all. Now if that were true, it would make sense to talk about imposing prices. I accept that. This goes hand in glove with their conclusion about no choice at all.

But if you take that premise away, then you get a different answer as to the question of whether you are imposing the prices on anyone. Once you acknowledge any customer is free, just as Day Lewis can buy or Lloyds can buy, the fact that they choose not is a matter of their own customer preference, not a matter of a price being imposed on them for something which they have to buy.

So they say this is semantic and say inconsistent with the authorities. But we say on analysis the authorities that they refer to all in fact do concern circumstances in which a price was imposed in circumstances where indeed the customer had no choice.

We set out our reasons in the reply. I am going to take you to the Defence first, which is at paragraphs 331-332. It is at {IR-A/6/124}. You see there that CMA -- this is the CMA's Defence:

"As a matter of law, an undertaking can abuse a dominant position by either offering, setting or charging unfair selling prices. Intas's argument is purely semantic and cannot be accepted. In any event, it is clear from the authorities that the list of abusive practices ... is not exhaustive; they are merely examples of abuse ..."

So there might be a different -- other than imposing prices, they might be presumably offering abusive prices:

"Nor does it follow from the wording ... that customers must be compelled or forced to pay the price in question in order for it to be abusive.

"As a matter of fact, Intas's contention that customers exercised a choice ... and were willing to pay more for them is incorrect ... an assured customer base ... that enabled it to charge unfair prices... "

That is the factual point which I have addressed. Let us just focus on the legal point. Footnote 563 is what is offered in support of that suggestion:

"The Tribunal held the 'offer' of an excessive access price to be abusive in *Albion Water II*; the 'setting' of unfair terms was abusive in Slovak Telekom ... The tribunal recognise that 'charging' an excessive and unfair price can be an abuse in *Guttmann*."

If you go to our reply, {IR-A/11/29}, paragraph 67 through to 73, we make the initial points which I have already shown you, but then at 70 we say:

"*Albion Water II and Slovak Telekom* are both margin squeeze cases, where the complainant could not obtain access to infrastructure unless it paid the price offered/set. Thus Albion could not obtain access to partial treatment and common carriage of non-potable water for its supply to its customer, Shotton Paper Mill, from anyone other than Dwr Cymru, and it had no choice but to pay the offered price. And in Slovak Telekom a company wanting to access the copper local loop in Slovakia could not do so other than from Slovak Telekom, and had no choice but to pay the price that Slovak Telekom set."

Just pausing there. The great come back on *Albion Water II* in the CMA's opening is: *Albion Water II* was not just margin squeezed. It was other abuses too. It completely misses the point. The point is if you wanted water you had to go to Dwr Cymru. You had to pay the price that was being charged. There was no choice in the matter. The same with if you wanted telecoms access to local loop in Slovakia you had to go to Slovak Telekom. There was nowhere else you could get access to the local loop so it made sense to be

classified this as imposing a price.

Now, on one level no one has to buy water. No one has to access the local loop, but if you are in that market and you do have demand for that, you only have one place you can go and the price is being imposed on you.

THE PRESIDENT: Yes, I mean, all I was making the point was there is a distinction between imposing a price where one has a choice and say imposing a tax where actually you have no choice.

MR PALMER: Exactly, so, and in *Guttmann* it is a live issue. It is still going through the courts. There was a strike out summary judgment case where it was -- the issue was whether you could be said to have no choice when the alternatives are obscured away is the rail tickets case, because the alternatives are so inaccessible that they are not actually a relevant choice put before the consumer. That was a case which was sought to be struck out, but has not been and continues to go through the courts and has not been resolved yet. I am not sure whether it can tell us anything else.

That is the first point. In circumstances where if we are right there was a choice here, we are not in a no choice situation, there cannot be an abuse because you

cannot meaningfully talk about a price being imposed.

The second point has already been trailed widely and I need not say anything more about it. It is the second limb of *Napp* point, which arises under abuse. You do not need to reduce your prices further and faster than the competitive process demands if there is going to be entry and effective competition within a reasonable period. I have covered that already, as has Mr Jowell.

The third point, if there was an obligation to go faster than those competitive constraints dictated, as I say, inexorably, but still there is an obligation to drop your prices further faster, as a proposition, if that there were to be accepted, one would have to go on to answer the further question: how quickly? To what level? I asked Professor Valletti that and of course he could not provide an answer. He shrugged his shoulders and said £20, but that of course is an arbitrary figure determined by the CMA's administrative priorities after the event. You get into the same questions and problems, which I posed in relation to the originator products earlier on. See further our closing submissions at paragraph 99. They are at {IR-L/5.1/170}.

Our fourth point relates to economic value. We have prepared a note, which I will hand up in a moment, in

response to the note that the tribunal handed down just before the weekend. I will not address you on that note now if I may. I will leave it with you to read and reflect upon. Before I do hand that up, let me just make our submissions and flag our positive case on economic value and then that note will address the question which was raised --

THE PRESIDENT: Yes.

MR PALMER: -- in that way.

The first point about economic value is it all depends on. It is a demand side function. It is a further reason to allow competitive process to work, because it begs a question. It begs a question to your customers: what do you value and how much do you value it by? It is not way of saying whatever you value, whatever price we decide to charge is how much you do value by it. It is a different enquiry from that and it is common ground between us, but it starts with an investigation into, from the demand side, what customers value.

That is a matter for them. It is not a matter for the regulator to say what they should or should not value. It is not a matter for the tribunal to decide what they should or should not value. But there may well be evidence that customers do value a particular

attribute of a particular product.

In this case one of the things which is clear was valued, notwithstanding, as I have made perfectly plain, there was no regulatory difficulty with dispensing off-label and so forth, what some pharmacies value is the assurance of knowing if we stick with full label, we do not have to worry about that.

You remember some emails where in response to initial mailings by Auden saying rival products do not have the full indication, the response is: well, we have got the full indication product. We do not have to worry about that. We need not look further.

Some pharmacies attach value to that. For some pharmacies, that is a function of a risk-averse attitude towards regulatory risk, as I have already covered.

As the market progresses and the regulatory risk becomes clearer, it may be, as Professor Valletti accepted, that a diminished value is put on that avoidance of regulatory risk as it tends towards negligible in the perception of the purchaser over time, which would explain why the value attributed to it declines over time and the prices go down over time.

The tribunal's view turns on all the evidence. Again, not just that which is set out in the Decision and not just that which the CMA identified as having

value. In that context, I refer you again to Dr Burt's evidence as to what his customers valued, as he perceived it, paragraphs 57-60 of his witness statement. That is at {IR-L-B5/1/1} and you will recall paragraph 57 is the one about regulatory risk I showed you a moment ago. 58 is the long list of matters which he told us that his customers valued and which I put to Professor Valletti and, insofar as he felt able to give any opinion on that matter at all, he understood and accepted that those things could attract value and he said could be included in the cost-plus calculation, for example, other matters might not be.

The point is that those are matters which customers value and somehow there has to be a reckoning as to what value is to be attributed to it.

THE PRESIDENT: Mr Palmer, is it your position that the approach we should take to value is indifferent as to where in the chain of supply one is looking? In other words, there is no difference in whatever value assessment one undertakes between the ultimate consumer, by which I mean here the person actually taking the medicament, and the stage above that, the pharmacy who dispenses the medicaments to the ultimate customer, but who is of course also in the chain a buyer.

MR PALMER: In my submission, the position is more nuanced

than has so far been put. Taking it in stages, the patient almost invariably for hydrocortisone tablets for adrenal insufficiency pays nothing at all, whatever age they are in, whatever age they are and whether they are in England, Scotland, Wales Northern Ireland. That is because there is a medical exemption certificate which if you have adrenal insufficiency you are entitled to get, because it is a chronic disease and provided you apply for that certificate, and why would you not, you get free prescriptions.

So the vast majority of patients pay nothing at all. What they want is the medicine which is going to treat their condition, which is hydrocortisone and they presumably value that medicine enormously because it is life saving, but they are not the ones paying anything, even the prescription charge, except in what must be very small minority of cases. Who is paying? The answer is the Department of Health is ultimately paying and they pay of course because they have designed the regulatory system in this way under the drug tariff exactly the same whether what is dispensed is full or skinny. That is what it means to put them in the same category together in the drug tariffs. They are paying exactly the same, but do they attach value to what they are buying? Yes, they do, because they are the ones

responsible for discharging or meeting the public good, which is the NHS system, and that includes meeting demand at the point of need and doing so on that free basis for these patients and, thereby, saving their lives. Is that a public good to which they attach value? Absolutely, yes, they do.

The pharmacists on which Mr O'Donoghue put particular emphasis are an important part of the chain, of course they are, as are the wholesalers, because each take their cut, if you like, at each stage of the supply chain. The pharmacists will value particular aspects of that drug which stand discrete and in addition to its life-saving properties, which are valued by the patient and by the Department of Health: for example, security of supply. Particularly important for, say, Boots which wants its own brand product. It wants security of supply so it can always rely on that product. It does not want to have to be dotting around between small suppliers here there and everywhere and they are prepared to pay a price to reflect that. So that is part of the value within the supply chain for them.

There are other aspects of what Dr Burt explained in his paragraph 58, which again are aimed at the wholesaler market and the pharmacy market, things which they will value.

All of this will be part of the value of the product which Accord is supplying and through that rather unusual chain of demand is being purchased.

THE PRESIDENT: That was a very full and helpful answer, if I may say so, in the context of this particular market and, obviously, we are concerned with this particular market. But would your answer be any different if one moved away from this particular market to something which was less fully regulated? In other words, if one had a more ultimate consumer driven demand, where one does not have prescription charge or zero price if one is exempt and someone else paying the price for the drug, but one has simply got a consumer who is paying out his or her own money for a good?

Now, if one is talking about value there, would you agree with the proposition that those who are further up the supply chain have a far more attenuated sense of value in that they will be focused on the price of the thing they are acquiring which they are then on selling, no doubt adding their own value, adding their own components to this thing. Will they be primarily focused on price and things like security of supply, quality, which are essential to their long-term business? But at the end of the day, they will be looking at what it is that they can produce that will

enable the ultimate consumer to be induced to buy more of that which they are producing. Is that something that will inform the supply chain rather more in the ordinary case than in this special case?

MR PALMER: It is difficult to say. It may be more a question for an economist, but of course in an ordinary product which is being bought just as a function of consumer preference, demand for some leisure product or some inessential matter, the question will be, from their point of view, how much do they value that product and the notion of consumer surplus comes into play in a way described in the tribunal's note, but there is other value to that product.

Why is the shop stocking that particular make of that particular product rather than a different particular make of that or very similar product may well depend on other considerations which are discrete from the attributes of that product which any particular consumer may value. Price of course would be a very significant one, but, also, such things as is their supplier able to supply other goods at the same time more simply rather than have separate suppliers for separate items. Can they all be delivered at once? Are they regular deliveries? Are they responsive to the demand? If it is getting low on stock and wants to

restock quickly, how quickly will that be met? Those are all sources of value at that level of the whole.

So in that respect not different, but obviously at the consumer level it may well be different, but I am not sure how much that tells us about the application of the legal test set out in *Phenytoin*, which if you turn to our closings at paragraph 122, which is at {IR-L/5.1/70}. As I say, we have a note which will more directly address the specific concerns that the tribunal has raised. {IR-L/5.1/70}. It should be paragraph 122. There is our summary of what the Court of Appeal say in *Phenytoin*, which may well be familiar territory. We agree it is not to be equated with the economic concept of willingness to pay. That is not adequate or else nothing would be excessive:

"There must be a 'reasonable' relationship between price and economic value to overcome that difficulty.

"The concept of economic value 'is 'legal' in a strictly limited sense that it has been ascribed in a meaning in a court judgment, but, at base, it is an economic concept which describes what it is that users and customers value and will reasonably pay for'."

So there is a distinction between user and customer. It may depend on what level of the supply chain you are the customer.

If we can move on there (d):

"Not the legal test for whether a price is unfair, but rather ... overall descriptor of the abuse. It 'needs to be factored in and fairly evaluated, somewhere, but it is properly a matter which falls to judgment of the competition authority as to where in this analysis this occurs.' It can be dealt was as part of the 'plus' in the cost-plus analysis, or as part of the unfairness analysis (as Professor Valletti suggested)."

We have given the reference for that and:

"The fact that a customer is dependent on its supplier does not mean that there is no scope for economic value to arise. 'Economic common sense indicates that dependency and the inferences to be drawn from its existence are indeed matters of fact and degree. Even if there is dependency there might still be some economic value but not necessarily reflecting full price demanded'."

So what follows from that is you need to identify as a tribunal, however difficult it is, what it is that users and customers value and what those users and customers will reasonably pay for those characteristics given the circumstances and the market context.

As I say, that is users and customers. No single

one individual at any one level. Certainly not just the ultimate patient or the ultimate purchaser in the sense of the funder, the ultimate funder the Department of Health.

So all of those matters within the supply chain which are valued, whether that be the avoidance of regulatory risk, whether that be security of supply, need to be identified and not discounted by the CMA on the basis that they do not think those things should be valued but it should be recognised that they are valued and it should be determined what value in fact it had for those customers, however difficult that is. That is the exam question that has been set.

It is in that context that the CMA try to dismiss the importance of the orphan designation. They say -- it is their closings, 305, which is at {IR-L/7/133} -- that we cannot rely on the value ascribed by pharmacies, and at certain points wholesalers, to avoiding the regulatory risk arising from the orphan designation because they pointed out and say well, the orphan designation had nothing to do with the intrinsic properties of the product. It did not reflect the investment or innovation or anything of that kind. So therefore it has no value, that aspect of this product.

That is just wrong. We know that customers valued

that. That is the issue. It is not for the CMA to dismiss this.

They also try to dismiss at {IR-L/7/134} 307, which I think may be over the page, maybe further down, the factors identified by Dr Burt that feature in their decisions to do business because they say they shed no meaningful light on the question of the economic value of its hydrocortisone tablets.

"As Mr Bishop accepted the factors adumbrated by Dr Burt were not specific to hydrocortisone tablets."

No, of course they were not, but they included hydrocortisone tablets and, as I put to Professor Valletti, that was not a reason to dismiss the value to be attached to those attributes.

They also in 308, immediately after that, completely ignore the fact that the market is differentiated. They talk about a bioequivalent commodity product in 308 which is not an accurate way to describe a differentiated product.

Then at 310 they attempt to take current prices as the benchmark for effective competition.

Go on to the next page:

"Here the current prices of competing hydrocortisone tablets are set in such a market and so provide a helpful proxy for their economic value."

That is wrong. It is the structures and dynamics of the market that identifies effective competition not the outcome, and the current market is no different to the market in the Intas period save that some competitors have now exited. The fact that different suppliers have beaten the price down between them so far down that no longer is it worth their while to continue to supply that product at the market price leading them to exit may well lead to the prices starting going up again as market exit occurs, none of that is an evaluation of market value which is a function of the demand side and what customers value.

So this is an incomplete answer and an inadequate answer on the part of the CMA.

Sir, those are my submissions on abuse. Just before the mid-afternoon break and before I turn to penalties, I want to say a very brief word about legal certainty.

You heard already from Mr Jowell about the legal certainty. I adopt those submissions and will not repeat that. We have also set it out in our closing arguments at 108 to 109 which is {IR-L/5.1/64} and 136-138 which is at pages {IR-L/5.1/78-79}.

Really just to cut that short for the purposes of summary at the moment, really what it amounts to saying is if we are wrong on dominance and/or if we are wrong

on abuse that would represent a wholly novel development of the law to a situation which has not arisen before. In particular, the submissions I was making on dominance, the particular position of Intas and the need to focus exclusively on the run-off period and what consequence that has for dominance.

Intas were entitled to rely, we say, on the very clear dicta in *Hoffmann-La Roche* for example as a matter of legal certainty and it is wrong as a matter of principle to overturn that. But if, as Mr Jowell submitted, it were to be overturned, the law were to be developed in a new way to cover these areas, then we say that would have particular significance for penalty, in particular intention and negligence must play into that consideration and if not, at that point as a mitigating circumstance when it comes to the amount of any penalty.

But there are significant reasons of legal certainty why it should not be developed in that way. It is not just the novelty in catching someone by surprise in that way. It would also be divergent from the CMA's approach in its other pharma cases, in particular in *Liothyronine*, and *Phenytoin* where in each case the infringement was found to have ended at the point when entry occurred.

So this would be a real development to take it

beyond that point and, as I say, we adopt Mr Jowell's dog law submissions on those points.

Finally, the implications of upholding Intas's appeal on either or both of these points does not set the unruly horse of excessive pricing bolting off in some dangerous new way, as it would if it were to be dismissed with the consequences for costs plus, the consequences for what effective competition means. But in terms of upholding Intas's appeal I do stress that this arises in a very unusual circumstance where we are focusing on the period of price drops rather than price rises, and implications would be very limited to such an unusual situation, an entirely novel situation where we have been told that we are dominant and abusing that dominance by dropping prices but not at the rate which the CMA after the event said we should have done.

So this would simply bring us into line with other cases, *Liothyronine* and *Phenytoin* if it were to be held that the relevant point is the point where those market constraints do not determine the pricing decisions, and so we remain at the point where we lose independence from those competitive constraints.

So those are all the submissions I want to make about liability. So after the short break I will deal with the penalty.

THE PRESIDENT: Very grateful. In that case we will rise and resume at 25 past.

MR PALMER: May I hand up to that note I promised you if it would be convenient to do so.

THE PRESIDENT: Yes, of course.

MR PALMER: Sorry, I had forgotten.

THE PRESIDENT: Not at all. (Handed).

(3.17 pm)

(A short break)

(3.25 pm)

THE PRESIDENT: Yes, thank you, Mr Palmer. We have read and taken on board that. Thank you very much.

MR PALMER: Thank you very much, sir.

Just before I deal with penalty, in my rush to the finishing line just before the break, I misspoke in one respect which I would like to correct, importantly.

Liothyronine and *Phenytoin* I said the infringement was found to have ended when entry occurred. I should have added when entry occurred and prices started to fall pursuant to that entry. So the same point which I have identified in this respect. That is the point that we relied on, not the mere fact of entry. I do not want there to be any confusion about that.

THE PRESIDENT: Thank you.

MR PALMER: Penalty, we have two grounds, ground 3 and

ground 4. The first ground focuses on whether intention or negligence has been established. This is where we say the failure of the CMA to focus on the Intas period becomes even more stark when you get to this stage of the analysis, despite the apparent acceptance of the *Areva* principles. That is Intas only responsible for conduct of its subsidiary during this period and the penalty must be specific to the offender and the offence. So despite the apparent acceptance of those at face value and, indeed, as also in accordance with *Areva* the separation of the penalty into separate time periods, according to parental liability, the CMA has failed to actually follow the logic of that through into its application of the attribution of liability and the factors which it considers in determining whether there was intentional negligence in relation to the Intas period.

Let us start with the test, which you will be familiar no doubt. We set it out. It is common ground. Our closing paragraph 143. That is at {IR-L/5.1/81}. We say:

"It is common ground [based on the authorities set out there] ... In order for the CMA to have power to impose a fine, the undertaking must have been aware, or could not have been unaware, or ought to have known,

that: (i) it was in a dominant position; and/or (ii) that it was imposing prices that were unfair."

Now, the CMA does not begin to wrestle with the fact that whatever went before the Intas period, it is still necessary for them to prove that any infringement was committed intentionally or negligently throughout the infringement period and, therefore, throughout the extent of the Intas period which forms part of the infringement period.

But the market, as I have submitted, is not static and there is no basis to assert that just because an undertaking ought to have known that it was dominant previously -- let us take that it as our initial premise -- then it ought to have known it remained dominant when it was unable to resist rapidly dropping its prices because of the effect of competition from market entrants. It is a different point which has to be focused on and the CMA has not done so.

So all the legal certainty points feed in here too, as I mentioned before the break, and we submit it cannot be said that the court ought to have known that it was dominant if it was not clear or foreseeable that it would be considered to remain dominant in this period in circumstances where no other undertaking has previously been found to be and a strong dicta from the Court of

Justice and from the tribunal in *Hoffmann-La Roche* and *Napp* to give very good reasons indeed to think that you are not dominant and/or are not abusing that dominance.

I am going to show you the Decision. The short point is that it impermissibly relies on evidence which pre-dates, indeed often long pre-dates, the Intas period to claim that a court acted intentionally or negligently in respect of the Intas period and it relies on some limited evidence from the Intas period which on analysis does nothing to establish either intention or negligence.

So if I can start with the Decision at paragraph 10.24, which is at {IR-A/12/974}. You will see this is where at 10.24 the CMA turns to the question of:

"Auden/Actavis knew or should have known that as the sole and subsequently major supplier of hydrocortisone tablets, it was a dominant undertaking in the relevant markets."

So this is Auden/Actavis in all its ownership periods that is being referred to in respect of the unfair pricing abuses:

"Evidence supporting this includes, for example... "

And if we go to the top of the page, you can see just at a glance, I will not go through them all, (a),

(b), (c), (d) all relate to events 2012-2014 relating to Auden and Allergan.

Then continuing further down the page, (e) again, shortly before May 2015, talking about Allergan's acquisition of AM Pharma. And then over the page, even up to (f) the point is that in January 2016, a year before the Intas period, at that point although there had been some market entry there was an email apparently saying market share is 100% plus. So akin to the pre-entry position.

It is only at (g), again, put that into focus, can we put the whole -- thank you. This is the whole fact which refers to Intas and, hence, the Intas period. There is only two matters set out. The first is:

"Intas ... were made aware of the CMA's investigation prior to the acquisition of Actavis UK limited [so at the end of 2016] including that this involved a potential abuse of a dominant position."

That is the first point.

The second point is that Jonathan Wilson remained in place as a Managing Director and Peter Kelly remained in place as Commercial Director, after the acquisition. So they remained and then in July 2017 Mr Kelly took over as Managing Director and they had been made aware of Auden's efforts to protect its dominant position through

Project Guardian and had monitored entry into the market.

Project Guardian of course being a project that was initiated in 2014, continued, was revived in 2015 and the PR, the latest aspect referred to is a PR campaign, based on some Project Guardian materials, was launched in May/June 2016. That was the end of it.

So it is a fact that they knew about that previous effort of Auden to retain its market share, legal effort, as the CMA has since accepted and:

"Mr Kelly had briefed Actavis field teams on the differences between Alissa's product and Actavis as part of its 'communications plan' ... After its acquisition ... Actavis therefore continued to operate under the management that had previously taken steps to preserve its dominant position."

My short submission on both of those points is that neither of them tells you anything about whether Intas ought to have been aware that it remained dominant in the period after the substantial market entry and ineluctable drops in price. The mere fact that they had been made aware of an investigation, which is at a preliminary stage, there are no conclusions, it is subject to the response of those who have had the accusations levelled at them, cannot be taken as

knowledge of the fact of infringement. Still less can it be taken of knowledge of the fact or some imputed knowledge or ought to have had the knowledge that if you allowed prices to continue to drop in accordance with the Scheme M mechanism and the direct constraints imposed by -- presented by competition, that you are continuing to be in a period of dominance.

It tells you none of those things and it sets up a rather worrying apparent principle that if you know that you are being investigated that is enough, or someone is being investigated, that is enough to give you constructive knowledge of the fact of an infringement, a conclusion which the CMA itself even has not yet arrived at.

That is put into stark light really by the fact that when the first statement of objections was subsequently issued to Intas, two infringements were identified. One in relation to the 10mg product, but the other in relation to the 20mg product. It was during the course of the investigation and consideration of Intas's responses that the 20mg breach was dropped in respect of Intas and the infringement period was said to have finished on 7 January 2017, ie the beginning of Intas period. So in respect of that breach, Intas was successful in persuading the CMA that what it had

initially considered to be an infringement was not an infringement or they dropped it for their priorities or some combination of the two.

But it throws into stark light the idea that you should have constructive knowledge of an actual infringement, when (a) it may not be borne out and (b) it relates to an earlier period of time not your period of time, is in my submission nonsense and unsustainable.

The second point that the same management is there is again irrelevant. Reliance of knowledge of events in 2015 does not establish that subsequent market entry and competition with its effect on prices, which I have said enough times, but is not enough to end that period of dominance or end any existing abuse.

Now, importantly, Dr Burt gave evidence on this in this connection {IR-L/5.1/86}. That is in fact taken from our submissions, but you can see the quote I am relying on from Dr Burt explained in his witness statement at 37:

"I strongly believed that we were not acquiring a business (in January 2017) that was dominant or engaged in excessive pricing -- We were obtaining a product that operated in a competitive market with multiple participants, and where prices had declined and were forecasted to continue to decline. I remember

thinking at the time that these were only at the stage of being allegations and, to the extent there was any prospect of an infringement decision, it would be focused on the period when hydrocortisone was being charged at a much higher price."

Now, that evidence was unchallenged. Although initially indicating that they wanted to cross-examine Dr Burt, the CMA just before the hearing began decided that they did not want to cross-examine Dr Burt so it must be accepted as true.

That does not rule out -- accepting that evidence of course does not rule out negligence on its own, but it does rule out intention. So it rules out knowledge and all we are left with is that he was not aware and could not be taken to be unaware and so all that leaves you with is the suggestion he ought to have been aware. Although the CMA nowhere find and have nowhere stated whether they considered that this was an intentional or a negligent breach, the fact that Dr Burt came here to give that evidence and that evidence has not been challenged leaves the CMA in a position where, in my submission, at the very least, they must accept this is negligent at most.

But my primary submission remains that it was not even negligent for the reasons that I have developed at

length. Even if I am wrong on all my submissions on dominance and all my submissions on abuse, that was in mind. It is a reasonable position to take and it is not possible to say that he ought to have been aware that this new precedent, this new position, reflected your legal obligations.

What does the Decision say on abuse? That is at 10.28, which is at page {A/12/977} of the Decision. Just for context, can we have 10.27 in the picture. Thank you:

"Auden/Actavis knew or should have known the essential facts establishing that its prices during the infringement periods were unfair".

Then there is evidence supporting this and, essentially, it is the familiar case being set out as to what amounted to the abuse.

That includes further down in 10.28 the lack of economic value, for example, but, again, see the genuine belief of Dr Burt at paragraph -- we need not turn to it now -- but paragraph 162 at {IR-L/5.1/90}. Again, it is the same point: a reasonable view to take in the circumstances. That is reflected in our closing submissions at paragraph 163 as well.

You then have at (c) (iii), which I think is at the bottom of that page, possibly over to the next page:

"Intas and Accord were made aware of the CMA's investigation prior to their acquisition".

That is the same point again.

Then at (d) the pre-entry position relating to Allergan is set out and then at 10.29, that is the only other point which could be at all applicable to Intas, in the Intas period, which is:

"None of the contemporaneous evidence seen by the CMA shows any regard for the interests of the NHS ..."

A reference to the Project Guardian matter, which is relied on in respect of events in 2014.

I just want to say something about the application of that point to Intas. {IR-C5/3/2} is the letter sent by Intas to the Department of Health in December 2017 of which the CMA makes much. Perhaps if we go to the previous page just to provide the context. Of which it makes much in the CMA Decision in terms of the suggestion is that this showed that Intas knew that it was charging excessive prices.

That is what is sought to be drawn from this letter, the variety of points.

That is a wholly unfair construction to put on this letter. What it actually shows is concern for the interests of the NHS. The first point in the second paragraph you see explicitly:

"It is not, however, the purpose of this letter to enter into the merits or otherwise of the position taken by the CMA, which Intas strongly contests. Irrespective of the legal position, the purpose of this letter is to ask the DH to consider taking practical steps to improve the functioning of the Drug Tariff price mechanism in relation to hydrocortisone tablets."

The specific suggestion that is put forward is on page 2 and under the heading "Possible steps the DH could take":

"According to the CMA, the present mechanism for establishing the Drug Tariff prices for hydrocortisone tablets does not fully reflect the lower prices in the market from the new suppliers mentioned above."

That is the new market entrants:

"We understand from the CMA that this is because the majority of competing companies supplying at lower prices than Actavis UK are not members of Scheme M.

"We therefore write to ask the DH to consider how this situation could be remedied. In particular, we suggest that, irrespective of its statutory powers, the DH could request information as to their supply prices from those suppliers of hydrocortisone tablets who are outside of Scheme M, and/or from the relevant wholesalers, on a voluntary basis. Given the importance

of the DH and the respect in which it is held, we would expect that suppliers would comply with such requests. Indeed, Actavis has received more than 20 requests outside of the Scheme M from the DH in the last six months alone, all of which has responded to in a timely manner.

"The use of all or at least most suppliers' and/or wholesalers' prices as input in the formation of the Drug Tariff price for hydrocortisone tablets would quickly lower the latter and reinforce the competitive process.

"We understand that the DH will have express powers to gather this information pursuant to regulations expected to be introduced following the recent consultation in accordance with the [new Costs Act]. Nonetheless, we urge the DH to wait for the regulations."

Indeed, those regulations were brought I think in July 2018 having precisely this effect that information would be gathered from all market participants, not just Scheme M.

So they were effectively saying: why not bring that forward on a voluntary basis?

What do the CMA draw from this letter? First, they say you have no concern for the interests of the NHS,

bizarrely. Secondly, they say it shows you knew you could be pricing lower so that therefore you knew your prices were excessive. That is a monstrosity of a distortion of this letter. What it clearly says is about reinforcing the competitive process in the sense which I have been setting it out, that the process which is something to be followed to see where the ultimate competitive equilibrium will land, that you do not know in advance where the prices will bottom out, that you need to rely on the market direct and indirect competitive constraints over time to take you there and it is not an abuse to do that.

If it is not an abuse to do that, then it is not an abuse -- and that was the belief clearly -- if we get into penalties, I am wrong about that, but that is the belief that is being put forward. If it is not an abuse to follow those processes, it is certainly not indicative of abusive intent or knowledge to say: here is how we could make this work even better for everyone concerned.

It is a monstrosity to draw from that an adverse inference against Intas in terms of its knowledge of abusive conduct.

Furthermore, we then have the response of the Department of Health to it, which is at {IR-C5/24/1}.

Appreciating, the second paragraph, your concerns and noting your suggestions, but setting out in the following paragraphs, I go straight to the fifth paragraph:

"Hydrocortisone tablets were identify as fulfilling the Category M entry criteria shortly before they were added to Category M in July 2014, and after consultation ... The Department has been monitoring the reimbursement price of hydrocortisone 10mg tablets since the CMA launched its investigation in April 2016. The price has been systematically decreasing reaching a reimbursement price of £34 in January 2018, calculated by using data from July-September. This reimburse price includes market prices of companies that submitted data under Scheme M and a margin. If the Department used Actavis's data alone in this formula, the reimbursement price would be higher."

That is certainly true. That of course was not being suggested. What was being taken from this: yes, we are monitoring this and we are getting sustained decreases, indeed systematic decreases. This is in the knowledge that the DH now have the power of course to intervene, both under the terms of Scheme M, as Ms Ford explained, as well as these new regulatory powers, but nothing is done and so Intas take some comfort from that

and conclude that the system is operating as it is intended to operate.

It does not show a lack of concern for the NHS. It does not show knowledge. It does not show intent and on evidence like that from the DH itself it is difficult to infer negligence and say you ought to have known that what was happening was not enough.

What does the CMA say all about this point in its closing? That is at {IR-L/7/144} paragraph 342. They address this point. They refer to Auden/Actavis. They do not say anything about the Intas position. Just says knew, should have known it remained dominant, knew, should have known, exploited the nature of its prices because they are above cost plus the reasonable rate of return and there was a gulf. They were not engaging with any of the points that have been advanced at all.

And the following page, paragraph 345:

"Rarity of excessive pricing cases and alleged uncertainty of the law. The short answer to this is that an undertaking does not need to have known that its prices were against the law. Arguments about the level of enforcement and later clarifications of the legal test do not detract from the key fact that Auden/Actavis knew or must have known that there was no justification of for the dramatic price increases for Hydrocortisone

Tablets over 8-9 years. Auden/Actavis cannot have been unaware of the adverse effect that its exorbitant prices would have on the NHS and patients."

Again, not engaging with the period of price drops or the Intas period at all. Case closed they say. We say far from it. Burden not discharged.

That is ground 3.

Ground 4 is the last in subject matter and it concerns the amount of the penalty. The penalty on Intas, as you may recall, ended up as some £44.4 million. We say that is manifestly disproportionate and excessive. We have put in writing and I will develop in a moment, but by reference to our written submissions as well, the reasons why applying the CMA's penalty guidance they have taken a disproportionate approach, always setting matters at the highest level that they can, and failing to reflect properly when most cases at all mitigating circumstances which would apply to Intas in respect of the Intas period.

There are five central themes. The first is that they wrongly adopt the maximum level of 30% of relevant turnover at stage 1. That is something that other appellants have referred to as well. Our headline point is there is a complete failure to take into account any

of the mitigating circumstances relevant to Intas in arriving at that conclusion. We say those mitigation circumstances are substantial. They must be taken into account somewhere. They are not taken into account anywhere.

The second theme is that they failed to separate out matters which are and are not relevant to the Intas period, despite ostensibly recognising the *Areva* principles and we summarised the failure to do that in annex 3 to our opening statement and it is contrary to what is said in the Decision that they would apply the *Areva* approach.

The third matter is the incorrect assessment of specific aggravating and mitigating features contrary to the terms of the guidance.

The fourth is the treating of the separate ownership period of Intas as an opportunity to exceed the statutory maximum for Accord-UK and impose at that stage a 400% uplift on Intas in the name of specific deterrence. We say the justification for that is wholly absent and the fifth is the failure to apply a proportionate penalty overall.

So starting with step 1. The use of 30% maximum is excessive. If you turn to the Decision at 10.171, which is at {A/12/1027} of the Decision. We can see that

under stage 1, the CMA says:

"Taking into account the nature of the Infringements, the specific circumstances of the case, and the need for general deterrence the CMA considers that each of the infringements is so serious that the maximum starting point of 30% of relevant turnover should be applied for each of the penalties."

That is in respect of all parties without distinction between any of them. It is a blanket approach in respect of the entire 10mg pricing abuse and immediately fails to ensure that the penalty is suitable to the offender and the offence.

Just contrast that with the position that the tribunal set out in *Eden brown* {M/82/30} at paragraph 78 second line:

"When it comes to assessment of seriousness in this context, each case is very dependent on its facts. We agree with the OFT that the seriousness percentage is not to be approached as an exercise of box-ticking of various elements, and para 2.5 of the Guidance makes clear that enumerated factors are not the only considerations."

So not a box-ticking. That matters in a case like this is the short point where separate penalties are being imposed in respect of separate penalties. If we

go to the Guidance itself which is being applied, that is at {M/148/11} paragraph 2.1:

"A financial penalty imposed by the CMA under section 36 ... will be calculated following a six-step approach."

Footnote 17, can we skip down to that:

"In applying the steps to individual undertakings in multi-party cases, the CMA will observe the principle of equal treatment, which is articulated by the ... (now General Court) ... as follows:

"The fact nonetheless remains that ... [the Commission] must comply with the principle of equal treatment, according to which it is prohibited to treat similar situations differently and different situations in the same way, unless such treatment is objectively justified."

A familiar principle and one expressly recognised to apply in the circumstances of a multi-party case.

Adopting that approach in respect of the Intas period, our submission is 30% cannot begin to be justified as the maximum penalty in Intas, in the same way as applied to all others, in circumstances where Intas never raised prices at all, but they only dropped them. It never entered into any agreement in combination with the unfair pricing. Customers had the

option to switch away at any time, as 50% did. They were not captive as the CMA now acknowledges. It is very different to the situation pre-entry or immediately post-entry where there was no choice at all but to buy that product.

The CMA relies in its Decision at 10.172 (b), that is page 1027 {A/12/1027} on a list of factors. Perhaps for context we could have the beginning of that paragraph:

"With respect to all infringements, the following factors are relevant to the CMA's assessment of their seriousness."

These are the factors which go into arriving at 30%. The first is:

"Likelihood of the infringements, by their nature, to harm competition".

That is broad and generic and very much box-ticking, but not irrelevant, I accept. But then go on "Nature of the product" at (b). Look at the final sentence:

"The Abusively high prices charged for this product did not affect the level of demand during the relevant period, which reflects the essential nature of the product and the lack of affordable alternatives."

No longer true by the Intas period.

At (c) you see the emphasis on:

"Auden/Actavis was the sole supplier of hydrocortisone tablets during the majority of the infringements and retained a significant market share even after independent entry."

We say there as a matter of choice and less serious than if you are the sole supplier. Then the rest of the paragraph relies on the agreements and consequential lack of competitive pressure arising from them. Again, not applicable.

At (e) general deterrence is relied on. Reducing prices insufficiently quickly requires less, we say, in the way of general deterrence than raising them in the first place. This is a very unusual situation. Normally, in order to drop prices following an abuse you have to raise them in the first place. Not true here. In effect, what is being done by way of general deterrence here is more broadly accurately categorised, in relation to our position at least, is a disguised price regulation objective and not a deterrence objective at all.

Fourthly, consider the new price control powers which are now in place and relevant to general deterrence as this tribunal noted in *Flynn Pharma*, the CAT decision at paragraph 461. You were shown that by Mr Jowell. You have already seen that. The tribunal

considered that the need for general deterrence was less in light of those new price control powers.

Then turning to page {A/12/1030}, the next page, there are some specific factors relied on in 10.174 in relation to the unfair pricing abuses in this case contributing to their seriousness at (a) directly and deliberately imposing such prices. But that of course is now inconsistent with the fact that the CMA cannot, having failed to challenge Dr Burt's evidence, sustain an allegation of direct and deliberate imposing abusive prices.

And (b), amounts to reliance on duration, which is double counting with stage 2.

Then there is the previous decision or practice, which is relevant, as the tribunal explained in *Roland v CMA*. It is at {M/182/37}, paragraph 87:

"We accept ... there should be broad consistency in the OFT's approach to the Penalties Guidelines and, if the starting point in this case was out of line with the CMA's approach in other decisions, this would indicate that the Guidelines may have been misapplied by the CMA."

{IR-L/5.1/98}, please, where we see in that respect there are decisions involving similar conduct, *Phenytoin* at 30% and *Fludocortisone* Acetate at 20%, but

neither of those cases are comparable:

"Both concerned conduct that raised prices, rather than, as here, prices falling and market share being lost."

We say there must be a difference:

"*Fludocortisone Acetate* was not an abuse of dominance case. Neither cases concerned medicines in Category M ... Apart from *Phenytoin*, the CMA has only applied the 30% maximum starting point twice before, one in *Galvanised steel tanks* (a cartel case involving price-fixing, bid-rigging and marketing sharing) and in Pre-cast Concrete Drainage Products (involving price-fixing, market sharing and a regular exchange of competitively sensitive information)."

We say our conduct in our specific period does not come close to that in the Intas period and there is no plausible basis for saying that all are equally serious.

If we go back to the guidelines at {M/148/13} we see the range of -- it is that first bullet point:

"The CMA will generally use a starting point between 21 and 30% of the relevant turnover for the most serious types of infringement, that is, those which the CMA considers are most likely by their very nature to harm competition."

You remember that was the fact that I said was

a relevant consideration at (a) of their subsequent list where they identified excessive pricing as ticking that box and, indeed, at the end of that bullet point, you see excessive pricing being mentioned as being one of the forms of abuse which falls into this category.

So under their guidance there is a range from 21 to 30%. We simply say that within that range there should have been a fact-sensitive, relevant to the specific case of the Intas period, assessment of where Intas lay. We say if that had been done fairly, and without the wish to put everything at its maximum, it would have come out right at the bottom of that range when you bear in mind there cannot be -- although excessive pricing is serious, if we are guilty of excessive pricing there cannot be a less serious variety of it than dropping prices in accordance with the established regulatory market mechanisms and existing competition in the market in the face of entry.

The CMA's response is at {IR-L/7/155} in its closing submissions at paragraph 369, which proceeds they disagree that our offending was less serious:

"The abuse continued to be serious during that period given."

Then there was a series of comparisons of our price with cost-plus and the current price of skinny and the

entry price in 2008, none of which are the applicable benchmark or held to be. They decided to cut off at £20 as the limit of the extent of the abuse as a matter of administrative priority. What that means, given the quasi criminal context, the presumption of innocence and the burden of proof on the CMA, is they cannot rely on a positive assertion that they ought -- Intas ought to have dropped the prices below £20. Yet here they do in order to establish the seriousness of an allegation they have not made in relation -- have not established in relation to liability. We say that is unfair and i*nappr*opriate to use that, least of all to use that as a way of suggesting that Intas's -- the seriousness of Intas's offending was the same as anybody else's and no different.

At paragraph 370, the following paragraph, they address our point about reducing, not raising, prices. They say:

"Exploitative prices are a serious abuse irrespective of price rises. What matters is the unfairly high level of prices."

But that of course ignores the honest belief now acknowledged by failing to cross-examine Dr Burt, honest belief that competitive market was operating under Scheme M as it was meant to. No credit given for that

at all or for the belief that the process was in operation, as indeed the Department of Health confirmed.

So that is step 1. We say it is over-egging it to put it up at 30% and unfair.

Step 2 is duration. We do not have a quarrel about that.

Step 3 mitigating and aggravating features. We have a number of small points on this. I say small, they are important. They relate to involvement of senior management, the compliance regime and cooperation where we are given an aggravating feature of 15% in respect of director involvement. We were given only 5% instead of 10% reduction for compliance and we were given no benefit at all for genuine uncertainty or cooperation.

I will deal with those very briefly in a moment. But that is all in detail in our written submissions. I do not need to go through all of those before this tribunal.

But our big point under step 3, mitigation, is if it is -- if the CMA is right that none of the mitigating factors as I have been through should be taken account of at all at step 1, then they are nonetheless mitigating factors which need to be taken into account at step 3. Nowhere in their response to this appeal has the CMA ever explained why those factors are not taken

into account under step 3. Whether it is right to take them into account at step 1 or step 3 does not ultimately matter to us. What does matter is that they are taken into account somewhere.

The specific circumstances of Intas's position are assessed by reference to the Intas period and not to all that went before for which Intas, as a parent company, cannot be held responsible.

This is a glaring hole in our submission in the Decision.

As to those smaller points, I say they are smaller because they are only worth 5, 10, 15%, but in the context of a fine which ends up at £44.4 million these are still substantial amounts of money so I do invite the tribunal's attention to them, because between them they are worth several million pounds. Contrary to the CMA's assumption when we get to stage 4, those sums do matter to Accord. They do matter to Intas. They do have an effect and they are serious, which is why we have developed at some length our position under each of these points where we say we are entitled to fair consideration under the penalty guidance which applies.

So far as director involvement is concerned, the CMA concluded, just to note, no need to turn it up, 10.198 at page 1039 of the Decision that the 15% uplift should

be applied for director/senior management involvement. But that was a figure which was applied in relation to the entire infringement period and not by reference to different ownership periods. So, again, no consideration of the differences between the pre-Intas period and the Intas period.

If I can take a quick look at *Ping* in this tribunal at {M/151/100} paragraphs 245-247. You can see at 245 they considered it helpful to take a step back to consider why it might sometimes be appropriate to treat director-level involvement as an aggravating factor meriting an increased fine.

The answer comes at the 246:

"An example where director-level involvement is likely to be treated as an aggravating factor is the case of a secret cartel."

That is then explained. What runs through it is in the final three lines of that paragraph:

"It is the fact that the intention to restrict competition extends to the highest echelons of the undertaking which aggravates the offence. This holds true even if the undertaking is relatively small."

That continues then to consider the facts. At 247 of the case before it and because of its public nature "the infringement could not have occurred without

director-level or knowledge. Junior staff could not have implemented the internet policy alone. It is the fact of director-level knowledge alone would treat it as an aggravating factor and this infringement could never have been considered as anything other than aggravated. However, applying an uplift would then become meaningless: an uplift should be reserved for more reprehensible behaviour."

Again, what is said about director involvement in Intas's case is just that the same management team was kept on. Those who had been involved, at the stage when prices were going up, were the same individuals who were there when prices were going down. That tells you nothing about the extent of their culpability, in particular given the honest belief at director level that you have had from Dr Burt that prices were now -- that that infringement related to a period before when prices were higher and the market price was now going down. Competitive process was now working as it should.

There is an absence, I have submitted, of evidence of intention given the failure to cross-examine on that basis. Knowledge does not do it as explained in *Ping* alone. It would become meaningless, and this is out of line with decisional practice as well in terms of 15% specifically rather than the precedents of 5 to 10%

uplifts. The detail of that is in our closings at paragraph 181(c) {IR-L/5.1/102}.

So that is director involvement.

Discount for compliance. We only got 5% rather than 10%. This is particularly stark. Again, the evidence on this has been provided to the tribunal through Ms Kops who again the evidence is unchallenged. You have her witness statement. It is there to be read.

In the Decision at paragraph 10.129, page {A/12/1047} of the Decision, the CMA speaks in approving terms of Accord's enhanced competition compliance programme. No need to go through the detail of that now, but it finds much to like.

Then at {A/12/1048} it notes that the same activities, at the top of the page there, were assessed as sufficient to merit a compliance discount in *Nortriptyline* market shares.

The discount offered on the basis of the same compliance was 10% in *Nortriptyline* but only 5% is offered now because they say from 10.221:

"Accord did not provide some of the underlying documentation necessary for the CMA fully to assess its compliance activities and programme."

And gives a detail of what they wanted in 3771. But what was supplied was the same. Ms Kops explained it

was supplied in *Nortriptyline* and nothing else was asked for. The CMA said, we do not have to specify what we need, it is down to you to produce. But having established a 10% discount in *Nortriptyline* on the information of compliance programmes it is perverse to say, oh you haven't provided us with enough, you only get 5% when the same material was being relied upon and had been submitted to the CMA in response to an RFI.

So Ms Kops has exhibited that material but she has also exhibited in addition the further material which the CMA said should have been applied. This tribunal has its own jurisdictional to consider these matters. It is not a judicial review where you can say well, the evidence was not before the CMA so we do not have to take account of it and we have now supplied it.

There has been no engagement with that material from the CMA, no further suggestion that material is inadequate. They simply say, you did not supply it to us. We say that is not good enough and we say we are entitled to an additional 5% to take it up to 10% on that point.

Step 3 mitigation, other identified points under the guidelines for mitigation is a genuine uncertainty. You have heard from me on that and the legal uncertainty. If nothing else, it is a mitigating factor. No credit

for that at all. That cannot be right.

Cooperation. On that you have Ms Kar's witness statement. Again, not cross-examined so accepted, where she details the extensive cooperation provided over an investigation period of over four years as the CMA wrote, re-wrote and then re-wrote again the statement of objections seeking repeated responses at every stage. They were always on time and, as Ms Kar explains, in addition voluntary provision on a monthly basis of market data throughout. Went above and beyond and exactly what cooperation means for the purposes of the guidance and is meriting of some reflection in accordance with the guidance but got none in the Decision.

So that is step 3. Lastly, we come, or penultimately, but the main last one is step 4 on which you have heard a lot already. It is the uplift for specific deterrence and I just want to show you how that was applied in Intas's case. If we go to {IR-A/12/1017} which is table 10.3. You can see the period A4 is the third substantive row down where you can see on the right-hand column the penalty prior to adjustment works out at £8.89 million. That is where all the stages that we have been through so far leave us, £8.89 million, representing that maximum 30% starting point and the

aggravation and mitigating features were taken into account.

That is contrasted in the middle column with 12.5 million, being the revenue differential above £20 per pack. Two factors are relied upon to increase from 8.894 million. Not to that 12.5 million figure which would represent a 40% uplift at this stage but to £44.4 million, a 400% uplift, an order of magnitude different.

How on earth is that justified in circumstances where that puts everything that has gone before in the shade. As Mr Jowell observed, effectively it renders pointless the precise and fine-tuned approach taken following the guidelines. It is enormous. It is exactly the proportion 100% of which the CAT expressed its scepticism in the *Phenytoin* case. You see that uplift, {IR-A/13/73}.

In the bottom half, under the brand section where the uplift is identified in the third column under the period A4 column, 8.894, uplift of £35.5 million for specific deterrence and proportionality it is said takes you up to 44.4 million.

How is it justified? Two reasons are given. The first is financial benefit. But, as I have submitted already, even if that were to be the correct approach,

that would justify a 40% uplift not a 400% uplift. But it is not a justified approach. The penalties guidance, so {M/148/18} on this, paragraph 2.21:

"The penalty figure reached after steps 1 to 3 may be increased to ensure that the penalty to be imposed on the undertaking will deter it from breaching competition law in the future, given its specific size and financial position and any other relevant circumstances ... Such an increase will generally be limited to situations in which an undertaking has a significant proportion of its turnover outside the relevant market or where the CMA has evidence that the infringing undertaking has made or is likely to make an economic or financial benefit from the infringement that is above the level of penalty reached at the end of step 3. Where relevant, the CMA's estimate would account for any gain which might accrue to the undertaking in other product or geographic markets as well as the relevant market under consideration."

So is the words are:

"The CMA's estimate would account for any gain."

That is the guidance. But what they do is go further. They say, paragraph 10.290, that the penalty needs to "materially exceed the financial benefit". That is not what the guidance said. But relevantly it

is what the draft, then draft new penalty guidance which was then out for consultation said. That is at {M/185/1}. There is the draft guidance as it stood at the time. Page 18. {M/185/18}, paragraph 2.22 where you see the language there, six, eight lines down:

"... so to be effective deterrence, should exceed likely gains from the infringement by a material amount."

That is the approach that the CMA applied. That is wrong in law. {M/16/36} is section 38 and it is subsection 8 we need:

"Appropriate level of penalty:

"When setting the amount of a personal under [this part] in respect of an infringement of the kind mentioned the tribunal must have regard to the guidance for the time being in force under this section."

The draft guidance was not in force and even though it now is in force it does not apply to earlier infringement on its own terms. So no basis to increase at all beyond accounting for the financial benefit which would take you to £12.5 million. Not £44 million.

The second and final factor relied upon is essentially the size of Intas. The Dcision deals with that at 10.279 which is {IR-A/12/1064}. It is 279-283. For your note I will not go through all of those reasons

now but you can see it relates to size and financial position.

Mr Jowell took you to the two authorities which I rely on as well or refer to them. They are *Eden Brown* at 99 {M/82/62} and *Kier* at 175 {M/81/62}.

I adopt Mr Jowell's submission. I do not repeat them. For your note it is transcript {Day12/164:20} to {Day12/165:11}. What he says applies equally to Intas so I asked you to review that in that context.

The central point that I stress is that the principle that comes out of those authorities is one which is precisely neglected by the CMA which is that it fails properly to balance deterrence against culpability of the offender and this huge uplift of £35 million does not reflect the relative culpability of Intas.

There are some useful tables to gauge how the financial gain and size have been factored into in practice. We can have a quick look at {IR-A/1.5/1}. That is a useful table to compare the different penalty approaches and you can see the amount of uplift applied in each case. We are A4, that Intas period you can see, those familiar figures and you can see as a percentage of the alleged gain 355%, vastly greater than applied in other cases, including 20mg unfair pricing abuse. That is one metric for proportionality.

Then on the following page, {IR-A/1.5/2}, in comparison of financial metrics and the penalty imposed. Here it is a comparison of different undertakings. Worldwide annual turnover. The penalty is a percentage of worldwide turnover. You see in Intas it is vastly in excess of others. This is not, I hasten to add, an argument that others should be higher. It is an argument that ours should be lower.

Similarly, worldwide annual profit after tax. You see vastly different percentages there. Again, order of magnitude different. These are just two measures to assess this.

There is one other mode to assess this which is {IR-L/5.1/112}. 19 (c). Again:

"The penalty comprises 30% of the total penalties imposed for the alleged 10mg unfair pricing abuses for all periods. Notwithstanding that it is approximately only 18 months (ie only 16% the entire period) and Intas is responsible for only 9% of the alleged financial benefit. To the extent any of the conduct participated in by the entity now known as Accord-UK can be said to represent an infringement it is less serious than the conduct alleged in respect of the earlier period."

That is three different ways in which we have cut it to try and get some sense of benchmarking or comparison.

On every single one Intas comes out worse.

Another final indication of the arbitrary nature of this 400% uplift is provided by the CMA's own document. This was their draft penalty statement issued to Intas. {IR-H/1119.1/27}. Paragraph 87:

"An uplift of 150% would be appropriate.

An uplift of 150% to the penalty would result in a penalty of 31 million at the end of step 4. That would be an effective deterrent and would not result in a disproportionate or excessive penalty ..."

The CMA said in its first draft penalty statement. When that subsequently becomes 400% there is no explanation as to why. Even that result, the 31 million, was too high as it still failed to factor in proper mitigation and the market reality that this reinforces at every stage of the ultimate decision the CMA has sought to push the boundaries, imposed to go to the maximum and barely to reduce for any mitigation at all. We say for any measure over the top it entirely fails to reflect relative culpability and renders meaningless everything that has gone before.

Step 5 is the step back for overall proportionality. We say given all of the above this is a grossly, disproportionate and unfair penalty. It fails to respect the principle of equal treatment treating

different cases differently. It fails to reflect relative culpability. If any penalty is due, it should be reduced very substantially indeed.

I have made half past four just about. Those are my submissions unless there are any questions from the tribunal.

THE PRESIDENT: Thank you very much, Mr Palmer, we are very much obliged to you.

MR PALMER: Thank you.

MR O'DONOGHUE: Sir, one tiny clarification if I may. On Friday Professor Mason asked me did AMCo have any CMO backup project or was it just Aesica and I said no. That is incorrect. The MIBE project, that was a CMO project. For your reference, sir, it is 3264 of the decision. {A/12/123}. So there was a second CMO project.

THE PRESIDENT: Thank you. So tomorrow we begin with the CMA. We have been looking at the timetable and provided it can be done without cutting anyone back we were minded to suggest a 10 o'clock start for the remaining four days, Tuesday through Friday.

MR GRUBECK: The 10 o'clock start works for us.

THE PRESIDENT: But the sting in the tail could be that we would be able to finish on the Friday at about 1 o'clock so that we can all draw stumps earlier. So the aim is

to take a leaf out of Mr Brealey's book and save half an hour a day or gain half an hour a day with a view to saving Friday. Does that suit everyone?

MR BREALEY: It does.

THE PRESIDENT: I do not want to pushback. In that case we will say 10 o'clock tomorrow morning. Thank you all very much.

(4.34 pm)

(The hearing adjourned until Tuesday, 20 December at 10.00 am)