IN THE COMPETITION APPEAL TRIBUNAL

Case No: 1524-1525/1/12/22

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Monday 6th November – Wednesday 13th December 2023

Before:

The Honourable Mr Justice Marcus Smith
Eamonn Doran
Professor Michael Waterson

(Sitting as a Tribunal in England and Wales)

BETWEEN:

Appellants

Pfizer Inc. and Pfizer Limited & Flynn Pharma Limited and Flynn Pharma (Holdings) Limited

V

Respondent

Competition & Markets Authority

A P P E A R AN C E S

Mark Brealey KC, Robert O'Donoghue KC & Tim Johnston (Instructed by Clifford Chance LLP) on behalf of Pfizer

Jemima Stratford KC, Tom Pascoe & Alastair Richardson (Instructed by Macfarlanes LLP) on behalf of Flynn

Josh Holmes KC, David Bailey, Jennifer MacLeod, Julianne Kerr Morrison & Conor McCarthy
On Behalf of the Competition & Markets Authority

Wednesday, 13 December 2023

(10.02 am)

Closing submissions by MR HOLMES (continued)

THE PRESIDENT: Mr Holmes, good morning.

MR HOLMES: Good morning, sir, members of the Tribunal.

We covered a lot of ground yesterday afternoon and I hope it will enable me to move swiftly, although please do interpose with questions because they were very helpful.

Just to take stock, before we broke, I was making submissions on the applicable framework of analysis by reference to the case law. I had addressed you on the basic test of unfairness, the two-limb approach as an appropriate means of applying the test, and the legitimate role for a cost plus assessment at the first limb by reference to a dominant firm's own costs.

If I may, I will tell you where I would propose to go from here. First, there are a couple more points on the case law. I will then make submissions on the excessive limb and why we say the prices at issue were demonstrably immoderate. As we discussed yesterday, there are a number of ways of assessing whether returns are reasonable or immoderate having regard to the time value of money and the risks involved, and in this case we say they all point clearly to immoderation. Finally,

I will address you on the factors relevant at the fairness limb.

Now, when approaching fairness, I will frame my submissions in the light of yesterday's illuminating discussion. I will proceed on the basis that this is a case 2 situation. We understand the emphasis the Tribunal has placed on continuity of supply. It is, as we see matters, the only possible differentiating feature between this case and the other two relevant recent cases of excessive pricing in generic pharmaceutical markets.

THE PRESIDENT: Yes, that is actually quite an important point to be clear about because if there is any other factor that shunts the case from case 3 to case 2, apart from continuity of supply, then we will need it articulated in reply --

MR HOLMES: You would want to know about it, yes.

THE PRESIDENT: -- because our position is we are obviously going to have to decide whether even that factor is case 3 or case 2.

MR HOLMES: Yes.

THE PRESIDENT: But, as far as we are concerned, that is the factor that moves it from 3 to 2.

MR HOLMES: Well, that is very helpful, sir.

As we discussed yesterday, concluding that this is

a case 2 situation does not determine the question of how much value should be afforded to the differentiation in play. My submission will be that this is an unusual type of differentiation: it does not fall into the paradigm examples identified in *Hydrocortisone* where we can readily see that a generous allowance should be afforded. On the contrary, we say that there are a number of features of continuity of supply which show that it would be wrong to assign significant value to it at the fairness stage.

Moreover, we say that the available comparator evidence, when considered, shows unfairness. That is clear in particular from the tablet ASPs. Tablets are as close a comparator as one could imagine in a case of this kind. They are the same active ingredient for the same condition supplied in the same main dose of 100mg and one can readily see why the Tribunal first time around wanted to know more about them, not about the drug tariff price, which is clearly not a market measure at all, but about the prices actually prevailing. That is the ASPs.

Those prices shed light on the demand-side value that capsules could achieve under conditions of competition which, though still dysfunctional, are at least more effective than the present capsules market,

and the prices achieved through that process of competition were well below the capsule prices and they suggest that the capsule prices were indeed unfair.

But the insights from the comparators in this case do not stop there. In my submission, the price trends for other AEDs where competition is in play and the evidence as to NICE's QALY-based assessment of phenytoin also point decisively to the conclusion that Pfizer's and Flynn's pricing was unfair. So that is the road map, and you will see, sir, that I have sought to address the guide perhaps even more directly than we did in our closing submissions, taking this as a case 2 situation with some differentiation which marks it out and assessing how that affects the location of value or fairness in this case.

THE PRESIDENT: I am grateful.

MR HOLMES: There is one remaining point, sir, then, on the case law from phenytoin in the Court of Appeal which is the question of economic value, and this was my third basic proposition.

If we could go back to Lord Justice Green's judgment at {XN1/5/47}. At paragraph 153 you will see that Lord Justice Green introduces the ground of appeal described above "economic value/patient benefit", and this is the ground relevant to economic value. In brief

overview the CMA was challenging the Tribunal's conclusion that this was a legal and not an economic test, that it was a discrete component or limb of the test which needed to be independently addressed after the *United Brands* limbs, and the Tribunal's finding that the CMA had assigned no economic value to phenytoin, so that is the ground.

After introducing it at paragraph 154, Lord Justice Green identifies the conundrum, so if we could enlarge the lower half of the page, please. In the second sentence:

"In broad terms the economic value of a good or service is what a consumer is willing to pay for it. But this cannot serve as an adequate definition in an abuse case since otherwise true value would be defined as anything that an exploitative and abusive dominant undertaking could get away with. It would equate proper value with an unfair price. This is a well-known conundrum in international competition law."

Then at paragraph 155, the conclusion drawn from the conundrum:

"The simple fact that a consumer will or must pay the price that dominant undertaking demands is not therefore an indication it reflects a reasonable relationship with economic value. But a proxy might be

what consumers are prepared to pay for the good or service in an effectively competitive market ..."

So willingness-to-pay in the real world is not the answer, instead, Lord Justice Green's suggested solution is one which connects back to economic value: the foundational concept of normal and sufficiently effective competition.

THE PRESIDENT: Well, it does more than that; does it not just connect back to: we are removing the dominance to working out what would be the price that would be paid if one had an effectively competitive market. So it is really completing the circle, is it not?

MR HOLMES: Absolutely, sir, that puts it very well.

What value would customers attach then to the product without the dominance? His Lordship proceeded to consider the ground and rejected it on the basis that the Tribunal's conclusions on economic value were ultimately rooted in factual findings on the evidence which it was entitled to make.

Turning on to page {XN1/5/51} and picking it up at paragraph 170, if we could enlarge the foot of the page, he notes that there were nonetheless some aspects of the Tribunal's judgment which he had concern about, and he addresses them by way of guidance for the remittal.

At paragraph 171 he notes that while the test is

legal in the strictly limited sense that it has been assigned meaning in a court judgment, it is at base an economic concept. This squares, sir, I think with the Tribunal's findings in *Hydrocortisone* and its rejection of the notion that, you know, this has no attachment to economics, and indeed the *Hydrocortisone* schema as we apprehend it is an attempt to work through the consequences of that conclusion.

Then in the third line from the bottom it describes:

"... what it is that users and customers value and will reasonably pay for ..."

"Will reasonably pay for". So the test describes, yes, what users and customers value and will reasonably pay for.

Again, therefore, not what they are in fact willing to pay but what they would reasonably pay absent dominance.

Then turning over page {XN1/5/52} at paragraph 172, his Lordship rejected the notion that economic value needs to be separately assessed as a requirement discrete from the other components of the test and you will see in the fifth line, the conclusion that:

"... the reference to 'economic value' is as part of the overall descriptor of the abuse; it is not the test. The test should ... when properly applied, be capable of

evaluating economic value. So, for instance, as the CMA argues, when evaluating patient benefit it would be possible to measure its economic value in the Plus element of Cost Plus, or ... in the fairness element. Equally, if there is evidence of the prices being charged in relevant, comparator, markets which were effectively competitive then those prices could be capable of acting as proxy evidence of the economic value of patient benefit."

So again, value under conditions of effective competition, the emphasis upon separating legitimate economic value from economic compulsion of market power, and in the final three lines of the paragraph the summary:

"In short, economic value needs to be factored in and fairly evaluated, somewhere, but it is properly a matter which falls to the judgment of the competition authority as to where in the analysis this occurs."

Then the conclusion further down the page, the ground of appeal fails because of findings of fact by the Tribunal which were not amenable of appeal, but a final observation to guide the remittal, in the middle of the paragraph:

"The CMA has advanced what seem to me to be plausible submissions that given the very high disparity

existing between cost, ROS and ultimate price the possibility of any 'economic value' attributable to patient benefit exerting any effect on the outcome is remote. The Tribunal did not suggest otherwise. Whether this ultimately turns out to be so, will be for the CMA to consider on ... remittal."

So on this issue the proposition we derive is simply that economic value must be considered somewhere, but it is not the third limb of the test, and an appropriate proxy to determine reasonable willingness-to-pay is what customers would pay under competitive conditions. Guidance as to this may be locatable as Lord Justice Green emphasised from other comparator markets, and it is there that we say tablet ASPs fit into the equation.

THE PRESIDENT: Yes, I mean, I entirely accept that. It also provides the link to the points that were made by Mr Brealey in particular citing *Attheraces*.

MR HOLMES: Yes.

THE PRESIDENT: So what was there said was that provided one has assessed price and economic value in the context of a workably competitive market, then that outcome is that which is fair. We are not in the business of rewriting a test of fairness that is independent of the operation of workable competition.

MR HOLMES: No, indeed, sir.

THE PRESIDENT: We are not trying to say -- we are not being socially redistributive or anything like that.

MR HOLMES: No.

THE PRESIDENT: What we are doing is we are saying for better or worse we are a market economy.

MR HOLMES: Yes.

THE PRESIDENT: The market needs to be working properly. If it is working properly, then none of us has any business looking at it anyway. We have here an issue that there is a dominance problem which may give rise to an abuse --

MR HOLMES: Yes.

THE PRESIDENT: -- and it is that abuse that we are first of all trying to characterise, which in excessive pricing is very difficult because the abuse is not removable by way of a counterfactual assessment because an excessive price is an excessive price.

MR HOLMES: Yes.

THE PRESIDENT: That is why one needs to remove the dominance and work out what is fair in that meaning.

MR HOLMES: Yes. We fully endorse that, sir. The important thing is to identify the extent to which there is value separate and independent from dominance and to seek to find ways of shedding light on what that is.

THE PRESIDENT: So just to complete the thought, if in

a workably competitive market the price that would have been paid in that counterfactual would have been well above cost, then that is a fair price.

MR HOLMES: Yes.

THE PRESIDENT: But that is the question that we have to resolve.

MR HOLMES: Absolutely, sir. I think you have hit the nail on the head.

Now, pausing there, we do say that Pfizer's submissions on willingness-to-pay are based on quite a fundamental misunderstanding of the correct approach to assessing willingness-to-pay applying the Court of Appeal's judgment in phenytoin. So as we understood Mr Brealey's submissions, Pfizer contends that the Tribunal can and should assess what the NHS was willing to pay for capsules, reflecting their value in a manner which is untethered from what the NHS would have been reasonably willing to pay in conditions of workable competition, and I think, sir, you rightly canvassed this point with Mr Brealey, if we could go to the relevant part of the transcript, it is {Day16LH1/50:14-19}, please.

If we look at line 14 you see, sir, that you put a proposition to Mr Brealey:

"So what you are saying is that economic value is

something which is relevant independently of the fact that it is not the outcome of a market process; it is simply a justification that one can charge more."

Mr Brealey says:

"Yes, and that has been the way of life for thousands of years [it was always thus] and, as I said earlier on, if I value my Aston Martin, I do not have one any more, but if I had one ... and I got it at a much lower price, I would be very, very happy, but I value [the] brand ..."

PROFESSOR WATERSON: We can have a whip round.

MR HOLMES: Sir, well, if it comes to costs assessment you should first consider the schedules.

"... I would be very, very happy, but I value [the] brand, I value the -- so it is not to do with workable competition as such."

Then to pick up the President's comments from page {Day16LH1/51:11}:

"In an effectively competitive market with workable competition, you have the price mechanism which determines value, and let us take it as agreed for the sake of argument that the equilibrium price in that situation subsists well above cost. So you have, through the operation of aggregate supply and demand in a competitive market an outcome that gives you what

economic value is, and therefore courts do not need to worry about what economic value actually means because the answer is provided to them.

"Where one has a situation where the position is not necessarily a competitive market, there is a detachment between what price tells you about economic value, and my point is to what extent is the Department of Health's view about economic value of assistance in terms of just -- all it tells us is what the Department of Health was prepared to pay, but it does not really --"

Then Mr Brealey there interposes:

"Full stop."

You say:

"Okay, so that is as far as it goes?"

Mr Brealey replies:

"But that is what demand side is to a certain extent all about, and that is why my fourth point is economic value, so says Lord Justice Green at paragraph 171, so says the CMA in the Decision, economic value is what the customer is reasonably willing to pay."

You, sir, put it to him that that is in a competitive market, and Mr Brealey says:

"No, it [does] not say competitive market in paragraph 171."

We say Mr Brealey's submissions here are not

compatible, with great respect, with the correct legal approach as set out in Lord Justice Green's judgment. Willingness-to-pay may well be high, that is the case where the product is, for example, essential and the customer has no choice but to purchase it. That is not, though, the correct focus of a competition law assessment. As we have looked at, Mr Justice Green did refer to the need to consider reasonable willingness-to-pay in terms of what would be paid in a sufficiently competitive market. Pfizer's submissions, we say, simply ignore that critical point.

So that was the state of the law at the start of the remittal, and we say that the CMA appropriately directed itself by reference to the Court of Appeal's guidance. Now, we have already discussed the *Hydrocortisone* schema at some length, and you are of course well familiar with the *Hydro* judgment, but if I could briefly open it just as a way of addressing you upon its application to this case, I will leap straight to the point where the cases are introduced, and that is at {XN2/29/156}. I can take this quickly.

Case 1, superior efficiency. That is at 322(1). The point is that in the real world less efficient sellers can often stay in business pricing at their inefficient costs, allowing more efficient businesses to

price above cost, and, sir, we agree entirely with this part of the *Hydro* schema: it identifies a type of case which should not be viewed as unfair, and that mirrors the observation made in the *Aspen* case in the passage which I showed to you that a price will be viewed as fair at limb 2, where the price differential is due to superior efficiencies, so, so far, so good.

Case 2 on page {XN2/29/157}, we have:

"Generation of additional value through the provision of distinctive value."

As the Tribunal states later in the judgment, this is the basket of cases where some level of producer surplus subsisting above cost can be justified, and the case is centrally focused, as we understand it, on value creation or generation by the dominant undertaking, and looking at the detailed discussion in 157, the Tribunal states after the heading that:

"One of the most unrealistic limiting assumptions of the perfect competition model is that it presupposes only one (undifferentiated) Product."

Now, just pausing there, sir, we agree that for many markets this is indeed an unrealistic assumption, and it is an important one to keep in mind when applying the unfair pricing rule.

In some markets where there is little or no

competitive effort devoted to innovation, quality or brand, we say that the assumption should be viewed as less unrealistic. Indeed, one would expect under conditions of competition for competition to focus on price and for that to force price down towards cost, and we say that is the case for generic pharmaceutical products, and I will show that by reference to some of the available comparators here.

We rely on the passage which we showed you yesterday from the *Liothyronine* judgment --

THE PRESIDENT: Mr Holmes, if you are saying no more than in the real world as opposed to the world of perfect competition there are instances where there is high elasticity of demand between products then you do not need to spend very much time persuading us of that. I mean, take petrol filling stations, you have literally the same product in the sense that it is standardised because otherwise your car will not drive if it is not.

MR HOLMES: Yes.

THE PRESIDENT: And you have differentiation through things like brand, but you have an inevitable following of price across different brands because of that very elasticity.

MR HOLMES: Yes.

THE PRESIDENT: Now, that is on a spectrum much closer to

the perfect competition world, but it is nevertheless not perfect competition because one does have the whole range of abilities to differentiate, whether it is brand name or other facilities in the filling station or location of the filling station, those are all things which are not catered for in the perfect competition model which do exist in the real world but which nevertheless do not create enough of a differentiation to enable the particular filling station to charge materially more than the filling station a few miles down the road.

MR HOLMES: Yes, well, you have my point, sir. It is nothing more sophisticated than that and I do not mean to tax you with points that are obvious.

The only elaboration, slight elaboration of the point, is to note that in generic pharmaceutical markets, you are about as close to a commodity product as you could imagine, because there brand is generally of limited significance. Continuity of supply.

THE PRESIDENT: Fair enough, though here one has the factual issue of the branded generic, as it was called in evidence by some witnesses, which is a wrinkle that we are going to have to deal with, but you are right, that is related to the continuity of supply question because it was felt necessary to be able to differentiate

between what were generic goods and that is a slightly odd thing to say, that a branded generic can exist, but clearly in this case it did.

MR HOLMES: Yes, well, that takes us -- there is a terminological issue here which I think might need to be teased out. It is true that the name here included Flynn. Branded generic, as I think it is ordinarily understood in the pharmaceutical market, is a product which is not any longer at the patented stage but which is still sold as a branded product. So Epanutin would be an example of that.

THE PRESIDENT: Oh, indeed, there are three layers --

MR HOLMES: Yes.

THE PRESIDENT: -- there is the patented product, there is the branded product and there is the generic product.

MR HOLMES: Yes.

THE PRESIDENT: But there is in this case an elision between the generic and the branding in that one has a differentiation amongst generics which is going beyond the description of the active ingredient to saying it is an active ingredient, namely sodium phenytoin, and it is Flynn.

MR HOLMES: Yes, sir, I mean, I should say first of all that Ms Stratford who is much more expert in matters of pharmaceuticals is indicating that I may have misstated

the position in relation to branded generics, so she can elaborate on that in due course or now if it would be helpful.

MS STRATFORD: Do you want me just to --

MR HOLMES: Yes, why not.

MS STRATFORD: I mean, if it is not helpful tell me to sit down, just so we are not proceeding on a misapprehension. What -- I believe it is uncontroversial, I hope -- is not right is that Epanutin, when it was still Pfizer's product was ever a branded generic. That is not right. I see Ms MacLeod is agreeing with me.

A generic is something that has come on to the market as a -- not put on to the market by the innovator. It has come on without doing all of the regulatory tests and trials that are very expensive as we all know, and sometimes those generics are branded. One significance of that is that branded products, whether they are generic products or innovator products, can go into the PPRS, it is now called the VPAS, I think it is now called the VPAG, a new scheme has just been agreed.

I just think we are at risk of terminological confusion here, and you will recall that Mr Williams, I think, did give evidence that Flynn capsules are not

a branded generic because the Department does not consider that using a manufacturer name constitutes being a branded generic.

MR HOLMES: That is very helpful.

THE PRESIDENT: I recall that evidence.

MR HOLMES: If it helps, we have the reference for that.

MS STRATFORD: I will sit down.

MR HOLMES: It is {Day7LH1/22:17} of the transcript just for your note, but I am not sure that it much matters in fact for --

THE PRESIDENT: No, just so that the parties understand what we are going to be doing, we will be defining as precisely as we can the borderlines between these various categories because we have something which sits somewhat uneasily in the normal categorisation and then we will be overlaying on top of that the price control regimes that apply because it is important to have the definitional label that one is using tracking, even if it is not the same as, the price control scheme definitions, and then superimposed on that we are going to have the messiness here of what I have been calling a branded generic, and it was used at times, but that is crossing into Ms Stratford's point that in fact that is not in the general scheme right, but what we have got is some kind of differentiation amongst a generic product

that is driven by the continuity of supply question, and how one labels that is going to be important because we want to be clear about what we are saying.

MR HOLMES: Yes. That is very helpful to know, sir, and reassuring as well. It seems a very sensible approach, if I may say so.

I fully take on board that this case does have the peculiarity of continuity of supply, and I think the Flynn point in the main is no more than a reflection of that. It was requested by the MHRA because of concerns about continuity of supply.

So what I propose to do is come to continuity of supply after first considering your various examples in *Hydrocortisone* to say where we see that particular feature as sitting.

Now, our understanding of the taxonomy I think has been sharpened by the helpful exchanges yesterday. What it comes down to is that the case 2 scenarios will vary in their treatment at the fairness limb, so the assessment of fairness or value will factor in the specific circumstances of the case, and in some cases, the nature of the value creation will readily justify a price well above cost as fair. In other cases, including case 2 situations, excessive prices will not be as easy to justify. So that is our starting point

for the application of this framework.

Based on that approach, we have no difficulty in accepting the examples given under case 2 as paradigm cases where value is easy to detect and should be given credit for. So, just to work through them, the prime example is product differentiation, and picking it up first at (ii) on page {XN2/29/157}:

" ... product differentiation [identified as] the prime example of ... generation of ... value ... exist in many forms: it is not confined merely to innovation (although that is important), but to providing a better quality product in other ways, [or] in catering to the subjective tastes of preferences of Buyers."

The sort of magic creative that is thrown into consumer-branded products.

For our part, we have no difficulty at in accepting that this is a fertile source of value. It generates consumer as well as producer surplus by creating new options for consumers to choose between. Such value generation makes the application of the unfair pricing rule in a differentiated product market such as the Aston Martin market extremely challenging.

Importantly, such value could very well arise in a highly competitive product market and would justify substantial divergence between price and cost, but we

say that the market in this case is not of such a kind. There is no product differentiation through innovation or variations in quality which is pre-assured by regulatory conditions attaching to market access. You need to show the regulator that you can manufacture to an appropriate standard as a condition of authorisation. No one is suggesting that continuity of supply was about some products being defective in terms of their quality.

It is true that brand was introduced by continuity of supply, but I think, sir, you have the causal sequence correct: it is continuity of supply which leads to the brand, it is not brand as an independent measure of value such as would operate in other markets.

Now, patent rights --

PROFESSOR WATERSON: Before we move on from product differentiation, can I just test your -- well, explain my understanding of this situation, of product differentiation and see whether you agree with me.

So in economics, it is common to talk about two forms of product differentiation, although sometimes products will have both. One is what is commonly called horizontal product differentiation, and the petrol station example would be a very simple example of that, but there would be many other examples, newspapers, for example, would be an example, or different sweetnesses

or drynesses of white wine or something like that, where some people will like one, some people will like another.

MR HOLMES: Yes.

PROFESSOR WATERSON: Then there is vertical product differentiation where some products are clearly seen as superior to others which does not mean that the other ones will not be ever purchased, but the vertically differentiated ones, those that are vertically viewed as higher quality, will definitely attract a premium and may also attract a bigger market, and an obvious example like that would be Coca-Cola compared with some no-name cola.

MR HOLMES: Yes.

PROFESSOR WATERSON: So to my mind, it is important in thinking about product differentiation, and in particular in the context of this market to think about the type of product differentiation that is associated with the capsule market within, if you like, either capsules generally or the phenytoin product.

MR HOLMES: That is very helpful, sir. It is something that I think I will need to reflect upon probably in the adjournment and come back to you with considered thoughts in relation to it, but I think we would certainly accept that those two dimensions of product

differentiation exist, they are clearly established in the economic literature, and their consequences for this case I think is something I would like to talk about with those more learned than I am behind me and perhaps give you more considered thoughts later during the course of this morning.

Just to rattle through the examples, on page {XN2/29/158}, the example is given at (b) of patent rights, intellectual property rights intended to protect and reward innovation, and the Tribunal makes the point that where such rights are in play the inventer will be able to command a premium either through licensing or exercise of the patent, and again we agree. This is to incentivise creativity and innovation across the economy; it is a pro-competitive dimension of competitive.

You made the point, sir, that there is no weighing of effort in deciding how long to afford by way of patent protection, how much protection is allowed, and true that is, sir, but it is still essential that there be creative effort in the individual case. The inventer must at least show novelty and an inventive step. They must to that extent show that they deserve the prize of the patent, and the aim of the system is to incentivise creativity across the economy by allowing inventers to

reap where they sow. It is key to promoting dynamic competition by preventing free-riding on others' innovation. Now for that reason, patent cases will be difficult ones, they are very rarely brought. This is not such a case, and we are dealing here with old generic products.

Continuity of supply we see as distinct from the patent example because it is not about creating incentives for the producer. It is not about rewarding manufacturers for creative effort in an upstream technology market. The focus is upon protecting patients in view of the problems with phenytoin. The manufacturer whose product a patient happens to be initiated on is the unintended recipient of a windfall gain in the form of market power.

THE PRESIDENT: Well, maybe one needs to be a little bit more precise about what it is that is generating the value.

MR HOLMES: Yes.

THE PRESIDENT: Of course the point that you are making that this is not a patent case is entirely accepted, but maybe one needs to move away from what this case is not to what this case is in order to attach a degree of monetary value to the fairness question.

So what is it that one might say Pfizer and Flynn

could charge for arising out of this continuity of supply which is, I accept, driven by patient need, we do not want them switching across manufacturer even if the product might be said to be the same thing generically, and is not the premium simply the incentivisation to Pfizer to keep the factory open.

MR HOLMES: Yes.

THE PRESIDENT: Then the question following on from that is how much above a reasonable rate of return ought to be factored in, if anything.

MR HOLMES: Yes.

THE PRESIDENT: So we can ditch the patent thing because the patent bargain is a different question of policy evaluation.

MR HOLMES: Yes.

THE PRESIDENT: Important but only an example of case 2.

MR HOLMES: Yes.

THE PRESIDENT: Here we are saying: well, it is important that the same factory carry on manufacturing the same product for patient benefit.

MR HOLMES: Yes. Sir, I entirely --

THE PRESIDENT: How do you value it?

MR HOLMES: I entirely agree that that is the question, and insofar as there is value here, you have put your finger on it. Sir, you must forgive me if I am proceeding too

slowly.

THE PRESIDENT: No, not at all. It is very helpful to get these out there.

MR HOLMES: I am only working through these carefully partly for my own satisfaction, but partly because you yourself situated continuity of supply by reference to these examples recognising its differences, and so I thought it might be helpful to tease out where we see the differences as lying before coming to address squarely continuity of supply.

THE PRESIDENT: I understand.

MR HOLMES: There is only one example left to go, at least from my perspective, which is the face mask example.

THE PRESIDENT: Yes.

MR HOLMES: I think you know where I am going with that. It is at (iv), if we could go please -- it may be the next page, no, bottom of the page {XN2/29/158}, there we are.

The face mask example.

This is of course, as you note, sir, a rather different situation where there is no product differentiation as such. It is really a case of temporary or transient market power, and what really differentiates it as we see it is the temporal aspect. It goes back to a discussion of entry barriers which you see in the first paragraph on the page looking up. If

we could go up, please, you see there that the Tribunal at the end of the paragraph, it describes:

"Provided the market remains contestable ... prices in excess of cost will serve to attract other Sellers, and competition will ensure that prices trend back to cost, and that consumer surplus is protected. Indeed, that is variant of our Face Mask Example."

So the premise for this example is the market remaining contestable which will ensure that competition can lead prices to trend back to cost protecting consumer surplus. Again, we agree that in many markets prices will self-correct within a reasonable timeframe, and in such cases, a finding of unfair pricing is unlikely. Where prices serve as an effective signal to entry in reasonable timeframes, they may not be viewed as unfair.

Now, sir, I am sure, again, you are going to -- I suspect you will not resist this conclusion at all, but not all markets are like this. In some markets, prices may have to rise to phenomenal levels and stay there for a very long time before any entry occurs, if ever, and in such cases we say competition law operates to protect customers against exploitative behaviour.

Barriers to entry do not need to be insurmountable and indeed, entry may have occurred. That was of course

the case in *Hydrocortisone* itself where the very high prices did attract entrants eventually and led prices to fall, but the Tribunal did not treat the case as falling within the face mask example.

Now, Professor Waterson may recall that a variant on this issue arose in *Liothyronine*. If we take a brief detour to see how the point was dealt with there, the reference is {XN2/28/115}, and you see at paragraph 323 that the argument that Advanz's price -- an argument was being made that Advanz's price increases were not unfair because Advanz implemented them in the knowledge that they would lead to new entry.

It is 322 in fact. I am sorry, it is at the top of the page.

So you see there the argument:

" ... Advanz's price increases were not unfair because Advanz implemented them in the knowledge that they would lead to new entry, increased competition, and a subsequent reduction in prices..."

The Tribunal says about this that the argument would have validity in an effectively competitive markets and there is then a passage cited from phenytoin in the Court of Appeal:

"Where there are no material barrier to entry, high prices can act as a magnet to entry which, in due

course, drives prices down. Many markets are thus self-correcting."

Then at 323, the Tribunal's view of the matter in a niche generic pharmaceutical market:

"In a case such as the present, where there were high barriers to entry, and effective competition was lacking, self-correction would not necessarily occur within a reasonable time. Prices were still falling at a significant rate some five years after competition started. Moreover, since demand for *Liothyronine Tablets* is inelastic, the reduced prices that entry may be expected to lead to in the long [run] would not result in an increase in the volume supplied."

In this case, sir, we say that the effect of continuity of supply guidance is to raise insurmountable barriers to switching of established patients. Such competition as can arise is in relation to the small cohort of patients who are being initiated for the first time and have yet to be locked into any particular manufacturer source of supply.

So the case falls within the exception to the face mask example rather than within the rule. It is a case where there is no prospect of competitive response to discipline the dominant firm's exploitative pricing.

THE PRESIDENT: I think that has to be right, I mean, the

face mask example is actually a very peculiar and extreme one, and the reason it is, is because in the face mask example, the vendor of the face masks was in the market already selling face masks for whatever they were being sold for, and then gets the windfall because of the onset of the virus.

MR HOLMES: Yes.

THE PRESIDENT: Normally, you have someone who identifies a need which they then proceed to satisfy. I mean, take the mobile telecommunications example that was put by the Tribunal to the experts in this case. If you are spending years putting together a network of nodes for carrying mobile signals so that you can establish a network of cordless communications, then you are going to be spending an absolute fortune for no immediate return. You are then going to have to charge a rate well above marginal cost to recover those sunk costs, and the benefit you get is the window of opportunity because it is going to take someone else years to catch up in making the same sort of investment, even assuming no patent protection at all.

MR HOLMES: Yes.

THE PRESIDENT: So it is exactly as you say: the contestability is measured over years, perhaps even decades, who knows.

MR HOLMES: Yes.

THE PRESIDENT: But nevertheless, it is a contestable market just not a very easily contestable market, but only because of the upfront costs in order to innovate. So, yes, the face mask example is an extreme one. It is not, dare I say it, particularly helpful in this case.

MR HOLMES: No.

THE PRESIDENT: That is why we are obsessing about the patent example because that is one which is certainly driven by different considerations of value, the patent bargain that we have been talking about.

MR HOLMES: Yes.

THE PRESIDENT: But it is a situation where you get a period of time that is an effective monopoly that is not related by definition to contestability. You are given an ability to exclude when others could enter, but for the right. Well, that is what one has here: one has an inability to contest the established patients on Pfizer sodium phenytoin or Flynn sodium phenytoin from which they cannot shift because of continuity of supply which makes it precisely like the patent case except the justification for it is completely different. It is not the patent bargain, it is patient benefit. That is why we have different questions of value which are altogether detached to jettison the usefulness of the

patent example now, altogether detached from the patent case.

So in a sense this is, unsurprisingly, a sui generis case. One gets benefit from a compare and contrast process with both the examples cited in *Hydrocortisone*, but to say that they are anything other than contrasting examples I think would be going too far.

MR HOLMES: Yes, well, we are absolutely on the same page there, sir, and I think you have my submission that what the face mask example helpfully highlights is the concern to attend to incontestability, a market where competition will not enter, will not ride in like a white horse at any future stage, so that the market is uncontestable. That is this example, but also --

THE PRESIDENT: Indeed. Just to throw -- because there is no sunk costs in the face mask example, I think one might expect the question of unfairness in terms of how high you can price to be subject to a rather more close scrutiny than an instance where, in the telecoms network, you have been spending millions getting into a position where you can actually differentiate yourself, because the face mask vendor, as I said earlier, has spent literally nothing getting into this happy position where they can charge more. So the only benefit is the attraction of further people to come in

in order to ensure that there is sufficient supply to meet the elevated demand.

MR HOLMES: Yes, no, well we would fully accept that as well, and of course there we have another point of reference for in case because this is a product long off-patent in which there was no substantial investment done but a market that was rendered incontestable by continuity of supply, and without, crucially, the consideration which weighs with patents about the need not to impinge upon the incentive for creative effort where the patent holder has at least engaged in the game and has obtained intellectual property protection based on an inventive step.

So let me turn, I think now, sir, if I may to say how we think continuity of supply should be analysed squarely and directly. We say that it should not justify a substantial differential between price and cost at limb 1 and we make five points.

The first is the important point that you canvassed with me, sir, yesterday, that this case involves locking patients into a particular drug which then becomes essential. This is not a case of genuine customer choice. Instead, and to the extent that the continuity of supply guidance is followed by particular pharmacies, the NHS is forced to pay for a particular supplier's

product because of the lock-in. Continuity of supply is, therefore, the source of market power.

You will recall how Dr Majumdar put it. He said that the effect of the guidance, it followed, would mean that each supplier was:

"... akin to being a monopolist over its pre-existing customer base."

That is in his first report at paragraph 66, {XE1/4/22}. We say that this should not justify exorbitant pricing. To afford it decisive value would run counter to the purpose of the rule against unfair pricing which is precisely to prevent firms from exploiting market power. In this case, large numbers of patients were initiated on this product when it was priced affordably.

Once started, the guidance means that they are unlikely to be switched to another generic version of the same product. Patients and the NHS are stuck with the product and the supplier should not be able to use that monopoly position to price gouge.

Second, the lock-in does not reflect any innate quality of a particular manufacturer's drug. It is simply a function of whoever's drug is dispensed on the first occasion and that arbitrary advantage should not justify a substantial premium.

Third, for a sense of the value of the drug under conditions of effective competition, one should consider the situation in advance of lock-in. So the correct approach, we would say, is not to abstract from a situation where there is continuity of supply, that would be to change the fundamentals of the market; it is a fundamental feature of the market, it is there, and it exists, but one does have a cohort of patients that are being initiated, they are not yet locked-in, and if you want to consider what value might attach to that under conditions of effective competition, we say that there is a simple thought experiment that you can use.

You can imagine for a patient prior to initiation with two or three suppliers in the market, what the supplier could in that case extract by way of value if they were pricing to supply the patient across the lifetime of their need. So there you do not yet have the lock-in, you are prior to the lock-in, and you are asking what value would attach to keeping production facilities on foot, the point that you were, sir, I think, rightly identifying, putting your finger on, as the source of the value here, and we say there it will be a bit like a tendering market: the suppliers would compete by reference to their cost. They would offer a price above their cost, but it would not be one where

they could extract value from the fact that the lock-in had already occurred. So that is one way of approaching this.

Fourth, we say that there is, in this case, no pro-competitive value creation by the dominant firm, no innovation, no investment in quality improvements, and no concern about wider economic incentives to innovate. There is therefore no new consumer surplus being generated through value-enhancing effort and no reason to treat prices as fair in order to protect and incentivise the competitive process. There is no scope for future competitive entry to correct the situation, and this again suggests that limited value should be afforded by reason of continuity of supply.

Fifth, the lock-in resulting from continuity of supply reflects significant disadvantages or defects of this kind of product, namely its narrow therapeutic index and non-linear pharmacokinetics which make it particularly unpredictable and creates some risks in the event of switching.

Sixth, you cavilled at this, sir, but I do say it is at least a point that goes to value: what evidence we have from the health professionals is that they attach less significance to this guidance than one might have thought from looking at the MHRA guidance itself. The

guidance was not followed by doctors, the people at whom it was specifically targeted. Exercising their professional judgment as prescribers, it appears they chose to prescribe generically. The effect of the guidance was felt instead through a significant number of pharmacies refusing to switch supplier and I fully accept that is a conclusion that we cannot look behind and it is actually borne out by the evidence from the tablet market, but we find this situation hard to distinguish from the effect of the orphan designation in the Intas period of the *Hydrocortisone* case.

Now, sir, that is a complex point, it is one we have developed in writing, it is not one I propose to labour now. I appreciate it will be one familiar to you but I just place that on the table at that juncture.

THE PRESIDENT: No, I think we will have to look quite carefully at the evidence in particular of the two doctors, because it is certainly fair to say that their view on continuity of supply differed, but it does seem, just to put my cards on the table, difficult for us to be looking behind what is a very clear statement of what should occur by reference to the MHRA guidance, and I think it was articulated in the receiving of evidence that we felt that a doctor looking at the guidance and for no very good reason prescribing away from that which

was the continuity of supply would be looking at a very difficult to justify course of conduct if the patient sustained an adverse outcome as a result.

I mean, I really would not want to be in a physician's position saying: oh well, gee, I just changed the manufacturer because I felt like it. I mean, I think that would be a very difficult position to justify given the way in which it is framed in the guidance, and that is really why I am cavilling.

MR HOLMES: Sir, your cavilling is well understood and is for entirely understandable reasons. I do not present this as a first-line reason for minimising the value of continuity of supply. It is nonetheless a striking factor on the evidence that health professionals did not in fact follow this, and the guidance appears to have had its effect not at the level at which it was primarily directed, but at the level of the dispensing pharmacies.

THE PRESIDENT: But I mean, what you have been articulating so far, and it is important, is why it is that the supplier of this monopoly product was able to command a higher price. If continuity of supply did not exist, then the problem vanishes. So do we not really need to ask ourselves a question on the supply side, what would justify a supplier taking advantage of his monopoly

position fairly to price higher. I mean, suppose this instance, let us suppose we have a factory in Germany run by Pfizer which has a limited capacity to produce capsules but there is an ability to choose which capsules that one produces, and an opportunity comes along to produce non-sodium phenytoin capsules at a higher rate than sodium phenytoin capsules.

Now, it would be hard to resist -- but I put it to you for you to push back on if you wish -- hard to resist an argument saying: well, we have chosen to use our monopoly power to price above the opportunity cost that we are forsaking in producing sodium phenytoin capsules by increasing the price so it is worth our while continuing that by reference to the opportunity cost production of these other capsules at a higher rate.

MR HOLMES: I would not push back on that for one moment, sir. I agree if there were evidence, anything to suggest that there were an opportunity cost here, that the productive assets could have been deployed to some other more profitable use, then that would put a different complexion on the case, but that really has not been suggested.

The suggestion is rather the one that Mr Doran rightly canvassed with me yesterday that the prices were

borderline profitable before price increases, but that pushes one really towards a price cost equation. If the difficulty is that the product is not being profitably supplied, the question one asks is how much is needed to remedy that difficulty, and that is not -- that is an obvious question that a customer would in fact ask, hence my thought experiment, but hence also the evidence in this case of what the Department of Health did when it indicated that it was unhappy with the price increases here. What did it do? It said: well, show us the costs, tell us what the cost position is so that we can understand if there is a legitimate justification of this kind in play.

THE PRESIDENT: The position would be much clearer in terms of valuing what was being provided if Pfizer were tied into providing a continuity of supply over a period of time which is not, I understand it, the case, but suppose there was an obligation to deliver tablets over -- sorry, capsules over a 10-year period and that had to be done. One can well imagine that one would, much as Mr Harman was saying, anticipate future problems in terms of future cost increases in the present price because one wants to avoid a hike, but here, as I understand it, there was no obligation to continue supply, so if that sort of cost hike that rendered the

factory less economic to run or more costly to run, then there would be a choice either to increase price or to cease supply.

So the continuity of supply point does need to be viewed as an asymmetric issue in that it matters very much on the demand side, witness the MHRA guidance, whatever that is worth, but it matters far less on the supply side because there is actually no obligation to supply, and it is that which we are valuing, not the patient benefit.

MR HOLMES: Yes. Well, sir, that usefully I think elucidates another reason why it would be wrong to attach significant value to the continuity of supply, the extent to which Pfizer was not in fact tied in to continue supplying.

My recollection is that in the first judgment the Tribunal made certain findings about the likelihood of discontinuation which I think do need to be considered and borne in mind when assessing this. I might give you the references after the break.

THE PRESIDENT: That would certainly be helpful because I am putting a hypothetical case rather than one grounded in the facts of this case and I do have well in mind the evidence of Dr Fakes where he does stress in his witness evidence the importance that Flynn attached to ensuring

that they had continuity of supply for not just these products but generally speaking, all their products including in particular sodium phenytoin Flynn capsules.

MR HOLMES: Yes, sir, although the evidence also shows --

THE PRESIDENT: And again we will have to look at that.

MR HOLMES: -- no concrete steps or investment was actually made to diversify sources of supply, so if one is locating value here, it is difficult to see where it sits with Flynn in terms of continuing to supply.

THE PRESIDENT: Mr Holmes, all we are trying to do at the moment is to locate where we should be sniffing around the evidence that has already been rendered rather than saying what the evidence actually is, and I simply recall Dr Fakes in his evidence making clear that on the terms that he stated in the witness evidence that continuity of supply to that extent was a factor that Flynn took into account. How far it goes, well, that is a matter which --

MR HOLMES: Another matter. Indeed, sir.

So you have my point about the thought experiment, how the competitive dynamics would play out prior to lock-in. Of course, by the time the price increases were imposed, the great majority of the customer base were already locked-in. They were put on this drug when it was at very low prices and, by the time the price

increases applied, they were already stuck, from the NHS's perspective.

The other way of skinning the rabbit is to look at matters empirically in terms of experience on another market where there is a higher level of competition, albeit still imperfect, but the continuity of supply issue remains in play, and that is the tablet ASP scenario which I shall come to later which we say is another way that the Tribunal can gain some reassurance as to what value might look like for phenytoin under more competitive, albeit still dysfunctionally competitive conditions.

Now, sir, I am conscious of the time. We could if you like take a 5-minute, 10-minute break now, I am about to turn to another topic.

THE PRESIDENT: Well, if that is a convenient moment, then we will follow your suggestion. We will rise for 10 minutes until 20-past. Thank you very much.

(11.12 am)

(A short break)

(11.25 am)

THE PRESIDENT: Mr Holmes.

MR HOLMES: Sir, two very quick wrap-up points arising out of the discussion.

First, in response to Professor Waterson's question,

you will be pleased to hear that I have had a rapid tutorial on the different forms of product differentiation from those much more learned than I am, and the way we see matters is this: horizontal differentiation, if I understood correctly, is where different consumers have attached different valuations to products in the market, whereas vertical differentiation is where everyone agrees that one product is superior to another. It does not mean they will all select that, but it does mean that they all view it as of higher value, and I hope that I have got that right.

PROFESSOR WATERSON: Yes, that is -- you have, yes.

MR HOLMES: Phew. So as we see it, prior to a patient being initiated, neither dimension of differentiation is in play. At that point, the health service, doctor and consumers, are indifferent from a quality perspective between, say, the NRIM product and the Pfizer/Flynn capsule, but once the patient has been initiated and they are locked-in, at that point we would perceive this as a case of horizontal differentiation because different consumers would value the product differently, or the value would be -- to put it slightly differently, the product would be valued differently to those making choices on behalf of consumers, users of pills. Those

who are on Pfizer pills, there will be an absolute value attached to keeping them on Pfizer pills, and those who are on NRIM pills will have an absolute value for keeping them on NRIM pills.

PROFESSOR WATERSON: Would you extend that to tablets as well in the sense that, as we heard from the medical evidence, some people are initiated on tablets and some on capsules?

MR HOLMES: Yes, sir, I think that is correct, that once you are initiated on one or the other, because you are on a particular manufacturer's product, whether it be capsule or tablet, there would be the same lock-in.

Now, the lock-in is not -- it is clearly not absolute, because not all of those making choices on behalf of the users that present themselves do respect the guidance, and there are some pharmacies who it appears are -- they do not care about carrying stock from different suppliers, and that may explain where you have several sources of supply in the market why a bit more competitive interaction can occur around the edges and why tablets, where you already had three established suppliers, I think, in advance of the November 2013 guidance, which appears to have strengthened the importance of continuity of supply, why there was some competitive dynamic, albeit, as we say, a dysfunctional

one, playing out.

Does that answer your question?

PROFESSOR WATERSON: Yes. That is satisfactory to what I asked.

THE PRESIDENT: There will be a number of other factual questions, I mean, I was intrigued by the point made by one of the physicians that capsules, because of the greater dosage range, tended to be stocked by hospitals because when you were experimenting with the right dosage you would use the flexibility of the four different dosages to get the right level of stabilisation.

MR HOLMES: Yes.

THE PRESIDENT: Of course, once you have got on to a capsule regime which you are using a mixture of different dosages well then you are committed. It may not be absolute, but you are committed.

MR HOLMES: It may explain, I don't think we can put it any higher than that, but it may explain the differential in terms of the size of the market between capsules and tablets. Insofar as there is any reluctance to prescribe one tablet and one capsule in combination, which you would think there should be, given the concerns about continuity of supply.

THE PRESIDENT: Equally, you might find that you are started

on a 100mg tablet and then for stabilisation purposes you need to bump it up by 25mg. The only show in town there is the capsule.

MR HOLMES: Yes.

THE PRESIDENT: The incentive to move to a completely capsule-related regime is probably quite high.

MR HOLMES: Yes.

THE PRESIDENT: But you are right, this is all a question of nothing we can make a finding of fact on, but it is material that I think is there in the record that we will be considering.

MR HOLMES: Yes, indeed, indeed, sir. I mean, the empirics of this are fascinating, we see through a glass darkly with limited information and some findings which are privileged because of the way in which they were found and established conclusively on appeal, and that somewhat complicates the position. It does appear that the jagged edges that that might create are not particularly pronounced because the new evidence which has come to light in relation to tablets is broadly consistent with the material that was before the Tribunal in the first appeal, but inevitably in the sort of searing heat of the forensic process there are all sorts of questions thrown up which it would be fascinating to know the answers to, and we do our best

with the material that we have in front of us.

The other short point, sir, is just to note for completeness that of course we do very much rely upon the passage at 338 of your judgment in *Hydrocortisone*, the red herring point in relation to patient benefit, and we say that that does helpfully elucidate that patient benefit taken independently of continuity of supply should not be viewed as the answer to this case because of the elision between market power and the health benefits to desperate patients.

So we therefore respectfully agree with you, sir, that continuity of supply is the only potential differentiating factor and you have my submission on why that should be afforded limited weight which focuses on the costs involved in maintaining production capacity open.

With that final point, sir, I would like to turn now to demonstrably immoderate in light of the time. We obviously rely on our written submissions and I do not propose therefore to deal with every point. On the excessive limb, we say that the Tribunal can conclude with confidence on the evidence before it that both parties' prices were demonstrably immoderate during the relevant period.

If I could take Pfizer first, Pfizer's revenues and

prices are at {XA1/1/177} shown separately by strength if we could turn that up, please.

So you see in table 5, there are the revenues and there are the prices. You see that the total revenues, if you tot them up, are about 71 million. The costs are not in dispute. You see at paragraph 5.131 at the foot of the page that the CMA took Pfizer's own measure of its production, purchase and distribution costs for phenytoin, and if we could keep this page open on the left-hand side and add page {XA1/1/179} on the right-hand side, you see there the direct costs compared with the revenues for each strength, and so, for example, for the 100mg strength which comprised 70% of the volumes, total direct costs across the whole infringement period were 2 million and the revenues generated were 37 million.

As regards common costs, you see at paragraph 5.137 further down the right-hand page that the CMA again took the costs from Pfizer's own accounting system which allocated a specific line for its common costs under the label "Sales, Informational and Administrative expenses", and those costs were incurred at the relevant business unit level and at Pfizer Limited and both sets of costs were allowed.

If you can keep the left-hand side but turn on the

right-hand side to page {XA1/1/180}, you see that these were allocated by sales volumes, that is the number of packs sold which gave a mark-up of £2.32. So a volume-based rather than a revenue-based allocation to avoid circularity where excessive pricing is concealed by lumping a large proportion of total common costs on to a very profitable product.

For your note, the CMA also did sensitivities based on other volume-based allocation methods such as per capsule and per daily dose, and they can be found at {XA1/1/536} and {XA1/1/537}. The punchline is they made no material difference to the excesses.

So for 100mg, we have again, 2.2 million of common costs to add to the roughly 2 million we saw of direct costs, so around 4.2 million to compare with the £37 million of revenues.

For the cost plus, the CMA looked at a number of metrics. Its primary measure was a ROS-based measure, and this is again based on a metric from within Pfizer's own business. It is the average ROS earned by the business units within which Pfizer managed phenytoin and other mature off-patent drugs, and if we turn to page {XA1/1/183} of the Decision, you can see at paragraph 5.155 that it was 10%.

Mr Brealey suggested that this was an unrepresented

regulated figure because other products in the EPBU were in the PPRS, but we say that the products were good comparators because they were old generics. Indeed, the EPBU ROS is arguably a generous comparison for Pfizer as capsules were among the highest volume products sold by the unit. You see that at paragraph 5.153 for your note.

Nor is the resulting ROS out of line with Pfizer's business generally. If you look at 5.157 on the same page, you see that the Pfizer UK business earned a lower ROS of 5% on average or 4% on a weighted average basis, and the resulting excesses are recorded on page {XA1/1/189}, if we could just move now to full page and look at page 189, and enlarge the table, please. You see the £71 million figure for revenues across all of the strengths, and that is costs including the 10% ROS return of, in cost plus, 13.8 million. So leaving an excess of 57.5 million. That is a total excess of 416%, and for the 100mg most popular strength the excess was even higher at 667%. So returns of 6.5 times cost for an old generic product, and the return equates to a ROS on capsules of over 80%, and, sir, you will have in mind that of course the ROS is bounded at 100% because of the way it is calculated. ROS measures profit relative to revenues, and profits cannot exceed revenues and thus

profit margins cannot exceed 100%.

So the 80% figure is an enormous figure, but the CMA did not only look at ROS, it looked at a range of other metrics as well. If we could go, please, to page {XA1/1/183} you see that the CMA also considered Pfizer's contribution margin threshold, so looking at the bottom of the page. Like many businesses Pfizer expected products to contribute a certain minimum percentage margin, and that was set at 15% threshold defined as revenue minus cost of goods, the direct costs measure, so another internal ordinary course of business measure, and turning on a page {XA1/1/184} you see that the CMA's 10% ROS for phenytoin is equivalent to an average contribution margin of 66% across all strengths, so far above the threshold contribution margin expected by the business.

The CMA also undertook a ROCE analysis, and again, this was based on Pfizer's internal business metrics supplied in response to a request for information. I showed you that yesterday. If you turn, please, to page {XA1/1/185} you see at paragraph 5.170 the ordinary course of business WACC rates, 8.7% and 9.3%, and you see at paragraph 5.171 at the foot of the page that these figures matched other reported evidence about WACC rates in the pharmaceutical industry.

The CMA also obtained information from Pfizer about the capital employed in producing phenytoin capsules, and this is of course not a capital-light business, we are here talking about the facilities involved in manufacturing phenytoin, and based on this information, turning on to page {XA1/1/186} you see that the ROCE calculation yielded a return that was materially identical, looking at the table, to a 10% ROS measure.

So the evidence as to a reasonable rate of return for Pfizer was mutually reinforcing based on the internal course of business evidence about Pfizer's average ROS and its expected return on capital employed.

Turning on to page {XA1/1/190} and looking at paragraph 5.192, the returns actually earned suggested an enormous return on the capital employed of 392%, so £392 of profit each year on each £100 invested. Now, I would love to know where returns like that were available in the market, they are certainly by no means usual in the experience of the pharmaceutical sector as is clear from Pfizer's own internal experience.

Now, none of these calculations have been the subject of an appeal. Pfizer has taken issue with the principle of cost plus but not the CMA's quantification of it, and in my submission, these figures should give the Tribunal a high degree of assurance that Pfizer's

returns were indeed demonstrably immoderate during the relevant period. There is simply a chasm between its costs and the prices it charged, and no error has been shown in the CMA's findings that Pfizer's prices were excessive.

Of course, you have my point that Pfizer knew that the prices would provoke a furious response, that was why it brought in Flynn to soak up the pharmacopolitical damage which they correctly anticipated, and when challenged, they refused to provide the cost information to the Department. Flynn described its arrangement with Pfizer as an intransparent arrangement which is, in light of that refusal, a fair description, and the lack of transparency about costs is unsurprising. Anyone looking at the price and cost figures would very rapidly discern that the differential between them was immoderate and demonstrably so.

Sir, that is all I have to say about Pfizer. We do not accept at all that there is any frailty in these figures, as Mr Brealey put it. If there were, you would be facing an appeal about the specific calculations, and you are not.

Turning now to Flynn, there is no challenge by Flynn to the CMA's measure of costs, either direct or common. The challenge relates to the finding that the margin was

excessive, and the CMA's case on Flynn similarly draws on multiple strands of evidence and analysis. It is not a crude and formal analysis based exclusively on ROCE as Flynn has at times seemed to suggest.

The starting point is that ROS comparisons are tricky given the unusual features of Flynn's arrangement with Pfizer and, in particular, the very high input cost resulting from Pfizer's excessive pricing upstream.

The Tribunal has the point that this supply chain was an unusual one: it was not about commercial need, it was about pharmacopolitical damage, and I have shown the Tribunal's findings in the first judgment about the nature of Flynn's activities. The relevant passage is at paragraph 346, {XN1/2/112}. So this goes to the risk element of the two factors that you identified as factors relevant to the man on the Clapham omnibus.

At paragraph 346, enlarging that, please, you see that halfway down:

"Flynn took over an established product and undertook only very limited commercial activity. Admittedly it held levels of stock to keep the market supplied and appears to have explored the possibility, without success, of establishing an alternative source of supply to Pfizer. However, the contractual indemnity, together with the terms of the Exclusive

Supply Agreement, in the context of Continuity of Supply and the established user base and distribution arrangements, provided a very substantial degree of comfort to Flynn and meant that it was taking very little business risk. Flynn's involvement in these arrangements was not to provide risk-taking or significant commercial activity."

That was not why it was introduced. So:

"Continuity of Supply meant that its customer base in the UK was to a significant degree guaranteed."

We say that these findings are borne out by the evidence in these proceedings in relation to the limited volume risk, the Pfizer indemnity, the liability insurance that Flynn had in place for £10 million and the outsourcing of key activities by Flynn. Under this arrangement, Flynn paid a lot of money to Pfizer and added a generous margin on top for very limited commercial risk.

Now, against that backdrop, looking at a ROS margin carries an obvious risk of distortion, and you can see that if you turn, please, to page {XA1/1/226} of the Decision where there is a nice illustration of the risk.

So we are in the Decision now, {XA1/1/226}. If you look at table 5.15 in the lower half of the page, this contains two columns, one showing Flynn's prices, costs

and ROS during the relevant period, so when prices were high, and the other showing Flynn's prices, costs and ROS after the relevant period when prices had come down, and the level of the ROS, you see the difference in the prices, but look at the level of the ROS: it is virtually the same. In fact, the after-period ROS is slightly higher at 30%, but the underlying profits achieved by Flynn are of course vastly different, and that reflects the distortive effect of the high input costs.

Looking at paragraph 5.348 you see the point expressed in per pack terms, so there is a confidential figure at the end of the paragraph for the 2018 to 2019 which falls to be compared with the figure of over £15 during the relevant period, more than six times higher.

Now, because of this risk of distortion from simple acontextual ROS comparisons, the CMA considered that it had to look at a wider range of evidence to determine whether Flynn's prices were demonstrably immoderate, and one obvious contextualising factor is the absolute returns achieved by Flynn during the relevant period for an activity, which you have my submission, was very low risk.

These can be seen in the Decision at page {XA1/1/236} in table 5.17. You see the excesses which

already factor in the CMA's allowance for a reasonable return totalling nearly £36 million, and if you could look also, please, at the excess per pack ranging from £6.27 for the 50mg strength to £16.30 for the 300mg strength, I would like to do another side by side if I may tax the EPE again. If we could keep that page but show alongside it page {XA1/1/228} of the Decision and look at paragraph 5.358 and enlarge the foot of the page on the right, please.

You see that the CMA looked at paragraph 5.358 to see what the average direct margin per pack was across Flynn's other high volume products in 2013, 2014 and 2015. Footnote 959 at the foot of the page explains that this captures products selling over 100,000 units or over, and the basis for focusing on higher volume products is the one explained by Dr Majumdar in his teach-in:

"... for a given amount of fixed costs, higher volume products require a lower return per pack (since fixed costs can be spread over a greater number of units)."

Now, for reference Flynn supplied 750,000 packs of phenytoin annually, and the cut off here is 100,000. You see the figures, and they range from £1.32 in 2013 to £1.64 in 2015, and you can immediately see how very

different Flynn's returns on phenytoin were during the relevant period. Unsurprisingly, therefore, phenytoin contributed a vastly greater profit than any of Flynn's other products considered in absolute terms.

If we could turn, please, now on the full page to page {XA1/1/215} and look, please, at figure 5.2. This shows that Flynn's returns on phenytoin were more than double the total return earned by Flynn across its other 13 products combined. As paragraph 5.302 dryly notes further down the page:

"Flynn's percentage ROS comparisons mask these stark differences in the level of profitability achieved by Capsules and the remaining products in Flynn's portfolio."

We say that this analysis serves to emphasise that on any view the profits generated by capsules were exceptional in the context of Flynn's business, a feat achieved in the context of a product with stable demand, limited commercial activity and little risk on Flynn's part.

This consideration of absolute returns is, we say, absolutely appropriate. Mr Williams emphasised that his pharmaceutical clients would consider not only margins but volumes. This is understandable, it makes perfect sense because it allows a proper assessment of the

business opportunity represented by a product, and it does so of course because margins and volumes together show the overall return to be expected.

Now, Flynn itself also assesses absolute returns in the ordinary course of its business. If I could give you a few references, Flynn's response to the letter of facts, which for your note is at {XA1/8/19} states that:

"Flynn, like any business, considers absolute returns as well as percentage margins when making business decisions."

There are references to board minutes and Flynn modelling on absolute returns at paragraphs 5.350 to 5.352 of the Decision, for your note that is at {XA1/1/227}, and there is also Mr Walters evidence during the first appeal at paragraph 22 of Walters 2, for your note that is at {XC2/4/7}, where he relies on the absolute profit figures per pack and the substantial decline in Flynn's sales of 100mg capsules over the period of the infringements.

The CMA also undertook a ROS analysis. It assessed a reasonable rate of return for Flynn based on a 6% ROS, and Flynn has sought to suggest that this was simply a recycling of the PPRS ROS, but we say that is not a fair representation of the evidence.

Among other matters, the CMA considered the ROS at

which Flynn itself indicated its evidence in the first appeal that it would have been prepared to supply phenytoin, so if you could turn, please, to page {XA1/1/233} of the Decision and look at paragraph 5.381. You see the Decision notes that:

"It was put to Mr Walters [in the first appeal] that, at a ROS of 5%, phenytoin would have been the most profitable product in Flynn's portfolio in 2013 and the second most profitable [product] in 2014 and 2015 [considered] (in absolute terms)."

And:

"Mr Walters accepted that Flynn would be incentivised to supply Flynn's products [Flynn's capsules] at this level of profitability (which [equates] to a ... 5% [ROS].

"Question: So it is quite clear that Flynn would have sold phenytoin if it had been able to obtain a 5% return on sales on it. That's correct, isn't it? It follows from this?"

That was the question of Mr Hoskins:

"Answer: If we had, we -- well, would we have made that decision? Probably, yeah.

"Question: Well, of course you would. It would have been your second most profitable product. You wouldn't look a gift horse in the mouth, would you,

Mr Walters?

"Answer: Well, I try not to."

We say that this is significant evidence: it amounts to the unvarnished acceptance, obtained through the forensic process in the first trial, that Flynn would indeed probably have supplied the product at a 5% ROS. The 6% ROS applied by the CMA is therefore neither outlandish nor theoretical. It is a direct practical measure based on available evidence, and it is a ROS above the level at which Flynn's witness at the last trial indicated a willingness to supply the product and the resulting excesses at a 6% ROS are shown at page {XA1/1/238} of the Decision in table 5.18, if we could go there, please.

You see that they remain demonstrably -- I apologise, sorry, it is table 5.19 on page {XA1/1/240}. You see that the excess amounts to 32,510,000 after the 6% ROS is deducted. Flynn's actual ROS for phenytoin was therefore, of course, much higher. It is recorded in the Decision at page {XA1/1/211} at paragraph 5.287, and it was around 36%, many multiples of the level at which they would have been willing to supply the product.

So in my submission the preponderance of evidence in the Decision relating to Flynn's profitability shows

that its returns were demonstrably immoderate and that is laying aside the ROCE assessment.

Now, as regards ROCE, the Tribunal has heard the evidence on it, and it will form its own view. It has also identified a way through that would involve really getting at the underlying intuition by considering the time value of money and the risks involved, and we fully understand the reasons for that and are supportive of it.

We say that there was no error in the CMA's reliance on the ROCE framework, it could be applied in this case, the CMA had the evidence it needed, and there was nothing odd or unorthodox about the CMA's analysis, and we rely on Mr Harman's evidence and the reasoning in the Decision, but whatever view you take of that analysis and evidence, we say that the Decision is in any event robust in view of the significant body of evidence collected about the extent of the limited risks undertaken by Flynn, the very large absolute returns set in the context of the rest of their portfolio and the ROS assessment which, based on their own evidence at the first trial, was a level above which they would have supplied phenytoin.

Now, at this juncture, I should briefly address you on Flynn's margin comparators. Flynn's case is that its

returns on sales of phenytoin were in line with what it describes as normal returns for Flynn's other products and certain other pharmaceutical companies, and Flynn relies in its written closings on a number of comparators. It might be convenient to bring those up. They are at paragraph 117 of the closings which are at {XL/4/49}. The first is at 117(a) phenytoin itself. That is obviously not a comparator.

Then second is the average ROS across its portfolio from 2015 to 2016 which was 24% to 25%. Now, there is a relatively simple answer to this point, and that is that this comparator is not, we say, exculpatory. It merely highlights the CMA's own case, and that is that in the real world, phenytoin is an outlier. That is apparent from considering the data. When one considers all of the real world data, including both input costs and volumes, phenytoin is in a class of its own, and for your note, sir, that is captured by figure 6.3 of Mr Harman's third report which shows that phenytoin capsules are a clear outlier: there is no other product in Flynn's portfolio that combines a high gross margin and high volume of sales, precisely the points that Mr Williams said were important from an industry perspective. For your note, that is {Day7LH1/16:20-21}.

Importantly, this is not merely a point that has

arisen following detailed expert evidence: Flynn itself recognised phenytoin as a clear outlier at the time.

If we could go, please, to an internal Flynn email which is at {XG/180/1}. On 24 September, at the foot of the page, 2012, the very day that Flynn hiked prices, Mr Walters wrote to his colleagues, including Dr Fakes, and this is what he said:

"Here's another management reporting task for you -- inclusion of phenytoin in the summary of the Priority Report skews the data far too much to make it useful in assessing the performance of everything else. I guess we need to see the combined summary and a summary excluding phenytoin."

So in other words, when assessing their own business performance, they recognised phenytoin was in a class of its own. It was a clear outlier in the portfolio.

Of course, the Tribunal reached the same conclusion in the first trial. If we could go, please, to {XN1/2/111} and look at paragraph 343.

If we pick it up in the sixth line, please, you see that the Tribunal notes that there were:

"... highly unusual features of Flynn's phenytoin business, namely the fact that its supplies were bought at a high price, it had high volumes and the Pfizer-Flynn Capsules did not involve as much commercial

risk to Flynn as did some other products. [That] may have made it difficult to draw reliable comparisons ..."

In the final three lines:

"Phenytoin clearly occupied a very unusual position in Flynn's portfolio, given its absolute level of profitability, its size and its input cost. On this point, we prefer the view of Mr Harman to that of Mr De Coninck."

We say that this was the correct conclusion to arrive at and is vindicated by the evidence considered by the Tribunal in this case, and indeed, for that reason, Flynn's resurrection of this comparator, which in our view clearly undermines its own case, despite the Tribunal's clear findings, is not well founded. This is not a scenario where the CMA can be criticised for having insufficiently investigated the position; this is Flynn's own products.

Now, can we go back to paragraph 117 of Flynn's closings, please, at {XL/4/49}. We have come now to (c), the third comparator, and this is five comparator companies identified by Mr Williams.

Now, of course, his companies of choice have moved over time. Mr Williams identified a wider range in his earlier reports before narrowing it down before the SO and then exchanging Sandoz, which he had chosen earlier,

for Alliance for the purposes of the appeal, and I can again address the relevance of these comparators very shortly.

Mr Williams has chosen comparator companies to Flynn, not comparator products to phenytoin, and he does not have information about the products that underlie the average ROS in issue, including the input costs or volumes or margins, all the factors which rendered phenytoin a clear outlier as the Tribunal found in the first appeal.

Moreover, even on their own terms, the figures, even in the small sample of five companies identified, show a broad range from 22% to 55%. Care therefore needs to be taken with any suggestion that there is a clear market-wide approach. Moreover, having narrowed down to companies similar to Flynn, what became apparent under cross-examination was that three out of five of the companies had been the subject of investigation for suspected anti-competitive conduct.

Now, Flynn dismisses this as a jury point, but we say it is not. Ultimately, the basic test is to see what could have been achieved in conditions of workable competition, and in circumstances where three of the five companies have been subject to an investigation for anti-competitive conduct, those comparators do need to

be treated with caution.

Now, this is the only area where in Ms Stratford's submission the CMA could have done more by way of investigation, but the question is what did Flynn want the CMA to do? It seems that what Ms Stratford is suggesting is that the CMA should have gone out to find a comparator product within these companies that matched phenytoin's very unusual characteristics, but there is no obligation on the CMA to do that. It fairly evaluated the companies that Flynn had put forward, it found that those companies were of very limited utility. Was it then required to go and find a further product which did in fact assist Flynn? In my submission, it was not.

Flynn makes it sound as though this would be a simple process of contacting a handful of companies and asking a handful of questions. Now, sir, that on this side of the bar was met with hollow laughs from the case team. Nothing could be further from the truth.

For the Tribunal's note we address this point in paragraphs 63 to 65 of annex 2 to our written closings at {XL/8/23-24}.

We know from the work that was undertaken in respect of the tablets market alone, which of course the Tribunal particularly directed the CMA to consider in

more detail, that adding even one further product would have been very onerous indeed.

Flynn suggests that the CMA should have considered the profiles of multiple product lines across five or six, including Sandoz, other companies, and we say that was not something that the CMA was realistically required to undertake. It would have turned this process, as the chairman put in questioning in the first appeal, into a market investigation of the whole pharmaceutical sector.

Sir, the fourth comparator that Flynn now relies on is *Aspen* at paragraph (d) of paragraph 117, and there it refers to a 23% average EBITDA of the 23 companies considered by the Commission.

Now, we say that this is a bad point for Flynn. We do not even know from *Aspen*, never mind what the products were, but what companies were chosen as comparators, and they were chosen of course as comparators to a different company selling a different class of medicines. Just because the Commission analysed the profitability of a sample of undertakings that were similar to *Aspen* does not mean that the average EBITDA is an appropriate benchmark in the present case. The attempt to bolster the comparators that Flynn has identified, its own products and

Mr Williams' comparators, by reference to an entirely different case takes Flynn, we say, no further.

Flynn, of course, does not contend that the CMA should have found further information about these comparators, and for good reason. They go, in my submission, nowhere.

The fifth comparator is in subparagraph (e) and what is said to be the allowable margin of 19% ROS under the PPRS is prayed in aid.

Now, there is more than a touch of irony in Flynn now adopting this point from Mr Williams. Flynn has spent years contending that the PPRS is irrelevant to its products, as Professor Waterson will recall from the first trial. The PPRS relates to branded products on a portfolio basis and as again Professor Waterson will recall, the Tribunal found that the CMA should not have placed reliance on the PPRS rate to the extent that it did in the first trial.

Even leaving aside that point and dealing with the point of Flynn's reliance on the PPRS, Flynn has ignored the ordinary margin allowed under the PPRS which is 6%. Instead, it relies on an expanded margin of 19% which incorporates the transfer price profit allowance and a further margin of tolerance of 50% above. Those expansions were specifically rejected by the Tribunal

following very detailed evidence on that very specific point, and that is clear for your note from paragraphs 336 to 338 of the Tribunal's judgment at {XN1/2/110}. It simply does not provide a benchmark, and indeed, it is notable that it was not pleaded in Flynn's notice of appeal as providing such a benchmark.

Taking a step back, Flynn is wrong to contend that the CMA has obtained no real world data and that the Tribunal's remittal of the excessiveness issue served no purpose. That is what it says at its closing submissions at paragraph 114.

Ms Stratford was similarly wrong to say, as she did in closing, that the CMA's analysis is not tied to any particular product or any particular company.

What the CMA has relied on is this company, Flynn, and this product, phenytoin. All of the inputs to the CMA's cost plus, Flynn's direct costs, the indirect costs attributable to phenytoin and the returns in the supply of phenytoin capsules are naturally drawn from the real world.

There is no basis for confining the real world to evidence that relates to other products and other companies. Prices, costs and capital are just as much part of business reality, and indeed, this company, and this product, is the focus of the Decision and also is

the issue which the Tribunal has to decide, and we say that this is obviously a defensible approach in view of the Court of Appeal's decision in this case on the appropriateness of looking to the dominant firm's own prices and costs and of applying cost plus at the excessive limb. So we say no error has been shown, and the evidence confirms a demonstrably immoderate difference between prices and costs for both Pfizer and for Flynn.

Can I now turn, sir, to the second fairness limb. Now, in the Decision, the CMA assessed whether prices were fair in themselves, and then it also assessed whether they were fair when compared with the tablet DT price, the tablet ASPs and other AED prices and in my submission the assessment was well founded.

The assessment of fairness in itself looked, among other matters, at the reasons for the price increase and the nature of the product: a generic, long off-patent, in which no new investment had been made. They also looked at the impact on the NHS.

These were factors approved in the first appeal and in the *Liothyronine* appeal, and they are relevant to the Tribunal's *Hydrocortisone* schema looking to understand the nature of the economic activity in play.

The CMA also undertook an assessment of whether the

prices were fair when compared, and in this connection it did a close and careful examination of the tablet market. It found that despite the limitations on competition, the prices generated during the most competitive period were well below the parties' capsule ASPs, and this provided reassurance that the prices were indeed unfair having regard to the economic value that would be achieved under more competitive conditions. The appellants have challenged the CMA's assessment by reference to various comparators and benchmarks of alleged value and I want to address those in turn.

I will begin with the tablet drug tariff and tablet ASPs, I will then deal with the other AEDs and finally, I will address you on QALY.

My submission is that these comparators all support the CMA's conclusion of unfairness at limb 2. They are relevant factors for the Tribunal to take into account when considering whether the prices were unfair.

So starting with tablet drug tariff and tablet ASPs, the first comparator benchmark is the drug tariff price at £30, and this is the price that all parties accept inspired Pfizer and Flynn to implement their price increases in 2012. The Tribunal will by now be very familiar with the shape of the DT price for tablets. If we could go, please, to the CMA's skeleton argument at

{XL/3/19}. It is shown in the first chart.

Can I start with the points which are not in dispute. The first is the level of the drug tariff from time to time, and you see the very significant increase from a low initial starting point and then the flat line of £30, which the appellants take as their benchmark, and then considerable further falls.

Second, it is also not in dispute that the £30 line sits significantly above the ASPs of tablets, and the second chart at the foot of the page shows the ASPs as they evolved over time falling to around £5.50 by November 2021, and turning on a page, you see the position during the relevant period: prices substantially below the drug tariff price throughout.

Third, and in the light of this evidence, it is common ground that the drug tariff price is not a competitive benchmark. That was the position of Ms Webster. She has been clear about this throughout her written and oral evidence. It was also the position of Dr Majumdar. He explicitly characterised the drug tariff price as a constrained monopoly price rather than as the product of workable competition, and Dr De Coninck for his part did not consider this to be an economic issue at all, and just for your reference that is at paragraph 51 of his position statement at

{XE6/4/15}.

The parties place significant weight on this benchmark and well they might as it is a benchmark which, when one considers like for like, sits above even the very high prices that were ultimately charged by Flynn for this product.

The question is what this benchmark can tell the Tribunal in circumstances where it sits far above the prices in fact charged and when no expert considers that it represents a competitive benchmark. We say that that is by no means clear. However, we do now know that this is at least Flynn's primary comparator for the purposes of the unfair limb.

Now, we say that the appellants' reliance on a form of monopoly price as a benchmark for a fair competitive price is clearly not well founded. There are disputes on the facts surrounding the drug tariff price, and these have been dealt with in openings and in written closings, but ultimately they do not take the parties anywhere for two key reasons: first, a discussion between a monopoly provider, Teva, and a monopsony purchaser, the Department of Health, does lead, as Dr Majumdar has said, to a constrained monopoly price, but it is still a monopoly price, as both Ms Webster and Dr Majumdar recognised. Ms Webster noted that it was

not only not a competitive price, she also made clear that a bilateral negotiation of that nature did not give rise to a price that would result from competitive forces.

As Professor Waterson picked up in openings, the contemporaneous documents made clear that the parties, and in particular the Department of Health, anticipated further reductions from the negotiated £30 level. That is at {XG/24/2}.

Secondly, the parties have at no point identified any suggestion that the Department of Health regarded the £30 drug tariff price for tablets, even if it did provide value for the NHS in some form, would provide value for capsules.

Flynn straightforwardly recognised that the Department of Health would have preferred to pay a lower price for capsules, and that is at paragraph 171(b) of its written closings, but in any event, the parties' reliance on the drug tariff price is flawed as a matter of law, and that is again for two reasons. First, it ignores the entire purpose of the remittal. If we could briefly turn up the judgment of the Tribunal in the first appeal at {XN1/2/121} and look at paragraph 379. So this is addressing the question of unfairness in comparison as put forward by the parties, and looking at

379:

"It is apparent from the above that the CMA clearly gave some consideration to the suitability of tablets as a comparator. However, it is not clear to us that it did so in sufficient depth. We emphasise that the purpose of a comparison at this stage of the analysis is to see whether what has been found to be a price influenced by market conditions where competition is restricted is unfair in the context of comparators. If the prices, and market conditions, are similar, it might suggest either that all of the prices are unfair, or that none are. Given the inherent difficulty in making assessments in this area of competition law it is all the more important to conduct a full and proper examination."

Turning on to page {XN1/2/123} we see that at paragraph 384 the Tribunal turns to consider whether a comparison between ASPs is more informative than a comparison with the DT price, and at paragraph 385 we see that in its written submissions the CMA raised the point that an appropriate comparison would be with tablet ASPs rather than the drug tariff price, and then turning on a page at paragraph 388 {XN1/2/124}, we see that the Tribunal accepted that the CMA's position was based on material contained in the Decision.

However, at paragraph 389, we see that the information available was limited and there was insufficient information for the Tribunal to form a conclusion.

Then at paragraph 390, the upshot:

"However, if it is indeed the case that new entrants have entered the tablet sector and that as a result price competition has reduced the tablet ASP, a matter on which we can make no finding on the evidence before us, this would suggest that one of the material reasons given in the Decision by the CMA for disregarding the tablet as a meaningful comparator, namely that it was subject to the same restrictions on ... capsule[s], would be wrong. However, that process would also be highly germane to seeking to establish the benchmark price in conditions of sufficient competition, as well as being informative on the question of unfairness. Assessing whether or not that remains the case, however, is clearly a matter for the CMA."

Now, ultimately, as we know, the Tribunal remitted the Decision in particular to consider a better understanding of the evolution of the tablet market and tablet pricing which the Tribunal could not itself do, and the reference to that is in paragraph 467 on page {XN1/2/146}.

We know also the Court of Appeal rejected the need for there to be a benchmark price established, but there was still a clear indication that further information about tablet ASPs, the actual prices and market conditions in the tablet market, would be helpful.

So the CMA went away and analysed that, and having undertaken that analysis, the appellants now seek to say that it is meaningless. They contend that the Tribunal can find that there was in fact great value in the drug tariff price, despite it not reflecting the underlying market conditions such as they were.

Now, with great respect to the appellants, if they were right, that could have saved us all years of work, but it is not right. The purpose of the remittal was to investigate whether the drug tariff price was in fact divorced from underlying market conditions. Having found that it was, it is of no utility as a benchmark.

The second and most fundamental reason that the appellants are wrong to place weight on the drug tariff prices is that it ignores the appropriate legal test that was ultimately laid down by the Court of Appeal. The basic test is whether the price is unfair, and it will be unfair when the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of normal and sufficiently effective,

ie workable competition.

A benchmark price which is not a competitive price cannot shed light on that question, and in the circumstances where prices are not reflective of competitive outcomes, they have been rejected. That was the case in both *Hydrocortisone* and *Liothyronine*.

So tablet ASPs are the right place to look if one wants to do a proper like for like comparison, and that is what I am going to turn to now.

We say that it is a good and obvious comparator for the reasons I have given you: same active ingredient, same strength as the most popular capsule strength and same features including continuity of supply.

The Tribunal has heard detailed evidence in respect of the tablet price which addressed two basic questions: first, do the prices charged by tablet suppliers in period 3 amount to prices reflective of normal and sufficiently effective competition, and, second, what do the prices charged by tablet suppliers show when compared to the prices charged by Pfizer and Flynn, and these points are dealt with in detail in annex 3 of the CMA's written closings at paragraphs 32 to 53. I will not repeat the detail here, but giving you the headline points, in summary we say that there were significant imperfections in the competitive conditions of the

tablet sector at all relevant times, but the price data that emerges nonetheless serves a useful purpose: it shows that even despite those imperfections a more competitive market, subject to continuity of supply, yielded prices significantly below those charged by the appellants during the relevant period, and they provide a clear confirmation that under more competitive conditions the demand-side value that would be assigned to capsules would be significantly less than the parties' prices.

Now, on the first question, were tablets supplied in a workably competitive market, we have set out in our written closings an overview of tablet prices. That is at {XL/6/9}, and if we could have that on the left of the page, please, and then show the next page {XL/6/10} on the right-hand side which shows tablet volumes. This hard, uncontested data is, we say, crucial. It undermines the parties' attempts to cherry-pick documents which paint a specific picture at a specific point in time. In the CMA's submission, the parties' arguments that this was an effectively competitive market at any stage are not well founded in the face of this evidence.

First, the starting point is a monopoly price that had risen exponentially before being negotiated down

somewhat, so just as in *Liothyronine* the Tribunal has to consider the degree to which that infects the analysis, the degree to which the price remains sticky.

Second, on the question of stickiness, each of Dr Majumdar, Dr De Coninck and Ms Webster agreed that the clinical guidance on continuity of supply was a barrier to or limitation on competition entirely consistently with the position set out by the Tribunal in the first judgment, and even if it is not adhered to at all times, it is a highly unusual regulatory feature which can operate as it did with capsules to bake in dominance of the incumbent supplier.

Third, and related to this, as can be seen from the table of volumes, Teva maintained an extraordinary market share across the entire period. This includes during period 3 where there are three players in the market, and the other two players are charging significantly less than Teva.

As Ms Webster has said, the data itself makes clear that there was a degree of market power on Teva's part which amounted to dominance or substantial market power as the CMA says in the Decision. They were pricing independently of competitors in the market without losing sales. That, for your note, sir, is at {Day11LH1/162:23} to {Day11LH1/163:3}.

So we say this is an unpromising start for any suggestion that within this period there was sufficient competition to unwind the high monopoly prices that had previously existed, and we say that during the period of triopoly, that period was insufficient to unwind those features. On this front, there are a number of segments of period 3 which warrant consideration. There is a drop in prices from September 2012 to December 2012, which you see on the left-hand graph, which is the most competitive interaction, and this was described by Dr Majumdar as the erosion of the duopoly price. The CMA accepts that there was price competition in this period, and, again, this is where many of the documents relied on by Pfizer appear, but by their very nature, prices on this downward trend cannot in the CMA's submission be properly considered to reflect the outcome of normal and sufficiently effective competition. This is the *Liothyronine* decontamination point writ large.

The period that follows, then, is from January 2013 to December 2013, and what one sees there is a bifurcation in the market with Wockhardt and Milpharm's prices dropping while Teva's remain at a significant premium while maintaining significant market share, and once again, that very short period we say does not represent the outcome of normal and

sufficiently effective competition. On the contrary, it suggests a market where one party is in fact dominant and unconstrained by competition, and then by January 2014, Wockhardt is starting to exit the market and is selling extremely low volumes, and there is not, therefore, truly in that period, a three-player market.

As such, there is at most a 12-month period of competitive interaction between the dominant market player and the other two smaller players in the course of 2013, and we know from objective studies that on average, a generic price will fall 80% to 90% lower over a four-year period. That is set out for your note in the Oxera report at {XN10/5/7} in the final two bullets, and as was found in *Liothyronine*, based partly on such evidence, competition takes time. It did not have time in this case, particularly given the features of this market.

Finally, just as the starting point is key, so is the end point. Pfizer has relied on prices in a range but focusing on the Teva price across period 3, which is the top end of that range, but, as is apparent from the graph at page 15, those prices are just a point on a downward trend, as was the position in *Liothyronine*, and we say that it is unsustainable that those prices

themselves demonstrated the outcome of anything other than a short burst of limited competitive interaction; they are not the product of normal and sufficiently effective competition.

So we say that the evidence shows that the market was not effectively competitive in period 3, but that does not mean, sir, that one should throw out the indications that derived from that market, and I am mindful here, sir, of what you said about comparators in other cases. They may shed some light, even if they are imperfect, one makes the best one can of the available evidence, and while this is not, we say, a benchmark of fully effective competition, it nonetheless does shed some light on where a more competitive process would take the prices of a very similar product indeed, in fact, probably the best comparator product that one could possibly hope to find in a case of this nature.

What the evidence shows is that if one compares like with like at Flynn's level of the market, the tablet prices are significantly below the prices obtaining in the capsule market during the relevant period, and you can see that comparison from the chart at annex 3 of the CMA's closing submissions at {XL/9/17}.

If we could enlarge the chart, please, the Flynn ASP is the purple line at the top of the page, and you can

see that it is materially above all of these other tablet prices for all but two or three months at the beginning when duopoly prices are unravelling and the market is clearly decontaminating on any view.

You will have well in mind, sir, that there is no need for any particular temporal alignment between the capsule price shown in this chart and the tablet price, because no one is suggesting a competitive interaction between capsules and tablets. So all one is really interested in is the gulf between the capsule ASP and the tablet ASPs, and we say that this shows that under more competitive conditions, the market would arrive at prices well below those that the parties together applied during the relevant period.

So in the circumstances, comparing like with like, a comparison with the tablet prices does not undermine the CMA's conclusion that the capsules prices were unfair; on the contrary, it sustains and supports it.

Now, Pfizer seeks to get around this problem by constructing an artificial price consisting of its own inflated upstream price combined with a Flynn substitute price at cost plus. Now, you have my submission that the Tribunal should be careful of this type of salami-slicing given the real world context and the fact that the parties discussed a split, they knew that each

would be pricing at a mark-up, and to abstract from Flynn's pricing is, therefore, not the right approach, but in any event, even if one focuses in on the prices after competition has had an opportunity to take hold, the gap between Pfizer's upstream prices at a different level of the market and the tablets ASPs is very large.

So the entrant competitors in the tablet sector were pricing at half, that is Wockhardt and Milpharm, were pricing at half of the Pfizer price in the second half of 2013, in the £6 to £8 range. Even Teva's price was well below the benchmark, Dr Majumdar's benchmark by the end of period 3 and below the Pfizer price. It stood at £9.84 by comparison with Pfizer's average supply price of £12.52 when divided by three, and prices fell further still in the period following period 3 as the market gradually unwound from the earlier monopoly pricing to £5.50.

So, again, a figure very far below Pfizer's average supply price of £12.52, and significantly higher than the indicators of a more competitive nature which can be derived from the tablet market.

So we say that once competition becomes even slightly more effective, the prices in the tablet sector fall to levels well below either of the parties' prices, and this proxy for demand side value confirms the

correctness of the CMA's Decision. The appellants' prices were not only demonstrably immoderate; they were also demonstrably unfair.

I am on the home straight now, sir, there are just two remaining points you will be pleased to hear. The first is the other AEDs and the second is QALYs, and I can take both of those shortly.

On other AEDs, Pfizer relies on the evidence that it served for the first trial in respect of these other products, and the Tribunal's assessment, you may recall at paragraph 398 of the first judgment, was that the argument for a meaningful comparison with other AEDs is considerably less compelling than for tablets, and we say that remains very clearly the position, and indeed, Pfizer candidly accepts as much in paragraph 215 of its closings.

The CMA accepts that tablets may be a suitable comparator, but, as I have outlined, they themselves do not show that the appellants' ASPs were fair and the attempt to resurrect without any fresh evidence on the point these ASMs or AEDs from the first trial takes Pfizer no further.

There are two discrete strands of evidence relied upon in Pfizer's closings. The first is Mr Ridyard's evidence. Can we go, please, to figure 6 in Pfizer's

closing which is at {XL/5/71}, and if we could enlarge the figure.

Just so we are clear what we are comparing with, this sets out reimbursement prices of the drugs. So it is the price not only of the drug but the margin added by wholesalers, and we have the phenytoin ASP by Pfizer in the second column and then the drug tariff price for phenytoin capsules in the third column, and we say that the drug tariff price is the appropriate point of comparison at the same level of the market, that is the reimbursement price. We say a comparison on that basis shows that the capsules price was indeed unfair.

Now, if we could -- it is helpful, I think, to split the chart into three, so we have at the lower prices for -- I am now going to mangle, I am afraid, the names -- clobazam up to sodium valproate, so that is the first six products. Now, all very far below the capsules drug tariff price, and they suggest, at least when considered on the basis of the weighted average and the generic price, you can see that gabapentin has a very high branded price, but you can also see from the weighted average price that it was obviously selling very low volumes in the market because the weighted average is very close to the generic price. So we say that these products suggest the capsules price was

unfair.

We then have some medium products from lamotrigine to topiramate, and I will come back to those, if I may. It is from that cohort that Dr Ridyard selected his comparators in the first appeal. Then we have the top prices on the right-hand side from zonisamide up to rufinamide.

Now, looking at the right-hand sector, the top four from lacosamide up are all patented drugs, and then quite markedly, in the mix of patented drugs is phenytoin tablets. Now, that of course reflects the frozen £30 drug tariff, and you have my submission about that: it is an example of regulatory dysfunction, not competitive pricing.

The last two to the left of phenytoin tablets in the sort of top cohort were only available as branded products. You can see that from the fact that there is only a weighted average and a branded price shown, and no generic competition.

So we say that again these top range prices tend to confirm that the appellants' pricing was unfair, it is up closer to those, although they are all markets that are not workably competitive, they are either branded markets with only a branded product in the market, or they are patented markets, so markets where there is

still patent protection.

So turning to the middle range, from lamotrigine to topiramate, we see that these are markets that had become competitive by 2012 from which this snapshot is taken, and look at the weighted average prices, so that is the middle bar, and they are significantly below the capsules drug tariff price in all cases.

There is a dynamic dimension to this which can be seen from the charts that Mr Brealey has taken the Tribunal to at various points, and they are at {XE1/2/18} in Dr Ridyard's report. I think it is his first report. No, his second report.

The first chart shows the price evolution for topiramate, and here we see that the branded price stays high and we see that the generic entrant enters at a similar price but that that price then drops considerably lower and continues to trail down.

Turning on a page {XE1/2/19} we see the same feature for lamotrigine, and on the next page {XE1/2/20} for levetiracetam -- I am sure I did not say that rightly, but I think you know what I have in mind. There is a slightly different trend on {XE1/2/23} for oxcarbazepine. There the generic price tracks up originally but then steeply falls later. These charts, we say, are really important. What they show is in

these AEDs the branded price is high whereas the generic price trends quickly and considerably lower in three of the four drugs and then trends lower after a break after a short period, in the fourth.

It is not in dispute that when that happens branded companies lose huge amounts of their market share. Pfizer's closings note that the branded drugs in issue only managed to retain between 8% and 19% of the market. That is at paragraph 221.

Now, what these AED prices relied upon by Pfizer actually show is that phenytoin, which retained remarkably high prices and high market share, did indeed reap trading benefits that would have been impossible under normal and sufficiently effective competition. It did not have to choose between volume and price but could maintain both, and we say that the competitive markets in the range here are evidence in support of the unfairness of capsule pricing. They are another factor in locating the mezzanine.

Now, just to wrap up this picture, ethosuximide is different: the price in that case is far higher for the generic. You may recall I showed you the very odd pricing chart on that in the Decision. It is at figure 6.17 at {XA1/1/377}. But the product is a tiny one in volume terms. If we could go back a page

{XA1/1/376} and look at 6.527. This was prescribed to 1,300 patients compared to around 38,000 taking capsules. So we say not a remotely suitable comparator, and also an outlier by reference to the other AEDs.

So in summary, once one strips out the non-competitive drugs, exclusively branded or patented, one is left with much lower prices than hydrocortisone capsules on all of the competitive markets when comparing like with like, and we say that the comparison confirms the unfairness of capsule prices.

Now, during the hearing, Pfizer has sought to elevate another piece of evidence which is drawn from Dr Skedgel's evidence, or shortly before the hearing in their written closings. It is a list of AEDs which is set out at paragraph 26 of their written closings at {XL/5/11}.

I briefly addressed you on this in opening. It shows a snapshot of prices from 2012 covering seven drugs, and again these are based on reimbursement prices, and the appropriate comparison is therefore to the phenytoin drug tariff price. Dr Skedgel confirmed in cross-examination that in putting forward this analysis, he has not taken into account whether or not the drugs in question were patented at the time of the data, October 2012, or whether the drugs were branded.

Four of the seven drugs were patented. I have already referred to pregabalin, eslicarbazepine acetate and lacosamide when considering the previous figures. Perampanel was also patented at the time and there can be no real dispute that new drugs under patent under a legal period of monopoly may charge higher prices than those charged for unbranded generics.

Moreover, of the seven drugs included in Dr Skedgel's table, only one had a generic version in 2012, only oxcarbazepine, and that is the only product therefore in which the data included a mix of branded and generic pricing. For all of the six other products, there were only branded prices available. Now, I do not think that is disputed, but it can be seen, sir, for your note from {XF3/32.1/1}.

Now, despite this, the drug tariff price for phenytoin for the 100mg dose is towards the middle of the list of comparative daily costs, so what this chart again simply shows is that the appellants reaped rewards on capsules that would have been impossible under conditions of normal competition. The comparisons are, with only one exception, all to products that are not themselves supplied under competitive conditions.

Finally, can I turn to economic value and QALY. So very briefly, Pfizer's submissions in this regard are

split into essentially three topics: first, patient benefit or therapeutic benefit, secondly, the costs avoided by the NHS because of the supply of capsules, and third, the reliance placed by Pfizer on Dr Skedgel's QALY analysis in this case.

In my submission, all three arguments make the mistake of equating economic value with the ransom price that can be extracted under conditions of market power contrary to the approach explained by Lord Justice Green in phenytoin and by the Tribunal in *Hydrocortisone* in the red herring paragraph.

The position is clear in relation to patient benefit: it is said that patients need phenytoin to obtain life-changing benefits of seizure control, but that in itself cannot justify charging more for the same medicine for the reasons succinctly explained in the *Hydrocortisone* judgment.

The same basic confusion underlies the avoided costs argument. It is said that the NHS saved substantial amounts by avoiding uncontrolled seizures, but this is again no more than the ransom value available to the maker of an essential drug. There are all sorts of horrible personal and societal costs if a person is deprived of an essential treatment, but that in itself cannot justify exploiting market power.

THE PRESIDENT: Ah, now it depends what you mean by avoided costs, does it not?

MR HOLMES: So this is the suggestion that a high price is justified in the case of phenytoin capsules because if the product were not to be supplied, the price of the alternative to the NHS would be higher as a result of patients becoming in some cases uncontrolled, having seizures, collapsing, basically being deprived of their essential treatment and, in the course of switching to another treatment, likely tablets, some of them not being stabilised and suffering the adverse effects that are consequential upon that.

THE PRESIDENT: Well, look, I take your point as regards the personal and societal costs, but I think there is a variant on that which has been articulated and so I will frame it for you to push back on, and it is this: recognising that it is very difficult to ascertain what the benefit of sodium phenytoin is to a given patient, because one cannot say whether a seizure would or would not have been suffered, even if no seizure was suffered when taking the medicine, because you do not know what would have happened had the medicine not been taken, let us suppose that for each patient the prescription of sodium phenytoin saves a seizure a year. Now, there is a huge personal cost in being afflicted with a seizure

which I completely recognise, but let us leave that out of account. Let us simply look at the costs on the NHS of dealing with a patient who has had a seizure, the trips into the hospital, the ascertainment of what needs to be done in order to treat the patient. All of these costs are monetisable.

Now, why can one not say the benefit of using sodium phenytoin, looking purely at the costs saved in terms of the hospital visits, can justify a price up to the cost of -- the costs saved to the hospital, leaving entirely out of account all of the human elements, just looking at those saved costs.

MR HOLMES: Yes, so one is imagining a world here --

THE PRESIDENT: One is imagining a world first of all of a great deal of certainty which I know does not exist, but if one says that the cost of a certainly avoided seizure is £10,000 then why can one not price the medicine to avoid those costs up to £9,999?

MR HOLMES: But sir, what that does is to imagine a world in which phenytoin is taken away --

THE PRESIDENT: Yes.

MR HOLMES: -- and patients as a result are being deprived of their medicine. Some of them may suffer seizures.

THE PRESIDENT: Yes.

MR HOLMES: It is saying that the product is essential to

patients, it has a benefit to the patient, and it has a benefit to the NHS which is calculable in monetary terms.

THE PRESIDENT: Yes, the benefit to the patient is not calculable in monetary terms. I am not going so far as to saying that one can price the seizure, so that is the reason you are interested in the drug apart from that.

MR HOLMES: It is still the ransom value, that is my submission. It is because -- basically what you are saying is: if I take this product away, if I stop supplying it, these bad things are going to happen, and, as a result, we should be allowed to price very high because those very bad things happening have a great cost for the NHS, potentially. That is what the argument comes down to, and we say that that is not differentiable from the patient benefit argument, and indeed, the Tribunal considered exactly this point in the first appeal by reference to a less extreme variant of the same argument, an avoided costs point.

If we could go, please, to paragraph 423 of the Tribunal's judgment in the first appeal which is at {XN1/2/133}, picking it up at the bottom of the page, you see that:

"... Flynn ... contended that any assessment of the economic value to the NHS of the continued supply of

capsules had to take account of the avoided costs of patients switching to tablets (ie the costs that the NHS would incur if Pfizer discontinued the [tablets])."

So you see that is a less extreme version of the same point, it is focusing on the cost of -- because in reality what would happen is that patients -- if you took away capsules, patients would in the first instance presumably be switched to another variant treatment in the hope that they would be stabilised and so the cost, the immediate cost for most patients who would hopefully be stabilised in consequence would be the cost of a different treatment to the NHS, whatever that happened to be, and one imagines, you know, in the hypothesis that perhaps they would be switched to another phenytoin variant if they have been stabilised on that in the past. Some would not be stabilised as a result of the switch, and they would suffer the even more extreme consequences and the even more extreme costs, but it is just a variant on the same avoided costs argument. Look at how the Tribunal dealt with that:

"This point was also taken by Pfizer at the investigative stage and rejected by the CMA for the reasons set out [in the original] Decision. We do not accept this argument. Quite apart from whether there was a real risk of discontinuation by Pfizer (and the

most Mr Poulton could say about this was that he believed Epanutin would have been discontinued at some point in the future, whilst accepting that any decision to discontinue would not be taken lightly because of the patient concerns), this argument has the appearance at least of taking advantage of market power to extract more value in terms of prices. As to the possibility of Flynn discontinuing the capsules, we have already discussed [that] in ... G(6)(a) above."

So we say that the argument here is rejected for two reasons, and we say that Pfizer's argument on avoided costs should be rejected for similar reasons in this case. The first was that the evidence did not support a real threat of discontinuation, and the Decision addresses this issue in detail in annex F which for your reference starts at {XA1/2/65}.

The second reason given by the Tribunal, which is the key one for present purposes, is on all fours with the Tribunal's subsequent analysis of patient benefit in *Hydrocortisone* which we looked at earlier.

What Pfizer is saying is that: we are providing value to the NHS because, if we took the drug away from patients who need it, then that would cost you more, but this is simply an example of a pharmaceutical company exploiting its market power to extract high prices

because the NHS is unlikely to walk away due to the potential devastating impact on patients. It is an extraction of a monopoly rent because there are captive patients.

So, that is my submission on that, sir.

THE PRESIDENT: Just pausing there, let us suppose a non-essential good that is desirable but not needed, and let us suppose that is purchased monthly at £100 a month, it does not matter what it is, it is something that is -- the demand exists that one is perfectly willing to pay that amount for this desirable but non-essential product.

Now, let us suppose something that is better comes on to the market. Why cannot the supplier of the better product price at least up to but just below the rival?

MR HOLMES: Sir, I think they can, and there is a choice for the consumer --

THE PRESIDENT: It is the choice that makes the difference?

MR HOLMES: -- the customer, as to where to switch. Here what is being said is: it is my way or the highway, and the NHS -- we can extract from the NHS the costs that it will face if we leave it without this essential product, and we say that that is a different situation, a qualitatively different situation from one in which a consumer can freely choose.

THE PRESIDENT: Right, but it is the case, or is it not, in the example that you have just been taking us to in the original decision, and that is looking at the alternative cost of a different drug?

MR HOLMES: Well, it was, sir, but in a situation where the patient is already locked-in on one treatment.

THE PRESIDENT: I mean, is it not just a variant of the relevance of non-substitute comparables. I mean, if you assume that the comparable is at a market price, then you take your new patient and you say: well, you have a choice between two forms of drug, you are not committed to either, the proper price or fair price for the drug under investigation is to be matched to the, presumptively, presuming it is a fair price -- of the comparable.

MR HOLMES: Have we moved on now, sir -- I may have misunderstood -- have we moved on now from the avoided costs as a result of seizure to the question of whether the drug tariff is a --

THE PRESIDENT: You answered the first point by reference to the second point, so I am eliding the two.

MR HOLMES: I think, sir, this is going to require some sustenance for me to give you a considered response. Again, at the risk of impeding the lunch hour adjournment, perhaps I could return to the question very

briefly afterwards. I have one more hour.

THE PRESIDENT: It is simply that I think this is how Pfizer at least are putting an aspect of the savings. They are not looking at the human cost. I do understand your point about extracting value from need, but I think the question of saved cost, it is a bit like the QALY approach that was being taken where you do not simply compare the value of the new treatment as against any old treatment, but you look at the costs of no treatment at all in terms of whether the new product is constituting value for money or not, and all I am doing is removing, as it were, the NICE apparatus that they use for comparing and contrasting value of new treatments and saying: well, if the benefit in purely financial terms to the health service is treating patients in a more expensive way, taking out of account the question of the human cost, which I do see is a blackmail question, but simply taking into account the alternative way of treating as a price that is effectively comparable, why is that not something that we ought to be taking into account in terms of ascertaining what is a fair price for the drug here in question. I have put that very badly, but that is I think the point.

MR HOLMES: No, you have not at all. It is extremely

helpful. I can give an immediate answer in relation to tablets insofar as the question is about switching to tablets, and that is the boot-strapping concern that I raised at the outset. One needs to be careful about allowing a dominant firm to justify exploitative abuse on the basis of prices in another market which is not itself subject to normal and sufficiently effective competition.

THE PRESIDENT: That is going to how far a comparator is informative. We are all agreed that we look at comparators but one needs to be careful about how much weight one attaches to them in that if a comparator is itself not the product of workable competition then it is of less value than one that is.

MR HOLMES: It also affect pricing decisions at the time insofar as dominant firms are making their own assessment by reference to available data so that if it were -- the reason why the comparator is excluded is so that dominant firms shape their pricing conduct in ways which do not take account of as legitimate comparators and benchmarks prices in other neighbouring markets which are coloured by market power.

So in my submission it does affect the position prospectively as well as when assessing matters after the event.

THE PRESIDENT: But there is no question, going back to the original point, of market power in terms of the avoided GP costs, that sort of thing, consultant costs. Those are simply costs that the NHS incurs if one is assuming a defined avoidance of a seizure through the purchase of the sodium phenytoin capsule.

MR HOLMES: Yes.

THE PRESIDENT: Basically it is Mr Brealey's point of £2 a day saves you X thousand, and of course, we have got a ballpark figure of, I think, 7 to 10 that we got from one of the earlier witnesses as to what it costs to deal with an epileptic who has had a seizure in terms of just the costs to the NHS, leaving aside the human costs.

MR HOLMES: Yes.

THE PRESIDENT: I think the point that Mr Brealey is making is, look, £2 a day is a bargain, why can you not say that a fair price is higher, I think putting it very crudely, that is the point.

MR HOLMES: A bargain by comparison with the extreme costs that are imposed on the health service in cases of uncontrolled seizures once the product is withdrawn.

THE PRESIDENT: Well, once the product is not used.

MR HOLMES: Very good, sir, perhaps I will return to that.

THE PRESIDENT: No one is saying it is not available. What we are talking about is at what price should it be

available, and I think the point that is being put, or at least I am trying to frame for you to respond to, is that if the, as it were, opportunity cost treatment, the alternative form of treatment is £10,000, why is that not an indicator as to the appropriate price for a better form of treatment.

MR HOLMES: Yes. Sir, look at it perhaps this way --

THE PRESIDENT: I am not saying that the alternative better form of treatment should price at higher than the opportunity cost treatment, I am simply suggesting that there is a link or rather, I think, Pfizer is suggesting there is a link between the one and the other, and --

MR HOLMES: In what circumstances could a firm price by reference to that opportunity cost other than because of a lack of competition and choice?

THE PRESIDENT: Well, in workably competitive markets that happens all the time, does it not?

MR HOLMES: One product prices by reference to another product.

THE PRESIDENT: I mean, our filling stations, take a very elastic demand, I mean, no one is suggesting that they are all pricing at cost, but they are pricing together.

MR HOLMES: They are pricing in competition with one another --

THE PRESIDENT: Indeed.

MR HOLMES: -- and if they want to increase their volumes they will do so by reducing their price, and that will, it is hoped, constrain the relationship between price and cost in a competitive market.

THE PRESIDENT: In these markets we find the prices do not go down because of the very elasticity of demand. I mean, we are getting into a different area of investigation which I think we probably ought to shy away from.

MR HOLMES: Let us perhaps, if we may, pause this until --

THE PRESIDENT: I mean, if your answer is no more than: Mr Brealey is wrong because it is the exploitation of patient need, and that is your answer, well, fine, then we will move on.

MR HOLMES: Patient need for the patient and market power for the NHS.

THE PRESIDENT: All right, well, if that is the answer, then so be it.

MR HOLMES: I would like to, if I may, give it slightly further thought because others may have different perspectives on it.

THE PRESIDENT: No, please do, my sense is that there is a little bit more to Mr Brealey's argument than --

MR HOLMES: Than I have done, yes. Well, it is important then that I attend carefully to it, and --

THE PRESIDENT: I may be wrong, there may be nothing to it at all, but I think the point has been made.

MR HOLMES: Yes. I am grateful, sir. If that were a convenient moment?

THE PRESIDENT: No, thank you very much. We will resume at 2.00.

(1.11 pm)

(The short adjournment)

(2.02 pm)

MR HOLMES: Sir, if I may impose on the Tribunal for just one minute more, I have three very short submissions to make.

The first, continuing our discussion from before the short adjournment --

THE PRESIDENT: Yes.

MR HOLMES: -- and the other two concerning QALY.

So the first submission. We say in the circumstances of competitive pharmaceutical markets at least avoided cost arguments are realistically unlikely to be available as the basis for justifying a price, and so the thought experiment that I would ask you to indulge me with is to imagine what would happen if a supplier in, say, the lamotrigine market, you know, the first line AED treatment, were to come to the NHS after generic entry and were to say: my product has very

significant savings that can be offered to the NHS in achieving seizure-freedom, it is the most popular treatment, we say that that submission in favour of a high price would be met with short shrift in circumstances where there were other competing generic products available on the market. The choice that the supplier would face would either be to price high and lose all volume, or to price low and obtain volume.

So in the practical realities in a market once competition have arrived, at least in the generic pharmaceutical sector we say that avoided costs would not be the basis upon which pricing could be achieved and that therefore this argument, we say, does, as the Tribunal found in its analysis of this point in the first trial, it does ultimately turn on the availability of market power and the exploitation of it.

THE PRESIDENT: Okay. I think you are agreeing that you can price at the price of the alternative, or up to the price of the alternative, as a fair price, I mean, that is reducing it to no more than the comparator argument, but I suppose the point is, taking on board but leaving to one side for the sake of argument the question of compulsion or need, if the alternative good is non-treatment and just treatment of the consequences, and that has a price, then are you accepting that that

is a price up to which the provider of a new product can price to?

MR HOLMES: Yes, the maximum willingness-to-pay of the NHS might take account of the avoided costs to the health service, so we would not dispute that for a moment, but of course the test is not what would be paid by the NHS, what its maximum willingness-to-pay actually is; it is what price it would reasonably pay under conditions of normal and sufficiently effective competition.

THE PRESIDENT: In that case, it may be that the example I had for you can be parked because I understand where you are coming from.

What I think we are agreeing is that the avoided costs, assuming that there is proper choice, the avoided costs can be a benchmark for ascertaining the price of a rival product that does the same job, but better. There might be an argument for going higher than that, but we are not in that realm, we are simply looking at the benchmark fair price.

MR HOLMES: Yes.

THE PRESIDENT: Good, well, in that case --

MR HOLMES: I would accept, sir, that the price of an equivalent product might be priced by reference to another product. That, of course, is -- as a practical matter that might well happen, and you heard

Ms Webster's evidence that it would be rational for the NHS to take account of avoided costs, but my submission would be that a price could still be found to be excessive and unfair insofar as pricing by reference to a comparator that was itself excessive and unfair led to a distortion and to boot strapping and you have my submission about that.

THE PRESIDENT: No, I have that.

PROFESSOR WATERSON: I was just going to say that in the case of a new product, of course, the QALY analysis is designed to do just this task.

MR HOLMES: It is, agreed, sir, and I think the President was observing before lunch, that is quite so.

THE PRESIDENT: Yes, the no treatment treatment is then the starting point.

MR HOLMES: Yes, yes, but that is not of course the situation in which we find ourselves here.

Then on QALY, two points. It is, I think relied on as a ceiling of what the NHS is willing to pay that that is simply a variant on the maximum willingness-to-pay argument. Again, it does not reflect a focus on normal and sufficiently effective competition which is the focus for the purposes of unfair and excessive pricing.

The third point is that the best available evidence in relation to QALY is what NICE itself did in 2022, and

of course, as the Tribunal has heard, NICE did undertake a QALY assessment then of phenytoin at much lower prices, and it found that phenytoin was not good value for money judged by the QALY standard.

So applying QALY thresholds, the authoritative public body found that phenytoin failed, and it was included in the guidelines for clinical reasons but that of course takes us straight back into patient benefit and where there is market power, we consider that patient benefit is a red herring for the reasons expounded in *Hydrocortisone*.

So we say that insofar as there is an indicator of value to be derived from the evidence on QALY, it suggests that phenytoin was not fairly priced during the relevant period. At much lower prices, the QALY threshold was failed, and that is a further factor that is relevant to take into account when assessing the fairness of the parties' prices.

Sir, there I am very conscious that Mr Bailey is waiting in the wings to address the questions you raised, so unless the Tribunal has any further questions, I shall cede to him.

THE PRESIDENT: Mr Holmes, we are very grateful. Thank you very much. Mr Bailey.

Closing submissions by MR BAILEY

MR BAILEY: May it please the Tribunal. I am going to address the Tribunal in six parts. The first is just one authority that sets out the Tribunal's approach to penalty appeals.

The second is the issue of intention or negligence, and as part of that the Tribunal's question yesterday about the degree of specificity that must be identified on the part of the dominant undertaking in relation to a fair price. I will also address the appellants' reliance on the drug tariff price in that respect.

Third, the allegation that the CMA has chopped and changed its case.

Fourth, the uplift to Pfizer's fine at step four of the CMA's penalty guidance.

Fifth, whether Flynn is right to contend that it has immunity from any fine pursuant to section 40 of the Competition Act, and finally, Flynn's challenge to the level of the fine based on the fact that it was fined more in the Remittal Decision than it was in the Original Decision.

So if I can start, then, please, with the authority, it is at {XN2/21/12}. This is a recent authority of the Tribunal, *Roland v CMA*, and I wish to show essentially four things in the judgment, and the first is at the

bottom of this page, it is the statute itself which of course is the starting point. You can see in subsection (3) of section 36 that is the jurisdictional gateway for the CMA to impose a penalty, and you can see that it must be that the CMA is satisfied that the infringement has been committed intentionally or negligently by the undertaking. Of course, that should not be equated with particular individuals in the undertaking.

The other point that I think it is worth drawing attention to is subsection (7A) where Parliament has directed the CMA to have regard in fixing a penalty not only to the seriousness of the infringement but also the desirability of deterring both the undertaking on whom the penalty has been imposed and also other undertakings as well, and that will be relevant to when I come on to Pfizer's challenge to the uplift on the grounds of deterrence.

Now, the Tribunal's judgment then on page {XN2/21/15} cites the Court of Appeal's judgment in the present proceedings referring to Lord Justice Green's judgment. Then, if we can pick it up, please, at paragraph 33 we can see that the Tribunal records that:

"... the Tribunal takes the CMA's decision as its 'starting, middle and end point' and that, having considered the evidence, the Tribunal may decide not to

interfere with the decision on the basis that its findings were reasonable in all the circumstances ..."

The Tribunal notes that that is consistent with its approach to penalties in both *Kier* and in *Argos* and *Littlewoods*.

It goes on to say that:

"... it would not be right for the Tribunal to ignore the CMA's own approach and the reasoning in the decision under challenge and that the Tribunal should look at the matter in the round and only interfere with the CMA's decision if it concludes that the penalty was inappropriate."

There are two other passages. The next paragraph, 34, neatly encapsulates, in my submission, the Tribunal's task. There are two tasks, the first of which is to adjudicate on the complaints about how the CMA has applied the guidance, in these proceedings there is no challenge to the lawfulness of that guidance, and the second is that the Tribunal should decide for itself looking at the matter in the round whether the penalties are appropriate.

The final point to note is at the bottom of this page in paragraph 36 where the Tribunal, and in my submission correctly, acknowledge that it:

"... may well be appropriate for [it] to give weight

to an evaluative assessment made by the CMA in relation to a matter of which the CMA has particular experience..."

I rely on the next passage:

"... such as the need for deterrence of a particular type of infringement because of its current prevalence ..."

Of course, that is particularly relevant here because the CMA as the enforcer on the frontline has experience of this practice, excessive pricing, not only in the *Napp* case but of course also in *Hydrocortisone* and *Liothyronine*.

It is right, I should acknowledge, if one turns over the page {XN2/21/17}, the Tribunal does say, although it may give weight to the CMA's experience in this regard, of course that does not reduce the characteristic rigorous scrutiny which the Tribunal subjects penalty decisions in this area, but it is, in my submission, a point that needs to be borne in mind when looking at the CMA's evaluative assessments.

If I can turn, then, to the issue of intention or negligence, and I would like to address that if I may in three stages.

First, I would like to look at what the case law says about intention or negligence, and the President

yesterday remarked it is important to try and locate the case law in particular with relation to this practice of exploitative pricing and so I am going to show you passages where the Tribunal itself has already done that.

Second, I would like to show you the CMA's own approach as set out in the Decision and as part of that I will seek to address the Tribunal's question yesterday about the fairness of the price, and then, third, I will look at the mainstay of the appellants' case that they say they relied reasonably on the tablet drug tariff price.

Now, as with so many aspects of domestic competition law, the Tribunal's judgment in *Napp* is a treasure trove of useful insights and I would like to show a few passages in that judgment if I may so that one can see what it says about this topic.

If we can go please to {XN2/1/123}, and you can see under the heading "Law", the first point that is made in paragraph 452 is that for the purposes of the jurisdictional gateway, the authority is not obliged to identify that -- it has to identify either that it is an intention infringement or a negligent infringement.

Then if we go over page, please, {XN2/1/124} to paragraph 455, if we just enlarge the bottom of the

page, we can see that the Tribunal approaches this matter in the same way as the European Courts do pursuant to what was section 60, what is now section 60A following Brexit, but we have to contain consistency with pre-Brexit case law. And you can see halfway down the Tribunal upheld:

"... the Director's submission that, in order to impose a penalty ... [it] has to be satisfied, as a threshold matter ... the infringement was either intentional, or negligent. However, he does not, for the purposes of crossing that threshold, have to determine specifically which it was."

So it is enough for it to either be intention or negligence without nailing your colours to a particular mast, at least at that stage of the analysis.

Now, yesterday Flynn's leading counsel showed the Tribunal an extract from *Paroxetine* which itself quoted *Napp*, and that is over page, please at page {XN2/1/125}.

You can see there are then two paragraphs which unpack the meaning of intention on the one hand, negligence on the other.

The important point about intention is that it refers to where an undertaking could not have been unaware that its conduct could have the object or effect of restricting competition, and the Tribunal also makes

clear, a point that has been consistently reaffirmed, that it is not necessary to show that you knew that you were infringing. That is no part of the test.

Then the Tribunal explains that you can establish intention. One way is looking at internal documents, that is exactly what the CMA did in this case. Another way might be to look at the conduct of the dominant undertaking and then to look at the actual or foreseeable effects of that conduct and infer an intention.

We can then see in 457 that the Tribunal says about negligence, which is a concept that the President asked about yesterday, that for these purposes, although it had not been discussed in EU law to a great extent, it is sufficient:

"... if the undertaking ought to have known that its conduct would result in a restriction ... of competition..."

Now, the Tribunal in *Napp* then goes on to apply that dicta with specific reference to excessive pricing, and it does that at paragraph 466 on page {XN2/1/127}.

It notes that there is little guidance in the authorities about how to do this, but it finds that:

"In our judgment, it must be shown that the dominant undertaking either knew (in the sense that it could not

have been unaware), or ought to have known, that it was, without objective justification, maintaining prices above the levels that would prevail in conditions of normal competition."

Now, I hope it will be helpful to then see what the Tribunal itself did to apply that test in this case, and what we can see in the same paragraph on page {XN2/1/128}, is we can see it noted three particular factors.

The first is *Napp* knew it had a virtual monopoly in the community segment, that was the segment for patients under the care of their GP.

The second is that it knew that the product it had was not subject to any competitive pressure, and then the last part is it knew its own prices were well above its competitors' prices, the prices it was charging to hospitals, the prices it was charging to export markets and of course, its gross profit margin, which is just simply the difference between price and direct costs.

I am going to come back to that because those are the essential facts which underpin the finding in 467 that *Napp* at least ought to have known the three points that are set out.

I would like to just pick up one further proposition from *Napp* which is of relevance to the present case. We

can see if we scroll down on this page, please, to paragraph 469 that *Napp* had argued that it acted reasonably because it thought that its prices could be justified by remaining within the PPRS as it then was.

If we can just pick up the last sentence, we can see *Napp*, not dissimilar from these appellants, arguing that the Director had further shifted his case on excessive pricing, and that it was now alleging that that it arose because of the pricing in the hospital segment.

The Tribunal's response to that at paragraph 470 was first of all to reject that *Napp* that had an objective justification, but then, if we can go over page, please {XN2/1/129} we can see that the Tribunal says:

"Moreover the fact that the Director's case has developed in the course of proceedings does not alter the fact that, objectively speaking, *Napp* maintained prices in the community segment that it at least ought to have known were well above competitive levels and protected from competition. We do not accept that the question of 'intentionally or negligently' under section 36(3) of the [Competition] Act depends on whether or not the undertaking was told by the Director how to conduct its business."

Now, in my submission, that passage foreshadows a point I wish to make, which is for all of the

wonderful terminology used by the appellants' counsel about the CMA doing acrobatic twists and turns, and of course that the CMA's case developed in the course of litigation, it does not affect what is relevant for the purposes of applying section 36. What is relevant is objectively speaking, did Pfizer and Flynn know the essential facts as to their abuse of dominance.

I am going to make good that by then looking at the CMA's approach in the Decision. I apologise, sir, did you want to ask me --

THE PRESIDENT: Well, are you saying that knowing the essential facts is enough to find intention?

MR BAILEY: I absolutely am saying that, sir, and I will show you how the Tribunal endorsed that in *Liothyronine*. Perhaps it is actually better to go there next before the Decision.

THE PRESIDENT: Sorry, what do you say the essential facts are?

MR BAILEY: Well, I was going to show you that as well, sir. I was going to show you *Liothyronine* on the law and then I was going to show you where the CMA identifies the essential facts. I know Flynn's counsel referred to it as a nostalgic crutch. It is not nostalgia, it is a recent judgment of the Tribunal and it is correct as a matter of law.

If one looks at {XN2/28/150}, this is the *Liothyronine* judgment, you can see "The Appellants' arguments" and you can see that they took issue with intention or negligence.

We would just invite the Tribunal to note that Cinven in this case in paragraph (4) of paragraph 124 had criticised the CMA's case on measuring cost plus as "chopping and changing", a familiar expression, and:

"... that would have required omniscience [apparently] on the part of any firm considering the position ex ante."

Now, the Tribunal then responds to this argument over page, please {XN2/28/151}, and can we go to the bottom and enlarge that, thank you very much.

So we can see first of all the Tribunal say:

"We are satisfied ... that Advanz knew or ought to have known ... the essential facts giving rise to liability ..."

Then what the Tribunal does in 427 and 428 is it sets out Advanz's knowledge of those essential facts, and could I invite the Tribunal to read those two paragraphs, please.

THE PRESIDENT: Yes, of course. (Pause)

Yes. Thank you.

MR BAILEY: I am grateful.

It is also worth noting that in paragraph 429, the Tribunal rejects Cinven's argument about fundamental changes in the CMA's position. It does so both on the facts but also as a matter of principle because the Tribunal says there what matters is not whether Advanz was aware of any specific legal characterisation of its conduct but whether it was aware of its anti-competitive nature citing the *Royal Mail* judgment.

If I could show then the Tribunal what the CMA identified as the essential facts, and I think it is helpful just to set the scene to go to {XA1/1/400} because what the CMA did was it set out the principles of law as it understood them and then it sought to apply those to the facts of this case.

Yes, can we go to the bottom of the page, please. You can see here it sets out the legal framework, and can we go over page, please {XA1/1/401}. The CMA makes the point at paragraph 9.34:

"Intention or negligence relates to the facts, not the law."

You can see from the quote in the middle of the page from the Grand Chamber of the European Court of Justice what the test is in terms of whether:

"... the undertaking concerned cannot be unaware of the anti-competitive nature of its conduct, whether or

not it is aware that it is infringing the competition rules ..."

And leading counsel for Flynn took you to the *Paroxetine* judgment which made the same proposition.

THE PRESIDENT: I do not think you need press us on that.

MR BAILEY: I am grateful. If I can turn over page, please {XA1/1/402} we can see then the essential facts. It starts at paragraph 9.41 over page for Pfizer {XA1/1/403}. What the CMA does is it sets out the essential facts first of all -- so this is the paragraph that sets out the facts relating to dominance.

In essence, what one sees is that firstly Pfizer knew of course that it was the sole manufacturer of its own product. Secondly, Pfizer was able overnight to impose a substantial increase in price. Third, at paragraph 9.41.3, Pfizer was well aware of the clinical guidance on continuity of supply. For the Tribunal's note at paragraph 124 of the Tribunal's original judgment at {XN1/2/42}, we do not need to turn it up, you can see a Pfizer email from the head of oncology which clearly acknowledges that fact.

Then if we go over page {XA1/1/404} we can see the remainder of the CMA's analysis is to set out that there were no competitive constraints either for NRIM or parallel imports or the Department of Health.

For reasons of time, I cannot go through all the footnotes, but the footnotes set out the documentary evidence that support those propositions.

So those are the essential facts that gave rise to Pfizer's awareness of its substantial market power.

Turning then to unfair pricing at paragraph 9.42, can we turn over the page, please {XA1/1/405}. Here the CMA starts with the proposition that Pfizer imposed overnight a substantial increase in prices, and of course, that was a point that the Chancellor, Sir Geoffrey Vos, picked up in paragraph 243 of his judgment at {XN1/5/69}. So the starting point is untrammelled pricing power.

The second point -- can we stay on the Decision, please, at {XA1/1/405}, thank you -- the second point is that Pfizer's prices, as Mr Holmes showed you this morning, exceeded any reasonable measure of costs. One does not need to get hung up on is this ROS or is this ROCE; the dominant firm is well able to compare its own prices with its own costs, and if, as here, there is an almighty gap between them, then it of course raises an important question. The question is what justifies that disparity between its prices and its costs. Well, in my submission, as the CMA sets out -- you see this at paragraph 9.42.4 -- the answer is that Pfizer's prices

reflected its substantial market power.

Pfizer knew this because its own customers promptly called out the fact that capsule prices went through the roof, to use Mr Brealey's metaphor. If ever there is a telltale sign that a market is not working well for customers, it is when there is a cacophonous outcry from customers, and to show you that Pfizer was aware of its market power I would like to show you one contemporaneous document, if I may. It is at {XG/198/2}. You have not seen this document, this is the reason why I wanted to show it to you.

THE PRESIDENT: Of course.

MR BAILEY: So this is a Pfizer internal email, and it starts with The Telegraph having reported that a:

"Pharma firm [that is Flynn] hikes the cost of epilepsy drug by 24 times."

A pack of 25mg went from 66p to £15.74. Now, the original email notes that this is because generics apparently are not subject to the same price control as the branded product, but if we can go to page {XG/198/1} it is important to see how Pfizer then seeks to explain the position.

The email at the bottom, if that can be enlarged, please, we can see a somewhat flippant comment:

"Guess who divested Epanutin to Flynn..."

And a smiley emoji.

Then some detail on the story that is a little bit more complex and it sets out various points about the background. If one looks at the final bullet point, we can see that Pfizer says:

"A price increase is only possible (from a commercial perspective) if there is no other manufacturer selling the same molecule (otherwise they would be undercut on price) and/or physicians are slow to switch from the brand.

"As this is an Epilepsy product, physicians are slow to switch patients to generic alternatives and so Flynn have been able to increase price -- not without criticism it would appear!"

Now, in my submission, that clearly demonstrates that Pfizer knew not only of its own pricing power, but it also knew of Flynn's pricing power, but it is right to acknowledge that there is an email above this and to show the Tribunal what is said in response at the top, there is a clarification made about when the MA was transferred, a clarification made that Pfizer sought ways to keep it on the market and to be commercially viable, although of course, in relation to that, the Tribunal will have in mind that in the first two months of charging its new prices, it more than recovered all

of the losses that it had made in the previous five years, and then of course finally they do say: look at the tablet. Well, it is not in dispute that they looked at the tablet and that they were aggrieved that the tablet price was much higher than the capsule price, and I am going to come on to address you on that in a moment.

If I can go back, please, to the Decision at {XA1/1/405}, and turn over the page, please, {XA1/1/406}, another essential fact is that Pfizer knew -- this is at paragraph 9.42.5 -- it knew or should have known there is no objective justification for this conduct. There is no investment, there is no improvement in the product, there is no innovation, and so in my submission if we go over page, please {XA1/1/407} you can see what Pfizer actually thought about this from the quote in the next paragraph.

If we go a few lines down, you can see that -- it is five lines down:

"Pfizer's internal documents recognised [in Pfizer's own words] the 'attractive commercial opportunity to increase revenues significantly due to an anomaly in the Drug Tariff'."

So in my submission, this was opportunism for Pfizer to engage in profiteering, and Pfizer in closing has set

out various aspects of Mr Poulton's evidence from the first trial.

I would like just to show the Tribunal one aspect of his evidence because it is quite important to the essential facts. It can be found at {XM/15.1/81}, please. This is where Mr Poulton for Pfizer is being cross-examined, and it starts at line -- we should see the question first:

"Question: ...I'm asking you ... that post-deal, the deal you did with Flynn actually meant not simply that [this] product became commercially viable, but it became an extremely profitable product for Pfizer."

Mr Poulton's answer was as follows:

"Answer: [Well] we didn't look at the profitability ... we were looking at price, and the reason why this project was able to even be considered was because we had an established benchmark price in the market for the same medicine. If that price benchmark hadn't been there, we couldn't have done this. We would have had no justification."

So in my submission, if the Tribunal agrees with Mr Holmes' submissions in relation to the drug tariff price, Pfizer's own witness accepts that there was no justification for increasing the price to the levels that they did.

MR BREALEY: (inaudible).
MR BAILEY: But you can obviously make those submissions in reply.
THE PRESIDENT: Well, Mr Bailey, I am not really sure how far subjective statements actually help very much. I mean, we see it all over the place, that persons involved in markets where there are infringements alleged say all kinds of things which may be right, may be wrong, and frankly, where does it take you?
MR BAILEY: I simply draw it to the Tribunal's attention because it was said in opening that we had only shown you documents. I show you simply the evidence given by the witness. It is not a key point, it is just simply that Mr Poulton recognised that the justification for the price increase was the tablet drug tariff and both appellants rely very strongly that it was reasonable for them to rely on the drug tariff price.
THE PRESIDENT: Okay, look, let me try and articulate why I raised the question about intention yesterday, and maybe we can try and deal with that.
MR BAILEY: Yes.
THE PRESIDENT: We are coming to the end of a very long trial at which we have been debating in some detail with great learning, this side of the Bench at least, what is excessive and what is unfair, and the notion that those

points are open and shut either as a question of fact or as a question of law is perhaps a little fanciful. These are difficult questions.

Now, given that these are difficult questions, the issue of intentionality, if the questions of fact are difficult, does seem to me to raise certain basic problems in ascertaining whether there was an intention on the part of infringer to infringe.

Now, you have started by saying that the question is, is the CMA satisfied that there was intentionality or negligence, of course that is right, but presumably you would accept that there must be objective justification for that satisfaction, and presumably you would also accept that the reasons for the CMA's conclusion need to be stated.

MR BAILEY: I accept that the CMA must demonstrate to the Tribunal's satisfaction that either the conduct was intention or negligence, and they must give reasons, yes.

THE PRESIDENT: Right.

MR BAILEY: I would not accept that the CMA has to pin its colours to a particular mast and demonstrate intention as opposed to negligence precisely for the authorities that I showed you.

THE PRESIDENT: It can run alternative cases, of course.

MR BAILEY: Well, it is not just an alternative case, sir, it is actually that they do not need -- if one looks at the --

THE PRESIDENT: Well, all right, but how do you give reasons if you are not willing to say that it is either intentional and/or negligent? I mean you have got to --

MR BAILEY: The test is whether the undertaking cannot be unaware that its prices were exploitative in nature, and the way that the CMA has identified that is to look at the essential facts that give rise to the unfairness, and, sir, you did ask me what are the essential facts, and first the fact is that the dominant firms --

THE PRESIDENT: Well, let us go through the essential facts. I will ask you a few questions and we can see what you say about that.

MR BAILEY: Of course.

THE PRESIDENT: So you started quite rightly with the question of dominance, but I think you would accept that the mere fact that an undertaking is dominant does not mean that there is axiomatically an abuse.

MR BAILEY: Absolutely, I accept that proposition.

THE PRESIDENT: Right, so let us park dominance and let us talk abuse in the context of abusive prices.

Now, we can, I think, accept that there is a knowledge on the part of an allegedly infringing

undertaking as to cost and price, so the gap will be known.

MR BAILEY: Yes, the gap which is the point made at paragraph 9.42.2.

THE PRESIDENT: So what, however, if there is a significant problem with cost allocation -- now, do not let us talk about this case, let us talk about the generalities. So let us suppose one has a major common cost which can reasonably be allocated in multiple different ways, some of which, if they are allocated one way, result in a marginal breach, some of which result in a major breach, some of which result in no breach at all.

MR BAILEY: So in relation to that hypothetical --

THE PRESIDENT: Yes, it is a hypothetical.

MR BAILEY: -- hypothetical, it seems to me if the dominant firm could show that these different ways of allocating common costs are indeed reasonable and are reasonably open to it, then that would go to the question of culpability, it would go to the question of did they know that their prices were unfair, or indeed, ought they to have known, and if actually it could be demonstrated -- and I would emphasise this is not in the facts of this case -- but if it could be demonstrated, then that clearly is a relevant factor in terms of -- because it goes to the question of the gap, as you were

saying, the common costs to be allocated and the gap might be narrowed.

THE PRESIDENT: The question I am asking is a little bit more nuanced. What I am putting to you is a case where there are various different ways in which one can allocate the common costs, and the outcome is that the Tribunal, having heard argument, decides that the correct way of allocating them is a way which leads to an outcome of infringement, but there were other ways of doing it, so the gap is in fact ex ante uncertain; ex post it is certain because the Tribunal has ruled.

So one moves from a finding of infringement that is entirely justifiable and right to a question of whether there is an ability to punish which requires you to move from the strict liability of the Chapter II infringement into the question of negligence or intention.

Now, you can, of course, say you should have known, but is the "should have known" to be allocated or to be answered by reference to what would be a reasonable allocation of costs in this case; is that the sort of question one needs to ask?

MR BAILEY: Yes, because it must be the case that the law is predictable, and it must be the case that a dominant firm, with its professional advisers, is able to look at its prices, its costs, its approach in business and be

able to work out for itself the likelihood of not only infringement but also the potential sanctions. So it would seem to me that if a dominant firm could show that ex ante acting in good faith it had adopted a particular approach to allocation of cost which led it to reasonably believe that its prices were fair, as a matter of fact, because of course it does not need to know are they fair or unfair as a matter of law, then, yes, I would agree that that is a relevant consideration to the question of intention or negligence.

THE PRESIDENT: Does it not go further than that? I mean, if, again on those hypothetical facts, how could you say that the penalty jurisdiction operated in those circumstances? I mean, I understand it is a relevant fact, but does it not go rather beyond that?

MR BAILEY: I suppose you would have to look at all the circumstances. You could not just focus on allocation of common costs. You would have to look at the internal documents, see what the strategic objectives -- because if, for example, that dominant firm also had documents that clearly demonstrated, irrespective of common costs, they were out to go and profiteer and price gouge, that would obviously be a relevant consideration as well, so I would be reluctant to accept that it would mean inexorably that there would be no intention or

negligence, but I would be perfectly prepared to accept that it would be a weighty consideration and in some cases, it might mean that no fine would be imposed if that was the appropriate approach.

Of course, again, in my submission, that is not the facts of this case.

THE PRESIDENT: I am sure we will come to the facts of this case, I am really trying to understand the approach that one does to these state of minds and how they make a difference to a strict liability finding of infringement. That is my concern.

So you are saying, I think, that even if perfectly competent people could differ as to the allocation of costs -- stick with one example -- and that a perfectly competent person could say: look, I would allocate the costs this way, I think this is the right way to do it, that is my belief, and it is a reasonable belief, and therefore the gap is narrow and not abusive, that is no more than a relevant factor and it can be outweighed by other things.

MR BAILEY: I accept it would be a weighty relevant factor.

THE PRESIDENT: A weighty relevant factor, okay.

MR BAILEY: But of course, as you know, sir, one has to look at all the circumstances.

THE PRESIDENT: I understand.

MR BAILEY: There may be other factors that point the other way. That is my only submission on that.

THE PRESIDENT: Yes, well the difficulty there is whose state of mind is one looking at? I mean, obviously it is the undertaking but we are talking about in almost all cases, an undertaking that is a legal and not a natural person, so does one go hunting around the documents in the possession of the undertaking to see bits that are just ill-advised or stupid, or just not very helpful, or does one look at the thinking that existed behind the pricing at the time? Is that how one does it?

MR BAILEY: Sir, I would say that you do both.

THE PRESIDENT: Okay.

MR BAILEY: The authority does not search around just for the incriminating documents, of course it will have regard to the internal documents. That is one part of the factual matrix.

THE PRESIDENT: Right.

MR BAILEY: Mr O'Donoghue in closing referred to a lack of putting a case to Mr Poulton and Dr Fakes, but of course, one should not synonymise the undertaking with particular individuals. Their beliefs and their knowledge is another part of the factual matrix. You have got the internal documents, you have got the

individuals within the undertaking and of course you have the conduct of the undertaking itself, which is the point that the Tribunal noted in *Napp*, and I would say you take those three things together. What do the documents tell us about what the undertaking understood and predicted? What do the individuals that were employed by the undertaking, what did they know and expect, and indeed also, what was the conduct itself and if actually you set prices at an unfairly high level --

THE PRESIDENT: Well, that is begging the question, Mr Bailey, is it not?

MR BAILEY: Well, there are various benchmarks that were available to the parties.

THE PRESIDENT: Yes, well, let us come to that. We have been paddling in the shallow waters, the question of merely excessive, which is, I think, the easier side of the equation, so let us move on to the question of unfair --

MR BAILEY: Yes.

THE PRESIDENT: -- and let us adopt the question of the location of the mezzanine, the line between the price, the ceiling and the floor.

Now, let us assume that this is a nuanced case, so let us stick to the hypothetical, let us not zone in on the facts of this case, but let us suppose that there

are a variety of factors that militate in differing directions as to where the price could go such that reasonable persons could differ as to what was or what was not an unfair price. In other words, it is perfectly possible for a reasonable person to say the price that was charged was actually a fair price for various reasons.

Now --

MR BAILEY: Just a point of clarification, when you say "a fair price", do you mean a lawful price?

THE PRESIDENT: Yes, that is what I am using, I am using the test that --

MR BAILEY: Yes. Well, so sir, I think on that we perhaps respectfully disagree, unfortunately.

THE PRESIDENT: Right, do go on, why is that?

MR BAILEY: Because the test is not whether the undertaking knows or ought to have known that the prices were either unfair in a legal sense or fair in a legal sense. That, in my submission, is absolutely fundamental. It is from the authority that Flynn's counsel showed you in *Paroxetine*, it is actually established throughout the cases. That is why I say it is about the essential facts, and so when one looks at whether or not the price is fair, one is getting into the question of asking oneself: well, what is lawful, and that, in my

submission, is not what the authorities --

THE PRESIDENT: I think we are probably on the same page, but let us test it a little further.

MR BAILEY: Please.

THE PRESIDENT: So let us take a situation where the Tribunal, weighing all of the factors, decides that in fact the price charged was too high and, having looked at all those factors and heard all the evidence, has reached a nuanced weighing of those factors and concluded a point of law that in fact the price as charged was unfair, but let us accept that this is a legal conclusion based upon the weighing of facts.

Now, what is the position if the adviser looking at those facts attaches different weight to them? Can you say in those circumstances that they intend or are negligent in relation to an excessive price?

MR BAILEY: Sir, we do not know what advice was given to these undertakings in terms of legal advice, so --

THE PRESIDENT: These ones here?

MR BAILEY: These ones here.

THE PRESIDENT: We are in the hypothetical, Mr Bailey, do not worry about that.

MR BAILEY: Oh, I see. So if we did know they had waived privilege like in *Liothyronine* and produced the advice, and if the advice had demonstrated that they had

considered the authorities, they considered the business in good faith, they reasonably reached a different view to that of the Tribunal, then in my submission it does not mean that you are exempt from a fine, in fact, the Court of Justice in *Schenker* makes that point, but there may be circumstances, as the Advocate General recognised, where that could indeed mean that there is no intention or negligence. Why? Because ex ante the dominant firm has basically done all it can. It took advice from eminent solicitors, it considered its business, it reached a view, subsequently found to be wrong by the Tribunal, but that should not be held against it in terms of any sanction that is imposed.

THE PRESIDENT: I see. So you are going as far as this, that you are actually going to have to show your thought processes, that you applied your mind to the question of price and to the question of unfairness and that you received a clean bill of health from someone competent to give it, and then that is a factor which goes to saying there is no negligence or intention. Is that the way it works?

MR BAILEY: I was engaging with your hypothetical, sir, and I thought that you --

THE PRESIDENT: No, no, we are in the hypothetical realm.

MR BAILEY: We are in a hypothetical world, which is a

wonderful place to be, but as I understood it, you were putting to me that the undertaking had taken advice so I was answering on that basis.

THE PRESIDENT: I was taking the case where reasonable persons could differ as to the weight of the factors that go into the location of where the unfair price does or does not exist. So I am not -- you made the jump to advice, and I can understand why you did so, but what I am interested in is in the mismatch between the strict liability where one hears all the factors, and one takes a careful view as to what is going on and one says, well, weighing all the factors, this is a price that is unfair, you lose, you are infringing.

Now, that I understand: nice strict liability, no problem. What I am asking is, given that my hypothetical case is a difficult case, it is not open and shut as one might allege in other cases, it is a difficult case, obviously that does not affect the finding of an infringement as a matter of law, our job is to determine difficult cases. The position is, though, how does one approach the penalty jurisdiction which explicitly says strict liability infringement is not enough, you need something more, you need to be either negligent or you must intend the infringement.

Now, I quite accept that ignorance as to the law is

no defence and you have articulated that, but I am focusing in on a factual uncertainty which the Tribunal has determined, or indeed the CMA has determined as part of its administrative decision. You then have got to say: okay, we have got the infringement, that is a first base for the finding of a penalty jurisdiction, but we have these additional requirements, the alternative requirements, of intention and negligence.

So taking my hypothetical facts that the outcome of the administrator or the court is one where reasonable people might differ --

MR BAILEY: On that, sir, just to be very precise --

THE PRESIDENT: No, please be.

MR BAILEY: It is not my submission that a dominant firm needs to waive litigation privilege in order for it to avoid a fine, I do not go that far.

THE PRESIDENT: Okay, that is fine.

MR BAILEY: But in relation to reasonable business people, can I just clarify is that where they have looked at the prices they are charging, looked at the costs that they have incurred, looked at the product and considered the investment and the quality and the differentiation, if any, looked at the internal documents that were produced in pursuing that conduct and perhaps also taken into account customers and how they reacted and then the

reasonable person on the Clapham omnibus disagrees with another reasonable person on the same bus, such that there is factual uncertainty. If that is the situation then I accept that reasonable people can reasonably disagree, and I accept that that would be highly relevant to the question of intention or negligence.

THE PRESIDENT: Right, well, let us take that in stages. Let us suppose one has an undertaking that is simply pricing as high as it can. It is doing what any competitive undertaking would be doing, it is keeping its costs as low as it can, and it is pricing what the market can bear.

MR BAILEY: Is this a dominant undertaking, sir?

THE PRESIDENT: Well, it has to be for there to be an infringement, does it not?

MR BAILEY: Indeed.

THE PRESIDENT: So yes, it is, but it need not know that factor. That, I accept, is an irrelevant point. So it is dominant, does not matter.

MR BAILEY: And is the market upon which this dominant firm is operating one protected by high barriers to entry and expansion?

THE PRESIDENT: Well, what I am putting to you is a situation where the dominant undertaking has neither enquired as to its dominance, nor has it enquired as to

the justification of its cost base, nor its price. All it is doing is trying to keep the costs as low as it can and the price as high as it can. It is not making any further enquiries. Now, on those facts, do you say that there is an intentional breach of competition law?

MR BAILEY: I would be reluctant to jump to any conclusion without knowing the other circumstances because, as Mr Holmes has explained to you, one does need not only to look at -- you have got a profit-maximiser in your hypothetical here.

THE PRESIDENT: Yes.

MR BAILEY: But there is a question about: well, are there any features of the product that justify that, will the market self-correct in a reasonable period of time, how do customers react to that, we pay many thousands of pounds for Apple products but no one is saying that Apple is guilty of unfair pricing, at least not in these proceedings. So I think it is very important to contextualise it, and I can understand why you would want to boil it down to certain key propositions, but there could be other aspects to the dominant firm's behaviour, for example, what strategy, if any, do they have in place? If it is basically whatever the market can fetch, we know from *Attheraces* and phenytoin that the Court of Appeal in both of those cases said that

actually that is why we have this prohibition; we have this prohibition specifically to stop dominant firms from simply gouging the market for as high a price as they can possibly charge.

Can I, sir, also --

THE PRESIDENT: That is very helpful, Mr Bailey. Just taking what you said a moment ago, you said: I think it is very important to contextualise this, and what you are saying quite rightly is that one needs to look at all the relevant facts and matters in order to determine the answer, negligence or intention; is that fair?

MR BAILEY: Yes, when I say "relevant facts", of course I do not embroider the decision, the Decision says "essential facts", ie the key ones that give rise, but apart from that terminological point, yes.

THE PRESIDENT: Very good. Okay, so it is important, then, that those essential facts be set out clearly so that one knows the basis on which the CMA has reached the conclusion that it has.

MR BAILEY: Yes, sir.

THE PRESIDENT: Okay, so it does not have to be now, but at some point I would just like a statement of exactly what facts are relied upon in this case. It need only be by reference to the paragraphs in the Decision, but I am not interested in the law, nor the law as to penalty

jurisdiction; what I am interested in is the articulation of the facts which have resulted in the CMA's conclusion that it is satisfied that this is both an intentional and/or negligent infringement of the Chapter II Prohibition.

MR BAILEY: Sir, to be clear, the CMA does not make an and/or finding. It says that it is intention or negligence, which is what the Tribunal said in *Napp* --

THE PRESIDENT: Yes, it does not commit. It simply says it is both.

MR BAILEY: It says it is one or the other. It does not need to say which one it is.

THE PRESIDENT: It does not say which one it is even though it has apparently provided reasons for that.

MR BAILEY: Sir, I can give you the paragraph numbers where the essential facts are identified.

THE PRESIDENT: Yes, of course.

MR BAILEY: It begins at paragraph 9.40 which is {XA1/1/402}, and then it runs through for Pfizer until paragraph 9.42 on page {XA1/1/408}. Then it takes in Flynn at paragraph 9.43, and that runs through to paragraph 9.47 which is {XA1/1/414}, and then the CMA addresses various representations that have been made on this issue, but the essential facts are identified in a series of subparagraphs, and then what the CMA has

done is it has sought to either cross-refer or identify in the footnotes the underlying evidence that supports those essential facts, and on the question of fairness, what the CMA effectively did was look at the substantial price increase overnight, look at the dislocation between each of Pfizer and Flynn's prices and any reasonable measure of costs, ask itself -- check whether the undertakings had any justification for charging prices that had such a gap between price and cost to which the answer was no, and take into the account the internal documents that the parties themselves prepared at the time of the conduct, and then, finally, the customer: one should never lose sight of that in competition law and of course the customers here were outraged and told Pfizer and Flynn that they were deeply unhappy. It is taking that body of evidence as a whole that we say means that each of the appellants behaved intentionally or negligently.

May I simply give perhaps a reference to an authority which I hope is helpful insofar as the Tribunal is considering whether an undertaking needs to know about the fair price, which is the question you asked yesterday, sir, and we have just been debating.

The Tribunal will be aware that in *Albion Water*, it was a very long running proceeding, one of the judgments

you have not been taken to is the third judgment which was chaired by now Lady Rose, and she in that judgment with her colleagues addressed the question of trying to identify a lawful price, and it is at {XN2/13/25}, and I just want to give you the references.

The argument by Dwr Cymru, Welsh Water, is set out at paragraph 68. You will see the Tribunal's response at paragraph 69, and the punchline was in the Tribunal's own words {XN2/13/26}:

"... that is a task that is almost impossible to accomplish ... we do not see how a claimant could prove that one [price] rather than [another] is the tipping point between lawful and unlawful conduct."

So my submission really is that if it is impossible to accomplish for a claimant, it would be impossible to accomplish for an authority, it would be impossible for a dominant firm and its advisers to predict ex ante whether or not they would be found to be fined, and so I do say that that is also relevant to how the Tribunal seeks to operationalise the intention or negligence test.

THE PRESIDENT: Mr Bailey, that is very helpful, but that does lead to the question of how one deals with Ms Webster's grey box.

MR BAILEY: Ms Webster's mezzanine? The grey box was before

the mezzanine.

THE PRESIDENT: The grey box was the wriggle room that she was according in terms of, in her case, unfairness, that is what she was addressing, Mr Harman was addressing, excess, though. There was of course some bleed across, but let us talk about Ms Webster's approach because the grey box is actually a very good instance of precisely what is troubling me now.

Let us suppose that the borderline exists somewhere in the grey box. Is it the case that if that is right, one has to articulate the infringement and the negligence and intention in relation to the infringement at a level above the grey box? In other words, does there need to be a margin of appreciation taken into account, and we are talking a penalty, but it may also be relevant to the question of infringement, but we are talking penalty here, does one need to consider the parameters of that grey box in order to work out whether there can be an intentional or a negligent infringement?

MR BAILEY: Sir, to take that in stages, I would suggest that any aspect of the discussion we are now having on penalty should not influence the Tribunal's approach to the question of infringement, to which you have had Mr Holmes' submissions. I would say that when it comes to the question of penalty, because the question is

not: can the undertaking identify a fair price, then one does not need to work out where that fair price lies within the grey box.

THE PRESIDENT: No.

MR BAILEY: So the question really should be on what prices did you actually charge and what are the indicators that that price is unfair as a matter of fact.

THE PRESIDENT: Well, yes, but is it the case that one has to be satisfied that the unfair price lies outside the grey box, because anything within the grey box cannot, taking Ms Webster's reasoning, be characterised as either an intentional infringement or a negligent one? Otherwise why have the grey box?

MR BAILEY: May I just ...?

THE PRESIDENT: Yes, of course. (Pause)

MR BAILEY: My understanding in relation to Ms Webster's grey box is that that is relevant in terms of when the Tribunal was assessing the gap between the floor and the ceiling, the costs and the price, I think it is common ground that no one is saying, certainly the CMA is not saying, that the dominant firm is obliged to charge at the floor cost price. It says that at paragraph 5.30 of the Decision.

THE PRESIDENT: Yes.

MR BAILEY: You then have what has sometimes been referred

to as a headroom above that which of course is where the dominant firm can legitimately price above cost. My submission is that that is not necessary in terms of working out exactly where that headroom lies to either work out the abuse or work out what the penalty is.

THE PRESIDENT: Well, look, Mr Bailey, the abuse is easy because --

MR BAILEY: If only that were so, sir.

THE PRESIDENT: -- all we do is we say, looking at all the evidence, is it or is it not excessive or unfair, and we just have a nice binary decision, we do not have to locate where in the gap between floor and ceiling the unfairness lies because all we are doing is saying, on the facts of this case are the requirements of unfair pricing, excess and unfairness, met.

MR BAILEY: Agreed.

THE PRESIDENT: So as I say there are a great deal of complexities in working that out, but it is at the end of the day a binary answer and we are not supposed to work out where the precise borderline lies.

MR BAILEY: Agreed.

THE PRESIDENT: Fine. So easy.

That is only easy because it is a question of strict liability. So the moment one introduces a degree of uncertainty, a degree of fuzziness, then that must, do

you accept, affect what one looks for in ascertaining whether the infringement that has been found is negligent or intentional, and, in that case, do not the parameters of the grey box actually matter? Because if it is within the grey box, I find it very hard to understand how you can say it is either negligent or an intentional infringement. In other words, in order to ascertain whether there is a jurisdiction to fine, you need to be clearer than one has to be on the infringement question as to where the infringing price lies, which is why I came to the question that I came to yesterday.

MR BAILEY: That is extremely helpful, sir.

Can I answer it in two parts. The first part is that if one is on the fence that the dominant firm has been pricing as you put it within the grey box, then in my submission there is a question as to whether there is actually an infringement at all. If the appellants persuade you that here their ASPs are within the grey box, then actually their prices will be fair.

THE PRESIDENT: Well, I am not sure that does follow because that would be buying into Ms Webster's articulation of the headroom. So bear in mind the question that we are asking on infringement is the nice binary one of is it/is it not. We are not actually asking ourselves

anything about margins of appreciation, we are simply saying on the facts of this case, the binary switch flips to excessive and it flips to unfair, end of story, we are not worried about the location.

So the location of the mezzanine or the location of the fair/unfair line is one that is specific in relation to the penalty jurisdiction. That is the problem.

MR BAILEY: Sir, I was going to answer it in two parts. The second part was that if one is interested in the fuzziness or the grey box, and if the dominant firm could in good faith reasonably show that it considered its prices were within that realm and could show that with evidence and the Tribunal was satisfied with that, then that is highly relevant to the question of whether they are culpable or at fault, but on your second point, sir --

THE PRESIDENT: Just pausing on your first point: are you saying that this is a matter that needs to be viewed entirely through the lens of the material that was available to the infringing undertaking without any kind of ascertainment by the Tribunal itself as to where the infringing price is to be located, because bear in mind all we have done is said that the binary switches of unfair and excessive have been met so as to find a strict liability of infringement. We are saying

nothing about where the price lies, and it does seem to me that we need, in order to understand whether there is intention or negligence, to calibrate in some way where the line lies in order to ask ourselves meaningful questions about what the infringing undertaking intended or whether it was negligence in relation to the location of its actual price.

MR BAILEY: So on the body of material, I am not saying that you judge the issue of intention or negligence purely by reference to material that was available to the dominant firm.

THE PRESIDENT: No.

MR BAILEY: Because the case 1 looks at it objectively speaking.

THE PRESIDENT: Well, I agree.

MR BAILEY: Happily we are agreed on that point.

On the question of whether the Tribunal needs to identify the dividing line or the range perhaps between where a lawful price tips into an unlawful price, my hard-edged submission is that you do not need to do that because I do say that it is no part of that jurisdictional gateway to establish either that the dominant firm knew its price was unfair and abusive or that it knew magically what the fair price was.

THE PRESIDENT: No, I accept that, but I do not think that

solves the problem.

MR BAILEY: So what do I say, therefore, the authority needs to satisfy itself of, and satisfy the Tribunal? It is the facts that show that the prices charged were unfair, the price increase looking in terms of how Pfizer and Flynn were able to impose the prices that they did and sustain them, the dislocation of price and costs --

THE PRESIDENT: Yes, but look, all of these are highly material to the question of infringement in the first place.

MR BAILEY: But also in my submission -- I apologise to interrupt, sir, but they are also highly material to the intention or negligence.

THE PRESIDENT: Oh, I agree. The problem I have got is that for strict liability infringement I quite see that one does not need to worry about whether these factors lead to any kind of need to assess where the line is drawn, but if one is talking about a negligent or an intentional infringement of what is otherwise a strict liability breach, then it does seem to me one has got to ask oneself in what way was the undertaking intending the infringement, or in what way was the undertaking negligent as to it, accepting that ignorance of the law is no defence, we are only talking about the facts here, but we are talking about facts which, on the strict

liability approach, the Tribunal is not engaging with.

MR BAILEY: Could I perhaps show the Tribunal at {XN2/28/151} just the passage from *Liothyronine*, because --

THE PRESIDENT: Yes, of course.

MR BAILEY: -- it is of course the Tribunal itself attempting to answer, no doubt far better than I ever could, this precise question about intention or negligence. So it is {XN2/28/151}, please. Then over page, please {XN2/28/152}. The passage that I had in mind is at 428, and if we just go through it slowly together:

"As to Advanz's knowledge that its prices were unfair ..."

So you can see at the beginning the Tribunal is looking at essential facts constituting the unfairness of which Advanz was or should have been aware, were that, number one:

"... in circumstances where there was no effective competition ..."

So just pausing there, I agree that is a relevant factor, and in my submission, the CMA in the Decision identifies that there was no effective competition faced by either Pfizer or Flynn. Number two:

"... made a series of very substantial price

increases ..."

Pausing there, I would agree that that is also a central fact and I have addressed you on why I say that that is relevant, and I suppose it is important in my submission that the Tribunal in this case did not seek to consider what would have been a fair price or a range of possible fair prices for Advanz, but they go on to identify a third factor which, again, in my submission is relevant and material, which is that in that case for *liothyronine* there was no material increase in production costs, nor is there here, or any improvement of the product, nor is there here, which would be applicable on any other basis.

So neatly, crisply, that encapsulates the Tribunal's finding of intention or negligence in that case, and you have my submission that the CMA really just acted consistently with the approach that was adopted there, and I apologise if that is disappointing.

THE PRESIDENT: Well, I fear it is, but only because it seems to me that there is on this basis no real distinction between a finding of infringement and a finding of intention, because --

MR BAILEY: Perhaps the distinction is this, sir --

THE PRESIDENT: Let me unpack that.

MR BAILEY: Of course, of course.

THE PRESIDENT: The reason I say that is because all of these factors are going to inform the Tribunal's conclusion that there was an unfair and excessive price, but we have agreed that all of those factors can go to the binary question of is it or is it not. So if that is enough for a finding of infringement strict liability, you are saying one does not need anything more in order to get over the line for intention or negligence beyond the bare knowledge of the facts that go to the infringement question itself.

MR BAILEY: Sir, I was going to agree with you wholeheartedly just until that last bit, because in my submission, there is a difference. It is well established that abuse is an objective concept, so that when you are answering the binary question as you put it in terms of excessive or unfair you can look through the facts, you can look at the comparators and the Tribunal can reach its conclusion for or against the CMA and it will make its findings. None of that depends on the mental state or the degree of knowledge of the undertaking, and in my submission, that is really, really important, it is your strict liability point.

Now, at the end of the point you put to me, sir, you said the "bare knowledge". In my submission, that is precisely what differentiates the intention or

negligence. What that focuses a light on is the knowledge or awareness on the part of the dominant undertaking, either actually or constructive knowledge.

THE PRESIDENT: I see, so provided the infringing undertaking knows the facts that have led to the Tribunal resulting in the outcome of infringement, provided it knows of those, or could have known of them, then it is satisfying the penalty jurisdiction?

MR BAILEY: I would agree with just one tweak, if I may.

THE PRESIDENT: No, of course.

MR BAILEY: I would not go as far as to say that dominant undertaking needs to be clairvoyant and predict exactly what either the CMA does or with the greatest of respect what the Tribunal does, so we are not engaged in that exercise.

THE PRESIDENT: Right.

MR BAILEY: But provided the dominant firm knew or ought to have known the essential facts found either by the CMA in its decision or the Tribunal in its judgment, then, yes, I would agree with that.

THE PRESIDENT: Well, hang on.

MR BAILEY: Sir, I think what I am saying is you do not need to predict the legal characterisation of the facts --

THE PRESIDENT: All you are inserting into my formulation is the word "essential facts".

MR BAILEY: I am also saying that what the dominant firm does not need to do is predict the Tribunal's reasoning and legal characterisation of the conduct.

THE PRESIDENT: No, I am not saying that.

MR BAILEY: Ah, in which case I agree, the essential factual building blocks --

THE PRESIDENT: So provided our judgment lays down the essential facts of the infringement and says: here we are, these are the facts, you lose, provided those are known or ought to have been known to the infringing undertaking, then that is it?

MR BAILEY: Yes, sir.

THE PRESIDENT: Okay.

MR BAILEY: Sir, I am extremely sorry, with an eye on the time --

THE PRESIDENT: You have been very helpful, Mr Bailey, I have been asking you a lot of questions which have been troubling me and you have been extremely helpful so you should not worry about the time.

MR BAILEY: I am very grateful, sir. I will do my best to compress the remainder of my submissions.

MR BREALEY: How long? I do not know what time we are rising.

MR BAILEY: Well, it depends how many questions the Tribunal has.

THE PRESIDENT: This was the point that was troubling us or me yesterday. We can, I think, go on for a little longer than 4.30. Mr Bailey was due to sit down at 3.00, was he not?

MR BAILEY: Yes, sir, I can do my level best to truncate --

THE PRESIDENT: No, Mr Bailey, you go on and we will ensure that --

MR BREALEY: We do not want to be too squeezed. We are squeezed now, but we do not want to be too squeezed.

THE PRESIDENT: I understand, I understand.

MR BAILEY: I will move to the next issue and be exceedingly brief. The appellants have criticised the CMA for chopping and changing its case, and I simply make two points about this.

The first is that the appellants are not required, as we have just been discussing, to be aware of the specific legal characterisation of their conduct by the CMA. It is a point made by the Tribunal in *Liothyronine*, paragraph 429 at {XN2/28/152}, and for the record of course we do not accept that there have been spectacular volte face, to use the hyperbole of Flynn's closings. You heard from Mr Holmes yesterday, we applied the two-limb *United Brands* approach, we did that in the original decision, we did that in the remittal decision, we considered the appellants' arguments in

evidence about comparators. It is true, as Professor Waterson will recall, that the Tribunal was not satisfied with the way the CMA had handled and investigated the tablet ASPs first time round, but in my submission, a shortcoming of that kind does not mean that the law becomes wholly uncertain or unworkable. Both of the appellants have referred to Lord Justice Green's comment in his 2019 judgment that granted permission to the CMA to amend its grounds of appeal, that is at {XN1/4/10}.

It is right that his Lordship did refer that it was open to Pfizer to refer to the alleged uncertainty evidenced by changes in the CMA's position, but that is as far as it goes. His Lordship did not say: a change in the CMA's position creates uncertainty, nor did Lord Justice Green say: this must be treated as mitigation. He just said: it is open to the appellants to refer to it.

My submission is that they have referred to it, but they are wrong, and indeed, I am not alone in saying that. In *Liothyronine*, the Tribunal rejected the same argument by the appellants in that case at paragraph 429 at {XN2/28/152}.

The third issue is step 4 and the adjustment for Pfizer on the grounds of specific deterrence. I have

showed you already section 36(7A) of the Competition Act which requires the CMA to have regard to the need for deterrence on the infringing undertaking. I will not, for reasons of time, show you the penalty guidance but simply give you the references at {XI/11/18}, paragraphs 2.20 to 2.22, but I would like to show the Tribunal what the CMA did in the Decision, because there are a number of factors that went into a multi-factorial assessment which the CMA had to weigh up, and as the Tribunal recognised in *McCann*, paragraph 312, {XN2/19/117}, questions at step four involve matters of evaluation and judgment.

To show you what the CMA did in the Decision and see the multi-factorial assessment, can we go to {XA1/1/441}, please. I would like to briskly walk through. We can see the heading there is "Specific deterrence" and there were a number of factors that the CMA took into account. The first is that Pfizer earned 99.9% of its worldwide turnover outside the relevant market.

Now, the reason why that is relevant is because you calculate the fine between steps 1 and 3 based on relevant turnover, so if you calculate it based on 0.01% of Pfizer's turnover, then you are going to produce a very small figure, relatively speaking, and,

therefore, it is going to have no impact on the undertaking. The Tribunal recognised that in paragraph 90 of Eden Brown at {XN2/9/33}.

Now, the second factor on the same page at the bottom is the overall size of the undertaking at {XA1/1/441}. We can see here that what the CMA does is it compares the step three penalty unadjusted of 16.8 million with Pfizer's size, and if we turn over the page, please, we can see the gulf. It is 0.04% of Pfizer's average annual worldwide turnover in the last three financial years of some £41 billion. I will not read out the rest of the metrics, the Tribunal can see them for itself. It is pocket change for the weekend for Pfizer in this respect.

The CMA also addresses one of Pfizer's arguments in closing about the fact that it is a North American company and it has most of its turnover there and federal antitrust law does not prohibit excessive pricing, and you can see that that is answered in paragraph 9.175. The headline is: we focus on deterring the Pfizer undertaking as a whole to ensure compliance with competition law in the United Kingdom, not simply the local subsidiary, and the President will recall Allergan ran a similar point in *Hydrocortisone* which was not accepted.

The third factor is at paragraph 9.176 overleaf, please {XA1/1/443} and here the point is that in calculating the step 1 to 3 penalty, Pfizer's turnover for the relevant infringement year was only £12 million. I say only 12 million because earlier in the infringement, it was almost double that, and so the CMA says: well, look, we are concerned the figure arrived at prior to step four does not reflect the serious impact of the infringements, so that is another factor that goes into the basket of factors that have to be weighed up. Then we get to financial benefit, which was the point that was mentioned by Pfizer's leading counsel on Monday, and the point here is essentially twofold. There is a point of principle which is explained in paragraph 9.177 to 9.179 that a penalty will not deter if it is manifestly below or around the financial benefit from the infringement, because otherwise the risk is the infringer says: I will infringe, pay the fine and I will still be better off.

Then the second point, which is over page, please {XA1/1/444} is how the CMA sought to calculate financial benefits, and I will be absolutely candid, the CMA was pragmatic and simple and straightforward in this case. It looked at the profits that Pfizer earned above cost plus, it recognised that not all of those profits are

illegitimate, and then all it did for the purposes of penalty and the issue of deterrence was make a comparison between the step 3 penalty of 16.8 million and you can see the figures of profits which are many multiples above that.

So even if one puts a grey box or a headroom above, you still have a big gap between the profits derived from the infringement and the step 3 penalty. Now, the other point that Pfizer makes -- and it is the last factor that went into the CMA's consideration -- are the Department of Health's powers under the Health Service Medicines Supplies (Cost) Act of 2017, and this is addressed at paragraph 9.188 and 9.189 at {XA1/1/445}, and I will simply make three very brief points about this.

The first is we say the mere possibility of the Department exercising a power to limit the price of an individual generic medicine at some unidentified point in the future does not ensure deterrence, which is the policy objective of the Competition Act.

We also say, just as importantly, if you turn overleaf, please {XA1/1/446} you will see that the Department's powers are not, to quote the words of an erstwhile Prime Minister, oven-ready. They are not operational. The Department has not even consulted on

the procedures and the methodology that it would use to apply the 2017 Act.

In my submission, in those circumstances where it has not even consulted as it said it would on how it would apply those powers, again, there is no guarantee of deterrence, and just for the record, that is explained in the Decision at paragraph 2.192 at {XA1/1/73}.

I should say in conclusion on this that Pfizer is wrong to say that the CMA ignored the Tribunal's comments in paragraph 461 of its original judgment. The CMA, as you would expect it to, gave anxious consideration to those comments, albeit obiter, in footnote 1866 of the Decision. It properly considered them but, for the reasons I have just set out, it came to a different conclusion in terms of deterrence.

So in my submission, when you weigh up those factors in the round, that is why Pfizer's fine was increased from the 16.8 million to just over 63 million, and then the CMA does not stop there, it then looks at that and asks itself is that proportionate, and if one looks at paragraph 9.198 of the Decision at page {XA1/1/447} you can see even that adjusted fine is only 0.15% of Pfizer's average annual turnover over the last three financial years.

So in my submission, that step 4 adjustment was appropriate, necessary and Pfizer's challenge should be rejected.

The fourth issue is the question of limited immunity --

THE PRESIDENT: The Flynn immunity and the Flynn increase of fine, Mr Bailey, what I am going to suggest, because I do have an eye on the time and Mr Brealey's point about time to respond is well made, would it unduly discombobulate you to put your points in writing and we would read them after the event rather than take up time now? I do not want to cut you off, but in a sense I am, but only because I do not want there to be --

MR BAILEY: Sir, what I would say, sir, is that in fairness to the appellants, if I put in written submissions then of course they should have the final say, and they should be able to reply to anything I say in those written submissions.

THE PRESIDENT: Well, that is very fair, Mr Bailey, and I am very grateful to you raising that point. Subject to that, is that an acceptable way of proceeding?

MR BAILEY: Yes, sir.

THE PRESIDENT: I am very grateful to you, Mr Bailey. In that case, what we will do is we will rise now for 10 minutes and take a break. We will run to 5.10. That

gives you an hour and a half, Mr Brealey. That is just about, I think, what you were promised, it is a bit less.

MR BREALEY: I am grateful.

THE PRESIDENT: I do not think we can go beyond that, but we will rise now. Thank you very much.

(3.31 pm)

(A short break)

(3.41 pm)

THE PRESIDENT: Mr Brealey, good afternoon.

Submissions in reply by MR BREALEY

MR BREALEY: Almost there, almost there.

Mr O'Donoghue will have a few minutes after me, Ms Stratford wants 45 minutes, so I have until around about 20-past.

My job, I think, what I want to respond to are the factors that should guide the Tribunal as to how to value a pharmaceutical drug, which you have been very interested in, so the factors which guide valuation, and also how does continuity of supply fit into that when you have a drug that is essential or you need it. So that is going to be the main thrust of the submissions, and I will do that by referring to three matters.

I am first going to just refer to the relevance of the drug being essential, which is obviously important.

Second, I will outline the factors that we say should guide the Tribunal as to the value, and then, third, I want to look at the evidence of the actual value.

So the essential nature of the drug, the factors and then the evidence in the case of the actual value.

Now, you will not be surprised to know that for the essential nature of the drug I want to go back to *Attheraces*, and I flag the point now, we have been accused of making errors of law by Mr Holmes. We say that the CMA, Mr Holmes, has committed the errors of law and it is very important for me in particular just to highlight the area of dispute because we do not want the Tribunal to make the error of law which we say that he says we are making.

So that is at {XN3/10}. Why are we going to this? Well, I think the Tribunal knows. The evidence shows that phenytoin as a molecule is essential for a significant cohort of patients, and on top of this, we have the continuity of supply.

What I am going to submit is, when we look at *Attheraces*, as a matter of law, the fact that the product is essential does not diminish its value, it is not bringing it down to the floor. It is basically more towards the ceiling, but it is not bringing it down to

the floor.

So *Attheraces*, if we go to page {XN3/10/3} and blow it up, I want to emphasise -- this is something we have not really teased out -- this was an essential facility case. So:

"This case involves a challenge, on competition law grounds, to the lawfulness of the financial and other terms on which a party in sole possession of valuable information (pre-race data ...) is willing to supply to another party. The legal basis of [the] challenge is that the party possessing the information has allegedly abused a dominant position in connection with ongoing access to, and the pricing of, information, the supply of which is an 'essential facility' for the established business of the other party (the supply of audio-visual services about British horse races)."

So essential facility, essential drug.

I refer to paragraph 5 where we see, if we can again blow it up at the bottom, please, this essential facility often arises in competition law: seaports, airports, pipelines, cables, wires. So this case will be the drug.

Paragraph 6 {XN3/10/4}, there is the Court of Appeal posing exactly the same question that this Tribunal has, how do you go about doing it. I would ask you to go to

page {XN3/10/22} at 107, at the bottom, we have "Market dominance" there and we have the same reference to "special responsibility", so we all know that dominance gives rise to special responsibility, and then at page {XN3/10/24}, again, we have seen this paragraph before, paragraph 119 at the bottom:

"It is not a law against suppliers making 'excessive profits' by selling their products to other producers at prices yielding more than a reasonable return ... ie at more than what the judge described as the 'competitive ... level'."

Then again, it is not a law where you complain about being overcharged for an essential facility. So again, the essential facility is well in mind in this case.

Two other paragraphs. One paragraph we have not seen, that is at page {XN3/10/26} at the top, paragraph 124. We see there why the judge said there was an infringement, and we see there that the BHB charges and those proposed prior, if we go on:

"If ATR had to pay £1800 ..."

And then the:

"... data income ... covered its costs nearly 4 times over (... a profit margin of 300% ...)."

So we had a similar argument there, 300%, and then I go back to page 218 where not withstanding the alleged

excessiveness -- that is at paragraph 218 {XN3/10/41} we have seen this before anyway, that is where the too narrow approach is taken.

We really do emphasise this and I know you have it on board, you have to look at the value of the data to the ...

So with that in mind could I then go to our alleged error of law which is important, and that is the -- I noted two passages. One was today's transcript page 11 {Day18LH1/11:10} where Mr Holmes says:

"Now, pausing there, we do say that Pfizer's submissions on willingness-to-pay are based on quite a fundamental misunderstanding of the correct approach to assessing willingness-to-pay applying the Court of Appeal's judgment in phenytoin. So as we understood Mr Brealey's submissions, Pfizer contends that the Tribunal can and should assess what the NHS was willing to pay for capsules, reflecting their value in a manner which is untethered from what the NHS would have been reasonably willing to pay in conditions of workable competition ..."

Now, in a nutshell, I disagree with that. We do say you have to be reasonably willing to pay, but we do not say in conditions of workable competition, and that is very, very important.

So if you go -- the cost benefit does not depend on trying to work out a competitive price, so the cost benefit does not depend on working out a competitive price. The price does not cause the cost savings to be any greater or any less. What competition will do is increase the consumer surplus because, with competition, the purchaser is making the same cost savings but a larger profit.

This is very, very important, and can we just go to page {Day18LH1/112:17} of the transcript today, we see a similar argument being made by Mr Holmes where he is now accepting there is a maximum willingness-to-pay:

"Yes, the maximum willingness-to-pay of the NHS might take account of the avoided costs to the health service, so we would not dispute that for a moment, but of course the test is not what would be paid by the NHS, what its maximum willingness-to-pay actually is, it is what price it would reasonably pay [we agree, but you do not need] under conditions of normal and sufficiently effective competition."

Because again, if you look at *Attheraces*, 218, you are looking at the avoided costs and you are looking at what a fair price would be.

I find these submissions quite astonishing when one looks at what the CMA submits in the -- says in the

Decision.

If we go to the Decision at {XA1/1/15}, because the submission is completely contrary to what is stated in the Decision, so this is the introduction and this is the introduction about the £30 drug tariff price of tablets. Now, the CMA do not like the £30 tariff, let us see why. At paragraph 1.53 "was not a like-for-like comparison", okay, well, we can disagree with that because people benchmark.

Paragraph 1.54, the drug tariff price is not reflective of competition. Well, we say that is not a condition.

Then 1.55:

"The evidence clearly demonstrates that the [Department] ... did not consider £30 to be the value of Capsules ... and were not willing to pay this price during the Relevant Period."

We pick this up in more detail in the decision at page {XA1/1/380}. Now, this is the part of the Decision which is talking about economic value, an "Assessment of economic value as part of unfair in itself", and we see here where the CMA says the excessiveness is unfair in itself, and we see first at 7.11 the capsules are very old, well we say, so be it. If we go over the page {XA1/1/381}, second, no product improvement, so they

say. Third, they refer to patient benefit, but it is 7.14 which is important for the Tribunal to recognise, and if we blow that up and also have a look at the footnotes, please, here is the fourth reason why the CMA say there is no economic value, and we say there is because the Department is willing and ready to pay it. They say there is no economic value because the Department is not willing to pay it. There is no evidence of any willingness on the part of the Department to pay a significantly higher price, and we will come on to that in a moment, but if one looks at the two footnotes, here at 1564 and 1565 we see the authority for the proposition that you do look at a purchaser's reasonable willingness-to-pay to see whether there is any value in the product. So you do not need workable competition.

So if you blow up the footnotes, please, we saw footnote 1564 to begin with yesterday, but we did not look at 1565, and 1565 is important because the CMA is giving legal authority for the proposition that you look to see whether the customer reasonably values this product:

"In *Scandlines*, the European Commission set out the 'demand-side is relevant mainly because customers are notably willing to pay more for something specific

attached to the product/service that they consider valuable' (see paragraph 227)."

We have not got time to go to it, but that is at {XN6/2/50}.

The CMA goes on:

"In that case, the customer acknowledged that the port of Helsingborg represented a value to *Scandlines* and its customers because of its unique location close to Elsinore ..."

Then:

"As recognised by the Tribunal, in *Attheraces* the pre-race data was 'of considerable value' and 'clearly very valuable' to customers and for which they were 'readily willing to pay a premium' ..."

Again, we are not talking about workable competition here, we are looking for evidence as to a reasonable willingness-to-pay.

Then lastly you see *Albion Water* at paragraph 226, and for your note that is at {XN2/7/75}.

PROFESSOR WATERSON: Would you say this is not a case of type 1 in the schema that the President laid out?

MR BREALEY: Inefficiency?

PROFESSOR WATERSON: Mm.

MR BREALEY: We say it is squarely within case 2, and we say there is distinctive value and I will come on to the

factors which should be guiding the Tribunal, but one of the distinctive values in this case is whether this drug, this molecule, phenytoin, leads to cost savings for the NHS.

How one can say that is not distinctive value when I am supplying someone with a product which is either allowing that person to make significant profits or incur significant savings, and to say that is not a distinctive aspect of the product, well, we just do not understand that. To say that it is old when it is having all of these cost savings again, it is clearly a case 2. We do not need to say in case 1 whether there is efficiency or inefficiency.

So that is what I want to submit on the law. It is very, very important that we are looking at a price by a dominant firm, allegedly dominant firm, and asking: is the customer reasonably willing to pay the price for this product, and we will come on to this in a minute, the question is: are you gouging the customer, are you gouging the Department, or is the Department on the evidence reasonably willing to pay. That is very, very important in this case. That is the law. We say we are not committing an error of law, we are saying that we are right on the law, and Mr Holmes is trying to persuade the Tribunal to get the law wrong.

Can I go to the factors that should guide the valuation of a pharmaceutical drug. The Tribunal has asked the CMA for guidance as to this and we do not believe the CMA is giving any reasonable answer, and I offer the Tribunal three main factors, three main factors.

The first one you may not like, but I make it anyway because it is the way that the pharmaceuticals base their prices. The first is the clinical benefit of the drug. A drug that works is more valuable than a drug that does not work. A drug that works better is more valuable to the NHS than a drug that does not work so well, it is common sense. The NHS has to provide the best healthcare it can and from a purely (inaudible) perspective, the better the medicine the NHS can obtain, the better the service it delivers.

In this case, phenytoin is efficacious at ensuring seizure-freedom to a significant number of patients. That has value to the NHS because it is providing a better healthcare system. We are not geared on to the patient here, we are looking at the NHS. I am providing a good healthcare system. I have got this drug, it is an improvement.

Second, the economic benefits to the NHS. That is the second factor.

If the drug works well, it means that less healthcare services are necessary. A good drug, therefore, will save the NHS avoided cost, and the witnesses of fact -- White, Green and Smith -- all agreed with this. And we pray in aid the 2012 letters that the Department of Health wrote to the CCGs which have been conspicuously ignored by the CMA in its closing.

The third factor, this relates to continuity of supply, the importance of the manufacturer or brand: is the manufacturer trustworthy? Does the name matter? And in the present case continuity of supply is relevant here because the guidance -- and maybe we can just go to the guidance very quickly, that is at {XN1/2/12}. This is the Tribunal's judgment. It is at paragraph 29. We see here that, category 1:

"For these drugs, doctors are advised to ensure that their patient is maintained on a specific manufacturer's product."

So Pfizer's name as a manufacturer was important, and indeed, so important that the Tribunal found that Pfizer was in its own market.

So to say -- we will come on to this in a moment -- to say on the one hand it is very important and then to say it is not important, again, it is cherry-picking.

We say those three factors are important factors that guide the Tribunal in this case to the value of the product, and indeed, it is how the industry works. This is value-based pricing.

THE PRESIDENT: Mr Brealey, your second and third factors I completely understand, and you said we might cavil at the first. I am not sure we do necessarily cavil at the first in that what you say is clearly right, clinical benefit matters. It would be folly to pay for something that did not work. The reason I think there is cavilling is because of the question of need, and of course, I accept it is not the NHS's need, it is the patient's need, and that is perhaps the problem one has with pharmaceutical products and medical treatments in that need is very close to value, and if one had a form of treatment that was desirable and not necessary, a magical treatment for hair loss that you could spray on the head and it would solve all your problems, well, I do not really have a problem in gouging the market there because it seems to me an unimportant matter.

On the other hand -- I would say that, of course -- on the other hand, when one is talking about an avoidance of seizures and the human cost of that, one can see that there is a factor going the other way which impels lower prices which is not that it is not

valuable -- not that it is not needed, but that that very question of need requires a degree of trimming in terms of the price that one could otherwise perhaps reasonably command.

MR BREALEY: I respectfully wholly disagree with that. That is why we went to *Attheraces* to begin with, because you do not get any authority for that in *Attheraces*. In *Attheraces* it was an essential facility. You can charge above cost, and you take into consideration the offer of the product, is it giving you, oh purchaser, a benefit? The level of that benefit is not diminished because of the essential nature. I desire something, it is £100, I really desire it, it is £150. I need it, it is £1. It is slightly counterintuitive.

The answer is where you have need or essential facility, an essential product, when you are looking for evidence of reasonable willingness-to-pay you have got to be sure that the purchaser is not being gouged, and that is what Ms Rose in *Albion Water* -- I have not gone to it, but she says that you have got to look to see whether the purchaser is being gouged and whether the purchaser is paying under protest or there is evidence of a reasonable and ready willingness-to-pay. But I do not accept simply because it is essential that the value is diminished.

THE PRESIDENT: But you are equating an essential facility with something that is needed.

MR BREALEY: Absolutely.

THE PRESIDENT: Okay.

MR BREALEY: That was the whole point in *Attheraces*.

THE PRESIDENT: Ah yes, I know, but *Attheraces* is all about information for horseracing which, in a sense, is not needed in the way an epileptic drug is needed. It may be needed in order to carry on your business, but it is not needed in the human sense that I was putting to you there.

MR BREALEY: We are dealing here with a pharmaceutical product and we are dealing here with competition law. If the Department wants to use its regulatory powers to price cap, so be it, but there is no rational reason why competition law is going to treat an essential drug any differently to an essential port or an essential facility. If competition law is, there needs to be some rational justification for that, because the pharmaceutical company is entitled to say: I am providing you with this drug, it is a really, really important drug, and at the same time, it is leading to significant savings for the NHS, and I want some recognition for that, and there is no correlation between that and exploiting your market power, it is

just a statement of the obvious that I am providing you a benefit.

THE PRESIDENT: That is very clear, thank you.

MR BREALEY: Sir, we do not buy into the CMA's narrative that simply because you have got an essential product that you are gouging the Department simply because you want to price above cost, particularly where your product, your drug, is leading to significant savings.

So just very, very quickly, we have looked at the essential nature, we have looked at the factors, can I just remind the Tribunal of the last piece of the jigsaw which is the evidence of the Department's actual willingness-to-pay. I know we have been through this before, but it is important, because the evidence in this case of the Department's willingness-to-pay is not consistent with the Department being gouged which is where you would draw the line for an unfair price of an essential drug or an essential facility.

We have looked at lots of demand factors, but there are two areas I just want to emphasise. The first is phenytoin itself. So what is the evidence on the value on phenytoin?

First, we have the Teva meeting, and in my submission, only a cynic would say that Teva was gouging the Department in that meeting when one looks at the

evidence, the Department threatening its statutory powers, thanking Teva for its co-operation, the Department saying it has provided value. There is no gouging of the Department in that meeting, in fact it is probably the other way around.

THE PRESIDENT: Would you say that one factor in showing no gouging is the failure to trigger the regulatory controls that existed?

MR BREALEY: Failure to trigger the regulatory controls, but the fact in the very first place they threatened a regulatory control to get the price that they wanted, so it really is a topsy-turvy land to say -- it did the trick.

So first the Teva meeting, we are not getting a sense, to use Lady Rose's or Ms Webster's gouging or protest, there is no protest there. There was a: this is the price we want. So that is the first piece of evidence which shows there is no gouging. Secondly is the continued market signal that £30 gave. From 2008 onwards the Department gave a signal to the market that this was the price it was prepared to reimburse, and it was a Scheme M drug, and we know that Milpharm looked at it, we know Wockhardt looked at it, and there is no reason why Pfizer and Flynn should not also look at it.

So that is the second piece of evidence which we

would say shows that the Department is not being gouged by this £30.

Third is -- we have seen this before -- it is the Department's Scheme M calculation, the internal calculation which said that £30 was the value. That was the Scheme M calculation model that we have referred to numerous times, the answer, question 6. So those are three pieces of evidence on phenytoin, the tablet.

We say then you look at the 2012 Department letters where they reject the CCGs' complaints. That is a further piece of evidence which shows that the Department was not being gouged. It recognised that phenytoin had cost savings to the NHS.

So we say the evidence is overwhelming in this case that the Department was not being gouged and was ready and willing to pay the £30 and the price at which Flynn sold its capsule, and it is conspicuous that Mr Holmes did not even try to attempt really to tackle those letters that I referred the Tribunal to. So that is what is the evidence of willing to pay for phenytoin, whether it be the tablet or the capsule.

Then -- and I am not looking at the ASPs now, and I am not looking at -- Mr O'Donoghue is going to look at QALY, but I just want to see the double standards with the other AEDs.

Could we just quickly go to {XL/5} of our closing just to see where it is, and page {XL/5/70}. As the Tribunal know, that is where, at paragraph 214 onwards, we are dealing with the other AEDs.

As the Tribunal said last time, this is evidence of what the Department is ready and willing to pay for other products, it is a data set, and we will not go through that given the time, and I want to just give the Tribunal, just for the transcript, the reference to Ridyard 1 is at {XE1/1/40} and Ridyard 2 is at {XE1/2/14}.

So that is the evidence that was given by Mr Ridyard at the last proceedings and, again, we say when one is looking at weight of this data set, the CMA has offered no evidence to gainsay it, to disapprove it, and I found it quite astonishing that so far we have been told that the data set is irrelevant and then at I think {Day18LH1/93:} of today's transcript Mr Holmes said: the charts, we say, are important. So we get today Mr Holmes saying the charts are important, but to date we have been told they are irrelevant and inappropriate.

For that can we just go to see what Ms Webster said, because she summarises the CMA's case. That is at {XE1/16/72} at section 5.

This is where she says the relevance of other AEDs

as comparators -- she is looking at relevance here. Again, I would ask the Tribunal obviously to read this.

Page {XE1/16/74} at 5.10 she refers to these other AEDs, so say the CMA, are not sufficiently similar to phenytoin. We say, well, it was a far better data set than was in *Liothyronine* and it is relevant.

But can I just then go on to how she then deals with it at page {XE1/16/75}. This refers to how the CMA dismisses the AEDs because they concern brands, and we say again this is yet another example of cherry-picking and double standards.

She says at 5.16:

"In my view, the branded prices of other AEDs were unlikely to reflect prices set under conditions of sufficiently effective competition for two reasons."

She goes on.

" ... the Other AEDs were dispensed in response to closed prescriptions, the sales of these volumes to pharmacies would have been protected from competition and prices charged to pharmacies not set with reference to competition."

Then she goes on at 5.18 and 5.19, but she is dismissing, as the CMA does, she is dismissing the relevance of this data set because it includes brands, and we have had weighted average, but the data set does

include brands.

On that, almost to finish, can I then go to our closing at page 11 where we deal with this what we say is the double standards {XL/5/11}. So that is where in the intro we are dealing with ASMs, and if one goes over the page {XL/5/12}, if we blow up 29, the CMA has rejected the data set because it includes brands, and we say:

"As to the inclusion of some branded products but not others, the CMA's distinction is particularly contrary. First, Mr Harman ... in the previous proceedings described Pfizer's phenytoin as 'quasi-branded' ... Furthermore, the concept of a branded generic is not an oxymoron; Category C ... for example includes such products. Second, the CCGs budgeted for the cost of both branded products and generic alternatives ..."

And that is what Mr Green accepted, but the third point I just want the Tribunal to be aware of, we say:

"... it is remarkable that, in the same breath, the CMA can: (a) conclude that Pfizer is dominant in its own market based on the need to dispense the same manufacturer's product ..."

So the real emphasis on manufacturer.

"... and then (b) disavow any comparison with

branded [or the manufacturer's] drugs (because they are ... often on a closed prescription)."

So they dismiss the branded drugs because they are dispensed on a closed prescription, but rely on continuity of supply which is essentially a closed prescription, because they say that the pharmacies must dispense phenytoin and particularly Pfizer's phenytoin.

So again, this is all part and parcel, we say, of the unsatisfactory way that the CMA treats our case on demand-side factors, and we would ask the Tribunal to weigh up all the factors.

The CMA does not weigh up this data set at all because they say it is irrelevant, even though we just heard this afternoon that it is important now. We ask the Tribunal to weigh up all the demand-side factors and compare it to the supply side factors as well, but I do emphasise that we have not committed an error of law when we are looking at customers' maximum or reasonable willingness-to-pay. It is not a reasonable willingness-to-pay in a competitive market.

Again, just to nail the point, in *Attheraces* you are looking at the benefits by a dominant company, you are evaluating that company, dominant company and the customer. If competition then comes along the consumer, the customer, will get a much greater consumer surplus.

That is my submissions, sir. Thank you for listening and being patient with us.

Mr O'Donoghue has a few extra submissions.

THE PRESIDENT: Thank you, Mr Brealey.

Mr O'Donoghue.

Submissions in reply by MR O'DONOGHUE

MR O'DONOGHUE: Sir, I can be extremely brief, five minutes.

Three rapid-fire points. First, just to pick up on Mr Brealey's no gouging point. We would submit there is a further source of comfort the Tribunal can obtain from that perspective. If one looks at the comparators and reference points we have put forward, they are unaffected by the harder edge of the 2013 MHRA guidance.

Now just to unpack what I mean by that, the £30 DT price was obviously set in 2007, long before the guidance, and of course was set by the customer and the regulator who, as Mr Brealey says, we must assume they know the value of what they are purchasing.

The tablet ASPs in period 3 are predominantly before the guidance, so that is uncontaminated. The other AED prices we rely upon, they are from 2012, again, pre-MHRA guidance, and importantly, the particular AEDs we rely upon, they were not placed in category 1 of the guidance, and, therefore, are not contaminated by the category 1 designation if I can put it like that.

Then of course the QALY, the discussion we had a couple of days ago, sir. The QALY only looks at new patients, not the legacy patients, and therefore is not baking in any contamination from the guidance at all.

So we say for those reasons the Tribunal can and should draw a high degree of comfort that the reference points and comparators we put forward are decontaminated from the harder edges of the 2013 guidance. That is an important point. So that is the first point.

Second, because we have been rather squeezed today -- again, no criticism of anyone, this is quick fire stuff -- we have reduced a couple of our points to writing. Mr Johnston and I have been beavering away, much to Mr Brealey's irritation, on a couple of notes today. If I can just hand those up and just telegraph what they are.

The first is a two-page note which deals with I think eight or ten cases, and this is to pick up on Mr Brealey's point that the mantra we face with each and every comparator we put forward is: well, it is not arising from workable competition, therefore we can put it in the bin, and what the Tribunal has before it I think are eight or ten cases which show that is simply not the approach in the case law. The case law of course we accept, if there is a benchmark from

a workably competitive market, that is a valid benchmark, but it is a non sequitur to say: just because the comparator does not arise in a fully competitive market therefore it is of zero probative value whatsoever.

So we give examples of regulatory benchmarks, *United Brands* itself, and so on. So the punchline is that there is a highly inclusive approach to benchmarks and one does not cut them off at the pass based on a workable competition distinction. One is looking at is there probative evidence which can usefully inform the difficult exercise of calibrating unfairness. So we put that forward for what it is.

The second longer note is something which has been quite concerning to us. There has been a lot of unpicking of the evidence in the first trial and in particular, there has been a lot of unpicking in relation to case 2 valuation of what Pfizer did and did not think, and in particular Mr Poulton.

Now, we have set out in some detail why that is (a) factually inaccurate and (b) actually quite unjust, because Mr Poulton was cross-examined in the original trial, the CMA in its defence said he does not need to be recalled, and yet they turn up at this trial and take various pot-shots based on his evidence. We want to

correct that record which is very important.

Just to give you one very important example, you will see on page 2 of that note -- sir, there were two points made by Mr Holmes -- sir, Mr Holmes made two points. You see the top of page 2:

"... price increase would not be eroded through competition."

Then he says:

"... they did anticipate one competitive response: parallel imports."

Now if you then look at paragraph 6 -- this is a contemporaneous document from Mr Poulton -- you will see in the second paragraph the quotation. This is in 2011. Pfizer observed that NRIM was entering the market and they apprehended they would get 50% of the market volume. So one year before the alleged infringement commenced, you have Pfizer observing: we have a new entry, they may get up to half of the market. So it is simply untrue to suggest that all that Pfizer apprehended was parallel imports and an absence of competition. They fully expected competition and it was factored in. Now, there is a bunch of other points, but that is among the most important.

Then finally before I sit down, sir, on the QALY, two very short points. First of all, Mr Holmes said the

reason we can put QALY in the bin is because it is a ransom price situation. That is plain wrong. First of all, it is considering, as I submitted earlier, only the situation of new patients and therefore the unransomed patient, and second, and more importantly, the QALY thresholds are not assessing maximum willingness-to-pay, they are assessing reasonable willingness-to-pay. They are not saying: we will buy at any threshold, they are saying we will not buy at 40, we almost certainly would buy at 20. So there is a reasonableness element incorporated, and of course because of the comparative exercise, if you are looking at products A, B, C, D and E and you conclude based on QALYs that A is much more cost effective than B, C, D and E, then by definition, you have concluded that there is a reasonable willingness-to-pay in particular for A, but perhaps not for the others. So the idea that this is simply a ransom price or a maximum willingness-to-pay turns the whole system, frankly, on its head.

One final point, again important. The second point Mr Holmes made was: well, we do not need to sweat too much about QALY because of course in 2012 we can see the cost effectiveness assessment. Now, I have made this point more than once, but it is very, very important: what NICE did in 2022 is they applied a rigid assumption

that if they could not find a relevant clinical study operating only at the level of the third line, they were not willing to accept clinical efficacy in relation to phenytoin.

Now, that is a particular approach, and it is what it is. Now, what Dr Skedgel has done, and I will show you what was said in relation to this, is to say: well, fine, but what one can also do as a reasonable approach is look at the first-line evidence, extrapolate the third line and base the efficacy number on that.

Now, I will just give you one reference and then I will sit down. I put to Professor McGuire -- we can see this in our closings at {XL/5/85}, please -- I put two things to Professor McGuire. I said first of all in (a), well, hang on a second, Professor Walker said that extrapolating from first-line to third-line is a reasonable thing to do in a clinical context, and then you see the quotation. I said to him:

"Question: You are not in a position based on your expertise to suggest it is wrong, are you?"

He says:

"Answer: Not at all ..."

So there was no challenge to that.

Then at the bottom of the page and then over to {XL/5/86}, next page, please, I also put to him, I said:

"Question: ... Based on what we have seen from Professor Walker, the significant extrapolations made by NICE itself ..."

You will remember, sir, I put a number of examples to Professor McGuire: well, hang on, NICE itself extrapolates from first-line to third-line in the 2022 guidelines, and from one area to another, so that is the extrapolation point, and then the Chen study:

"... that Dr Skedgel's proportionality assumption [which is the extrapolation] at the very least is a reasonable one?"

And he said:

"Answer: I could agree with that."

So what the Tribunal has is a reasonable, albeit different approach, from Dr Skedgel and the 2022 guidance.

Now, these are simply different ways of looking at the same question, and for my purposes, if it is reasonable we say that it is sufficient, and the fact that the cost effectiveness study on a different basis in 2022 said something different is neither here nor there.

Thank you very much, sir.

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

Ms Stratford.

Submissions in reply by MS STRATFORD

MS STRATFORD: Thank you, sir.

I am conscious that during the past six weeks we have covered a very significant amount of legal territory relevant to excessive pricing, and there has frankly been a blizzard of points and counterpoints. Obviously I cannot, in the remaining time, answer everything that I could come back on coming from Mr Holmes and Mr Bailey in closing, so what I am going to do is pick what seem to us to be the big points that really matter for Flynn or where we say the CMA has misrepresented our case in some important respect.

I just want to begin by emphasising an important distinction which was sometimes slightly lost in Mr Holmes' submissions.

The main question for the Tribunal is whether the CMA's finding of excess against Flynn based, as it is, on its primary ROCE benchmark is wrong. If it is, the Decision is likewise wrong and must be set aside, and almost all of this trial from Flynn's perspective has revolved around the CMA's finding that based on its benchmark of 10% ROCE, Flynn's margins were excessive. We have spent -- I am not exaggerating -- years preparing evidence explaining why that benchmark was

inapposite, days of this trial cross-examining Mr Harman about it, and the reason we have done that is because it is the case that has, for the past several years, been put against us.

Now, I hope I am not putting it too high when I say that it became clear this morning that the CMA, whilst certainly not formally abandoning the point, is very much detaching itself from Mr Harman's one-size-fits-all ROCE benchmark. Mr Holmes said barely anything about it and simply invited you to read the written submissions, and as well-worn litigators I think we all know what that means.

From Flynn's perspective, this is a rather surprising development because, as I say, Flynn's entire appeal has been focused on the CMA's ROCE benchmark, which is the basis on which Flynn has been found to be excessive, and I just want to show you very briefly why that is. If we could please go to {XA1/1/235}, this is in the Decision, and the section is headed:

"Calculation of the reasonable rate of return and Cost Plus for Flynn's Products."

So this section is the heart of the CMA's case against Flynn, and it begins at 5.390:

"Having assessed what is a reasonable rate of return for Flynn's Products ..."

Pausing there, that is the 10% ROCE benchmark.

Then at 5.391 you see:

"Using the reasonable returns calculated in Table 5.12 ...

Again, this is the 10% ROCE table, it is the table 5.16 below.

"... [calculate] the resultant Cost Plus figures for each of Flynn's Products on a total revenue and per pack basis..."

Then we see those cost plus prices in table 5.16.

Then if you could just very kindly skim through, if we go down, please, 5.392. Going over the page we see table 5.17, which is by now very familiar, where the CMA calculates Flynn's excesses.

Now, the punchline, if we could just go a few pages on to page {XA1/1/240}, please, and we get the CMA's conclusion at 5.417:

"The CMA concludes that each of the excesses set out in Table 5.17 ..."

Then you see:

"... is ... 'material' and 'sufficiently large to be deemed excessive' ..."

So the CMA's finding of excess does hang on table 5.17 which in turn hangs on the 10% ROCE benchmark. Now, as I say, Mr Holmes has now, I am sure

he would say not formally, but forensically, if I can put it like that, distanced himself from the ROCE benchmark. And the reason he feels able to do that is because there is the cross-check, the 6% ROS rate which the CMA says shows Flynn's prices to be excessive in any event.

So I am just going to need to spend a little time, and it will be a little time, exploring the 6% rate which has emerged, frankly, at the eleventh hour as a mainstay of the CMA's case on excessiveness against Flynn.

So just to take stock of where we have got to -- and I know this is familiar territory, but in the first appeal the CMA put forward a primary benchmark of 6% ROS cross-checked by ROCE of 8-12%. Both were rejected as being theoretical and based on idealised competition.

On remittal the CMA swapped the order, so they put forward a ROCE of 10% as their primary benchmark cross-checked by a ROS of 6%. As you know we say that is just a re-ordering of the CMA's previous benchmarks and they should be rejected for the same reasons.

Now we have a quiet but definite change of emphasis where the CMA puts the 6% ROS benchmark back in the mix, whether as its primary benchmark or -- I can hear a lot of noise coming from my right which I expected, but I do

submit forensically something has happened, and we have, if you like, come full circle to where the CMA started 10 years ago.

So let me deal with the 6% ROS cross-check, where it comes from and what it is designed to do. And could I just, please, if we could go to {XA1/1/239-240}, still in the Decision, and perhaps -- I do not know if I could very kindly ask the Tribunal to glance swiftly through paragraphs -- starting at 5.408 where this section begins and it goes through to 5.416.

THE PRESIDENT: We will read those.

MS STRATFORD: Maybe I will just sort of keep talking in the interests of --

THE PRESIDENT: Keep talking and we will cast our eye over it.

MS STRATFORD: -- speed.

THE PRESIDENT: We will try and do two things at once.

MS STRATFORD: I am grateful.

So as you can see, this is the section of the Decision, a cross-check to which we say the CMA seems to have pivoted. What will strike the Tribunal, I suggest, beyond a recognition that 6% was used as the primary benchmark in the first Decision, and rejected in the first judgment, is that no clear source for this 6% figure is given here in these paragraphs.

The reality is one of two things: either it has been plucked out of thin air, or it is just a recycling of the CMA's benchmark from the last occasion which was based on the PPRS, and, as I have said, was rejected.

In his submissions, Mr Holmes pointed to a passage of cross-examination of Mr Walters from the previous appeal, so if I am not going too rapidly, and please stop me if I am, could we possibly pull that up. I hope this reference is right because it is still in the Decision. So if we could try this: {XA1/1/233}. We have the passage, and Mr Holmes showed this to the Tribunal this morning. It was put to Mr Walters that had Flynn known that phenytoin would earn 5% ROS, it would have taken that over nothing because nobody would look a gift horse in the mouth.

Now, just to make a very obvious point at the start, it does not explain where the 6% came from, the figure was 5%, but the more important point is that this passage says nothing about what is a normal competitive rate of return. What was being put to Mr Walters is that if you were offered a guaranteed tenner, let us say, or nothing, you would take the money, but of course that is not the situation that any business thinking of launching a new product or is launching newly themselves into the market, which is what Flynn was doing, that is

not the situation that they find themselves in, and most fundamentally, the test is not what is the absolute minimum return that is required to supply the product, it is what is a normal competitive return.

THE PRESIDENT: What you are saying, I think, is that this is taking the time value of money but ignoring risk, hence gift horse.

MS STRATFORD: That is not how I have thought about the point. It is that really this is pressing Mr Walters and pushing him down to: would you have accepted something rather than nothing and he unsurprisingly says yes. But that does not really help you if you are asking the question: what is a normal competitive return?

We do say that the 6% cross-check is a very shaky foundation indeed for the CMA's decision on excessiveness, if that is now being put forward as the main basis or a main basis for it. The only other analysis in the Decision which Mr Holmes prayed in aid of the CMA's case of excess against Flynn is this morning, absolute returns.

The point in short is that Flynn earned what the CMA says was a high level of absolute profits because of the high input costs charged by Pfizer and high volumes.

Now, I am going to come back to that very shortly.

Neither of these features are as exceptional as the CMA makes out, but if we could just start with the basics, the actual amount of profit that Flynn makes on these products by strength and, again, if we could just bring up, please, {XO/1} and I will keep speaking, that is one of our hand-ups which you will, I hope, be familiar with, you will not actually find these figures in the Decision which is why we had to hand them up. The CMA did not even calculate Flynn's absolute returns on each product which does, in our submission, already tell one something about the weight that Mr Holmes can now place on this as a freestanding basis for the CMA's finding of excess.

More fundamentally, absolute profits are by their nature not readily comparable, and it is perhaps for that reason we are not aware of a case where a price has been found to be excessive based on the absolute returns in pound terms earned by the seller, and that is obviously because what looks like a large amount of profits in pound terms for one business might look tiny for another.

You will recall Mr Harman frankly accepted that neither he nor the CMA knew even on a ballpark basis what is a normal return for a generic drug in absolute pound terms.

So how can one look at these figures and say that in themselves they are excessive? The obverse point, of course, is that if the CMA is right in its reasonable rates of return for Flynn then that involves Flynn earning the £66,000 per year and I do not think I need to go back over that point again.

Now, the Tribunal might say to us: do we have to close our eyes to the fact that higher volumes and higher input costs equal higher absolute profits? That is not our position, just to be clear. We do not dispute that the input cost and volumes will affect the absolute returns of a product, that is just a mathematical truism.

In an ideal world with unlimited information, one might want to look for other individual product comparators which match those features exactly, but we are in the real world, and the question is how does one ascertain in a realistic way a normal rate of return for the product in question.

The first point about that is that I showed Mr Harman the figures for Flynn's other products which show no actual consistent relationship in the real world between returns and input costs, but even putting that to one side, Flynn's other products also show that the input costs are not that unusual. Even within Flynn's

small portfolio of 12 products, a quarter of them had higher input costs than phenytoin. So we are based on that limited sample in the realms of exceptionality and we make a similar point in relation to volumes.

Now, the point that the CMA fairly makes is that Flynn does not, in its small portfolio of 12 products, have a product that ticks all the same boxes as phenytoin, particularly in terms of input costs and volumes, but if what the CMA is interested in is close comparisons with other products, then what the CMA should have been doing is to check what returns are obtained in the real world on similar products, and, in that respect, we have offered up a ready-made platter of products in the form of Mr Williams' comparator companies which have been selected precisely because they sell products with similar characteristics to phenytoin.

Now, Mr Holmes' response this morning to that was, he said, "Mr Williams has chosen comparator companies to Flynn, not comparator products to phenytoin, and he does not have information about the products that underlie the average ROS in issue." I am afraid, I have not got the page number of the transcript to hand, but I think that is accurate.

Mr Holmes said that the CMA has rejected the

comparator companies and, therefore, did not need to do further investigation, but if we could please just briefly bring up {XB/9/113}, this is the CMA's defence, and I want to look at paragraph 263 to see the reason why the CMA rejected those companies.

They said there:

"The narrower comparator set in Williams 6 ..."

So that was the first time he had his five companies.

"... does not address [these] issues. As Mr Harman demonstrates, there is still a great deal of relevant information as to the comparability with Capsules missing."

Now, if the CMA's reason for rejecting the comparisons is that there is a great deal of information missing, how can that be used as a justification for not gathering the missing information? And we say that is a bootstraps argument.

If one just steps back for a moment, one can see what the CMA is trying to do here. It has its cookie cutter 10% ROCE benchmark, or at least it did until this morning, which it says can be applied to the whole industry.

When a company comes to the Tribunal with actual margins achieved in the real world, it says they need to

be ignored unless one can find a match with an individual product, and then, when asked to gather information about individual products, the CMA guffaws and says: that would be a lot of work, so you have to default to the 10% ROCE.

What I have explained, I hope, is it would not need to be a lot of work. You simply ask: one, what other products do you have with similar volumes; two, what other products do you have with similar input costs; and, three, what are the returns on those products. We do not accept that that would be a disproportionate task.

So the reality is that the CMA has done no investigation into the returns earned by a single pharmaceutical company or a single product on the market, contrary to what it was told to do by the original Tribunal.

I am very mindful of time, but I am going to crack on.

That leads to a broader issue about comparators which I can make very quickly. Mr Holmes appeared to acknowledge that the CMA is obliged to fairly evaluate the comparators put forward by the undertakings for the purpose of the "unfair by comparison" assessment, so he agreed with the way that the Tribunal has characterised

the relevance of comparators and the appropriate question is to ask what weight can be placed on them, but --

THE PRESIDENT: Yes, I think there is now agreement that it is not an admissibility question; it is a question of weight. There is substantial disagreement about weight, but that is a different matter.

MS STRATFORD: Yes, but what I wanted to just add very briefly on that is, with respect to the CMA, to inject a dose of reality.

The CMA has concluded in fact that each and every comparator, price and margin, which the appellants have put forward should be given zero weight. That is, if one is being intellectually honest, a binary approach. Indeed, Ms Webster, you will recall, confirmed in cross-examination that she used a binary rather than a weighted approach in her assessment of comparators. Sir, I just wanted to stress that and suggest that that is the opposite to what Mr Holmes and the CMA are now professing to be the correct approach, namely a weighted approach.

Moving on, the Tribunal asked Mr Holmes yesterday afternoon what relevance the CMA has attached to the supply relationship between Pfizer and Flynn, and the first and most important point that emerged from

Mr Holmes' answers is that the CMA has not treated that relationship as illegal or anti-competitive in a way that would fall to be ignored or that Flynn and Pfizer are in some way to be compressed into a single undertaking. The costs that Flynn paid to Pfizer are to be taken as they actually were.

Despite that, Mr Holmes repeatedly said that the relationship was what he called an "artificial arrangement" designed to increase the price of the product and give each party a slice of the pie, and we had a bit of this again this afternoon from Mr Bailey.

Well, it is true, and we have never disputed that the premise of the arrangement was that Pfizer's Epanutin -- the Epanutin capsules were loss-making or only marginally profitable because, as we know of the waterbed effect within the PPRS, while the DH had agreed to pay £30 per pack for the identical tablets.

The business proposition was therefore of course to increase the price, and of course, the motivation behind that was to make profit for both companies. That in itself is a perfectly normal business transaction, but the suggestion that there was some sort of agreement to divvy up the profits by fixing prices is simply wrong and is not one that is available to the CMA.

The Tribunal will not see any documents in which the

parties colluded on their prices so as to fix their shares of profits and the CMA has, as I have just said, disowned any case based on that allegation.

The other point that Mr Holmes made is that Pfizer engaged Flynn to act as a shield for pharmacopolitical damage that might otherwise come Pfizer's way. Could we just briefly bring up the original Tribunal judgment at {XN1/2/128}. I want to look at paragraph 404, please, where the Tribunal held in the final sentence:

"We do not consider the CMA has shown why the possible transfer of reputational risk should be included as an element in the assessment of unfairness."

The CMA did not appeal that finding, and we say the same is true now as it was then.

There is also an important factual point. Mr Holmes described the arrangement as an unusual one. That is factually incorrect. Mr Williams explained that it is entirely normal for the marketing authorisations of old tail-end products to be transferred to smaller specialist companies such as Flynn. Flynn's factual evidence explains that this is an important part of its business. This was not some form of unique arrangement. I can give you the references for the transcript if that would be helpful, but maybe Walters 1, paragraphs 5 to 7 at {XC2/3/2-3} and Fakes 1, paragraphs 15 to 18, which

is at {XC1/1/5-8}. Also in the transcript {Day7LH1/27:} to {Day7LH1/28:}.

Finally on this point just stepping back, it is a caricature of Flynn's role to suggest that it is just there to absorb the damage. One of Flynn's skills is in managing supply chains to make sure that tail-end products are continuously supplied to often declining patient populations. It has achieved that. It has never experienced a stock-out of phenytoin. NRIM, on the other hand, runs a shakier supply chain and has experienced multiple stock-outs and we have set out the references at paragraphs 41 and 205 of our written closing.

If I may, I am going to come back now -- and I apologise I am jumping around a little bit but in the time available it is not quite as polished as it might be, but I just want to come back to what we see as a fairly foundational point that Mr Holmes made.

He submitted yesterday that it was a repeated refrain of Flynn that the CMA erred in sticking to a cost plus analysis despite the Tribunal's criticisms in the original CAT judgment. Just one reference: {Day17LH1/122:5-9}. This is a straw man, so I just wanted to deal with it very quickly.

Flynn has never taken issue with the proposition

that a cost plus benchmark may be used for the purpose of the excessiveness assessment under limb 1 of *United Brands*. Its appeal has always turned on the calculation of Flynn's plus which, in itself, shows that we do not object to cost plus per se, and I will just give you one reference to our pleadings, maybe without even going to it, although it does state it very clearly. Paragraph 28 of our reply at {XB/11/16}. It says -- I will just read a tiny bit of it:

"Flynn therefore did not, and does not, dispute that an authority may in appropriate circumstances use (as at least one of its benchmarks) a Cost Plus measure for the purpose of the excessiveness assessment."

It goes on, but I will not read more.

The entire focus of this ground of Flynn's appeal is that the CMA has erred in its calculation of the plus element. The CMA's error, as I have probably laboured, perhaps, you may say too much, is its assumption that the plus should be no greater than the firm's WACC.

Let me then move on to the previous Tribunal's finding that this theory that a seller's plus should be no greater than its WACC is wrong. That is the context in which Mr Holmes made the point that we were objecting to cost plus per se, and I just want to very briefly strip the point down to its basics.

Mr Harman's theory in the previous appeal was that the test for excessiveness is whether a firm's ROCE is greater than or equal to its WACC, and I will just give you the reference for convenience, it is Harman 1, paragraph 4.8 at {XE1/13/40}.

That model was rejected by the original Tribunal for two reasons, as the Tribunal knows. The first: it was overly theoretical, and the second, that it modelled ROCE rates that would obtain under idealised rather than normal competition.

Neither of those criticisms have anything to do with whether cost plus is a sufficient approach in itself or -- and I particularly stress this -- with whether the Tribunal should be looking for a benchmark price. They are freestanding criticisms of Mr Harman's evidence.

Mr Harman has now come back to the Tribunal with exactly the same test for excessiveness. Again, just for the references, Harman 3, paragraph 3.2.16 at {XE1/15/25}. We say that falls to be rejected for the same reasons, but for good measure I have explained why, on its own terms, Mr Harman's theory is in fact subject to the same flaws as the original Tribunal identified, so it is based on finance theory rather than evidence of real world returns, and identifies the very lowest price at which Flynn could sell without making a loss.

To put the point the other way round, if this Tribunal were to find that Mr Harman's theory is indeed first, overly theoretical and secondly, based on perfect competition, do you have to put those flaws out of your mind because of the Court of Appeal judgment? We say of course not because the Court of Appeal judgment said nothing about Mr Harman's evidence. It left the original Tribunal's assessment undisturbed in that respect.

Moving on, there was an exchange yesterday in which the President asked Mr Holmes why the CMA's cost plus spreadsheet did not contain a line for its reasonable rate of return. I do not know whether the Tribunal recollects that.

If we could just bring up, please, {XO/22/1}, we have plotted the line for this. The third yellow line on this chart represents Flynn's reasonable rates of return which are identical to Flynn's capital costs as calculated by the CMA which is the first yellow line, and the reason I wanted, despite the lack of time, to go back to this is it is very important to be clear -- I want to try and be very clear that these are not contested figures. This is the CMA's actual reasonable rate of return for Flynn taken from the Decision and the calculations provided by the CMA underline the Decision,

and of course, this reasonable rate of return is based on the 10% ROCE benchmark which Mr Holmes diplomatically distanced himself from this morning, but nevertheless, this document is not -- I just wanted to get across, it is not a piece of advocacy; it contains the CMA's reasonable rate of return for Flynn as it is actually found in the Decision.

These are aggregate figures in pound terms across the entire relevant period, and what we have also done is to plot the same figures expressed as prices per pack at annex 1 to our closing submissions which we saw yesterday, {XL/4/88}.

So in short, it is true that the CMA has not provided the Tribunal with a document plotting its reasonable rate of return for Flynn, but we have.

If the Tribunal wants to see the CMA's rate of return in graphical form, it is on the bar chart that you may recollect in our written closings at {XL/4/18}. Maybe it could flash across the screen, thank you. A 10% return on capital gives Flynn the returns represented, as you will recall, by the very slender grey line. We say it is a paltry amount and, as we have shown on the graph, it is far less than pharmacies and wholesalers make.

So the really key point on excessiveness that I want

to leave the Tribunal with is that, if the outcome of this case is that sellers of generic medicines have to price their medicines at cost plus, a miniscule rate of return to cover their interest rate to the bank, that will, frankly, be met with shock from the whole industry. The logic of the CMA's position as we understand it is that all generic medicines are commodity products, and they are commodity products which ought to be priced at or very near cost.

Mr Holmes said this morning that generic medicines, and I am quoting, "are about as close to a commodity product as you could imagine". That is the philosophy, if you like, behind the CMA's entire case as against Flynn. It is also what Ms Webster said when she assessed the tablet market. It is what Mr Harman said when he explained his ROCE WACC theory.

Now, of course the CMA can say in the abstract that there might be a case of a generic medicine where pricing substantially higher than cost could be justified, but in practice it is difficult to see when, if ever, that scenario would arise, and that is because on the CMA's logic there is a blueprint that all generic markets ought to follow, which is that exclusivity is lost, multiple sellers enter the market and prices plummet to at or near cost, and the CMA's case is that

any drug which does not behave like that is at risk -- and I stress "at risk" -- of being found to have been priced abusively.

The CMA having settled on its blueprint, it is inevitable that any other generic medicines that might be put forward as comparators to justify pricing higher than cost will be rejected because, if the comparator is priced above cost, they will be dismissed as not fitting the CMA's blueprint of workable competition which means pricing at or around cost.

So all roads lead to cost, so not only Flynn but all the Flynns of this world will be confined to their £66,000 returns plus whatever discretionary amount is allowed on top of that, so the minimal returns based on what is needed to pay the interest rates to their banks but no more.

We think it is important, with respect, for the Tribunal to realise that this is the position that the CMA is putting forward so that there is no risk of sleep walking into giving a judgment which frankly could shock the medicines industry, and many other industries, as betraying a real disconnect between the law and reality.

We all know that sellers, including of generic medicines, price substantially above cost much of the time. It is normal behaviour. We all know that

businesses do more than earn enough money to pay the interest rate on their bank loans. Mr Williams' and Dr Fakes' unchallenged evidence in this appeal was that if a seller of a generic were told that it could only earn a margin of some 2% ROS to cover its finance costs, it would walk away, yet that is the judgment that the CMA is asking you to write. It is asking you to say, not only that generic medicines should be priced at this very low level, or risk a finding of abusive and quasi-criminal conduct. In my respectful submission, that is not the reality and it just is not the law.

Finally -- it may be I have time just for two more points, so my penultimate point is one which on one view straddles the issues of excessiveness and unfairness. It is the tablets market and in particular the margins earned on that market.

This morning you and Mr Holmes agreed that economic value should be assessed by trying to ascertain the price of a product in a workably competitive market, and you put to Mr Holmes, and he agreed, that if workable competition would produce a price significantly above cost the economic value of the product should likewise be untethered to cost, and it is just for the note on today's transcript {Day18LH1/3:22} to page {Day18LH1/4:5} where Mr Holmes said that tablets

can give some reassurance as to what value might look like for phenytoin under what he called more competitive, albeit still dysfunctionally competitive conditions, but to the extent that this market does, as Mr Holmes accepts, shed light on what a workably competitive price for tablets looks like, it is very important, we say, to look at what the relationship is between price and cost in that market.

When we do that, we see that tablet suppliers were pricing well above cost, and, again, if we could just flash up on to the screen {XE1/11/38}, we can see high percentage margins which show that all suppliers in the tablet market were pricing well above cost, and over the page, if we just flick past it, we can see the same picture in absolute pound terms.

So to the extent that my learned friend accepts that this market, in his words, "sheds light" on what outcome a normal competitive market would produce for this product, we submit that it shows a very significant gap between cost and price. It certainly does not support the CMA's case that in a workably competitive market suppliers would be pricing at cost.

This is now my final point, I promise, and I am very grateful to everyone for listening to me so patiently in what is undoubtedly the graveyard slot, but a word if

I may on the case 2/3 debate.

We endorse the submissions of Mr Brealey that this is a case 2 case. The CMA's position, as I have said, seems to be that all generic drugs are created equal and all should follow the same blueprint of essentially behaving as a commodity, but all generics are not created equal. There are two features or, sir, as the President put it, two factors of phenytoin that call for particular attention.

The first is that this is a tail-end drug operating in a declining market. It is not a statin which is guaranteed to sell millions of units per year for years to come. The number of patients on this drug is already small and will become even smaller, and that is one of the reasons why Mr Doran pointed out yesterday that Pfizer spoke about discontinuing the drug.

If someone is going to service this declining user base, they frankly need more incentive than earning enough to cover the interest on their bank loans. That is why the President, I respectfully suggest, why you referred this morning to the need for an incentivisation to Pfizer to keep the factory open.

The other particular feature of phenytoin is of course continuity of supply. Mr Holmes sought to paint this as a sinister feature of the market, but it is not.

It is not a creation of Pfizer, Flynn, NRIM or anyone else involved in the supply of phenytoin. It is a very particular medical requirement, and that requirement is met by ensuring a continuous supply of the drug to patients who need it, which is precisely what Flynn has achieved over the past ten years.

Sir, that is all I wanted to say subject to anyone -- no one is telling me I have missed something out, and I have gone one or two minutes over for which I apologise.

THE PRESIDENT: Not at all, no, thank you very much, Ms Stratford. We have no further questions of you nor indeed anyone else.

MR HOLMES: Sir, may I raise very briefly one point of housekeeping? May we have permission to put in a short written response?

THE PRESIDENT: We anticipate a number of notes: Mr Bailey's notes, a response to those notes, a response to Mr Bailey's notes. If you could put them in single documents rather than have a flurry, that would probably assist, but we will obviously read what comes in.

MR HOLMES: Of course.

THE PRESIDENT: We are very grateful to all of the parties for their considerable assistance. We are obviously going to reserve our judgment.

I know I speak for everyone when I extend my thanks to those who have made this hearing possible. The transcription has been tested to not quite destruction, but we are very grateful for the long hours that you have sat, and that goes also for the staff at the Tribunal. I am sure I am speaking for all when I say a big thank you.

Thank you to everyone for the excellent submissions. We will hand down a judgment as soon as we can. Thank you very much.

MR BREALEY: And happy Christmas.

THE PRESIDENT: Thank you.

(5.13 pm)

(The hearing adjourned)