IN THE COMPETITION APPEAL TRIBUNAL

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

Salisbury Square House
8 Salisbury Square
London EC4Y 8AP

Monday 6th November – Friday 1st 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

Thursday, 9 November 2023

(10.30 am)

Opening submissions by MR HOLMES (continued)

THE PRESIDENT: Mr Holmes, good morning.

MR HOLMES: Good morning, sir.

Can I start with a couple of references. First, Mr Doran asked yesterday whether there was any other mechanism during the relevant period for controlling generic pharmaceutical prices other than general competition law. I think I have that right.

MR DORAN: That is right.

MR HOLMES: The available regulatory powers have been addressed in the other pharmaceutical pricing cases. Most recently, for your note, they are dealt with in paragraphs 99 to 104 of the Tribunal's judgment in *Hydrocortisone*, which is at {XN2/29/47}, no need to go there now, but just so that you have that, and these deal with the Secretary of State's general powers to intervene on price, other than through a voluntary scheme which does not apply in this case, but the voluntary schemes are also dealt with at paragraphs 105 to 107 and the punchline is that there is a general power but it could not at the relevant time be applied to a manufacturer or supplier to whom a voluntary scheme applies.

MR DORAN: Thank you very much.

MR BREALEY: At what relevant time?

MR HOLMES: During the period of the infringement.

MR BREALEY: Right. Not in 2007.

MR HOLMES: Flynn was a member of the PPRS and therefore outside the scope of the power.

The second reference --

THE PRESIDENT: But they could be excluded by the Secretary of State from PPRS and the scheme.

MR HOLMES: That is correct. You will recall the discussion of this. There was a sort of rigmarole that could have been followed to remove them from the PPRS which would have enabled the general power.

The second reference is to a slide deck from the *Liothyronine* case which explains in some detail how category M works, and you will recall that it is not the category applicable to capsules, it was the one applicable to tablets, and the Tribunal asked about how the calculation was done. I do not propose to go there now, but so the Tribunal has it, the bundle reference is {XO/3}. It is in the overflow bundle, {XO/3}.

Now, when we broke yesterday we were discussing Flynn's reliance on simple ROS comparators as a basis for assessing a reasonable rate of return, and you asked me a couple of questions which were partly framed in

terms of an adapted version of the coffee shop scenario.

THE PRESIDENT: Yes.

MR HOLMES: So you asked -- tell me if I have this right, but I think you asked first whether cost of capital is a relevant cost for the purposes that we are exploring here, and whether there should be a line in the cost calculation to account for that, and you also asked how one should deal with a situation where a business has spectacularly high costs of capital as a result of borrowing on unfavourable or even rapacious terms. Does that correctly crystallise, sir, the questions that you were putting?

THE PRESIDENT: That does, and it may assist if before you unpack the answer to those questions if we circulate a little printed-out spreadsheet that I was doing last night. Let me hand this. We will send a soft copy separately, and can I say at once that there are absolutely errors in the computation of this. Professor Waterson has already spotted at least one, and it will, I am sure, have to be corrected, but the thinking is to create two coffee houses, A and B, which are identical in all regards including as to their costs base and the prices they charge for their two products.

MR HOLMES: Yes.

THE PRESIDENT: Save that in the case of coffee house B,

there is a bank loan which was used to purchase the business which has servicing costs which I have deliberately made rather high so that they create, in effect, a loss-making scenario for the coffee house B in circumstances where coffee house A is making a healthy profit, and the concerns that we have are, yes, what do we do if the annual servicing costs are rapacious as in this scenario they might well be, but also what does one do about coffee house A where these costs do not emerge, and what I understood you to say yesterday was that one would need to adjust the costs of coffee house B downwards if they were rapacious, and one would have to adjust the costs of coffee house A upwards if they were not properly reflected in their costs base, and the concern that I have is that whilst if one is valuing a business to purchase or to sell, that might very well be a sensible thing to do, it is not self-evidently a sensible thing to do if one is trying to work out what is an excessive price, because in the case of coffee house A they can quite easily price down to a lower level than coffee house B, and the gap between cost and price is for coffee house A, correspondingly bigger.

MR HOLMES: Yes.

THE PRESIDENT: If it were to be the case, therefore, that coffee house A happens to be dominant in the espresso or

the cappuccino market, I would not particularly fancy some clever accountant saying: you have the gap wrong, judge, because in fact you have failed to take into account these capital costs which are entirely hypothetical and in fact, the costs base is higher than you think and, therefore, the argument is, it is not excessive whereas otherwise it would be.

Now, of course do feel free to respond in any way you wish, but the reason I am articulating this now is because I want it firmly on the radar of those experts who are addressing it because they will want to, no doubt, explain in detail why this is wrong and why the approach is right, but you can also have a go, but I think it is principally with the experts in mind that I am raising this.

MR HOLMES: I am very aware of that, sir. If it helps -- and all of this of course, as you say, subject to the expert discussion -- could I give you my attempt at the questions?

THE PRESIDENT: I would be delighted to hear it.

MR HOLMES: I will obviously take instructions on this and if there are any further submissions that arise out of it then perhaps I might make them later in the course of today.

Starting with your former question whether cost of

capital is a relevant cost for the purposes we are exploring here, and whether there should be a line in the cost calculation to account for that, can I take it in stages beginning with the business and how the business might approach matters.

So first, does it make sense to take account of the cost of capital as a business person, an entrepreneur or investor and how might that be done? The answer, we say, is undoubtedly yes, it is an essential element of the business planning process.

So to take the coffee shop example, both coffee shops have capital tied up in their business. They both have premises, let us say. The premises are part of the capital, they are equity in the business, and that capital, the premises, could be used for lots of different purposes. As the owner, you have choices about how you use the capital, and you expect or you should expect to see a return on the capital to reflect that investment. So you need to take account of the capital employed when you are deciding if it is worth investing or continuing to invest that capital in the business.

Now, I appreciate the Tribunal is well aware of this, but just let me, if I may, take it in stages. We say that is not a subjective assessment. There is

a market for the equity which will reflect its opportunity cost. The coffee shop owner might, for example, find that it is better to stop using it as a coffee shop and use it for some other commercial purpose, or rent it out on the commercial property market, or they might sell the shop and invest the money elsewhere, and it is the cost of capital which informs that assessment.

Now, as you rightly pointed out, sir, the business could also raise capital in the form of debt, and that is your example, coffee shop B is effectively adding capital in the form of debt alongside the capital held in the form of equity, and the cost of debt is not subjective either. There is again, a market for it, and banks are expert at assessing whether to make this type of investment and on what terms.

THE PRESIDENT: That point I completely take, but just to take a step back to the capital analysis for the smaller business. Now let us suppose it is incorporated, but it is not a public listed company and you do not have that sort of fluidity of anticipation of return that you would in a listed company. So you have simply got a corporation which has shares where there is a quite deliberate policy not to pay dividends, and that may be right, that may be wrong. My point is there if that is

what the owner is doing in order to price lower in order to, as it were, keep the costs lower, why should competition law reinvent matters and say: well, you, the entrepreneur, have actually got your costs base wrong and in fact it is higher than it should be, and, therefore, we are going to do down the consumer, who after all is key here, by inflating the costs base so as to make a competition infringement less likely rather than more.

MR HOLMES: Well, if I understand your example correctly what they are doing is capitalising their returns, so they are keeping returns in the business which will be reflected in their capital. Anyway, that is perhaps a point I will come back to after taking instructions.

THE PRESIDENT: They may be doing that, my question is, though -- maybe as a matter of analysis that is what they are doing, what, though, is the consequence in terms of building a cost stack for their cappuccino.

Now, if you are saying: well, they are accumulating capital but there is no line in the cost stack because they are not seeing it that way, well, that is fine. If, on the other hand, you are saying, no, we need to insert this line, then that is where I start needing a little bit of help.

MR HOLMES: Yes, I understand, sir. Perhaps if I could come

back to that in just a moment.

THE PRESIDENT: No, of course. So you will not have a problem with the bank, because the bank will charge what it can because it is a commercial undertaking and even the corner shop that is wanting to minimise its costs will be faced with a very shrewd cost line based upon the debt that is lent, I mean, that I do get.

MR HOLMES: For present purposes, just sticking at the level of business planning and before one turns to consider how a competition authority should approach matters, the terms offered by a bank will reflect an assessment of risk and the returns expected at that level of risk, and if the coffee shop owner decides to raise capital in this way they can shop around and see what terms are available, and they need to make sure for their business planning that the business covers the return they should expect on their capital, both the shop and the return that the lender should expect on their capital, the cash which has been loaned to the business. So both of those will be factored in in one way or another to rational business planning.

So the return on capital is definitely something that businesses do in fact take account of, and there is a framework which can be used for assessing the combined cost of equity and debt, frequently is with more

sophisticated businesses, the weighted average cost of capital, and that reflects the return expected by equity investors and creditors as part of a unified equation. It is a yardstick against which businesses and investors can then assess investment opportunities, and within particular sectors of economic activity you may see particular levels of return which reflect the market's perception of the risks involved. So there are concrete indicators, this is not a totally subjective process if the Tribunal had any concerns about that.

Next question: should a competition authority or this Tribunal take account of the cost of capital when assessing profitability levels in an excessive pricing case? We say that if it is possible to do so, it certainly should be done. It is a measure of the return that the business can expect to make given what is invested in it. Businesses need to pay returns to investors to incentivise continued investment in the business. The cost of capital allows us to estimate exactly that: the returns that investors expect or require, and that then allows us to calculate the excess that remains after providers of capital have been adequately compensated.

In my submission, it does not matter whether you call that a cost or a return: whatever label you use it

should be reflected when assessing whether there is any excess. To adopt a neutral terminology, it is the plus in cost plus.

How can you estimate the cost of capital expected by investors in a business given its risk profile? Well, if you can measure the capital employed and you have market indications as to the cost of capital for the business and for the sector, you can use that to assess cost of capital directly, and you assess what capital is in the business. So there is no neglected value in the business which is not taken into account when assessing the cost of capital.

Alternatively, you can look at it indirectly by comparing the return on sales achieved by other businesses, and this may give you a sense of the rate of return expected by investors, but the businesses -- you have my point -- need to be sufficiently similar in terms of their risk profile, their costs structure and their capital intensity, so you would need to consider whether they are appropriate comparators by reference to those circumstances which affect the economic profitability.

There is otherwise a real risk of subjectivity and distortion, justifying a rate of return by reference to other businesses which differ significantly from the one

you are assessing, and once you have the cost plus and you determine the excess, that is of course not the end of the matter. The appellants have repeatedly suggested that the CMA requires Flynn to price at cost plus. You saw it in the hand-up yesterday, the Flynn note on the annual permissible returns for Flynn, as though this were ex ante price regulation strictly at the level of cost plus.

That is not correct. The excess needs to be separately assessed to determine whether it is sufficiently material, and that point is made, just so that you see it, in very clear terms in the Decision at paragraph 5.89 at {XA1/1/168}.

You see that the CMA made clear that it:

"... [did] not consider that any profits earned above the cost of capital are automatically 'excessive' in the context of [limb 1]. The CMA expects to observe variations in the level of returns earned between firms, on different products and over time. It recognises that, at some points in time, observed returns may exceed what might otherwise be termed a 'normal' profitability level. It is for this reason that a proper degree of ... judgment is required in considering whether any observed differential above the cost of capital is 'excessive' and that prices are

likely to be considered excessive for the purposes of Chapter II only where the profitability of a dominant firm exceeds the cost of capital by a material amount, and over a sustained period of time."

This is the generous headroom point which you will recall was discussed in *Hydrocortisone* and was also discussed in *Liothyronine*.

THE PRESIDENT: Yes.

MR HOLMES: In this case the CMA only intervened having found an extremely generous headroom, and I will show you the CMA's analysis of that in a moment.

So turning to your second question, I will try to do justice to it although I appreciate that you are concerned not only about how to deal with the costs of the debt-laden coffee shop, but also the debt-free coffee shop, so this may need some elaboration.

How to deal with the coffee shop with excessive prices, excessive borrowing costs? I have made the point that there is capital in both businesses for which some return is to be expected, that is the equity in the store and no doubt some other capital items as well, but in your example one obtains capital in the form of debt on bad terms, and I think your concern is that this introduces a degree of subjectivity given the different borrowing costs that may be exhibited in the market.

THE PRESIDENT: Well, either subjectivity or an unjustified adjustment so as to make all undertakings equally efficient when they are not. So why do you adjust for the coffee shop that has no debt and why do you adjust for the coffee shop that has, perhaps imprudently or for other reasons, entered into a level of debt at rates which are bad?

MR HOLMES: Yes, I understand.

We would say, I think, that there is no adjustment, one simply takes into account the capital which is tied up in the business in one form or another in determining what is a reasonable rate of return.

As regards the risk of a bad deal on the price of debt, you have my point that the banks -- sorry?

THE PRESIDENT: Capital -- I am so sorry, so let us take the bricks and mortar of the coffee shop, which is capital. If it is encumbered, if it is mortgaged, how do you adjust for the capital value? Do you take the mortgage into account? Do you ask yourself why has it been mortgaged? Has it been to pay for an all expenses paid trip to Barbados to look at other --

MR HOLMES: I see.

THE PRESIDENT: Or do you say only if you have mortgaged it for the purpose of the business do you take it into account, but either which way, the mortgage is reducing

the capital value of the business because you have laden it with debt.

MR HOLMES: Well, no, sir, with respect there is another item of capital which is introduced into the business as a result of the debt. So you have the equity --

THE PRESIDENT: Right.

MR HOLMES: -- and then you have another line item of capital in the form of the cash which is made available to the business as a result of the debt.

THE PRESIDENT: Right, but what happens if it is not made available to the business? What happens if it is used for something else? You take it out of account?

MR HOLMES: Well, then it would not be taken into account as working capital associated with -- or capital associated with the process of production which is under examination.

THE PRESIDENT: So there is quite a major process of differentiation between exactly the same bricks and mortar. You have to ask yourself in each case if there is debt over that, why has that debt been incurred in order to work out whether that is an item, or the extent of that item in the cost stack for the cup of coffee.

MR HOLMES: Well, certainly to apply a cost of capital approach you need first of all to work out what capital is employed, and you assess that by reference to the

particular product which is being produced, and the CMA sought to do that in the Decision, and then you apply to that a cost which reflects the costs of both equity and debt, and that can be combined in a metric known as the weighted average cost of capital, and that will then provide you with an indication of the business's cost of capital.

Now, in terms of the debt-borrowing costs in your second scenario, you would expect that to be disciplined by the competitive process assuming the business is investable between banks who assess risk as their course of business, it is their trade, but let us imagine that a business strikes a bad bargain and pays over the odds. It incurs an inefficient cost of capital and its investor takes an outsize return.

Now, as in any market, there is the risk of making a poor deal and incurring an inefficient cost of capital. A competition authority testing for excessive pricing is likely to start with evidence as to the actual cost of capital of the business in question, and any inefficiency may be taken into account to the benefit of the company in assessing its cost plus.

Now, depending on the circumstances, it is possible that a competition authority might discount a cost of capital that was very inefficient having regard to

available market metrics of the cost of capital in the business in question. It was posited, for example, in Albion Water II that the costs that should be allowed should only be efficiently incurred costs when calculating cost plus, but happily those issues do not arise in this case because no capital has been deducted on the basis -- or capital cost has been deducted on the basis that there was anything inefficient in the terms that were secured or were available to Flynn, so we say the problem simply does not arise in this case.

Can I turn, then, to consider what the CMA did in this case. The CMA concluded that in Flynn's case it could reliably estimate how much capital is required to supply phenytoin capsules and it also found evidence as to returns investors would expect on capital.

The excess in the parties' prices is then the amount remaining after direct and indirect costs and after providers of capital have received a fair return on their investment.

In understanding Flynn's cost of capital, it took account of a number of pieces of evidence. If you turn to page {XA1/1/205} at the foot of the page -- this is the Decision, the document we are in -- you see in paragraph 5.267 that it took account of the valuation analysis undertaken by an investment bank of Flynn,

Jefferies, in December 2012, and turning over the page {XA1/1/206}, that used a central case of 10% for the WACC and a sensitivity analysis using a range of 8% to 12%. So that was one item of evidence considered.

The CMA also considered evidence of the WACC in the pharmaceutical sector, and if we could turn to page {XA1/1/204}, so back a page, you see at 5.260 that Pfizer's WACC was around 9%. That is the rate that Pfizer uses for its internal planning purposes, and that Flynn's expert relied on an analysis by KPMG to demonstrate that the average cost of capital for pharmaceutical companies was between 7.7% and 8.2% between 2010 and 2014.

The CMA also considered the WACC of various pharmaceutical companies based on publicly available data which were all within the range from 8% to 12%. You see this on page {XA1/1/186} at the top of the page, you see in the sentence there, the first three lines, a range of 8% to 12%. The details are given in footnote 839 at the base, if we could go down and enlarge, so you see the companies there that were considered all on a pre-tax basis.

So it is not correct, as Ms Stratford submitted yesterday, at page 14 of the transcript, lines 1-7 {Day3LH1/14:1-7} that the CMA did not consider the

return on capital employed that was expected and achieved in the case of other pharmaceutical companies.

These WACC figures are to be contrasted with the actual return on capital employed achieved by Flynn during the relevant period based on the CMA's assessment of its capital base. This is explained at page 241 of the Decision at paragraph 5.420 {XA1/1/241}.

And looking at 5.420, you see that:

"... Flynn's Prices over the Relevant Period generate profits which equate to a return on capital employed of 247% ..."

By comparison with the range we just saw, 8% to 12%. A 247% return, just to make this concrete, means that for every £100 invested in the business, Flynn enjoyed a return of £247 each year during the relevant period. A nice return if you can get it. This needs to be set against the risks that Flynn assumed. The CMA assessed these in the Decision and concluded that they were low and its assessment matches that of the Tribunal in the first appeal.

If we could turn, please, to {XN1/2/112} and look please at paragraph 346 at the foot of the page. You see there that the Tribunal refers to the CMA relying on:

"... the limited commercial activity undertaken by

Flynn and the limited commercial risk it accepted..."

And:

"Flynn denied that its commercial activities and level of risk ... were low and relied on Mr Davies' evidence in support of this view."

And the Tribunal's considered assessment based on the evidence was that it preferred the CMA's view:

"Flynn took over an established product and undertook only very limited commercial activity ... it held stocks to keep the market supplied and appears to have explored the possibility, without success, of establishing an alternative source of supply ... 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. Continuity of Supply meant that its customer base in the UK was to a significant degree guaranteed."

PROFESSOR WATERSON: Can I just raise a point here, that this is to do with the 6% return on sales.

MR HOLMES: Yes.

PROFESSOR WATERSON: You have been talking about return on capital, I think.

MR HOLMES: Yes. It was simply that we have a basket of return on capital figures for different pharmaceutical companies which do not look at all outlandish, 8% to 12%. If you look at the ROCE that was actually achieved on our assessment of the capital base, and it is 247%, and you might ask in those circumstances whether there was something exceptional or unusual about the phenytoin capsule product in terms of its risk that might explain those levels of return.

PROFESSOR WATERSON: Sorry, you were only talking about risk here, you were not --

MR HOLMES: Yes, apologies. I perhaps did not make the transition clear. It was simply, if you like, a cross-check to assess the nature of risk in this business to see if one would expect such outlandish returns.

PROFESSOR WATERSON: Yes.

MR HOLMES: Now, the CMA considered sensitivities with much higher capital costs afforded to Flynn and with a return on sales of 6% equivalent to a weighted average cost of capital of 31%, and neither of these flexes materially affected the extent of the excess found.

The CMA also evaluated Flynn's comparators to see if

they shed light on the reasonable rate of return that could be expected for phenytoin capsules, and it found that phenytoin was highly unusual.

So take, for example, the other products in Flynn's portfolio. The CMA examined those carefully. Ms Stratford suggested that the other drugs earned a ROCE that was comparable with capsules. That is on the CMA's assessment not correct.

If we could turn, please, to {XA1/1/166}, you see what the CMA found. It is in paragraph 5.83 at the foot of the page.

The CMA's high level analysis showed a weighted average ROCE across Flynn's other products ranging between 18% and 26% during the relevant period, and that is contrasted, over page, with the 247% average ROCE earned on capsules. So it is not accepted in these proceedings that the ROCE of the other products in Flynn's portfolio was remotely comparable with the ROCE achieved in relation to phenytoin.

Now, as regards the ROS on those products, the CMA examined whether the other products were comparable to phenytoin, and it found that phenytoin was a clear outlier being the only product which combined high unit costs, high margins and large volumes, and you see this on page {XA1/1/214} of the Decision.

This shows margins per pack and volumes, so you have the volume on the -- I always get my -- the Y axis, yes, apologies, this is the trouble with a lawyer addressing an expert panel -- the Y axis shows the sale volumes and the X axis shows the direct margin per unit, and you can see that there are some products that command higher direct margins than phenytoin, but look at the volumes, they are supplied in tiny, tiny volumes, and there are other products which command equivalent sales volumes but their margins are very much less, and if you look at those comparators, it is also relevant to note that Circadin, for example, is a patented product, so we are comparing here a patented product with an unbranded generic, little white pill.

We say that this is relevant to assessing the profitability of the product because lower volumes typically require higher returns as the capital costs are spread over fewer units, and turning on a page to {XA1/1/215} you see the consequences: phenytoin achieved more than double the total return earned across Flynn's other 13 products combined.

Turning on another page to {XA1/1/216} you see that phenytoin was also unique in combining high unit costs and high sales volumes, you see again it is on the high right side of the figure, it is a clear outlier. The

resulting reasonable rate of return for Flynn is set out on page {XA1/1/209}. It amounts to £1.5 million over the four-year infringement period. Now, you will recall that Ms Stratford handed up a sheet yesterday which suggested the return allowed to Flynn on the CMA's assumptions was £66,000 per year. Do you recall that, sir?

Contrary to her submission, that does not reflect the CMA's assumptions or approach. What Flynn has done in calculating the £66,000 figure is to strip out Pfizer's excess and substitute a strict cost plus price, and this depresses its capital base very substantially, thereby reducing the reasonable return suggested on the basis of the CMA's ROCE assessment.

By contrast, the CMA calculated Flynn's capital base at Flynn's own urging by valuing Flynn's working capital based on Pfizer's inflated supply costs despite the circularity that that risked introducing.

So the figures in the table Ms Stratford handed up are, I am afraid, misleading insofar as they are presented as the CMA's position. The correct position is as set out in table 5.12, and it is in the region of £350,000 a year if you divide 1.5 million by the period of the infringement.

In any event, we say that the CMA was right to

reject Flynn's ROS margin comparators given the unusual situation generated by the parties' arrangement where Pfizer took a large upstream profit and Flynn then added a substantial mark-up of its own equivalent to 200% above the combined cost plus of Pfizer and Flynn for both the manufacture and the supply of the product.

You have my point that Flynn's margin comparators are of no assistance at all to Pfizer, it was upstream, it had low input costs, and its ROS was huge, its margins were enormous. One sees this in the Decision at {XA1/1/189}, table 5.7, and you see that for the main strength, 100mg, its margins, were 667%, and across all four strengths they were 416%, so this is really a debate between myself and Ms Stratford, Flynn; Pfizer gains no benefit from this ground.

If I could turn now to Pfizer. Unlike Flynn, it seeks to avoid margin comparisons for the reason I have just shown you, the huge percentage returns which it enjoyed, and instead it seeks to focus on price comparators, and we say that its price comparators are inapt.

It relies, first, on the £30 drug tariff price for tablets. Now, as you pointed out, sir, that is not a market price at all. It is not a comparator which sheds light on the prices that would prevail for any

other product under conditions of effective competition which is the enquiry to which we are directed by the case law.

The price in relation to tablets were at the relevant time well below the drug tariff, and you have seen this already but just to remind the Tribunal, it is at {XA1/1/293}.

Enlarging the figure, please, 6.1, you see that the drug tariff price sailed along at £30 and the actual prices charged by tablet suppliers were very significantly below that, so insofar as there was competition at a price generated by a process of competition, and as you know, we dispute whether there was effective competition, but insofar as there was a market price, it is reflected in the jagged lines below the drug tariff. So we say it is not an indicator of the benefits that can be obtained in conditions of normal and sufficiently effective competition which is the focus of the fairness enquiry.

Despite the way this was presented by Mr Brealey, there is relatively little dispute about the facts that underlie how the £30 price was arrived at. There was a very significant price rise by a monopoly provider, Teva, under the operation of category M of the drug tariff from 2005 to October 2007. Those price rises

were from £3.87 in April 2005 to over £113. That is set out for your note in Decision paragraph 6.167 {XA1/1/285}, so it's egregious case.

It is not disputed that there was an outcry by NHS stakeholders and a meeting arranged between the Department of Health and Teva, and at that meeting the Department of Health managed to persuade Teva, a large and respectable player in the pharmaceutical industry, to agree a phased price reduction achieved by progressively reducing the drug tariff for tablets until it reached £30. There were also meetings in relation to the capsules price increase as we will see, and I will show you how those played out. In short, the parties toughed it out.

There is no dispute as to what happened at the meeting between Mr Beighton and the Department of Health. Mr Beighton's evidence on this point was largely accepted by the Tribunal in the first trial and is not disputed by the CMA. The documents which the Department of Health has now disclosed, which Mr Brealey took you to, support that interpretation, so the subsequent documents confirm what the Tribunal in any event found.

It is not in dispute that there was a hard coding of the price of £30 into the drug tariff following the

meeting, although, as Professor Waterson flagged, the Department's expectation indicated at the time was that there would be further price reductions over time. That is at {XG/24} for your note.

The reason for the hard coding is, with respect, obvious. Otherwise the adjustment to the drug tariff would not have prevented Teva, who was at the time a monopolist, continuing to utilise the normal operation of category M by raising its prices, and it is not in dispute that that price stayed at £30 even after generic entry started.

The appellants dispute the Department of Health's own characterisation of that as being an oversight, but the Department of Health made enquiries and it explained the basis for that characterisation at {XH/152/7}.

If you look at 7(b) down the page, that explains firstly that the oversight was discovered in a meeting with the CMA, and:

"After it was pointed out the policy team queried it with the analytical team who explained that they were instructed to maintain it at £30 (see answer to 6(a) and 6(b)) without any explanation as to why the price was fixed, when/in which circumstances the price fix should be stopped or be reviewed."

So the instructions to the team responsible for

setting the drug tariff failed to explain that it should be lifted once some competition arrived in the market, and it remained in place even when market prices began to fall, but ultimately, and for whatever reason, the drug tariff did not in fact move after there was entry in that market; it only began to do so in 2016 when the oversight was drawn to the Department's attention and the Department gradually modulated the drug tariff price down to levels reflecting the state of the market, and since then it has continued to fall, and by June 2022 it stood at £6.42. The question for the Tribunal is what reliance can be placed on the £30 drug tariff price, detached as it is from competition in the market.

Pfizer's counsel suggested that everyone else in the market was pricing by reference to the drug tariff, and it was unfair to penalise Pfizer and Flynn for doing so, and he relied on examples of entrants to the tablet market initially setting their prices by reference to the drug tariff price when launching a tablet product, but, as Professor Waterson canvassed with Mr Brealey, it is no part of Pfizer's case that tablets and capsules are on the same market. Indeed, one only needs to look at the capsule prices before September 2012 to see that could not possibly be the case. Pfizer supplied capsules at £2.10 for 84 100mg capsules and the drug

tariff stood at £2.83. Tablets are sold in packs of 28, so you need to divide those figures by three to achieve equivalence. The prices would therefore be 70p for Pfizer's price and 90p for the drug tariff price.

If we look again at figure 6.1 in the Decision at {XA1/1/293} we see where tablet prices were on the eve of the price change: £25 with a drug tariff of £30. So those price differentials clearly show a lack of any competitive interaction between capsules and tablets.

So we therefore say Mr Brealey's comparison is inapt. Pfizer and Flynn were not in a position of a generic entrant to the tablet market deciding at what price to launch its product in competition. They were instead planning a huge price increase in relation to a different product on a different market in relation to which they were at the time the only source of supply. They were not bringing competition but seeking to exploit the lack of it.

Now, undoubtedly Pfizer and Flynn were inspired to increase prices by the tablet drug tariff. They saw that price and to use Ms Stratford's phrase, they wanted a piece of the pie, but for them, the drug tariff was not a reference point for competitive entry to the market in which it actually applied. It was instead used as a justification for increasing prices in the

capsules market whereas the parties well knew competition was lacking, and I will show you that by reference to the contemporaneous documents.

When pressed on this, Mr Brealey sought to contend that the drug tariff price was nonetheless a reasonable indicator of the value that the Department of Health attached to a closely related product with the same active ingredient. His case was that Pfizer and Flynn were entitled in 2012 to rely on that indicator arrived at in relation to another separate product, tablets, in 2007, to show what the NHS was now willing to pay.

Now, it is unclear what the legal basis for this argument is, but at all events, we say that it simply does not stack up on the facts. As I will show you, the Department and the NHS made very clear that they did not accept the price increases for capsules as valid or fair, and they did not regard the drug tariff price for tablets as an appropriate benchmark for assessing the value of capsules. Pfizer and Flynn were therefore quickly disabused of any belief they may have held about the Department's conception of the value of capsules. The drug tariff price is therefore, we say, not a helpful basis of comparison to Pfizer or, for that matter, to Flynn.

Now, as Mr Hoskins observed at the first trial, if

you are going to look for a tablet comparator that fits within the legal framework laid down in the case law, a more obvious place to look will be the tablet ASP. Those are at least selling prices in a market, they could therefore in principle be an appropriate proxy. But you then need to consider whether they in fact reflect fair and effective competition.

Mr Brealey says that tablet ASPs were what the remittal was all about, and we respectfully agree that they were a central focus, and that is of course in itself another strong indicator that the £30 drug tariff price is not the answer to the CMA's infringement findings. If it were, there would be no reason for the case to have been remitted at all.

On remittal, the CMA carefully investigated the market conditions and ASPs in the tablet market as instructed by the Tribunal, and its findings are set out over pages {XA1/1/281-355} in the Decision. Mr Brealey did not engage with that analysis, and the careful quantitative assessment which it contains. Instead, he cited a handful of emails showing some competitive interaction. Now, the CMA of course accepts that there was some competitive interaction, the question is whether it was sufficient to be effective, and that needs to be assessed looking at the data as well as the

qualitative evidence.

A number of the documents he referred you to were from 2009 when there were only two suppliers: Teva, the incumbent, and Wockhardt. If we could go in the Decision, please, to {XA1/1/325} and {XA1/1/326}, if we could present them alongside one another, please, so figure 6.3 -- no, I am so sorry, it is {XA1/1/324} and {XA1/1/325}, please.

So you see on the left-hand side the volumes in figure 6.3, and you can see that Teva took the lion's share throughout, and figure 6.3 shows prices, and you can see that they tracked closely and did not fall substantially during that period, if at all. Turning on to page {XA1/1/326}, you see the reason. Wockhardt confirmed to the CMA, at the top of the page, 6.329:

"Wockhardt confirmed to the CMA that its entry strategy was, indeed, to gain market share whilst at the same time trying to maintain price stability and avoid a price war ... Referring to the fact that selling prices were high (in the £20s range) when it entered, Wockhardt stated that there was 'never any reason or intention to move on pricing at this point'. Wockhardt explained that the high level of the Drug Tariff price and the fact that there were only two suppliers in the market facilitated this strategy, adding that 'prices

would only have moved if another player came to the market'."

And at 6.330 you see that Teva felt the same way and you can see what it said from the internal email from October 2008 which is quoted there.

So the parties' main focus in the written submissions and evidence is, therefore, not on this 2009 period to which Mr Brealey referred you repeatedly, but on a subsequent period referred to as period 3 in the Decision when there were temporarily three players in the market following entry by Milpharm, and this was the period from September 2012 until early 2014. You will hear evidence from the experts about how strong competition really was during that period. I would make just two points.

If we could turn, please, to page {XA1/1/330} and {XA1/1/331} in the Decision -- oh, sorry, 329 and 330 in the Decision, my pages are out. No, I was right, sorry, it is 330 and 331.

You see on the left-hand side, the time series graph for price, and you see falls from a high starting point with the competitors pricing below Teva, the incumbent, and you see from the figure on the opposite side that Teva still took most of the volumes during this period. The yellow line on the left-hand side is Wockhardt, and

it ends in July 2014 when it withdrew from the market and after that you see that prices go back up. Care is needed in relation to the rise in Wockhardt's pricing, you see that bump in the yellow line, from January to July 2014.

During that period, Wockhardt was selling very low volumes as it prepared to exit the market, and you can see that from figure 6.6 where you can see in quarter 1 and quarter 2 of 2014 the volumes decline very substantially, and it is explained in 6.351:

"... Wockhardt experienced a significant decline in its sales volumes in the months before it exited, declining from approximately 3,900 packs per month during 2013 to just 900 packs per month in 2014 up until its exit in July."

So any three-player interaction is really tailing off from January 2014 onwards, and the CMA found in the Decision that the prices in this period do not show normal and sufficiently effective competition on the basis that Teva still enjoyed market power, prices were falling from very high levels that were a result of a monopoly followed by a duopoly.

This is, therefore, analogous to the position in *Liothyronine* when pricing took a long time to come down once competition began and were not the output of

effective competition on the way down, and it is also analogous, in my submission, with the position in *Hydrocortisone* where there was found still to be dominance and excessive pricing as prices fell in the Intas period.

Just looking at the graph, you can see that there is a decline from a high level, once you get the three players, looking at 6.5, you see decline from a high level, and that is the high prices unwinding during a spell of three-party competition which then ends, we say, substantially from January 2014.

But based on that comparison -- so that is why we say there was not normal and sufficiently effective competition during this period, among other reasons, but even assuming that these prices were the product of normal and sufficiently effective competition, the question is where they get the appellants. The comparable price to the tablets' ASP for the parties is of course Flynn's price, so that is the price at the same level of the market which resulted from Pfizer's and Flynn's combined pricing conduct, taking you through to delivery to the pharmacy and the wholesaler which is what the tablet suppliers were all doing, but based on that comparison, the tablet ASPs are of no assistance at all to the appellants.

After both appellants have taken their profits, the resulting capsules' ASPs were well above tablet ASPs for almost the entirety of the relevant period, and one can see that from a figure in our skeleton argument at {XL/3/29}.

If we could just enlarge the figure. You see that the purple line is Flynn's average ASPs over the relevant period and you can see that there is a short period at the outset of two or three months as prices are declining from their very high levels during duopoly when Flynn is below, but very rapidly they come down well below Flynn's price, and you see that for almost the entirety of the period, all of the tablets' prices are materially lower, up to a third or a half lower in terms of the cheapest prices available in the market. We say that this is the only appropriate comparison to Flynn's ASP.

Pfizer attempts to deal with this problem by --

PROFESSOR WATERSON: Can I just check, is this the weighted average price for Flynn?

MR HOLMES: This graph shows the separate prices. Sorry, for Flynn?

PROFESSOR WATERSON: For Flynn.

MR HOLMES: Across the strengths? Let me check, it may be for 100mg. Yes, it is just 100mg.

PROFESSOR WATERSON: 100mg. Okay, thank you.

MR HOLMES: That, I suppose, is the closest comparison because that is the strength of tablets.

PROFESSOR WATERSON: That is all I wanted to check.

MR HOLMES: I am grateful.

Now, Pfizer, as I say, attempts to deal with the problem that it is at a different level of the market by abstracting from the reality of its arrangement with Flynn. It is driven to calculate an adjusted selling price which was never in fact charged in the real world in an effort to find a more flattering comparison to the tablet ASPs, and the way that it does this can be illustrated by reference to the graph I began with yesterday on page 7 of the CMA's skeleton argument. That is {XL/3/7}.

What Pfizer does is to take the -- again, just for ease of reference, let us use 100mg which are 75% of the volumes -- it takes the green parts of the bar, the parties' combined costs, both Flynn's and Pfizer's, including their cost of capital, and the solid red bar representing its own additional margin which gets you up to about £39 and some pence. But it then simply erases the striped red line represented by Flynn's excess.

Now, Pfizer and Flynn, as we will see, planned the price rises together. Each knew that the other expected

to reap substantial profits. Flynn was introduced into the equation precisely in order to achieve the price rises, and I will show you that, but Pfizer's proposal, in defending its very large mark-up, is just to airbrush out Flynn's excesses and in place of Flynn, Pfizer thereby effectively substitutes a hypothetical supplier who confines itself strictly to the striped green line shown at the base of the cost stack, the cost plus assessment.

Now, on the basis of that highly advantageous comparison, Pfizer seeks to suggest that its phenytoin price to pharmacies and wholesalers is not substantially above phenytoin tablet ASPs.

Now, if I may say so, sir, that is certainly a rich submission. It allows Pfizer its excess during the relevant period in its entirety but strips Flynn back to cost plus, and we say there can be no justification for that double standard.

Moreover, the approach treats the cost plus measure shown at the base of the bar as though it were the highest price that could permissibly be charged by Flynn under the competition rules and that reflects a submission of Mr Brealey's on Monday. He said that the CMA cost plus was:

"... the price ... we should have entered [at]

otherwise it would be [an] abuse and you would be fined several tens of millions of pounds".

But I have shown you, sir, that is not the CMA's position. The CMA does not take cost plus as the level at which parties are required to price to avoid a finding of excessive pricing. Excessive pricing was found when Flynn charged at many multiples of this.

The CMA separately assessed the parties' costs and a reasonable rate of return and then considered whether the excess was sufficiently material to give rise to excessive pricing, and the Decision makes very clear that cost plus is not the threshold for abuse. I showed you the relevant passage earlier at 5.89.

Even after its adjustment, Pfizer's adjusted ASPs are still not enough, we say, to produce a basis for comparison which is helpful to Pfizer. During the period when the tablets market is alleged by the appellants to exhibit workable competition, the market generates prices well below the adjusted capsule ASPs.

If we could go, please, to {XA1/1/352}, you see here what this graph shows is it compares the tablet ASPs to Pfizer's and Flynn's ASPs with an adjustment up. There is a slight confusion which you may have seen which arises from the fact that some of these graphs adjust capsules down to 28 tablets, and some of them adjust

tablets up to 84 to produce a comparison that has the same volume per pack.

What this does is it adjusts tablets up, and we would suggest that that is probably the right way of doing it given that we are looking at the reasonableness of the capsule price. Nothing really turns on the point other than a presentational consideration.

THE PRESIDENT: There is absolutely no difference in terms of dosage between tablets and capsules, just to be clear?

MR HOLMES: I do not believe so, sir, but that may be a matter for the medical evidence to confirm. So far as we know, it is not, sir, but obviously you will be hearing from Drs Walker and Sander and they can perhaps confirm the position.

The purple line at the top is Flynn, and you have my point that that is sales well above the comparisons, and then you have Pfizer. This is not, I think, the Pfizer adjusted ASP, this is just the Pfizer excluding Flynn's pricing altogether, or indeed any element to cover the downstream distribution, but even on the basis of this comparison you see the downward trend in the tablet prices until the end of 2013 when Wockhardt's volumes are reduced as it prepares to exit. So you can see down, the prices in particular of the entrants, tracking

down until they hit £20, at that point, one-third of the prices of capsules, and you will see that Teva, the incumbent, is also materially below Pfizer's price without any margin for distribution.

At the point when Wockhardt prepares to enter, you see that Teva's prices tick back up and then fall a little, but until then, all three suppliers in the market were below the Pfizer ASP before any adjustment to include even Flynn's cost plus.

If you look beyond Teva, the incumbent, to the new entrants, you will see that their prices are trending well down to around half the Pfizer ASP. So the output of this competition is producing prices, as I say, a third of those of tablets. So the tablet ASPs, we say, do not help Pfizer or a fortiori Flynn.

The final comparison that was made is to other AEDs, and in view of the time it may be that I should pause there. I am conscious of the shorthand writer, if that is a convenient moment.

THE PRESIDENT: If it is for you, Mr Holmes, then it is for us.

MR HOLMES: I am grateful.

THE PRESIDENT: You have had a number interruptions from us this morning. How are you doing for time?

MR HOLMES: I think we are making fair -- I am afraid it

1 will run into the afternoon.
2 THE PRESIDENT: We have banked on that.
3 MR HOLMES: I am grateful.
4 THE PRESIDENT: We will, in that case, rise for ten minutes
5 until 11.50. Thank you.
6 MR HOLMES: I am grateful.
7 (11.39 am)
8 (A short break)
9 (11.52 am)
10 MR HOLMES: Sir, you will be pleased to know I am very
11 nearly at the end of my headline points, so I think
12 probably there will be two sections and not three
13 sections to my submissions today, but the final point
14 concerns the other AED comparator, and this was a point
15 that was mentioned in passing by Mr O'Donoghue, but it
16 featured also in Pfizer's skeleton argument, and
17 I should briefly give you our case on that. If we could
18 go to Pfizer's skeleton to see what is relied upon, it
19 is at {XL/1/43}.
20 Sir, you will recall these are prices of other AED
21 treatments. I do not know if we can slightly enlarge
22 the figures starting with figure 3, is that possible?
23 So you will see at figure 3 it shows a series of
24 alternative AED treatments, and gives a weighted average
25 price for them in two time periods. The first is just

a snapshot in September 2012, that is the green line, and the second is averaged across the infringement period, so September 2012 to December 2016.

Now, these comparisons were all considered in the Decision. To state the obvious, they are all in separate markets from capsules. We say that the blue line is the more relevant to consider as it shows the situation across the infringement period and not just a snapshot in 2012 which is heavily affected by evolving competitive conditions for the other products, and levetiracetam, for example, the second product, only saw generic entry in 2011 just before the start of the infringement period, and you see that the difference that that makes to the price in September 2012 by comparison with the weighted average price across the period of the infringement.

Now, the top four products are shown to be cheaper than phenytoin sodium which is in fact phenytoin capsules, on average, over the course of the infringement period.

It is clear that lamotrigine, levetiracetam, topiramate, are all considerably lower in price. You see that they are all below, quite substantially below, the phenytoin sodium line, and that is despite the fact as explained in paragraph 6.475 of the Decision that

they are first-line instead of third-line treatments for particular types of seizure.

The only product which is shown as higher is ethosuximide and it is a first-line treatment for absence seizures. In the NICE guidance, capsules were, during the relevant period, listed as a "do not offer AED" for that seizure type. So there is no overlap between ethosuximide and capsules in terms of their clinical use and the patient base they treat, and that, for your note, is explained in Decision paragraph 6.524.

Ethosuximide is prescribed to a tiny cohort of patients. In 2016, there were only 1,300 patients treated with it in England in comparison to 38,000 patients taking capsules, and that is explained in Decision paragraph 6.527.

It was also subject to particular difficulties relating to its competitive supply, and the price was increased significantly following debranding, so it is unlikely to be an effectively competitive comparator and that is explained in the Decision at paragraph 6.528.

So we say that the only product which is more expensive in figure 3 is an obvious outlier and not suitable as a comparator.

Moreover, as respects to the other cheaper AEDs, the prices need to be set alongside the analysis in the

Decision of the available generic pricing in the market. May we please show the current page alongside {XL/1/43} -- sorry, show this page alongside {XA1/1/373}. Thank you.

This shows, you see the figure 6.16 at the top of the page, this shows the cheapest defined daily dose for phenytoin sodium and each of the other AEDs shown in figure 3.

You will see that the phenytoin sodium line is shown in yellow, and you see the big increase in 2012, the graph joins annual plots, so you do not see the vertical cliff but a steep diagonal climb from 2011 to 2012, and you see throughout the infringement period that the other products are all cheaper, and most of them are substantially cheaper, and you see from the legend, the defined daily dose is taken from the World Health Organisation, that is at footnote 2 to the figure.

You see that those prices are all much cheaper than figure 3 would suggest, and that is because figure 3 is an average which includes the high-priced branded treatments in the market which push up the average, although they represent a relatively small proportion of the market, and you get a sense of the distortive effect of the branded prices by turning to page {XA1/1/366} of the Decision, and you see that these are the same AEDs

but looking at the branded prices which were relied on by Dr Ridyard in the first appeal.

You see that most of them are more expensive than phenytoin even after the price increases, and these branded products, we say, are not good comparators, they do not reflect the available competitive pricing in the other AED markets, and when one looks at that one sees that capsules are the outlier.

Now, the Tribunal was also shown figure 4 {XL/1/43}, so if we could now go to the left-hand page of {XL/1/43} only, please, and enlarge figure 4.

We say that this is of limited utility as a basis for comparison. The first point to note, although it is not acknowledged in the skeleton, is that this is a 2012 snapshot. I think Professor Waterson asked a question to that effect and that is the answer I understand on examining the data, and therefore it does not capture the declines in prices that occurred in some other products during the relevant period.

The figure 3 blue line approach we say is a more realistic basis of comparison, the one we saw higher up the page, and I made my submissions about why those comparisons do not help.

The same products also appear multiple times, if you look to the column to the left, with different dosages

making it difficult to know which comparisons should be drawn. So you can see the different doses of perampanel: 2mg, 4mg, 8mg, 12mg. The comparison also includes a number of branded treatments. Some of the prices are for branded products, for example, perampanel only appears in the October 2012 PCA data which this figure is based upon, in its branded version, Fycompa. Similarly, eslicarbazepine acetate only appears as the branded Zebinix.

So we say that figure 3 is more helpful than figure 4, and it suggests that phenytoin sodium is clearly more expensive than any conceivably relevant comparator AEDs.

Just to recall the Tribunal's findings in relation to other AEDs in the first appeal, I am sure that Professor Waterson has this well in mind, but it is in {XN1/2/126}, and if we could remove the right-hand side of the screen now so it is just the text and centre it and enlarge it, you see at 398:

"The argument for a meaningful comparison with other AEDs [the Tribunal considered] [was] considerably less compelling than that for tablets, mainly because they differ widely as products even though they address the same medical condition ..."

And you have seen the qualification I have made that

they do not in fact all address the same medical condition:

"... and there is no comparative economic data, particularly as to the cost structure of those AEDs. In our view, their relevance as meaningful comparators is limited to showing what the buyer is prepared to pay for a treatment that addresses epilepsy for a given patient."

So in summary, we say that none of the appellants' comparators does harm to the CMA's conclusions in the Decision. Subject to any questions I propose now to turn to the factual context.

THE PRESIDENT: Yes, that is very helpful, Mr Holmes.

It is a point which does not relate to anything that you have said now, but it is something which -- your reference to branded and debranded products.

MR HOLMES: Yes.

THE PRESIDENT: My understanding is that although it was sold as a generic, the Flynn capsules had an element of branding attached to them.

MR HOLMES: Yes.

THE PRESIDENT: To what extent do we need to worry about that, or is that something which is just a background fact which we acknowledge but do not have to worry about? It does seem slightly odd to have a generic

brand.

MR HOLMES: I fully agree. My submission is that it is a point of context but it does show the extent to which the parties were alive to the risk that their conduct would lead to parallel imports, and the inclusion of the brand provided a source of protection because it provided a trademark basis on which there could be a limitation on the use of the products within the UK.

MR O'DONOGHUE: Sir, if I may, from our perspective, of course, the maintenance of the brand name on the capsule Epanutin gave patients considerable comfort, in a continuity of supply situation.

THE PRESIDENT: Well, really I think my question is a little more general, which is it seems, on the face of it, odd to have a shift from a branded regime to a generic regime when in fact the outcome is not a generic regime but a differentiated regime.

Now, it may be that there is very good reason for it, I quite see the continuity of supply is almost -- well, no, it is inconsistent with a generic approach, and some differentiation is obviously implied in that, and it is that tension, I think, that I am raising, not so much to hear argument about it, but to understand whether it is something that we need to roll our sleeves up and understand or whether it is something which is

just, you know, one of those things.

MR O'DONOGHUE: Sir, we say it is not trivial or merely context. Of course, Mr Holmes is as quick as lightning to say: do not worry about the other AED brands because they are brands. So it is a substantive point. We will address you as that as we move forward, but I would not want this lost in translation.

MR HOLMES: No, no. To be clear, continuity of supply, one can readily see that could provide an argument for including in the generic name a reference to the supplier, so we do not dissent from that.

Equally, there is no dispute that this product was debranded for regulatory purposes and the effect of doing so was to remove it from the PPRS, and indeed, that was the mechanism whereby price increases were then applied in the market. So that is all common ground.

THE PRESIDENT: Indeed, no, that I understand. I suppose what I am saying is: is there any definition in law that we ought to be aware of which ensures that when you debrand, you do debrand? It would be quite an odd thing to be within the branded control, say: no, no, do not worry, it is all generic, and carry on as before. That would be a very strange situation, and I suppose what I am asking is, is there some general legal basis that we can look at to articulate what is generic and what is

branded.

MR HOLMES: Yes. I do not have the answer.

THE PRESIDENT: No, no, I raise it because it is clearly a point of significance --

MR HOLMES: Yes.

THE PRESIDENT: -- because if any one of you say it is, then it is.

MR HOLMES: Yes.

THE PRESIDENT: That means, I think, we do need to --

MR HOLMES: Bottom it out.

THE PRESIDENT: -- bottom it out.

MR HOLMES: Yes, understood. Perhaps we could liaise between ourselves and see whether we can find any relevant legal materials that we can draw to your attention.

THE PRESIDENT: I am grateful.

MR HOLMES: Turning then to the factual context and starting with the product itself, the key points I think are uncontentious, and I am sure the Tribunal has them well in mind, but in brief summary: phenytoin is an old epilepsy drug developed in the 1930s, long off-patent, supplied in the UK in the form of capsules and tablets. In the case of capsules, Pfizer was the sole supplier until September 2012. At that time, they were supplied as a branded product, Epanutin, and from that date, the

arrangement with Flynn led to Flynn becoming the supplier while Pfizer remained the manufacturer and the product was debranded, removed from the PPRS, and supplied as a generic.

Pfizer and Flynn supplied in four strengths, 25mg, 50mg, 100mg and 300mg, and you have the point that the 100mg strength is supplied in packs of 84, but the other three are supplied in packs of 28.

In April 2013, NRIM launched a rival capsules product, but only in the 100mg strength, and the position as regards tablet suppliers during the relevant period is set out in the Decision in table 6.9 {XA1/1/321}. You see for the first period Teva was the monopoly supplier from at least January 2005 until September 2009, that was when you saw the very large price increases, and then the meeting with the Department of Health, and it thereafter continued to provide tablets. Wockhardt started providing tablets in October 2009 and did so until July 2014. Milpharm started providing tablets in September 2012 and at that point the market moved from a duopoly to a three-player market.

There were no other tablet providers in the period under question and Wockhardt's exit in July 2014 returned the market to a duopoly. In terms of

comparative volumes, capsules are a much larger volume product than tablets. If we go back in the Decision to {XA1/1/30}, you see at paragraph 2.9 that:

"During the Relevant Period, the NHS dispensed approximately four times the number of 100mg ... capsules ... compared with 100mg ... tablets ..."

The CMA's skeleton argument gives the precise figures for your note at paragraph 30: 196 million capsules to 47.5 million tablets.

Phenytoin is now rarely used as a treatment for new patients, and its use has been declining in the UK for a number of years. Other treatments are preferred in the medical guidance, and the Tribunal will hear medical evidence during the course of next week about that, but there is no dispute that phenytoin is and should be a third-line treatment which should not normally be used for people with newly-diagnosed epilepsy.

To the extent NICE analysis is relevant, the CMA did not ignore it. As I will come to later in the grounds, the key point, though, is that NICE has consistently assessed phenytoin as a third-line treatment since 2012 and nobody gainsays that conclusion.

Most patients are legacy patients, that is to say patients who have been stabilised on the product and for whom it is an essential and effective treatment for

controlling seizures. The product has a narrow therapeutic index, that is to say there is a relatively small difference between the blood level of the drug that is necessary to achieve therapeutic efficacy and the blood level that if exceeded might result in adverse side effects. It also has non-linear pharmacokinetics, that is to say that the blood levels are not proportional to the dose.

The combination of NTI and non-linear pharmacokinetics make it difficult for practitioners to regulate the appropriate dose, as you observed, sir. Small increases in dose can result in toxicity and small decreases can result in loss of therapeutic efficacy, and that is a point that will be explored with the medical experts.

This has given rise to the advice on continuity of supply which recommends that patients should be maintained, if possible, on a specific manufacturer's product, and specific further detail and references are provided in paragraph 108 of our skeleton argument for trial.

Continuity of supply was considered in the Tribunal's first *Phenytoin* judgment, and its operation is described in paragraphs 21 to 30 of the Tribunal's judgment. I do not think we need to go there, but the

upshot is that for category 1 products from November 2013, which included phenytoin, doctors were advised to ensure that their patients are maintained on a specific manufacturer's product.

The economic consequences of the guidance for market definition and dominance were considered in the first judgment in paragraphs 121 to 134. If we could turn, please, to the judgment, that is at {XN1/2/44}. At paragraph 129 you see that the Tribunal noted the point to which Mr Johnston referred on Monday that most scripts for capsules were generic or open and that had been acknowledged in the CMA's Decision, and in the penultimate line, the Tribunal observes that:

"... doctors, to whom the ... Guidance was addressed, appeared largely to be either ignoring it or leaving it to pharmacists to implement rather than applying it themselves."

The last part being over the page.

"However, the extent to which, as a matter of fact, pharmacists applied the MHRA Guidance in the great majority of cases where the prescription was open is a critical part of the CMA's findings on market definition since it is that behaviour, at the point of delivery of the product to the patient, which would give effect to Continuity of Supply."

So pausing there, sir, whether or not doctors were following the practice in prescribing the continuity of supply guidance may have had effect at the level of pharmacies, and that is the point alluded to here.

If I could now ask you just to refresh your memory of paragraphs 130 to 131 on this page and 133. So if we could just move down so that 130 and 131 are revealed.

THE PRESIDENT: So 130 to 133 you want us to read?

MR HOLMES: Yes. 132 does not take matters very far forward, but 130 to 131 and 133 do.

THE PRESIDENT: We will read that. (Pause)

Yes.

MR HOLMES: Sir, I am showing you this just because you have expressed an interest in continuity of supply and it is just to confirm a point that I think you raised during earlier argument that it is guidance and it should not be treated as a hard and fast rule, and that was the finding of the Tribunal first time around.

The overall conclusion is given on page {XN1/2/52} at paragraph 150, and you see there:

"Overall ... looking at the evidence in the round ... the CMA was correct that Continuity of Supply had a significant impact, in practice, on pharmacists' dispensing practice, tending to favour the existing supplier of products on which patients were already

stabilised ... however ... there was clearly still a degree (even if limited) of switching from Flynn to NRIM after publication of the MHRA Guidance [in November 2013]."

THE PRESIDENT: That is helpful, Mr Holmes. Just to be clear, are we right in proceeding on the basis that the CMA's Decision in relation to market definition and dominance is substantially informed by the question of continuity of supply?

MR HOLMES: Yes.

THE PRESIDENT: Are there any other material factors that we ought to be bearing in mind, or is that the one that really drives the market definition?

MR HOLMES: Sir, I think other barriers to entry were also identified and there is also substantially quantitative assessment of the interaction between both NRIM and parallel imports, an indication, for example, of the uncertainties of supply that parallel imports provided in the market, with consequence that they did not provide any significant or sustained constraint on the parties' conduct during the relevant period. I mean, that is all set out and explored at some length in the first judgment.

THE PRESIDENT: Indeed, of course, no one is saying that dominance requires a 100% share, there are always going

to be rivals. It is the question of what is preventing switching from one product to another, and, as we know from *Hydrocortisone*, applying a simple SSNIP test is rather difficult in this market.

MR HOLMES: Yes.

THE PRESIDENT: But leaving on one side, therefore, the mechanism for ascertaining market definition and dominance, the reason the SSNIP test would have been satisfied had it been capable of being applied was the continuity of supply question that people would be reluctant to move away from the capsule produced, manufactured, by Pfizer, because of continuity of supply.

MR HOLMES: So others will correct me if I am wrong, but my recollection of the materials is that for NRIM it was a factor of central importance. In the case of the potential constraint provided by parallel imports, continuity of supply is of course not a relevant consideration because it is the same product.

THE PRESIDENT: Because it's the same supply, indeed, that is fair, but there you say there may be reasons parallel imports are harder to come by which means that even though the will to substitute might be there, the ability to do so is not.

MR HOLMES: Yes, sir, the Tribunal has seen this in

previous, it is an arbitrage trade, so volumes can be found here and there and they are bought up by some wholesalers and some pharmacies, but there are some pharmacies who need stable supply who would not therefore view parallel imports as a substitute, and that affected the Tribunal's assessment and the CMA's assessment of the extent to which parallel imports in fact provided any material constraint on the parties' dominance.

THE PRESIDENT: I am grateful.

MR HOLMES: Sir, I am reminded by Mr Bailey that from paragraph 236 the other factors relied on by the CMA are set out in some detail: market shares, high prices and profitability and the general level of competitive constraint provided by NRIM and parallel imports is assessed.

THE PRESIDENT: Yes. I mean, those are of more relevance to dominance than the definition, but I take the point.

MR HOLMES: Yes, sir, although they might show the extent of competitive constraint at the level of market definition as well.

THE PRESIDENT: Yes.

MR HOLMES: If we could turn now to the conduct, the Tribunal knows the main lines: Flynn bought the UK marketing authorisations from Pfizer for a pound, and as

planned with Pfizer, it debranded the product thereby removing it from the PPRS and both parties then applied very large margins to the price increasing it many times over.

Pfizer continued to manufacture at its plant in Germany. The distribution arrangements remained the same: they were subcontracted by Flynn to the same pre-wholesaler, UDG, as Pfizer had previously used. The products went from Pfizer to UDG, were stored in UDG's warehouse and were delivered by UDG to customers, and the respective roles undertaken by the parties are covered in Mr Fakes' evidence which the Tribunal will be hearing next week.

So that is the arrangement in overview. Its regulatory aspect was to escape the PPRS and the parties have all referred to the Tribunal's description of the PPRS in its judgment in the first set of appeals and that is a convenient place to just recap on its features. So starting on page 14, that is {XN1/2/14}, we see at paragraph 37 that the PPRS was a non-contractual voluntary scheme, and that Pfizer and Flynn were both members, and over the page at the top of the page you see that:

"It controls the overall profit that scheme members make on the sales of their portfolio of branded licensed

medicines ..."

So it is a profit-based cap, applicable across a supplier's portfolio of branded products. Looking on to paragraph 38 you see that it is based on specific target rates of return applicable on a portfolio basis rather than to individual products, and the target rates of return include various allowances and are expressed either at the supplier's election on a ROCE basis or on a ROS basis.

At the end of the paragraph, members submit annual returns and if a member is over the profit target by more than a specified percentage, which was 40% under the 2009 scheme and 50% under the 2014 scheme, they have to repay the excess to the Treasury.

In paragraph 39, the Tribunal notes that a branded product's price can be adjusted by price modulation, increasing it by up to 20%, and there would need to be offsetting reductions in other products subject to the overall profit cap, so that is the scheme in a nutshell, and the effect of it is that before September 2012, capsules had to be priced in a way which observed the overall profitability cap on Pfizer's branded portfolio, and this limited the extent to which prices and profits could be increased by Pfizer.

Epanutin's profitability, the capsule's brand, was

1 therefore limited, and to be clear, the profitability of
2 the individual product cannot fairly be assessed in
3 isolation because of the nature of the scheme. I think
4 it is a related point to one that you made yesterday,
5 sir, in questioning.
6 There is no suggestion that Pfizer was not
7 profitable on a cross-portfolio basis, but Pfizer's
8 evidence in the first proceedings was that, considered
9 in isolation, the Epanutin product was either
10 loss-making or only marginally profitable, and that is
11 recorded in the first judgment at paragraph 52.
12 THE PRESIDENT: It does mean that there is going to be quite
13 sophisticated consideration being given as to which
14 drugs form part of your branded portfolio and which
15 drugs you take out of it in order to maximise your
16 profits.
17 MR HOLMES: Yes, sir, you can see the calculation. We will
18 see that they did consider the impact on their PPRS as
19 a result of the withdrawal of Epanutin, so that did
20 weigh in their considerations, as one would expect for
21 the reasons --
22 THE PRESIDENT: Really what you are asking yourself is to
23 what extent is branding an advantage in terms of
24 differentiating myself from other products, and am
25 I prepared to lose that advantage in order to remove

myself from a price restriction.

MR HOLMES: Yes.

THE PRESIDENT: But the price you ought to pay is an absence of product differentiation which is where my question about branded generics comes in, because if you are able to continue to differentiate yourself in a manner as if you are a branded product, even though you are generic, then there is an additional factor to take into account in moving in and out of the two schemes.

MR HOLMES: Yes, sir, and we will see that from the contemporaneous documents, that they did indeed weigh up whether the loss of branding was worth it, although it exposed them to a greater risk of generic competition as they saw it, bearing in mind the gains that they expected to -- I will show you that shortly.

So that I think conforms with what you say. I should say though, sir, that we do not view continuity of supply as a meaningful source of value, and certainly not a source of value that would justify anything remotely resembling the price increases that are imposed.

THE PRESIDENT: Well, that submission contains two points, does it not? It may be we ought to get our *Hydrocortisone* classification out, then. Please let me be clear, if you want to say that the classification in

Hydrocortisone is wrong or inapplicable then you should feel free, but just for shorthand, we have two cases in *Hydrocortisone*, we have the case 3 situation where there is no product differentiation and we have the case 2 situation where there is some but where the value of that is not considered in any part of *Hydrocortisone*.

On that basis, so parking the second point that you made that you dispute the value of continuity of supply, do you accept or do you not accept using the *Hydrocortisone* definitions that the capsules, because of continuity of supply, fall within case 2 rather than case 3, or is that something which is contentious?

MR HOLMES: So, sir, I think broadly -- and you will hear expert evidence about all of this -- one can see some important intuitive reasons why there are some products which need to be considered carefully and differently in the context of unfair and excessive pricing analysis, and an example would be a product that is under patent which I think is one of the examples that you allude to in *Hydrocortisone*, where there is a legal monopoly or exclusive right conferred, it is not a monopoly because of course there might be other products that perform the same function as the patented product, but in any event, an exclusive right to use the particular process or formulation, active pharmaceutical ingredient, for

a specified period of time to incentivise innovation, and it would be an odd thing for competition law to cut across that valuable and important public policy objective.

So I think the case law recognises, and we would agree, that in the case of a product with a strong, intangible element of that kind, one needs to be very cautious. The difficulty we have, though -- so that we accept insofar as it goes -- we do say, though, that the examples given in *Hydrocortisone* are -- and I think this was the Tribunal's intention -- they are somewhat stylised and in the real world they are unlikely to admit of sharp edges. There might be products that have some degree of product differentiation, but a minor element of product differentiation or one which really does not have any significant value attaching to it, so it is largely a commodity product but with some element of differentiation, and that, I think, needs to be factored in.

The other point specifically on continuity of supply is you see what we say in our skeleton argument about this: we view continuity of supply as a disadvantage of the capsules product. It effectively gives rise to a lock-in for those patients who are on it: they have to keep taking it once they are on it, or there is a strong

reluctance to move them from it once they are on it, and so as a result, there is a kind of a lock-in there.

THE PRESIDENT: Well, yes, of course, but the point viewed from the other side is that the benefit that is being conferred by Pfizer and Flynn is ensuring that that supply continues, and the point we are debating is whether that is something which is adding value and can therefore be charged for. Of course you are right, it is a bad thing for the patient to be locked in, but that locking in occurs as a result of, as we have seen, really quite firm guidance emanating in 2012, 2013.

MR HOLMES: Sir, if I can push back on that?

THE PRESIDENT: No, of course.

MR HOLMES: How do you differentiate that from any narrow product market where the supplier has a monopoly? What you are effectively saying is they are giving value because they are carrying on making the product, they are continuing to supply it in the market. The same could be said of any monopoly supplier in any market of a valuable drug, so it would apply equally to hydrocortisone or to liothyronine.

THE PRESIDENT: Well, I am not sure that is right and it would be helpful for you to explain in detail why that is not right because I do not understand, and it certainly was not a feature in *Hydrocortisone*, that you

were tied to a particular manufacturer's brand or a particular factory output of product. We did not have that argued before us at all.

Here, it has been made clear that on medical advice, not on some clever marketing strategy from Pfizer or Flynn, but on medical advice, that you ought to stick to the same brand, and that differentiates these capsules, phenytoin capsules, from other things, and that is why I was so interested in the market definition.

MR HOLMES: I understand, sir, but take a product that is quite difficult to make and so as a result generic manufacturers take a while to tool-up, if they tool-up at all, so there are high barriers to entry there.

THE PRESIDENT: Yes.

MR HOLMES: You could say that the one supplier in the market is supplying value to the patients who use this valuable treatment because they continue on the market, they do not take away their marbles and leave, they do not basically flounce out by ceasing to supply the product.

You would not say that that ransom -- if they were then to impose high prices as a consequence of that, you would not say that that ransom cost was value.

THE PRESIDENT: Well, I think we did. It may be we were wrong in saying so, but that is precisely the face mask

example that we push into case 2 in *Hydrocortisone*. Now, let me be clear, we are absolutely up for revisiting these things because these are questions of fact, not law, but just to be clear about where *Hydrocortisone* comes from, face mask is a case 2 situation where you are doing no more than responding to an excess of demand over supply and you are pushing the price up; the point being you are allowed to do so provided you are not benefiting from any factors that make the market incontestable.

So if it takes you three months as a rival supplier to gear up your face mask rival product, well, then, for three months you can charge effectively monopoly rates, but if you are benefiting from other factors -- and of course, as you know in *Hydrocortisone* that was the orphan drug factor -- if they are illegitimate then you cannot properly maintain your price higher because there is no legitimate product differentiation.

Your case looks very close to what we certainly found a tricky case but which we in the end categorised as case 2, the face mask example.

MR HOLMES: Yes, so I think we would say that there are cases where there is valuable product differentiation which needs to be taken into account, but we do not see this as an obvious case of product differentiation.

I think that is something we will need to revisit. I do not want to lose the opportunity to show you the contextual documents.

THE PRESIDENT: No, of course.

MR HOLMES: I suspect this is a discussion we will return to, but if I could make one further submission: even if one accepted that there was value deriving from keeping manufacturing open, which I think was the way that you phrased it in the note --

THE PRESIDENT: Yes.

MR HOLMES: -- we do not see that as requiring a departure from a consideration of the relationship between price and cost and the extent to which price exceeds cost. On the contrary, if the underlying concern is to ascertain what would be valuable, what would be the value of continuing manufacturing, keeping manufacturing open, under conditions of effective competition, well, if there were a competitive market, what would be the price that would attach to keep a manufacturing service open?

THE PRESIDENT: Mr Holmes, I think on that point you are pushing at an open door, and I would only refer you to 344 and 345 of *Hydrocortisone* where we make absolutely clear that in a case 2 case we are emphatically not deciding how high the price can go even if you are in that case. So the whole question of what is excessive,

what is unfair, is open for argument. So the degree of value added is not something that *Hydrocortisone* comes close to deciding. It quite deliberately eschews that point, and that is entirely up for grabs in terms of the argument here.

MR HOLMES: That is a very helpful indication, sir. It may be that we misread your note, but we took it to be suggesting that once you are into case 2, one then views the relationship between price and cost only as a floor and not as a relevant metric or consideration when determining what would be a reliable benchmark of economic value.

THE PRESIDENT: That is certainly a question that is up for argument here in these proceedings.

MR HOLMES: Yes.

THE PRESIDENT: The only point I am making is that you are not going to get any answer to that question out of *Hydrocortisone*.

MR HOLMES: No.

THE PRESIDENT: So even if it is classed -- and I understand that is a matter for debate -- as case 2, you do not get any further in terms of where the ceiling and floor sit in studying the *Hydrocortisone* decision. So I want to be very clear about what are the overt limits and I think it is set out reasonably clearly in 344 and 345

and that is precisely why those paragraphs are there, because we did not consider these questions in that case.

MR HOLMES: Sir, I have found this interchange, for my part anyway, extremely helpful in understanding the Tribunal's emerging thinking on these questions, and it is a point on which I would like to make fuller submissions later in the light of the expert evidence that you will be hearing, but just to wrap up the conclusion that I am making, and if you like, to push a little harder on the open door that you have indicated is still very much up for grabs in the light of the *Hydrocortisone* framework, we would say that in seeking to determine the value that would attach to keeping manufacturing facilities open under conditions of effective competition, the equation would be very much one of the costs involved and you would expect if there were competing suppliers that maintaining security of supply, keeping a facility open, would reflect the costs that are involved in providing the product.

So a relationship between price and cost would remain of importance to that process of assessment, and so I think that is probably as far as I can take it for now, so if I may, I will return to the documents.

THE PRESIDENT: No, of course.

MR HOLMES: Now, what we say the documentary shows is first that it was a third party, Tor, that put Pfizer on to the possibility of radically boosting the profitability of capsules by debranding them and then drastically increasing their price.

In the course of July 2009, Pfizer was contacted by Tor Generics, which is a small pharmaceuticals company, who had spotted the opportunity. If we can go, please, to {XG/44} and pick it up on the second page {XG/44/2}, you can see this developed.

This is an email from an individual at Tor to Pfizer's portfolio manager for generic brands, Jenny Shaw, and the date is 8 July 2009, and it sets out some worked proposals for capsules and other Pfizer products, and the Tor representative says that:

"Further to our meeting last Monday, I now have ... data ... to hand and revenue figures per product, so am able to do some realistic existing comparisons for you, alongside the generic growth potential I have proposed at our meeting, should you be able to give me the fostering agreement on the products discussed."

Then turning on to page {XG/44/4} you see that she comes lastly to Epanutin in the second paragraph on the page, the Pfizer capsules brand, and the comparison she draws is with phenytoin tablets, the drug tariff price,

the price for which was £30, and she notes that the Epanutin brand 100mg is currently worth £860,000 a year, that is pounds, based on the £2.83 drug tariff price at the time, and to gain the whole phenytoin capsule 100mg market she proposes that, in the third underlining:

"We apply for all Epanutin licences as a Phenytoin generic licence for each of the four strengths with the reasoning that the product is written predominantly generically. We then TERMINATE THE BRAND and replace with the generic livery only, and this will also stop all PI imports, as there will be no brand comparison."

So she was already mindful of the risk that if you put prices up you get products rolling in from other low-price markets and she has a plan to address that.

THE PRESIDENT: How does that work? Sorry, I am not sure I follow the thinking.

MR HOLMES: Sir, I think the way it works is you have to piggy-back on an existing licence in order to get a PI licence for access to the market. This is an area where others will be more expert than me, but I can come back to it perhaps.

THE PRESIDENT: We can (inaudible) -- no, that is fine.

MR HOLMES: Yes. Her suggested pricing is then set out. You can see at the bottom of the page:

"We come in again under the radar at say 15% less

than the [tablet drug tariff] price ... and therefore we will need to set our DT according leave @ £25.50 per 28pk."

And at the foot of the page the opportunity is said to be worth 35 million after wholesale discounts.

Then she says:

"If we take your costs as those of your brand list price currently; I think you will see there is significant profit IF we roll the product out in the right way."

Then an important qualification:

"[The] comparison works where there is no other product available to switch to; I will need your feedback now ... on whether you think Sodium Valproate or Epilim [two other AEDs] would squeeze our scripts eventually maybe 12 months down the line if PCTs are looking to save money."

Further down the page the proposal is for a profit share in the underlined passage between Pfizer and Tor, and this suggestion, it is fair to say, provoked a cautious reaction within Pfizer.

If we turn to page {XG/44/1} of the present email chain you will see the Pfizer individual who had met with Tor relaying her thoughts. If we could just enlarge that a little bit, it is a little small for my

failing eyesight, she says that she has:

"... just been reviewing the product that ... Tor ... has proposed..."

The revenue impact is described. You see under the detail the reasons for Tor's involvement. So picking it up in the third line under the "Detail" heading:

"... [The] proposal is that we do it via Tor to distance ourselves from the price increase."

We will see that this is a theme that recurs:

"Clearly, we do not need Tor to do this and could just try to go down this route ourselves, however, I believe that we would struggle to get the price increase required with the [Department of Health]. Also, this idea came from [Tor] rather than ... ourselves and my view is that we need to recognise that."

So Pfizer saw from the outset that the Department of Health would be a potential obstacle and that they wondered whether they would get it through themselves.

Turning over the page {XG/44/2} there was also a concern as to whether it would be fair to impose such a radical price increase, and if you could just enlarge the top of the page, please, in the penultimate paragraph:

"My other concern is just an ethical one -- the top

line money looks great, however this would increase the price of phenytoin capsules to the NHS drastically and to be frank, doesn't feel right.

"Clearly we need to make money on the product and therefore, I wonder if a conversation with the DOH with these findings could simply increase our pack price to enable profitability. It would certainly not add £19m to the top line but might sit better?

"Or on the other hand, maybe I am just being too nice!!"

Now, despite the ethical qualms within Pfizer it is clear from the contemporaneous documents that what really rankled was that Teva was able to earn large profits on tablets, and if we could go next, please, to {XG/47/2}, you see that Steve Poulton explains the terms of the proposed deal in an email from September 2009, if we could just enlarge that, please. He says that:

"We have an attractive commercial opportunity to increase revenues significantly due to an anomaly in the Drug Tariff. The summary is below and I would draw your attention to the following extracts which sum up the dilemma.

"It could still increase our [established product] revenues ... by [over] £6m (and I have a significant shortfall to find in 2010).

"Whilst legal, this would increase the price of phenytoin capsules to the NHS significantly. How does that fit with [our] Trust initiative?"

The email then proceeds to explain the two presentations available, tablets and capsules. You see that tablets account for 90% of the molecule value but only 44% of the packs sold. There is then a comparison drawn between the prices of tablets and of capsules, £30 compared with £2.83 for the 100mg strength of capsules, and the conclusion:

" ... what we need to try to do is readdress this situation and make Epanutin more profitable to Pfizer."

So the clear objective, as the Tribunal found, radically to boost the profitability of Epanutin and this was by exploiting what Pfizer described as an anomaly in the scheme of regulation from which Teva had been able to benefit and which Pfizer wanted to gain the benefit of as well.

Tor and Pfizer therefore continued to discuss, and as regards the practicability of the scheme, the documents show a growing confidence that the scheme was sustainable given the limited scope for any competitive response to the price increases. If we could please turn to {XG/46/1}, you see this is another email from a Tor rep -- from the Tor rep, and she says, enlarging

the top of the screen:

"Briefly, I see the opportunity re Epanutin for us sustaining realistically for 3 to 5 years ... Jenny actually said in the meeting that Epanutin is such an old licence, that it would be Nigh on impossible to get a licence granted for a generic based on the old trials and licence that currently exist -- the brand being [around] 70 years old ... therefore, even if a generic company decided to throw tons of cash at it to go for it from scratch (which is exceedingly unlikely, due to costs and time for trials being [around] minimum 2 years and then they would have to prove stability data etc; which they couldn't base on your brand ..."

So Tor's assessment then, based on what it had been told by Pfizer, was that there was limited risk of generic entry.

Then looking at the bottom of the page you see what the Pfizer manager suggested at the previous meeting about the risk of switching to other alternative AED treatments. If we could just enlarge the final paragraph, you see reference to:

"... uniqueness of the situation with ... Epanutin in the UK; [regarding] the licence, the age of the product, and its placement in the market re competition from alternatives (which Jenny did dispel to me some

while ago, saying Epanutin was [a] last resort medicine); as therein lies the longevity of our plan."

So Pfizer, as it weighed its options with Tor, understood that it was in a unique position: its product was an old product, a niche generic with limited risk of entry, and little competitive threat from other AEDs given that it is used as a last resort medicine.

There was also a clear awareness of continuity of supply and the limitations this created for switching. One sees this from another internal Pfizer email chain at {XG/47/1}.

If we could pick it up in the third line from the bottom of the first page, so just enlarge the bottom of the page you see that an individual at Pfizer chips into an email chain and states to others at Pfizer:

"I do not believe it is medically safe to switch between branded and generic AEDs and particularly with phenytoin as it has such a narrow therapeutic window."

Looking up at the second email in the chain, another Pfizer person chips in:

"If it helps there is specific guidance against switching and indeed that these products should be written by brand name to ensure consistency of medication within the BNF."

This feature of the product of course contributed to

the ethical dilemma, and you see at the top of the chain the reference to "a strong concern/reluctance on the advisability of doing this from a patient care/Trust perspective".

The author asks if there is another way to deal with this by pointing out the anomaly in the drug tariff, you see in the second paragraph, and getting the Department of Health to reset the tablets tariff, in other words lower the price of tablets saving tens of millions and ensuring a level playing field, so removing the advantage from Teva.

The same suggestion recurs in another email from Steve Poulton of Pfizer in February of 2010. It is at {XG/58/1}. You see the subject is "Epanutin" and he begins by saying that:

"Following the presentation [the preceding] Friday [the second email in the chain, please] we need to progress this. The ... upside is huge -- and we are ... behind budget on our two main growth engines ... This means we cannot afford to dismiss it lightly."

He then raises various questions about the business case, and then towards the foot of the page he raises the continuing concern about the fairness of imposing such massive price increases under the heading "Trust":

"We need to work out how we can position this as 'no

change' with patients & physicians; and at the same time 'change' with [Department of Health] and payers without being accused of hypocrisy by pursuing a trust agenda, yet taking the opportunity to fleece the NHS in time of funding crisis."

You will then see some doubts are raised at the foot of the page about the suitability of Tor as a partner, if we can just enlarge that, please, and over page {XG/58/2} some actions are set out and then in the final paragraph of the email:

"Maybe a 'no-goer' but as an alternative; is there an opportunity to go to [the] DH and have a sensible debate with them about the inequity in the tabs/caps prices and explain (in the spirit of openness) that we cannot afford to sell it at this price and that we could implement a scheme such as this (without going into details). The aim being to obtain a special price increase outside of PPRS; or at least get them to cut the Cat M price of tabs to the same as caps and prevent Teva making supernormal profits."

So two points emerge from this email chain. On the one hand, Pfizer saw the risk of its being accused of hypocrisy given its ethical commitments if it took the opportunity, as it put it, to fleece the NHS, but in view of the huge upside there is also a shift away from

the earlier emails which queried whether to proceed, given this ethical dimension, and to focus instead on how the change might be presented.

Second, the email also sheds light on Pfizer's perception of the Teva tablets drug tariff price. Firstly, you can see it clearly rankles with Pfizer. As an alternative, they would be as happy to see Teva losing its advantage, but Pfizer also candidly describes what it regards Teva as charging supernormal profits. The Tribunal will have in mind, of course, that the Teva pricing at £30 drug tariff price is now prayed in aid as a benchmark fair price, the price they were describing at the time as one that generated supernormal profits, and it is said to show that the Pfizer price, following the September price increase, was fair by comparison with other products.

PROFESSOR WATERSON: Could I just ask, what would be the advantage to them of bringing Teva's price down? Is it simply, you know, his is bigger than mine sort of thing?

MR HOLMES: It is a very good question, sir. I think there is certainly an element of that perhaps. There is also a concern that pharmacies, I think expressed in one of the documents, would not have any particular incentive to dispense capsules over tablets because of the very much larger pricing of tablets and the margins that are

enjoyed above it, but there is also a degree of confusion to be honest in these documents, because of course that just does not work as an explanation, because we know capsules and tablets are not substitutable in any event, and prescriptions have to specify whether the product is in capsule or tablet form, so that really does not explain it. So I think there has to be a healthy dose of "theirs is bigger than ours" in all of this, sir.

I will pause there in view of the time, if that is convenient.

THE PRESIDENT: Of course, Mr Holmes, if that is convenient. We will resume in that case at 2.00. Thank you very much.

MR HOLMES: I am grateful.

(12.58 pm)

(The short adjournment)

(2.03 pm)

THE PRESIDENT: Mr Holmes, good afternoon.

MR HOLMES: Good afternoon, sir.

In a moment I will resume my chronological consideration of the documents. Could I very briefly, though, return to a point you canvassed this morning, and that was the inclusion of Flynn in the generic name of the capsules following removal from the PPRS to use

neutral terminology.

It is a point we will no doubt return to later, but could I just show you what Flynn's industry expert said about how this affected matters in the first trial. That is at {XG/405/6} at paragraph 15, if we could just enlarge that. You see his view of the matter was that:

"Phenytoin is a generic product, and whilst [he understood] that Flynn was required ... to include an identifier ... it [was] still an unbranded generic and [in his] view should be treated as such for the purpose of identifying appropriate price comparators. The fact that it is an anti-epileptic drug and has a narrow therapeutic index [did] not in [his] view affect the position, as is demonstrated by the success achieved by NRIM in generating such a significant volume of sales and effectively winning patients from Flynn."

Now, I do not suggest huge weight should be attached to it, but I thought in view of the discussion we had had it was perhaps useful to show you how one of the experts with industry experience approached the question of whether the Flynn mark meant that the product should be treated as a branded product for purposes of comparison.

MR BREALEY: Just for completeness, our experts differ, so Mr Harman took a different view, the CMA's expert, and

Mr Ridyard took a different view. So there are other views out there.

THE PRESIDENT: There is a surprise.

MR HOLMES: Just to make life a little simpler for the Tribunal, yes.

I have shown the Tribunal just before lunch an email which showed that Tor was in doubt, Pfizer was doubtful about proceeding with Tor by early 2010, and it was therefore considering other partnership options besides Tor, and in this connection, it had begun discussions with Flynn, and on 8 March 2010, Pfizer met with Flynn to discuss the possibilities for working together, and that can be seen from the handwritten note of a meeting between representatives of the two firms which is at {XG/60/1}. This is a note prepared by Nick Foster of Flynn.

If we could enlarge the top, you see from the date at the top of the page that it is 8th of the 3rd 2010, and the referencing to Flynn/Pfizer, this is obviously his day book or his meeting book. Looking at the middle of the page, the notes record that Pfizer is:

"... looking to get --"

If we could go down the page slightly, sorry:

"... looking to get into partnerships with people to move some of the older products..."

THE PRESIDENT: Eg Epanutin.

MR HOLMES: Eg Epanutin, exactly, and then:

"Epanutin, could: debrand it, foster it via Flynn. That would raise prices as generic product? No reason shouldn't be similar to the generic tabs.

"Would need to manage the PIs [that is parallel imports] as there are a number of licences."

So essentially the same plan as Tor had been proposing: a debranding followed by a substantial increase using the price of tablets as a benchmark, and subsequent emails show Flynn weighing the opportunity.

If we could go to {XG/62/1}, which is an email from David Walters of Flynn to a consultant working in the field and he explains that:

"... Pfizer sells Epanutin ... the competitors sell generic phenytoin ... at [approximately] 10 [times] the price ... Thus there is tremendous scope to increase the price of the capsules, which can only be done by genericising the product."

And then an indication that Flynn was already alive to the potential barriers that would protect such an initiative against a competitive response:

"This is an area where the tablets and capsules are recognised as not being readily interchangeable, so doctors and patients would be reluctant to switch."

So Flynn, and as we saw from the earlier traffic, Pfizer, were both alive to the protection from any competitive response to a price increase that continuity of supply and the guidance against switching would provide them with.

The discussion then continued, and in the course of June and July 2010, Flynn prepared a PowerPoint presentation detailing its proposal to Pfizer. I think you saw one page of this. If we could turn, please, to {XG/70}, you see on page {XG/70/1} the title:

"Epanutin proposal July 2010."

On page {XG/70/2} the current position is described:

"Epanutin ... is economically unattractive at its current list price.

"Competitor products (tablets) are sold at ... 30 [times] the price."

Then the point that:

"Tablets & Capsules are not easily interchangeable..."

Given the continuity of supply guidance, that is the protection against competitive reaction. Then a reference to the PPRS:

"Pfizer [cannot] change the price of [a] branded product due to [the] PPRS."

But:

"... capsules must continue to be available..."

And the proposal concerns how to turn Epanutin into an economically attractive product.

Then the next slide shows what Epanutin would achieve in sales value if priced at the level of tablets {XG/70/3}, a great deal of money, between £50 and £100 million depending upon the percentage of the market obtained, and a recommendation that price is pitched at half of the price for pheny tablets initially, ie £15 for 28 caps which is equivalent to £45 for 84.

Now, we know of course that the Flynn ASP in fact ended up being rather higher than that at £54.40 on average and £59 on launch for the 100mg tablets.

Over page {XG/70/4} one sees the potential issues:

"Continued patient access to phenytoin caps.

"Pharmacopolitical damage [to] (Pfizer)."

The expression we saw in the earlier materials:

"Parallel imports."

That is as a result of arbitrage opportunities which higher pricing in the UK would open up, and then:

"PPRS considerations."

The point you adverted to earlier, sir.

The next slide {XG/70/5} then describes the strategic options to address those issues:

"Pfizer uses Flynn Pharma as the MA holder to avoid

pharmacopolitical damage.

"Flynn debrands..."

And then:

"... sets the UK price..."

So as we saw with Tor, the inclusion of Flynn was intended to shelter Pfizer against the fallout from, as it had described it earlier, fleecing the NHS at a time of funding crisis.

Pfizer can point the finger at Flynn as the party setting the UK price, and this takes us back to where I began my submissions: the attempt to use the arrangement to shift responsibility we say continues to this day in the arguments advanced in the course of these appeals.

In terms of mechanics, you see that the plan is to give Flynn an exclusive supply arrangement so that the chain between Pfizer and Flynn is a closed one. As the Tribunal observed in its note to inform the expert discussion, that is what gives Flynn market power in its own narrow market for the supply of capsules, and otherwise the structure of the deal is said to be flexible, including in terms of agreeing the supply price.

The next slide identifies the risk of parallel imports {XG/70/6}. The parties were aware as set out

that the prices charged in other European markets were much lower than they planned to apply by way of a price increase in the UK, and that created an obvious potential for parallel import flows to the UK, potentially disrupting the parties' arrangements by providing a source of external competitive pressure.

Given the common manufacturing source, such parallel imports would not be constrained by the continuity of supply.

The next slide evaluates how much of a problem for the parties' plan parallel imports might be. It asks how much could PIs impact sales, and the first bullet notes that there should be no impact on three of the four strengths representing 25% of the market, 25mg, 50mg and 300mg. This is because they are supplied in very low quantities outside the UK and are not sold in Greece or Spain, two of the big sources of parallel trade, so parallel imports of those strengths were likely to be low.

That is explained for your note in the first Decision at {XA2/1/258} at paragraph 4.432.

As the first bullet notes, these alone could be worth £15 million to the parties. The second bullet then assesses the position for 100mg capsules where there is the greatest risk of PI, and about this they

are equally sanguine. Even if 50% of sales of 100mg were lost to parallel imports, the upside would still be over 20 million, and in fact as the Tribunal may have seen from the requested volume figures provided in advance of the hearing, the loss of sales was in fact materially less than 50% on the available figures.

As the Tribunal found in the first judgment, the impact of the parallel trade on the parties' market power was not significant.

If we could briefly turn up the first judgment {XN1/2/80}, and consider paragraph 248:

"As to pressure from parallel imports, we note that the CMA did not regard this as significant, mainly because of uncertainties of supply. This was not disputed. We also note that Mr Poulton referred to Pfizer's efforts to limit supply in other EU countries to the needs of the local market and that Mr Walters referred at the hearing, in response to a question from the Tribunal, to Flynn's concern to protect its trade mark rights from use by parallel importers."

Now, if we could go back to the slide deck we were just considering after that brief detour {XG/70/8}, the next slide deals with the other potential issues flagged earlier, patient impact and PPRS.

As regards to patient impact, the assessment was

that this would be minimal, and that is of course on the basis that the products are the same as before, and the packaging would be designed to resemble Epanutin, and the PPRS impact would also be negligible.

In the first sub-bullet, the income for a generic would not be within the PPRS calculation, so it would not affect Pfizer and it would not affect Flynn in terms of their PPRS calculations. There would be some scope to increase price on other products in the branded portfolio as a result of the reduction in sales following removal of the Epanutin brand, and you note there is a reference to approximately £130,000 of price increases for other products being possible.

So this is the portfolio point: if you are losing some allocation of profit on this product, that can be moved across to another product, but there is also some loss and allowances under the PPRS mechanism for marketing and information, and overall they think it is net 76k negative, but set against the very large upside described earlier that was obviously immaterial to their calculations.

So that was the state of the plan as of summer 2010. The interposition of Flynn in the supply chain to protect Pfizer against pharmaco-political damage and an assessment that given continuity of supply constraints,

the scheme would be effective with any loss of volumes to parallel imports more than made up for given the huge upside in profits.

In October 2010, Pfizer requested a more detailed proposal from Flynn to use for its internal approvals process, and the documentation prepared by Flynn is consistent with the earlier slide deck but it helpfully explains some of the points.

If we could go, please, to the frequently asked questions document which was included in that pack which pithily captures the thinking behind the proposal, it is at {XG/79/1}.

You see first question:

"Will there be any impact on patients ..."

And the subpoints explain there will not be, the product formulation will not change, that is the key point at (a).

Second, you see the question:

"This change will mean loss of the brand equity inherent in the 30% of scripts that are written by brand and leave the business open to generic competition."

This was the trade-off, sir, that I think you were adverting to earlier. So you lose a degree of protection insofar as you have got a base of closed scripts that will now be written openly in the absence

of a branded product, and the question is does that need to be set off or does that represent a problem for the proposal? Will it leave the business open to generic competition? The answer shows the specific features of the product which provided shelter from competition. You see at (a) the point in the Tor email earlier:

"There have been no generic competitors to date."

And then crucially at (b):

"... continuity and consistency of [medicine] is encouraged in this therapeutic area [so] prescribers could specify 'phenytoin capsules, Flynn'."

So again, awareness of their market power when considering the viability of the scheme.

Then at 3:

"Pharmaco-political fall-out, damage to reputation?"

And the answer:

"Flynn Pharma carries [the] risk."

So that is why it is in the picture.

Looking down at 6 there is some discussion of parallel imports and two points are made:

"There is currently a level of [parallel imports] which is limited by the availability of stock. No more stock would be available to importers."

So the key point here is that Pfizer controls the pump handle: it supplies in other lower price member

states and it can control how much stock it releases on those markets, and that puts a natural brake on parallel trade, the point that was also acknowledged in the first Tribunal's judgment.

Then at (b):

"Transfer of the Trademark to Flynn would act as a further barrier to imports and sale of stock branded as Epanutin."

So trademark objections could also be used to limit parallel imports, and again, this was also a point identified by the Tribunal in the same paragraph.

THE PRESIDENT: Just moving up to a point at 2 where there is reference to the scripts being written, is the move from branded to generic irrespective of how things are, as it were, packaged significant in that if you are a generic a doctor simply cannot write a closed prescription because when they draw down their menu in their pharmacopeia you will only get the generic phenytoin capsule or tablet, and there is not an option to say: I want the Pfizer brand. Is that an explanation for the mismatch which puzzled us earlier between the guidance saying: you must make sure that you stick to the same manufacturer, and the fact that most prescriptions are open, not closed?

MR HOLMES: That may very well be the case. It sounds

plausible to me, sir, but it is not something on which I have any knowledge myself. Certainly once Epanutin is withdrawn from the market there would be no scope to prescribe that product because it would no longer appear in the BNF, and equally it might not be in the electronic drawdown menus of GPs. I am seeing nods behind me, but obviously if there is any clarification I will make it later.

Question 7:

"How would the reimbursement price of generic phenytoin be set?"

The answer is:

"Phenytoin capsules are currently included in Category M of the drug tariff with reimbursement price set as [the] brand price. With no brand price as reference [to] the new reimbursement price would be based on list prices for the generic."

Now, the reference to category M is in fact incorrect, the relevant category was category C. But the underlying point is valid. Category C applies to drugs which are not readily available as a generic from multiple sources, and for that, prices are determined based on list prices, and that is the anomaly of the drug tariff referred to in earlier email discussions within Pfizer which created the attractive commercial

opportunity which the parties then proceeded to exploit.

In December 2010, the matter was put before Pfizer's UK management forum for approval, and the outline of the arrangement is confirmed in Flynn's board minutes of 15 December 2010 at {XG/84/3}. If you look at "Pfizer" in the middle of the page:

"The planned meeting of 6th December of the Pfizer UK leadership group was postponed until 20th December. They had raised a small number of questions which have been addressed. If our proposal is accepted by Pfizer, the product rights will be acquired by Flynn and a profit sharing agreement will be drawn up. Epanutin capsules & tablets are not interchangeable, so the number of scripts should be maintained when the product is sold generically."

And then:

"Need to get feedback from the meeting."

So again, a clear recognition of the competitive constraints that would allow -- or lack of competitive constraints as a result of lack of interchangeability which would protect the position after the price reduction.

At the 20 December meeting, Pfizer's UK management forum approved the proposal in principle. The parties then began to draw up commercial agreements in the first

half of 2011, and the documents show that the reason for involving Flynn in the arrangement was to shield Pfizer from reputational risk, so for a clear illustration of this, if we could go to an internal Pfizer email dated 17 June 2011 which is document {XG/97}.

The email is from one Pfizer employee to two others at Pfizer, Steve Poulton and Jason Perfitt, and it reports a conversation with David Walters at Flynn.

One of the questions which had clearly come up in the course of the conversation is recorded in the third paragraph:

"Why not do it ourselves?"

Sorry, it is at the top of the page, regarding the question of why not do it ourselves. That is to say why did Pfizer need Flynn at all? Why not simply debrand it and sell it as a Pfizer generic product, and at 1 the answer is that Pfizer could do it, there are not any PPRS issues, but at 2, the reason:

"It's ALL about reputation.

"He [that is Dave Walters] suggests [googling the] Daily Mail [coverage of the] Hydrocortisone [price increase]..."

Our old friend hydrocortisone, which you, sir, will recall from our trial at this time last year. You see the reference in the URL:

"Drug firms accused of profiteering raising prices one thousand per cent.

"He says would Pfizer execs want the Daily Mail camped on their doorstep."

And of course, the Tribunal will have well in mind that a 1,000% increase is quite a modest one by comparison with the 24 times increase in this case.

At (b):

"... would Pfizer ..."

We have got that.

By the end of 2011 the parties had reached agreement, that was enshrined in contracts signed over the first half of 2012, the £1 asset sales agreement, an exclusive supply agreement specifying supply prize and minimum order volumes, subject to annual review, and a quality technical agreement setting out the parties' respective responsibilities for quality assurance.

So Pfizer's marketing authorisations terminated on 23 September, and on 24 September 2012, Flynn launched its product under the name "Phenytoin sodium Flynn hard capsules."

In the run-up to launch, Flynn met with the Department of Health on 18 July to discuss its plans for the capsules product, and the DH's note of the meeting is at {XG/155}.

You see at point 1 that:

"The meeting was arranged to ascertain the company's reasoning and intentions for changes to Epanutin ..."

At 2:

"The company confirmed that they have been in discussion with Pfizer to acquire [the product] with a view to genericising [it]."

And:

"Pfizer had agreed to continue manufacturing ..."

Then at 5 the notes records a discussion about price:

"The company advised that ... it would not be economically viable for Flynn to continue selling Epanutin capsules as a brand without an uplift in price."

Pausing there, given the supply price which was agreed with Pfizer, that is really a statement of the obvious.

"That said, they felt the company had two options ... they could genericise the product or alternatively, if they were awarded an increase on the current price of Epanutin ... they could create their own brand eg EpaFlynn."

At 7, the Department of Health:

"... advised the company to submit a product launch

application for the Pricing Committee to review and asked for an indication of the prices if the products were genericised or sold as a brand."

So that was on the basis that for Flynn, like Pfizer, was a member of the PPRS and its pricing of a branded product would require to be approved under the PPRS.

Then at the foot of the page at 8, reference is made to tablet pricing and the drug tariff price for tablets, and you can see that the offer is 10% to 20% below the drug tariff if sold generically and 25% to 30% if sold as a branded product.

Over page at 9 {XG/155/2}:

"DH confirmed that when looking at price of new products, some of the factors the Pricing Committee would consider is the effect on the drugs bill and the price of comparable products. Whilst DH acknowledged the need for this product to remain on the market, DH expressed the difficulties in agreeing to a launch price that was significantly higher than Epanutin."

So from the outset of discussions, the Department of Health flagged the difficulties of agreeing a large price increase insofar as it had power to oppose it under the PPRS.

Following the meeting, the pricing committee met and

discussed Flynn's request for a price increase in the EpaFlynn branded product scenario, and the outcome of the discussion was communicated to Flynn on 28 July 2012. The email is at {XG/159/1}.

You see that it is from an individual at the Department of Health to a Flynn representative, and it explains that at the 18 July meeting the Department of Health advised that it would discuss the issues regarding EPMU at the next pricing committee meeting:

"The PC considered [that is the pricing committee] the relevance of the various aspects of the 2009 PPRS in this case."

And in the third paragraph:

"Under the terms of the PPRS rules on the pricing of new products, the PC was unable to agree with your proposal to [de]brand Epanutin and launch the new product at an increased price of approximately 30% below the current Drug Tariff price."

And in view of the discussion at the meeting that must, I think, be the tablet drug tariff price.

Instead, as set out in paragraph 4, a price increase application would need to be made by reference to the profit caps under the PPRS. Flynn could choose to apply a price increase subject to the overall profitability of its branded NHS business being assessed through its

annual financial return.

There is also a copy of the minutes of the pricing committee at {XG/160}.

You see at that meeting there was a discussion about whether Flynn qualified for any large price increase under the terms of the PPRS, and the pricing committee also engaged in a more general discussion about the cost implications for the NHS of any large price increase, and based on that discussion, including the wider consideration, its decision was that there was no provision for this type of price increase under the PPRS.

So the first exposure of the appellants' planned price increases to the Department of Health did not meet with any positive reaction, and as a result, Flynn decided to proceed with the debranding and generic relaunch at much higher prices outside the control which was provided by the PPRS.

When the prices were announced, the response from NHS stakeholders to both Flynn and Pfizer was unmistakable and immediate.

At {XG/185/1}, you see an internal exchange within Pfizer, and in the lower part of the message you see an email on 28 September later in the same week as Flynn took over and raised prices, so these are the first

rumblings of the reaction, and it is from a Pfizer commercial development manager, and he explains that he was at a London procurement programme today. Epanutin pricing was raised:

"In short, and by way of example, the East of England [Strategic Health Authority] prescribing costs, like for like annual volumes, will increase by £5.6m."

The price increases are then shown by reference to drug tariff prices payable by the NHS, you see the £2.83 to £67.50 for the 100mg, and reference is made to this being a 2,385% increase, and the rep explains:

"The impression from the NHS is that we are linked to this. I stated this was now a Flynn product and not Pfizer and any pricing issues should be referred to them. I assume this is all we can say?"

And the response from the head of customer and channel marketing is "yes", at the top of the page:

"Yes [that is] correct ... all enquiries need to be directed to Flynn. It is worth noting that the price of the Flynn product is 25% less expensive than the ... tablets."

So the NHS procurement teams were indeed addressing their enquiries to Flynn and as an example on 8 October --

THE PRESIDENT: We do not know, presumably, what the NHS

procurement teams were saying, to say, the Department of Health?

MR HOLMES: We know that they contacted the Department of Health and I will show you that in just a moment.

As an example on 8 October 2012, David Walters of Flynn was in correspondence with the clinical lead for finance and governance at the South Devon and Torbay Care Commissioning Groups or CCGs, and CCGs were at the relevant time the body that had to foot the bill for drugs in the NHS, each for their local area, it was the procurement body.

You see in the middle of the page what this CCG lead had to say, if you go down, please -- sorry, no, we are in the wrong document. We need to go to -- sorry, I will come back to that. I will come back to that if I may.

In the response -- could we have {XG/215}, please. This is Flynn receiving reaction, and do you see what he says. This is a Pfizer document. I am so sorry. I cannot do this on the hoof. We will have to come back to it.

If we could go, please, to a letter at {XG/193}. This is a letter from twelve care commissioning groups only two weeks after the price rise, the Greater Manchester Medicines Management Group, and they wrote to

object in the strongest of terms to the Secretary of State and senior Department of Health officials, copying Flynn and Pfizer, and you see at page {XG/193/1} the subject line:

"Abuse of Monopoly."

In the fourth line in the first paragraph you see that the price change is described as:

"... a clear case of abuse of a virtual monopoly position for purely commercial gains. This change, if unchallenged, will cause the NHS to pay an unnecessary and unwarranted, additional £41 million for no clinical benefit and potential harm if supplies are disrupted [and] confused."

Turning to page {XG/193/2} the change is summarised, and in the third paragraph the letter explains that:

"Personal communication with ... [Flynn] David Fakes ... has confirmed that the capsules will continue to be manufactured by Pfizer in exactly the same way as they always have been, from the same factory as all other Pfizer worldwide supply. This is due to legitimate concerns of ... bioavailability in the predominant epilepsy indication. The only pharmaceutical element which is changing is the product name ... the Epanutin brand will continue to be marketed internationally by Pfizer, except in the UK."

Further down the page there is a summary of the impact on the NHS drug tariff and you see at the foot of the page:

"The NHS nationally will be adversely affected by £36 million per year ... This increase in costs will provide no additional health benefit for patients."

Then turning on to page {XG/193/4}, the summary:

"... the needs of the NHS and patients are not best served by this cynical increase in costs, as the product cannot be switched to an alternative, equivalent formulation for the majority of indications.

"This is an abuse of a monopoly supply position and the DH should mandate that the price being paid ... should remain [the same] ... the only credible alternative is that the companies must make a case for a modest price increase, but this must stand up to economical and clinical justification.

"The NHS must make a stand that this unethical, anti-competitive behaviour at the expense of patient care will not be tolerated."

On the final page, you see Flynn and Pfizer are at the top of the copy list, Flynn Pharma, David Fakes and Richard Blackburn of Pfizer UK. {XG/193/5}

Just going back to the Flynn email, the early reaction, it is at {XG/191}, you see in the middle of

the page an email to David Walters from a GP who is the clinical lead for finance and governance at South Devon and Torbay CCG and he says:

"A staggering increase, not just sizeable, of 2000% plus!

"An increase of £102k to Torbay alone. Some £50m nationally. Very difficult to understand.

"Patients and practitioners have very little option to change.

"Perhaps you could expand on your explanation as I find it unacceptable."

Then at the top of the page the response, David Walters understands:

"... and fully [respects] your views. All I can add is that the pricing was discussed openly with the Department of Health prior to the change."

So these are just a small number of the responses that one finds in the file. There are many other examples of trenchant complaints from up and down the country to Pfizer and to Flynn, and I could show you many more, but I do not think it is a useful expenditure of time now. They are set out --

THE PRESIDENT: What do we get out of this?

MR HOLMES: Well, I think they show first of all an awareness on the part of the clinicians of the lack of

alternative, the lack of options, so they confirm the extent to which market power prevented any means of avoiding this price increase by prescribing any alternative product or dispensing any other alternative product. So they confirm the earlier indication in the internal documents that we saw which show the parties' own vivid awareness of that fact. This was a scheme that they could make stick because of this degree of market power, because of the circumstances of this particular product.

You also get from it that the purchasers of this product, the CCGs, they are the ones who actually hand over cash by way of reimbursement, were savage in their reaction. There is no way that they can be described as happy or willing to pay these amounts. They felt that these amounts were being extorted from them as an abuse of monopoly position, and those are matters that should not be ignored when considering exploitative abuse. They are relevant to an assessment of whether the prices are unfair in themselves, and the reaction on the part of purchasers was taken into account by the CMA in that context.

Ms Morrison reminds me it is also relevant generally to economic value and the extent to which there was any sense in which this was viewed as good value on the part

of the purchasers.

To see further reactions, of which there are many, I refer you to annex C in the Decision which continues over 14 pages, and they show what can only be described as the white hot fury of NHS practitioners and procurement bodies at the price increase that was imposed.

The fact that the Department of Health and the NHS was unhappy with the new prices and did not accept them as justified was also made clear at the time. The position was discussed by Flynn at a board meeting on 24 October 2012, and the minutes are at {XG/21/1}. I think it is {XG/212}, please.

If we go to page {XG/212/2}, at the foot of the page you see a discussion of phenytoin, and in the sixth line you see that David Walters advised the board that:

"... customer groups and the DH were unhappy about the pricing of this product."

And the agreed action was to:

"... appoint a PR person or agency to deal with future issues of this nature."

Although capsule was lower than tablet price, follow up discussions with the DH were considered likely. As I anticipated the Department of Health contacted Flynn to seek information about their arrangements with Pfizer

and a note of the call is at {XG/213/1}. It is dated 24 October 2012. The relevant official explains that he spoke with an individual at Flynn about their arrangements with Pfizer, and you can see from the second paragraph that Flynn replied that it could not divulge details of the arrangements with Pfizer as they were bound by confidentiality clauses:

"He [said] ... it was a simple 3rd party manufacturing supply contract with no royalty or one off payments. He also said that he would be happy for the contract details to be released to the Department if Pfizer agreed to this. His only other comment was that he expected other generics to enter the market which would drive down the price. I read from this that it would force Pfizer to lower the selling price to Flynn."

As regards the reference to generic entry, we have seen what the parties themselves thought about the threat of switching given continuity of supply, and turning on to page {XG/213/3} you see that another Department of Health official was similarly sceptical. In the second paragraph:

"We are not so convinced about the potential [for] generic competition -- there is only one other MA for one strength the 100mg and as we all know patients are meant to be established on the same manufacturer's

product."

So now we have seen the parties, the CCGs and the Department all recognising the difficulty with obtaining any competitive discipline on the price, the fact that patients are meant to be established on the same manufacturer's product. For its part, Flynn and its advisers were relaxed as to the threat of any regulatory constraint. If we could go, please, to {XG/218} and pick it up at page {XG/218/2}, you see there is an email of 1 November 2012 from the director of a company, Woodberry Associates Limited, a consultancy which had been engaged to work with Flynn, and the email is sent to Flynn's directors. There is a reference to a "productive" call, then a discussion of the regulatory environment:

"Flynn is not a member of Scheme M so not directly affected by the attached?"

And the attached were the Scheme M rules which for your note are at {XG/59} of the bundle:

"If we had been members then we could have increased price but the starting point would have been the Pfizer brand product price and generally not higher, is that correct?"

And then this:

"The ultimate power of the Secretary of State to

regulate prices seems quite useless here as they cannot force us to sell the product.

"This must be all about negotiation. The NHS needs the product. We want to sell the product but do not have to and we need to make a reasonable profit. Somewhere between these [two] positions will be the final price to be agreed. That price must take into account the price of competitors, eg the generic tablets of Teva.

"The publicity adds heat to the situation and is uncomfortable but does not deal with the real issues.

"Have I got hold of the 'right end of the stick'?"

And turning on to page {XG/218/1} David Walters of Flynn replies:

"I am not sure whether or not the brand price would have come into it had we been members ..."

Pausing there, he is right about that.

"... but other than that I agree ..."

So agreement on Flynn's side that regulatory intervention was useless in this context.

The negotiation of course was against the backdrop of the parties' market power and the lack of scope to switch patients given the medical guidance. Against that backdrop, Flynn met with the Department of Health on 6 November 2012. Now, there are several notes of

this meeting, one by the Department of Health and two Flynn drafts, the latter with amendments added by another Flynn attendee at the meeting.

You have seen the Department note. I would quite like to take you to Flynn's amended note of the meeting which is at {XG/226}. This is what Flynn took away from it, and we can largely work from that.

You see the attendees at the top of the page, on Flynn's side David Walters, David Fakes and another, and then the attendees from the Department of Health: Susan Grieve, Isabelle Izard and Richard Mattison, and David Walters indicated that he:

"... wanted to discuss the letter to Jeremy Hunt that had been widely circulated in DH circles and copied to us and ... refuted the assertion [that appears to be an amendment] that Flynn has a monopolistic position as suggested in the letter and also to provide an update on the issues around continuity of supply."

The DH lead then:

"... advised that the DH had received a lot of representations and Parliamentary Questions had been raised and that [the Department of Health] needed a rationale to justify and explain the increase in cost to the NHS."

David Walters then made a series of points and you

see in the second bullet reference to previous discussions with the DH proposing a PPRS price increase, and in the fourth bullet, you see the point that Flynn benchmarked its price against the phenytoin sodium tablet price. About this you see that a Department of Health attendee, II:

"... commented that the much larger market share of the capsules made the total cost very difficult for them, more visible and hitting hard NHS pockets. The DH were struggling and trying to understand the justification."

So the point here is the economic impact of the price of -- the price increase in capsules is much greater because their volumes are so much larger than for tablets, and the DH were struggling to try and understand the justification.

The penultimate bullet explains that Flynn then followed the genericisation process and in the final bullet Flynn rejects again the suggestion of market abuse in the Greater Manchester letter on the basis that:

"... by definition the market is generic."

Now, that provokes an immediate response from the Department:

"[Susan Grieve] said that there is no direct

competitor to the capsules ..."

Flynn's view is then stated:

"... the tablet was competing as an alternative that could be prescribed and that the other generic products approved could be launched at any time."

Now, on this point, it is helpful to see a little extra detail of the Department's position as to whether the market was competitive. That is at {XG/224/1}, this is the Department of Health note, if we could briefly look at that. It is broadly consistent with the Flynn note but if you look at 7 you see the Department attendees explained why this market was not competitive, consistent with Pfizer's and Flynn's own internal appraisals of the situation and contrary to what Flynn was telling the Department of Health at this meeting:

"DH understood the company's position, but emphasised that without more information, it was unable to consider whether the price increases were justified. In these circumstances, it was likely that it would consider what other options it had available. It noted, for example, that ... there had been a maximum price scheme for generic medicines and action such as this could not be ruled out in this case."

And then this:

"Due to the narrow therapeutic index of the medicine

in question, the Department did not consider that this was a competitive market."

So the continuity of supply point.

"Further, it did not consider comparisons with the tablet relevant, as the products [were] not interchangeable."

That is of course because of the advice to maintain patients on the same formulation and, as the note explains, tablets and capsules are different formulations which may incur different costs and the tablets had significantly less of a market so had less economies of scale:

"Although a price increase might have been justified for Flynn's product, the scale of it was the concern."

And as the note explains -- so the Department clearly rejected Flynn's contention that this product was subject to any effective competitive constraint.

Just flipping back, if we might, to the Flynn note {XG/226}, the Department also explained the limits of regulation in this area, so if we could go, please, to page {XG/226/2} and pick it up in the middle of the page, the DH lead stated:

"SG stated that Scheme M relies on competition, which as there is no direct competition for capsules currently on the market, does not apply to this

product ... capsules ... therefore falls outside PPRS and Scheme M. In SG's view, the product falls between the two schemes (as do others -- not named)."

So this is the gap in regulation.

In the DH official's view -- and the department:

"... do not know [the] cost breakdown and ... currently have no justification of value for money that they need from us. Unless they can understand it, the DH has to go away and see what powers are available to it to do something about it."

Flynn then advised that it could not disclose its cost of goods as this was confidential information.

The Department:

"... confirmed they recognised the need for some increase[s] in [price], but needed to be able to justify the large increase as value for money. [David Walters] advised we might have to discontinue the product if we didn't make sufficient margin. [The DH official] advised that we need to give a breakdown of all our costs or they would have to review what options were available to DH to enforce any powers they had, noting that nothing had been invoked since [Scheme M] was introduced."

So no regulations since Scheme M was introduced.

DW [for Flynn] stated that the main element of our

costs was the cost of the finished [products] ... supplied.

"[Flynn] felt that the discussion with DH PPRS on price at launch was sanctioned by default as it went unchallenged."

But that was clearly rejected:

"SG stated that this could not be the case as PPRS [has] no remit on pricing of generic products and that Scheme M was not a pricing approval. We should not (in SG's view) view, assume that the DH and NHS are happy with the price of ... tablets."

Flynn said that it was dealing with supply issues, but the Department lead returned to prices. She:

"... asked [Flynn] to approach Pfizer for discussion [of] supply pricing and release of the supply prices to us ..."

And Flynn agreed to ask them. In my submission, anyone reading this, Flynn's note, could not be left under any illusion that the Department of Health had agreed to Flynn's pricing or indicated that it regarded the prices as reflecting fair economic value. On the contrary, the Department made clear that it thought the product was not subject to competition, that the main tools of regulation were not effective here, the falling between the two schemes, and that more cost information

was needed by Flynn before any justification of the price rises could be accepted.

There was also specific rejection of tablets as an appropriate benchmark, and an indication that it should not be assumed that the Department and the NHS was happy with tablet prices.

Looking at the end of the note, you see the actions for Flynn down a page {XG/226/3}, these are Flynn's take home from the meeting:

"Approach Pfizer to discuss reactions to and pressures on product pricing and [importantly] to release cost information."

And second to:

"Write [a] letter explaining value for money setting out the various points the DH and NHS might and should consider to justify and understand the higher price."

Now, that second point does not fully capture the information which the DH note records Flynn as having been asked to provide.

If we could go back, please, to {XG/224/2}, and could I ask the Tribunal, please, to review point 8.

(Pause)

THE PRESIDENT: Yes.

MR HOLMES: So the Department was seeking, and Flynn was offering to provide, cost information about the supposed

added value that Flynn was bringing to the table: the one-off cost of the marketing authorisation, third party manufacturing costs, the cost of the API, dual sourcing and buffer stock building costs and bioequivalence and packaging:

"The company emphasised the importance of making supply more resilient to overcome shortages. [That] was why it was investigating dual sourcing and also building reserves of the medicine, both of which involved extra costs."

So that was what Flynn was offering to bring forward by way of justification, and following the meeting there was then an update email on 12 November 2012 at {XG/231/1}. You see at the foot of the page the Flynn representative emailing to say that:

"It was good to meet ..."

And that Flynn was meeting with Pfizer on that day:

"... to discuss supply issues and to request release of cost information."

On 14 November in an internal email chain you see a report of that meeting between the appellants. It is at {XG/234/1}.

If you look at the bottom of the email chain the author notes:

"Flynn Pharma met with the Department of Health last

week and we have had a request from Flynn based on this discussion.

"Flynn made a commitment to ask Pfizer for our costs structure for the production and delivery of phenytoin capsules. When asked, Flynn said that this information is confidential to Pfizer and they have no sight of this. They stated they would ask but expected Pfizer not to comment."

There is no note of that in the meeting notes, but in any event, taking its lead from that suggestion you see Pfizer's planned response at the top of the page:

"We therefore need a statement --"

Sorry, could we try {XG/234}, please.

At the bottom of the page:

"We therefore need a statement to Flynn stating that our manufacturing process and cost structure is not appropriate to share as we are a global supplier of phenytoin and the information is commercially sensitive and confidential."

At {XG/235} you see the resulting email acknowledging the request, passing from Pfizer to Flynn, in the way that Flynn suggested they expected, acknowledging the request but refusing to respond to it.

On 16 November 2012, Flynn wrote to the Department to relay the news and to offer its own justification for

the price increase. The letter is at {XG/238}. You see in the first paragraph the reference to Flynn having undertaken to come back to the Department to:

"... provide a level of detail and explanation of what we acknowledge is a significant price increase."

There is then a discussion of the divestment rationale, and over page {XG/238/2}, "Cost of Goods" Flynn relays Pfizer's refusal to engage.

In this letter, there is also no concrete information provided about Flynn's costs. At page {XG/238/5} there is a discussion of securing supply chain resilience, but again, no specific indication of costs incurred, and on the final page in the penultimate paragraph a statement that:

"Flynn (and Pfizer) are fully aware of Department and stakeholder concerns in regard to the supply and pricing of this product in the UK ... Flynn ... has to ensure commercial viability and return is important, but we recognise also the legitimate concerns as to (NHS) cost and continue to discuss supply pricing with Pfizer.

"We welcome further discussions with the Department on these matters."

So a suggestion that Flynn and Pfizer were continuing to discuss supply pricing, but no further details of that were provided, and a failure to provide

any cost information in response to the clear request from the Department.

On 10 January 2013, Pfizer met with the Department and one of the topics discussed was phenytoin capsules. The note is the at {XG/249}.

On the second page {XG/249/2}, you see at paragraph --

THE PRESIDENT: Can you say who is at the meeting?

MR HOLMES: Oh, of course, yes, sorry, sir. The meeting, it consists of, from the Pfizer company, Ian Franklin, Caroline Hiseman, Jacqui Mount and Sion Evans and from the Department of Health, Mat Otton-Goulder, Richard Mattison, Jamila Rogers-Wright.

On the second page, you see at paragraph 12 {XG/249/2} that the Department sought comments from the company in respect of the increased expenditure to the NHS:

"The company stated that the product was sold to Flynn ... as it was no longer economically viable to keep it on. No further information was given at the time of the meeting. However, the company undertook to look into the Department's concerns and revert in due course."

Now, Pfizer never provided any substantive information in relation to its costs subsequent to that

meeting, and given the lack of easy regulatory solutions available, acknowledged by the Department at its meeting with Flynn, the Department instead pursued a complaint to the CMA and a formal investigation was opened in May 2013 which included the question of excessive pricing.

Now, standing back, in my submission what the contemporaneous documents clearly show is that Pfizer and Flynn's arrangement was, as the Tribunal described it in the first judgment, a clear-eyed strategy to increase price and each to gain substantial profit in the process of doing so. It was done in awareness of the limited competitive threat posed to the capsule product, and the purpose of introducing Flynn into the equation was to take the heat of criticism. It was all about preserving Pfizer's reputation.

The nature of the arrangement can be seen from a Flynn document produced in April 2013 which records the history of phenytoin and also assesses the risk of Pfizer terminating its agreements in relation to phenytoin as it had the right to do, and the relevant passage is at {XG/499/4}.

Picking it up in the penultimate paragraph, you see that:

"... no valid reason for Pfizer or Flynn to

terminate the agreements has developed since [launch] ... and, indeed, the reality is that such a future scenario is implausible. Were it to be so, Pfizer would need to return the product under a brand name ... which for the capsules had ceased usage in September 2012, return to the earlier NHS pricing and in effect, publicly acknowledge through its actions, that the original sale was an opaque arrangement to conveniently enhance their returns in the interim period ... The reputational risks, adverse publicity and damage to governmental relations in the UK would render a 'return' untenable. In short, notwithstanding the Pfizer agreements provided for a theoretical return, there is no going back."

Now, as regards the price rise, the documents show that the parties were fully aware of the Department of Health's negative reaction. Flynn knew that the Department was very unhappy with the price rise and was also unhappy with benchmarking against the tablet price, and that was confirmed in the course of oral evidence at the first trial.

If you could go, please, to {XM/15/169} this is Day 4 of the first trial and it records Mr Hoskins KC, the CMA's leading counsel, cross-examining David Walters who, as we saw, attended the November 2012 meeting with

the Department of Health, and you see at line 5 that Mr Hoskins puts a document to Mr Walters. It was a record of a meeting between the OFT and Flynn in 2013 which records that the DH was very unhappy, seeing this as an unacceptably large price increase in the absence of any additional value added to the product.

You will see that the witness is asked:

"That is an accurate reflection of what you believe the DH's state of mind was following the ... 6th November [meeting], isn't it?

"Answer: That's correct. They were focused on the price increase.

"Question: They were very unhappy?

"Answer: With the increase, yeah."

Turning back to page {XM/15/160}, Mr Walters also confirmed the Department's unhappiness with tablets as a benchmark as the documents have shown. So if you start at line 16, the question is:

"Question: The DH, you were aware that they were not happy with using tablets as a benchmark, and you --"

The answer:

"Answer: Well, from that meeting onwards."

That is again the 6 November meeting.

"Question: From that meeting onwards?

"Answer: Yeah."

So there was clearly therefore no acceptance of the price increases. That is shown in the contemporaneous documents, and it is confirmed in the subsequent witness evidence that was before the Tribunal at the first trial.

The parties knew that, and their response was to pull up the drawbridge and to refuse to provide cost information to enable the Department and the NHS to make sense of the new pricing.

So, sir, those are the documents. I have taken some time to show them to you, but we think the factual context is important given the issues about economic value which are in play and the question of the fairness of the pricing.

Subject to any questions from the Tribunal, those are my opening submissions.

THE PRESIDENT: We have no questions at this time, Mr Holmes, thank you very much.

MR HOLMES: I am grateful.

THE PRESIDENT: On that basis, we have a long day on Monday. We are starting I think at 10.00 and finishing at 5.00 which is absolutely fine, but we will rise in that case until 10.00 am. Mr Brealey?

MR BREALEY: May I just make a short point -- two points? Could we just get that document back up on the screen?

Two points.

The main point I just want to flag -- I know the Tribunal will have it -- is that quite a few documents have been referred to by Mr Holmes in opening, and a lot of the documents were put to the witnesses in cross-examination and are dealt with in their witness statements, so I just want to put that in context because, as we went to before, the reference to "fleece", the reference to "supernormal", were all dealt with in the evidence, in the witness statements, and in cross-examination, particularly of Mr Poulton, and so I do not want it to be just kind of left hanging there for the next three or four weeks that we accept everything that has been submitted in opening as to what these documents say.

THE PRESIDENT: You can certainly take it that we are not regarding anything that is said by anybody as uncontentious unless you flag it in red and point a red hand to it. We will regard everything as, generally speaking, contentious unless you say to the contrary.

MR BREALEY: Thank you.

THE PRESIDENT: But of course we will be assisted in due course, probably in closings, with reading to put things in context.

MR BREALEY: Yes, we will deal with a lot of these documents

in our closing, thank you.

THE PRESIDENT: Indeed, and we understand that all sides have difficulties in presenting a complete picture because the volume of documentation is, particularly in this case given it is a second time around, quite heavy.

MR BREALEY: Of course, yes.

THE PRESIDENT: Very good. Well, thank you all very much. We will resume at 10.00 on Monday. Thank you.

(3.13 pm)

(The hearing adjourned until 10.00 am on Monday, 13 November 2023)