IN THE COMPETITION APPEAL TRIBUNAL

Case Nos. 1275/1/12/17
1276/1/12/17

Victoria House,
Bloomsbury Place,
London WC1A 2EB

30th October 2017

Before:

PETER FREEMAN CBE QC (Hon)
(Chairman)
PAUL LOMAS
PROFESSOR MICHAEL WATERSON

(Sitting as a Tribunal in England and Wales)

BETWEEN:

FLYNN PHARMA LTD AND FLYNN PHARMA (HOLDINGS) LTD Appellant

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

- and -

PFIZER INC. AND PFIZER LIMITED Appellant

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

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HEARING – Day 1

A P P E A R AN C E S

Kelyn Bacon QC, Ronit Kreisberger and Tom Pascoe (instructed by Macfarlanes LLP)

Mark Brealey QC, Robert O'Donoghue QC and Tim Johnston (instructed by Clifford Chance LLP)

Mark Hoskins QC. David Bailey, Hugo Leith and Jennifer Macleod (instructed by CMA)

Monday 30th October 2017

(10.32 am)

HOUSEKEEPING

THE CHAIRMAN: Good morning, Mr Brealey. Before you begin, there are one or two matters of detail to address. We've got some housekeeping points to make, and also I think I want to say something about confidentiality.

On confidentiality, we've had a flurry of last-minute submissions requesting various matters be kept out of open court. That's the gist of it. Now we're not making any rulings on confidentiality this morning at this stage but I just want to say a few words.

First of all, our preference in these proceedings is that they should take place in open court. I think everything points in that direction. When it comes to our judgment, assuming we make one, that should contain as few as possible redactions.

Secondly, we accept there are valid confidential justifications. We've been looking at the issue of names of junior civil servants. These can be dealt with in court, I think, by proper and appropriate sensitivity. I don't think counsel has any problem with that and we will deal with that also in the same way.

If there's material, genuine material, if you like,

for which confidentiality is claimed, but which counsel wish to refer to openly, and which may find their way into the judgment eventually, then I propose that we deal with these points as they arise as and when the document or issue is put forward as being relevant.

Now, in that regard in particular, we've had a letter from the Government Legal Department on behalf of the Secretary of State for Health, raising certain issues about confidentiality and I think actually also about the correctness of certain pieces of material. Insofar as these issues concern third-party interests - and this looks like a third-party interest here - I have to say they would have been easier to resolve if the party had been directly represented, but in the absence of the party in question, we will try and deal with the_issues as best we can. If necessary we may have to ask, for example, the Secretary of State for Health to instruct somebody to come along and explain the position because I'm not sure we can necessarily do it adequately by letter. I think that's all I want to say on confidentiality.

On housekeeping, we've had some late additional expert reports filed at the end of last week by the appellants. I understand the CMA does not object to their being admitted and on that basis we propose to

admit them. I have to say, they were fairly late. That's not very good practice and the documents themselves were not last-minute documents, they were documents that had existed for several months. One report dated from June and I presume Mr Goosey will have had his questionnaire available when he conducted his survey. Okay it is fine, we like to admit relevant evidence, but it does put the staff under pressure, and indeed the other parties under pressure, when it's come up at the last minute.

Subject to that, I think we're down to the timetable. You revised the timetable slightly, we're quite happy with that. This week is a normal week, four days starting at 10.30 ending at 4.30, normal breaks, so we'll take a break in the middle of the morning session and in the middle of the afternoon session. Next week we can be flexible, as we've indicated, but I suggest we deal with that as we get nearer to next week.

I should perhaps add, on my left is Mr Paul Lomas, on my right is Professor Waterson. They are new to the Tribunal, they are not new to the world of competition. I hope you will find them an adequate and knowledgeable panel. Thank you.

Thank you, Mr Brealey.

Opening Submissions by MR BREALEY

MR BREALEY: Thank you, sir. I suppose I should formally introduce everybody, although I believe that you do know everybody. I appear on behalf of Pfizer obviously with Mr O'Donoghue and Mr Tim Johnston. Flynn is represented by Ms Kelyn Bacon, Ronit Kreisberger and Tom Pascoe, and the CMA is represented by Mark Hoskins, right at the end, David Bailey, Hugo Leith and Jennifer Macleod. That is the cast of people who have put their names to the skeletons, I guess.

I have various issues that I wish to address today, but before I do so, I would like to put this case and this appeal in context.

The publicity put out by the CMA in this case refers to a price increase. Indeed, the head of the CMA's investigation team went on record publicly stating that the price increase had cost the NHS and the taxpayer tens of millions of pounds, and that the CMA had imposed the highest ever fine to prevent "the exploitation of the NHS and the taxpayer."

That was the publicity that was put out, shortly after the decision. In my submission, when the Tribunal comes to look at the evidence in this case, in my submission, by these statements, the CMA has lost the requisite degree of objectivity. In fact - and I don't

say this lightly - the decision should be regarded as rather political. The CMA is quite obviously regulating a price for the pharmaceutical drug on behalf of the NHS.

If the adjective "political" seems a little emotive, there is some justification. It is actually quite extraordinary for the competition authority, which is supposed to be impartial, to visit the Government's offices to gather information and ask questions of them. It is as if the CMA was called in by the Government. Yet that is exactly what happened, for example, on 31st October 2013 when the CMA visited the Department of Health at the Department of Health's offices and the CMA's team leader is even on record as thanking the Department of Health for hosting the meeting.

The competition authority should not get too close to anyone, and that includes the Government, and we shall see in this case, certainly our submission is, the CMA has got far too close to the Department of Health. This fireside chat in October 2013 is not a minor point, it is a serious point, because it is consistent with the mood music in the decision, the way that the evidence has been distorted, and the way that the CMA dismisses as irrelevant what is quite clearly relevant.

There are clearly cost pressures on the NHS, no

purchaser desires a price increase, and the NHS can be no exception. But the law, article 102, is not concerned with a price increase. The law is concerned with the price, and whether the price is unfair. An important consideration to determine whether the Pfizer price was unfair is to see what the Department of Health pays for other epilepsy drugs, which we call AEDs.

The CMA has offered no positive evidence on comparable AEDs, because it says that it is under no obligation to consider them. We say that that does not accord with common sense, let alone the law, the legal principles.

What I want to do at the outset, before I move on, is look at some of the evidence on comparables. I think it is important to put this case in context. I have my cabinet here of the relevant products, and I would like to emphasise to the Tribunal the sort of prices that the Department of Health, the NHS, is paying for these products, comparables.

This is in Mr Ridyard's expert report, but I'd like to take the Tribunal to some of these. The first one is of topiramate. Topiramate is sold in significant volumes both as a generic and as a brand. So topiramate is T-O-P-I-R-A-M-A-T-E. That's for the record. Topiramate is sold in significant volumes, both as

a generic and as a brand so it's off patent, just like Phenytoin. This pack here is Topamax, that's the branded version. Topamirate, Topomax, is used as a third line adjunctive treatment and like Phenytoin, treats generalised and focal epilepsies, so as the Tribunal will probably have picked up, generalised epilepsy is where the seizure occurs in both parts of the brain, focal is where it occurs in one part and spreads. So it treats both generalised and focal.

I come to the cost. For Topamirate, the generic cost was £291. This is for six months' treatment. So the benchmark is six months' treatment in 2012. These are the figures I'm going to give. Six months, 2012. So for Topamirate, a generic cost, six months, is 291 and the branded, Topamax, is 667.

This compares to the Pfizer price, the Pfizer price, of £268, the Flynn £389. I'm concentrating at the moment on the Pfizer price, but the Flynn price was £389. I just add by way of an aside, remember that the Flynn tablet, the Pfizer tablet does have the name Epanutin on the capsule. So it is a semi-brand.

But to recap, the cost of the generic Topamirate is £291, the cost of the branded product, Topamax, is £667, and this can be compared to the Pfizer price of £268. So it can be seen therefore that in no sense can the Pfizer

price be regarded as unfair when compared to Topamirate and Topamax, it is less.

I come next to another product, another AED, to treat epilepsy. This is Levetiracetam.

Now Levetiracetam is sold again in significant quantities. It's used as an adjunctive second-line treatment, there is no patent protection, so the branded version is Keppra which we have here. Used like Phenytoin to treat generalised and focal epilepsies. For Levetiracetam, the generic cost for six months in 2012 was £232. The branded version here, £471. So generic, 232, branded Keppra, 471.

Again, that compares to the Pfizer price of 268. So the Pfizer price is a little bit more than generic, but less than the widely prescribed Keppra.

Again, the Pfizer price can in no sense be compared as an outlier or unfair compared with this AED.

I move onto another one, I won't go through them all, this is just in opening.

THE CHAIRMAN: I was going to ask how many you were going to go through.

MR BREALEY: Two more. I think it is important to put it in context, we are told in the defence they start off with the price increase in the decision, the price increase is always the price increase. We have got to

look at the price. Now, there is a big issue between us, the CMA and Pfizer, as to whether it is right to look at comparables. If comparables are irrelevant, then what I'm saying is irrelevant. If comparables are relevant, then it becomes quite important to know what the comparables are, and I've got two more.

I will be quick because I've got a lot to do today. The next one is oxcarbazepine. It's O-X-C-A-R-B-A-Z-E-P-I-N-E.

Again, oxcarbazepine is sold in significant quantities and used more in focal epilepsies, phenytoin is used to treat focal epilepsy, as we know. There is no patent protection and the branded product is Trileptal. That is the Trileptal packet.

The generic 6-month treatment cost in 2012 for the generic was £296. Again, compared to the Pfizer price of £268. So 296 compared to the 268. The branded, this is the branded one, was slightly lower at 249. Again, if this is a comparable product, the Pfizer price can in no sense be regarded as an outlier or unfair when compared to this AED.

I come last to the Phenytoin tablet. As the Tribunal will have picked up, this has exactly the same molecule, exactly the same dosage and it is exactly the same treatment, so it treats exactly the same thing, but

it is sold by Teva in a tablet form, not a capsule. Exactly the same molecule, same dosage, 100 milligrams, exactly the same treatment sold by Teva in a tablet form. You'll have seen from the evidence of Professor Walker that they may be taken together, so the capsule may be taken together with the tablet. A patient may take 100-milligram tablet with a 50mg capsule.

This is an important point. The evidence in this case - and the only evidence in this case - is the price of the Teva tablet was agreed by the Department of Health as being a fair price, and I'm going to come onto this in a few minutes. The Department of Health used the threat of its statutory power to force Teva to lower the price of the tablet. The market saw this, the market knew that the price had fallen to a certain level because of the Department of Health's intervention.

THE CHAIRMAN: I think it is only fair to say that that's probably going to be argued against.

MR BREALEY: It is, it's going to be a big issue, and I'm going to deal with this in opening.

THE CHAIRMAN: That's your proposition?

MR BREALEY: Yes. Well I don't think it's actually denied that the market saw that the price had come down, but we'll see what Mr Hoskins will say in a second.

THE CHAIRMAN: You said the price was agreed.

MR BREALEY: Anyway I'll leave it at the moment. It's an issue.

THE CHAIRMAN: You carry on. I will hear what you say.

MR BREALEY: I will say, in answer, the only evidence that the Tribunal can rely on is the price came down because of the Department of Health's intervention. Now that, is a submission.

Just look at the prices. So Pfizer's price, as the Tribunal probably picked up, was benchmarked at less than half the price of the identical drug in tablet form. Less than half. Again, the Pfizer price in 2012 was 268, for six months' treatment, 268, the tablet price, same molecule, same treatment, £588. You compare 268 to 588. 588 was the value that the Department of Health attached to the phenytoin in tablet form.

Yet the CMA says that the price to the NHS of phenytoin in tablet form is an irrelevant consideration. We say that is nonsensical and the CMA has taken its eye off the legal ball.

In the decision, Pfizer is capped to cost plus 6 per cent. Just have a look at what that means, in practice. Cost plus 6 per cent.

For a 6-month treatment cost, this equates to £31. Thirty-one pounds. Remember, Pfizer is competing with

other pharmaceutical companies here. Novartis manufactures one of these, I think. Novartis manufactures Trileptal, clearly Pfizer is in competition with Novartis. Pfizer is limited to cost plus 6 per cent. That equates to a 6-month treatment of £31. Again, compare the £31 to the phenytoin tablet price of 588, oxcarbazepine, 296, Keppra, 471, Topamax, 667. Thirty-one pounds compared to those prices. Anything over £31 is considered abusive.

The CMA, in its £31 cap, refuses to ascribe any value for R&D, for the millions spent on drugs that never come to the market. It refuses to ascribe any value to the benefits that phenytoin has for patients, notwithstanding that it describes phenytoin as an essential treatment, and as we've just seen, the CMA refuses to ascribe any value to phenytoin by reference to the value that the Department of Health clearly attaches to other similar AEDs.

This is not competition law, it is price regulation, pure and simple, and the Court of Appeal has given a serious warning about using competition law as a substitute for price regulation. We shall see - and this is an issue between the parties, and I will ask the Tribunal to rule on it - the Department of Health had the power to regulate the price of phenytoin and

declined to do so. It had the power to regulate the price of phenytoin and declined to do so. It simply passed the buck to the CMA. And if the Department of Health wanted to save the NHS tens of millions of pounds it had the power, but it chose not to exercise it.

I wanted to open that case because it is, in our submission, highly relevant to consider the comparables and whether the price is unfair. And the CMA constantly drips the prejudice by referring to the price increase, coming out of the statutory price regulation of the PPRS, and does not focus sufficiently on the price.

With that introduction, the tribunal has a mountain of written submissions. What I'd like to do is address the tribunal on certain discrete issues, and I'll set them out and then hopefully you can proceed.

The first is, I would like to emphasise to the tribunal the cases on the nature and quality of the evidence relied on by the CMA. One has to remember that this is an infringement decision, and a record fine has been imposed, and the findings of fact will be binding in any subsequent civil proceedings. So it is very important to work out how the CMA has proved its case, the quality and the nature of the evidence. That's the first thing.

The second thing I'd like to do is explore with the

tribunal the Department of Health's statutory powers to regulate the price of a generic drug because we say it clearly did have the statutory power.

The third point I'd like to emphasise today is how Pfizer benchmarked the capsule price by reference to the tablet price, because when one reads the decision, those key facts get lost.

The fourth point I would like to do is explore the law on unfair pricing. Clearly I haven't got have time to go through the whole of the law on unfair pricing, but I will go to the key decisions, but I want to concentrate on the CMA's position that it is under no legal obligation to consider comparators. So when I come to the law on unfair pricing, that is what I want to emphasise. I want to explore the CMA's position that it can wilfully shut its eyes to any comparator.

The last point I want to deal with, it will be late in the afternoon, and it is quite turgid but it's got to be done, I want to look at the flimsy and inconsistent evidence in the section 26 statements given by the pharmacies. That is the continuity of supply which is a big part of the CMA's case.

So I want to look first on the nature of the evidence, then statutory powers, then how Pfizer benchmarked, law and unfair pricing comparators, and

then the flimsy evidence on continuity of supply. So it's a lot to get through.

Can I then kick off with the first issue, which is the quality of the evidence relied on.

Now, by way of introduction, we know that the decision relates to a pharmaceutical drug, phenytoin, yet the CMA has not adduced any live medical evidence on the treatment of epilepsy. There is nothing. We have called Professor Walker, who is an expert in epilepsy, and he describes the CMA's blunt dismissal of phenytoin as old, and the CMA calls phenytoin old, and he says that's unfair, and I'm sure Mr Hoskins will ask Professor Walker questions about that. Phenytoin remains a very valuable form of treating patients, particularly those who have not benefited from the first line treatment.

But as I say, the CMA has declined to engage with Professor Walker. Indeed, we are told in the CMA's skeleton that we were not informed of the relevance of Professor Walker's evidence until closing. There is also clearly an issue about how the price of the phenytoin tablet was reduced, to which, sir, you've already referred. But again, the CMA has declined to engage with the evidence of Mr Beighton and continues to rely on snippets of notes of meetings with the

Department of Health.

We've also seen that the continuity of supply principle forms a crucial part of the CMA's case, yet it has not called any pharmacy witness. It relies primarily on section 26 statements. The Tribunal is therefore faced with a situation where there are factual disputes, the CMA has not engaged with witness evidence, and instead relies in the main on notes of interviews and section 26 statements. So it is quite important to kick off today with the law on section 26 notices and notes of interviews, and actually look at the evidential value of these, remembering that this is an appeal on the merits.

As we say in the skeleton, as Pfizer says in the skeleton, clearly section 26 notices are an important investigative tool for the CMA. When the power is exercised to obtain documents, there is no issue because the documents will speak for themselves, you can give what weight you want to. Where the power is used to obtain raw data, for example sales data, again, there should be little issue with it.

But when the power is exercised, as in this case, to obtain testimony as a substitute for witness evidence, extreme caution has to be taken. The statement may be made by a person with no direct knowledge of the

relevant fact, the statement may be based on hearsay upon hearsay, neither the alleged infringer nor the Tribunal is able to test the response in cross-examination.

It is, in my submission, an extremely prejudicial way of seeking to prove an infringement. An extremely prejudicial way of seeking to prove an infringement. What I'd like to do is take the Tribunal to the case of Durkan, Tesco's, the CMA's submission in Paroxetine where again the CMA actually essentially agrees with me and then to the recent case cited for the first time, as I understand it, in the skeleton, the London Metal Exchange which takes the CMA nowhere.

So if we can go first to Durkan, that is authorities bundle A3, tab 20.

I know that the Tribunal will know well the whole -- the bid rigging saga, but this is the case of Durkan and the issue was whether Durkan had given a cover price to a company called Mansell who had made a leniency statement. So the issue was whether the company Durkin had made a cover price to Mansell, who had made a leniency statement. Durkan called a witness called Mr Sharpe. The OFT then interviewed Mr Goodbun from Mansell, but did not call him as a witness, and the issue was whether that was a deficiency or not. We can

pick it up at paragraph 104, page 34, where we see the nature of the issue.

"Mansell also made their employees available to be interviewed by the OFT. On 17th April 2007 two investigators from the OFT interviewed Peter Goodbun in the presence of Mansell's solicitor. Mr Goodbun was the Estimating Manager of the Mansell office which handled the […] tender. The transcript of that interview was one of the principal pieces of evidence relied on by the OFT to establish the involvement of Durkan in Infringement 220."

So this case is -- this bit is about Infringement 220.

"... and we will need to examine what was said in more detail later. The transcript records ..."

So this is a point that the CMA make about section 26A notices.

"... that Mr Goodbun was reminded at the start of the interview that it would be a criminal offence (under section 44 of the 1998 Act) for him to knowingly give false information in the course of the interview."

We can skip paragraphs 105 and 106 because it explains how as a result of the leniency material that there had been a cover price, and that was disputed.

108:

"At the hearing before us, four witnesses from the appellants provided statements and were tendered for cross-examination on the issue. But there was no witness statement provided by the OFT, and therefore no cross-examination to test the OFT's version of events. The evidence before us comprised of a report of a transcript of Mr Goodbun's interview."

The OFT's decision not to lodge witness statements in support of its case caused us some concern, as we made clear at the outset of the hearing in this appeal. The OFT were asking us to uphold a finding of infringement - for which it had imposed a fine of over 3 million - on the basis of a transcript of an interview with a person who was apparently not the person who had written the notes on the key contemporaneous document. Mr Beard argued that the criticism of the OFT's approach to proving its case would be a complete triumph of form over substance. There was no real difference between the transcript we were shown and a witness statement setting out the same facts supported by a statement of truth."

As the Tribunal may remember, this became quite a big issue in the construction bidding case, and what the OFT did was put in a document at the end of the 25 appeals.

But what the Tribunal says here is that really the OFT misses the point. If I pick it up five lines down:

"The significance of the failure to produce a witness statement is twofold. First, Mr Goodbun has not been pressed about any of his answers, his comments in the interview in 2007 appear to have been simply taken at face value throughout the investigation and this appeal. If, once the appeal has been lodged the OFT had gone back to Mr Goodbun to take a witness statement, they may well have filled in many of the gaps that currently exist in the account of what happened."

Just pausing there, when this afternoon we come to look at the section 26 notices, it is startling how, with the greatest respect, the CMA cherry-picks parts of the section 26 notices, doesn't refer to others, but also, there are inconsistencies in the section 26 notices themselves. If those section 26 notices became witness statements by somebody, the gaps could be filled in.

It goes on:

"Faced with only the transcript of the interview, we do not know for example whether, Mr Goodbun's evidence was based on what Mr Hart had told him what had happened or whether it is simply inferring from the marks on the documents the same facts as any person familiar with

what went on generally in the industry could infer. We do not know what Mr Goodbun's reaction would have been, had he been told that Mr Sharpe vehemently denied he had been given a cover price."

So that's the first failing. There are gaps.

"The second disadvantage of relying on an interview transcript is Mr Goodbun's evidence has not been tested by cross-examination."

When we come to see the evidence about the Department of Health's reducing the price of the Teva tablet, this becomes quite important.

"The second disadvantage relied on interview transcript is that Mr Goodbun's evidence has not been tested by cross-examination, a process which might also have generated a better understanding of the strength against the case against Durkan."

Then it goes on to reject the OFT's suggestion that it was for the appellant to call the witness.

These are the cautionary notes, the tribunal goes on to find there was no infringement, as the Tribunal probably knows. That's at paragraph 125.

But the evidence of the note of the transcript was flimsy because it simply can't be tested in cross-examination, and it's not a substitute for a witness statement which fills in the holes.

Can I now go onto the Tesco case, because the bid rigging construction was a kind of watershed in the way that the Tribunal has to look at the authority's decisions. In the old days, as you probably remember, the OFT would adopt a decision, no witnesses, and you would basically almost have to take as read what the CMA OFT said. Then we had the 1998 act to appeal on the merits, OFT has to prove its case, not just say that it was right, it has to prove its case in this forum.

Then we had the bid rigging construction appeals where clearly a different philosophy, a rigour, a different rigour is attached to the nature of the evidence that the CMA has to adduce in order to fine somebody. But again, I've said already, findings of fact in an authority's decision, as we know, is conclusive, and one has to kind of think about what is the sort of evidence that you would have to have in a civil trial.

Can I go on to the Tesco's case, it is the same bundle A3, tab 25. This is Lord Carlile. Again, as the Tribunal will know, this concerned the exchange of the supermarkets' confidential future prices for milk. We can pick it up at paragraph 137. Now I refer to this case because the law on the quality of the evidence should be agreed. What I'm saying is not particularly

controversial, because the OFT/CMA also relies on the law when an appellant does not call a particular witness. And we see this is what has happened here. Paragraph 137, again this is about the exchange of confidential price information, under the heading "Reliance of notes on interview":

"The OFT in the decision and Tesco in its notice of appeal relied on notes and/or transcripts of interviews, together with the notes of interview that had been conducted with individuals who were employed by one or other of the companies under investigation at the time of the infringement."

Go on to 138:

"By the time of this appeal, the OFT [this is the OFT, the authority] submitted in the light of the tribunal's judgments in Construction Bid-rigging appeals, the tribunal should place no substantial weight upon these notes of interviews."

So this is the CMA/OFT submitting that the tribunal should place no substantial weight on these notes of interviews. Why? This was because the individuals in question were not being called to give evidence before this tribunal, and therefore their evidence would not be tested by cross-examination.

"Further the OFT contended that its case did not

depend upon these notes of interviews. Tesco's went further however and submitted the OFT could not rely on the notes of interview at all".

So each party is saying they can't rely on the notes of interviews, but that the appellant is saying that it can.

Paragraph 139:

"We share the doubts of other tribunal panels as to whether material contained in a note of an interview, (especially one conducted by lawyers, acting for an admitting party rather than by the OFT) - even if reviewed and confirmed by the individual concerned - can constitute a proper means of evidencing alleged infringements in a case of this kind. See for example Willis at page 67."

And Willis, for the Tribunal's note, is at tab 23. Just to flag it, tab 23, page 28, where this time it is paragraph 66 of the OFT's evidence. So again, similar, this is back at 139:

"We agree with the OFT therefore, that the tribunal should place no substantial weight upon the notes of interviews, some of which were not in any event contemporaneous."

This is important also for the section 26 notices because there is an issue about what effect the 2003

guidelines had, and when one reads these section 26 statements, very often one doesn't have a clue what period the pharmacy is talking about.

So we agree with the OFT, therefore, that the Tribunal should place no substantial weight upon the notes of interview, some of which were not in any event contemporaneous.

"We note that the OFT's position that its case does not depend upon these transcripts/notes and would observe that, to the extent that Tesco considered one or more of the interviewees to have made statements pertinent to the disposal of this appeal, it was open to Tesco to seek to call that individual as a witness. Our approach to the various notes of interview, whichever party sought to rely on them, has been a cautious one, and we have looked for corroboration, whether from contemporaneous documents, surrounding circumstances or witnesses who did give evidence before us, wherever possible."

So you can take them into account, but no substantial weight should be placed on them, and the Tribunal should be looking at corroboration in other documents.

I said I would go to the Paroxetine case. I don't know whether it is in the bundle, but I will give the

Tribunal a reference to it. It is just again another summary of the CMA referring to Durkan and Tesco in support of a submission that the appellants could not rely on evidence that was not adduced in court before the Tribunal. I am not sure whether it is in the authorities bundle, but I will give the Tribunal a note. Again, it is the CMA making very similar submissions to what was made in Tesco. But it is the up to date version.

THE CHAIRMAN: Can I just be clear, Mr Brealey, we're talking about notes of interviews?

MR BREALEY: Mm-hm.

THE CHAIRMAN: You're extending the point to cover responses to section 26 statements?

MR BREALEY: I am indeed, yes.

THE CHAIRMAN: Are you going to come onto that, or are you just going to ask us to take that as read?

MR BREALEY: I'm going to come onto it when I come onto the pharmacy statements.

THE CHAIRMAN: What you're saying at the moment is that essentially we should look at the section 26 responses in the same way as the Tribunal has looked at notes of interviews, even where those notes of interviews are taking place under a caution about a criminal offence being committed?

MR BREALEY: Correct.

THE CHAIRMAN: That's your point?

MR BREALEY: Correct. The question is well why? Well the first is that the person who gives a section 26 statement doesn't come to the Tribunal or to court, and put themselves forward for cross-examination.

The second point is that the person who's giving the section 26 notice, we shall see this afternoon, is very often a junior lawyer. So the company may be under some sort of penalty if it gives misleading information, but the person who has sent the statement to the CMA is not necessarily testifying personally to the truth, and when we come to it, it's based upon hearsay upon hearsay, upon what my understanding is, what my expectation would be. Does that matter? Well yes it does because when it comes to the continuity of supply and the issue of switching, the CMA is putting continuity of supply as a fact. It is stating as a fact that because of this principle of continuity of supply, there would be no switching between NRIM and Flynn. And what is it based on? It's based upon hearsay upon hearsay in a section 26 notice.

I'll come on to the London Metal Exchange case now. In our skeleton, we make these points in the skeleton about the section 26 notice. The London Metal Exchange

is at A2. The CMA say: well, a section 26 notice is like a witness statement. So A2, tab 10. Again, I don't know if the Tribunal remembers this, but this was, I think, the first time that the OFT had made a kind of an interim order, it made the interim order. So this is A2, tab 10, the London Metal Exchange.

THE CHAIRMAN: We can assume Mr Hoskins will remember it well.

MR HOSKINS: I wish that were true.

MR BREALEY: I think he must have remembered it because it was in his skeleton, and I should also say he should --

THE CHAIRMAN: That's the reason, is it?

MR BREALEY: That's probably a bad reason.

He should also remember, because he was in Durkan making the submission, as I seem to recall.

So this is not just me making it up as I'm going along.

THE CHAIRMAN: I'm very glad to hear it.

MR BREALEY: I'm just emphasising that this is accepted, both by the CMA and by the appellants, the Tribunal is very cautious about looking at what people say in documents and they don't come and justify it under cross-examination.

The London Metal Exchange, this was the first time OFT had issued interim measures. The OFT then withdrew

it, Mr Hoskins and the LME sought its costs, and the question was then essentially whether there was sufficient evidence in the first place to order the interim measures. It had adopted the interim measures not on any section 26 notices, but then it had gathered more information with section 26 notices and that had made it decide to withdraw the interim measures. So it was a costs application.

If one goes to paragraph 138:

"Section 35 of the Act gives the OFT significant power over undertakings suspected of having infringed the relevant prohibitions. Such power is similar to the High Court to grant an injunction".

Before I ask the Tribunal, what the tribunal does here is say, "Look, a section 26 statement can be analogous to a witness statement". And that can basically support an interim injunction, just as, in the High Court, someone can swear a witness statement and that can form the basis of the court granting an interim injunction. But that is a completely different thing to say: well it is now a witness statement, and I can use it to prove a fact at the final hearing when that witness may be giving hearsay upon hearsay upon hearsay, opinion evidence, et cetera, et cetera.

So this is, in the context of well, if they'd had

a section 26 notice, it would be similar to a witness statement in the support of an injunction.

138, section 35 gives significant powers:

"It is therefore relevant to compare the quality of the evidence on which the OFT relied on in this case ... with the quality of the evidence which the Court requires in order to grant an injunction, particularly on an urgent basis."

So then this is where we get the interim injunction, 139:

"Where a party seeks an interim injunction in the High Court it is incumbent upon it to support the application with evidence in the form of a witness statement which should include a statement of truth, a statement of case, provided it is verified by a statement of truth. The application is verified by a statement of truth. The evidence must set out the facts on which the applicant relies ..." et cetera, we're all familiar with this.

140:

"The obvious justification for the requirement of a statement of truth is that it provides some assurance that the statement is made with an honest belief as to the accuracy of its contents."

So that is what is happening. The obvious

justification for a statement of truth is that it provides some assurance that the statement was made with an honest belief, and the court, even the Tribunal now, can proceed on the basis to grant an interim injunction on the basis of such statement.

141:

"Given that the addressee is expressly put on notice as to the consequences of knowingly or recklessly supplying false or misleading information, a response to a section 26 notice has similar significance to a witness statement supported by a witness statement of truth."

What the tribunal then goes on at 142, 143, is to criticise the OFT for granting essentially an injunction on documents that were not supported by a statement of truth. So had you got a section 26 notice, that would have been backed up by a statement of truth, and we can see why you could have granted the interim injunction and we can see why, therefore, you shouldn't have to pay the LME's costs. But the OFT was criticised for relying on documents which were not supported by a statement of truth.

But that, to say that a section 26 notice is the equivalent of a witness statement, well, we shall see when it actually comes to the pharmacy evidence it's

not, but even if it is, what is it evidence of? It can be evidence to support an interim injunction, but then the Tribunal has to think: well what is it evidence of? Is it actually proving a fact? Is what is said in the section 26 notice an opinion? What they expect to happen, do they have direct knowledge of the fact?

MR LOMAS: Mr Brealey, in the High Court in those circumstances, when the witness statement was admitted at trial and the witness was not available, it's admissible as evidence, it is only a question of weight.

MR BREALEY: Weight, yes, you have to make an application obviously and then very often, as you know, sir, the High Court will give it very little weight. It is just not the case that you pitch up in a trial, particularly when you're going to get -- well you'd only get fined in the High Court, but you don't pitch up at trial with a bundle of witness statements and say, "Well I'm not going to call these people." The judge would just look at you say, "Well what planet are you on?"

THE CHAIRMAN: So you're not disagreeing with the statement in 141 that a section 26 notice has similar significance to a witness statement, but you're saying the witness should have been called?

MR BREALEY: I'm going a little bit further than that, because I think first of all one has to identify the

section 26 notice, the response. Here, you can have a section 26 statement by the company whose interest it is to obtain the interim relief. And so it's focused on that issue.

THE CHAIRMAN: So you're saying this statement has a context?

MR BREALEY: Yes. When we come to the section 26 statements for the continuity of supply, it is removed from this context. It is a third party and a junior lawyer who has done the Round Robin or whatever, has asked people, they've asked people and they've asked people, and so it's not even a section 26 notice by somebody who has direct knowledge of the --

THE CHAIRMAN: So you're saying we should look at what they say and who's saying it and what they --

MR BREALEY: Correct.

THE CHAIRMAN: Okay.

MR BREALEY: Then, after that, one can say well, if that person had come to court, could they be cross-examined? Are they saying inconsistent things in this section 26 notice? Because these section 26 notices are very often inconsistent. You can pick 1 paragraph in support of the CMA's case, you can pick another paragraph in support of Pfizer's case.

So in appropriate circumstances a section 26 notice,

that's what the Tribunal has -- can be analogous to a witness statement, particularly if the company who is seeking the interim measures has signed off on the section 26, but not in all circumstances, and then one would also look at the nature of the evidence in the section 26.

I would also make the point that in the notes of an interview, the OFT was interviewing the person, can actually clarify what that person says. So that's what very often happens in the transcript. You say something, then you clarify it. There is no clarity in the section 26 notices. In some of them, there is just 1 section 26 notice, and that's it. For example, the Co-op. You know there's an issue about, I don't know if I have it, discounts. CMA never went back to the Co-op and asked them about that.

All sorts of things that we shall see this afternoon about the section 26 notice which are really, as a forensic point, difficult.

MR HOSKINS: Before we leave, if you're finished with this case, can you read paragraph 142, the final sentence, because it goes to the weight point that Mr Lomas raised and also goes to the issue of corroboration in relation to the context of the claim.

MR BREALEY: "On the other hand, where the OFT obtains

information in response to section 26 notice it would normally not need to conduct further investigation as ... unless it has other information which ..."

THE CHAIRMAN: I'm not quite sure where that gets you. I think we understand what's being said here.

MR HOSKINS: I'm not trying to make submissions, I'm just trying to save time for when I come back to this.

THE CHAIRMAN: We'll take that as read, Mr Brealey.

MR BREALEY: Thank you.

I'll leave that, but just make a point about the Government legal department letter that we got on Friday evening. This is in the context of what I've just been --

THE CHAIRMAN: I thought you were going to say, that is a note of an interview.

MR BREALEY: Well --

THE CHAIRMAN: We're allowed to mention that, I think, in open court.

MR BREALEY: I don't think this is -- but --

THE CHAIRMAN: You're going to be careful what you read out.

MR BREALEY: Okay. What I would ask, then, if the Tribunal has it to hand --

THE CHAIRMAN: The Tribunal does have it to hand, yes.

MR BREALEY: This is 27th October 2017. It is the second point, and there are issues, I'll just say, there are

issues about whether what is said is formal or informal, whether it is accurate or inaccurate.

THE CHAIRMAN: I like the concept of when you speak freely, you may be wrong. That's something I could take home.

MR BREALEY: So this is what, you know, a defendant to an £84 million-pound fine is faced with: a note of an interview that may be formal or informal, it may be accurate or inaccurate and has no way of testing it.

What is particularly striking - and this is what the tribunal, in Durkan and Tesco have referred to - is that it's one thing to kind of rely on a section 26 notice at the beginning, but once the authority knows that there is an issue, a debate, and the defendant has actually proffered live witness evidence on the issue, and the authority simply stays silent and, strikingly, the Department of Health stays silent, does not engage at all, it is an extremely unsatisfactory state of affairs.

With that, I don't know whether that's convenient point because I'm going to go onto topic 2.

THE CHAIRMAN: I think it would be appropriate to take a ten minutes break now. Thank you very much.

(11.35 am)

(A short break)

(11.45 am)

MR BREALEY: I won't go to it because it -- just for the

Tribunal's note and for the record, I referred to the Paroxetine case, and the relevant citation is Day 17, page 23, line 19, where Mr Turner is putting the boot into poor old Mr Kon who is acting for GUK.

THE CHAIRMAN: I'm sure Mr Turner would never put the boot into anything, Mr Brealey.

MR BREALEY: The CMA there is saying well Mr Kon is not calling the witness, is not there for cross-examination, and he goes through the Durkan and the Tesco case. But we'll put it in the bundle and refer to it in closing.

What I'd like to do now is go to the second issue, which is the Department of Health's price control powers and how the department used them to force a price reduction as regards the tablet. So we'll look at the two things together, actually the powers and how the Department of Health used them to force down the price of the tablet.

The first thing we just need to do is look at the decision. I don't know if you have the decision to hand.

THE CHAIRMAN: We have the decision. We really do.

MR BREALEY: Okay, page 185. Page 185, the Department of Health's discussion with Teva, so it is at the bottom, 478. We see the Department of Health and Teva discuss the Department of Health's concerns about the steady

rise in the price of the tablets, this discussion led to Teva reducing its price.

I'd like the Tribunal to note 479, paragraph 3479. I'm going to come back to that, that is not highlighted as confidential, 480 is. But for present purposes, all I need to do is ask the Tribunal to note the statement, and it is the CMA putting this forward as a statement of fact, the Department of Health told the CMA that it did not actually set Teva's revised price, or negotiate this with Teva. Rather, the Department of Health asked Teva whether there was something, it, Teva, was able to do about the price of the tablets.

The Department of Health has not obviously come forward to support that, but the equally important point is that the reader of this document is being told that, as a fact, the Department of Health did not actually set Teva's revised price, or negotiate this with Teva.

THE CHAIRMAN: I think the fact is that the Department were being asked to accept the fact that the Department told the CMA that.

MR BREALEY: Yes, absolutely. It might be more generous to. But that is the relevant bit in the decision on the factual point. Now I'd like to go, we can put the decision away, but I will come back to that, to bundle H1. Just to flag the point, this is relevant to two key

issues, what I'm going to submit for the next 30 minutes.

The first big issue is whether the tablet price is a reasonable benchmark. The second one is that if the Department of Health does have statutory power to regulate the price of phenytoin, that is relevant to whether Pfizer or Flynn can be dominant, and it is also relevant to any coherent theory of harm where someone who has the power to regulate a price and decides or declines not to, can then complain that the price is excessive.

Or whether the person who is putting forward the price does it in good faith, it benchmarks it by reference to a tablet, thinking that well, if that person is unhappy with it, it can always regulate that price. Under competition law, whether if a purchaser has that legal power, and that legal power carries with it, we would say, some economic power, but has a legal power to regulate my price and decides not to, can you really -- can it really be said that I'm dominant over that person? Is there a coherent theory of harm on abuse there?

This issue goes to those two main points: fair price --

THE CHAIRMAN: Are you saying it goes to dominance?

MR BREALEY: Yes.

THE CHAIRMAN: Or to abuse? It is quite important.
MR BREALEY: Well, both.
THE CHAIRMAN: Both?
MR BREALEY: Abuse because it's relevant to fair price and whether the Pfizer price is excessive, or unfair. So if the Department --
THE CHAIRMAN: And that's through the comparison with the tablets?
MR BREALEY: Yes.
THE CHAIRMAN: Right. The other is essentially a buyer power problem. You're saying you can't be dominant where the purchasing authority could regulate, but decided not to.
MR BREALEY: Correct.
THE CHAIRMAN: Okay.
MR BREALEY: And it is relevant to fines.
I should put on the record - and we said this in our reply - we do challenge the finding of dominance post-November 2013. Just so Mr Hoskins knows that. We do challenge the finding of dominance post-November 2013. One of the reasons we've always done that is we've always said that the Department of Health has the power to regulate the price of phenytoin, and before I go onto the documents, just to flag the point, one of the reasons that the CMA says that there was no such power, is because ...

I'm going to come and deal with this, but the CMA relies on unattributed comments by the Department of Health for this, but it seems that the Department of Health has stated that it has no power to control the price of a generic if the company is part of the PPRS scheme. So if I'm a manufacturer of branded products, I'm in the PPRS, and I then put a generic on the market, somehow the Department of Health loses the power to regulate the price of the generic because I'm part of the PPRS. We shall see that, as a matter of statutory interpretation, that is not correct and we shall see that is not the view the Department of Health took publicly for quite some years.

With that, we've been to the decision. I'd like to make this point on the Department of Health's powers, in three stages. First, I'd like to go to the Department's maximum price scheme. First, I'll go to the maximum price scheme. Then I shall go to scheme M, the second thing I shall do is go to scheme M. Lastly and thirdly, I'll look at the evidence of the meeting between the Department of Health and Teva. So I'm going to look at the maximum price scheme, then scheme M, and then the meeting between the department and Teva.

The first point, the maximum price scheme, we need to go to essentially the National Health Acts. For

this, we need to go to, as I say, H1, tab 2. If you could have open, when you have tab 2, tab 18 open, not for very long, but I just want to show the Tribunal that the acts are similar in terms.

THE CHAIRMAN: This is all old law.

MR BREALEY: The 1999 Act is old law, but was the context in which the Department of Health, we say, regulated Teva. So it is important to look at the old law, but the reason that I am asking the Tribunal to put the finger in tab 18, is that this is the Act that was applicable in 2012 when we say that the Department of Health could have regulated the price of phenytoin.

THE CHAIRMAN: Okay.

MR BREALEY: I know it has been amended, they say it was a loophole, we say, as a matter of statutory interpretation, it was not a loophole, the Department of Health always had the power to regulate the price of phenytoin.

Just to identify the relevant sections, if we look at tab 2, section 33 of the 1999 Health Act powers relating to voluntary schemes. This is the power relating to a voluntary scheme. If we just look at tab 18, that equates to section 261 of the 2006 Act. If we go back to tab 2, section 34, this is an important section, the power to control prices.

The Secretary of State may limit any price which may be charged for the supply of any health service medicine, and then we have - and we'll come on to this again and again - section 34(2):

"The powers conferred by this section are not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary schemes applies."

This is where we start getting to the point that apparently the Department of Health made to the CMA, well if you're a member of the PPRS, I can't regulate the generic under section 34(1) and we see that that has its equivalent in section 262. So tab 18, 262.

THE CHAIRMAN: The PPRS is a voluntary scheme.

MR BREALEY: PPRS is a voluntary scheme, so is scheme M, and we'll come onto those.

We can just go on to section 35, statutory schemes. This is the 1999 Act. A statutory scheme, this is essentially, we're going to come onto in a moment, the maximum price scheme. I'd ask the Tribunal to note section 35, so section 35(1), you can have the statutory scheme limiting the prices. Note section 35(7):

"A statutory scheme may not apply to a manufacturer to whom a voluntary scheme applies."

So again, 35(7) says this statutory scheme will not

apply if the manufacturer is a member of a voluntary scheme, and section 35 has its equivalent in section 263. Lastly, section 36 of the 1999 Act allows the Secretary of State to ask a company to provide any information to the Secretary of State. So this notion that the Secretary of State did not have power to ask for cost data, et cetera, is wrong, section 36 and that has its equivalent in section 264.

I won't go to tab 18 again but I just wanted to highlight that they are the same. That is the 1999 Health Act which is the relevant legal context for when the Department of Health intervenes, and we say in the price of the tablet.

PROFESSOR WATERSON: Can I ask, these refer to a manufacturer or supplier, they don't refer to a product. So are we covering the whole of the spectrum here?

MR BREALEY: Yes, well that's essentially what happened, so if we then go to, I think, tab 44, I think we have to go to H2. I want to keep open H1. I think it's tab 44, yes. This is a relevant point. This is the 2017 Act, and this amended section 262, and one sees there:

"If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers confirmed by this section may not be exercised at that time in relation to that

manufacturer as regards that medicine."

So this is what -- I don't know if you've got it, but it's tab 44, the 2017 Act, section 4. You see -- so just to pick up on this point, and the point is said well does it apply to the manufacturer or to the medicine? What the 2017 Act does in that section 4 is make it clear that section 262(2), when it refers to a voluntary scheme, you've got the words "As regards that medicine".

Now, whether or not it needed to be amended is another matter. Because in my submission, the Act, the 2006 Act, and the 1999 Act, would already be interpreted that way. So the amendment was a belt and braces point. It did not actually alter the correct interpretation of the 1999 Act or the 2006 Act, because on any rational interpretation of those Acts, it would have applied as regards that medicine, and we'll come on to this point in a moment.

So the point is fairly made, does it apply to manufacturer or product? In 2017, they did amend it to make it clear that it was as regards the product, but in my submission, that was always the case in 1999, and was the case in 2006.

PROFESSOR WATERSON: That's your submission.

MR BREALEY: It's my submission and it's how the Department

of Health interpreted it, as we shall now see.

That is the Act, the 1999 Act. We're in H1, tab 3, what happens is that the Department of Health then have a consultation to set maximum prices for generics. This is tab 3. I won't go through this, but one will see on the first page, for example:

"These proposals are intended to correct the effect of last year's turbulence in the market for generic medicines in order to protect the financial position of the NHS."

So this, we shall see the maximum price scheme, was adopted to protect the financial position of the NHS. Now this was for generics, so it's not brands, it is for generics, and I would like to keep the eye on the ball as regards the medicine or the manufacturer.

Can it be said that the 1999 Act when it refers to the, "The powers do not refer to someone in a voluntary scheme" covers all voluntary schemes or the voluntary scheme as regards the product in question?

So it goes out to consultation, and then if we go to tab 5, again, this is to all interested parties, to all generics. Measures to control the price of generic medicines, and this includes the phenytoin, the phenytoin tablet.

If we go to the second page, this is what the

Department of Health is telling all interested parties in the year 2000, the details of the maximum price scheme:

"The main features of the maximum price scheme will be as follows: who the statutory scheme will apply to, the scheme will prohibit the sale of uncertain unbranded medicines to community pharmacists at more than the maximum price."

Then I'd ask the Tribunal to note paragraph 7:

"The scheme will apply to companies whether or not they are members of the voluntary PPRS. It will not affect current arrangements for determining the prices of branded medicines under the PPRS."

So the Department of Health in 2000 is telling the industry that: "I'm going to regulate the price of generics, and that includes you, even if you, manufacturer, are a member of the PPRS."

THE CHAIRMAN: Because, you would say, that's for other products?

MR BREALEY: Because it's for other products. It just makes absolute -- it's common sense, the notion that you have these wide powers to control prices - and we'll come onto it a little bit more - but the notion that you have these wide powers to control the price of a medicine and it would apply to brands or generics, and the notion

that just because you become a member of a branded scheme, you lose all power to regulate a generic, is a nonsensical interpretation of the powers. And that's not how the Department of Health perceived its own powers in 2000.

When it adopted the regulations in 2000, it imposed a price cap on the tablet, the phenytoin tablet, that was manufactured by Teva, even though Teva was a member of the PPRS. One has to ask the question: well, if it was always the case that they did not have the power to cap the price of the tablet, then it would have been ultra vires as regards Teva. So the Department of Health, if it was here today, would have to accept that what it did in 2000 was ultra vires because it had no power to cap the tablet price because Teva was a member of the PPRS.

But it's not here today, and we really don't know what its story is. But that is, to begin with, why - and I'll come on to scheme M now - but if the interpretation placed on it by the Department of Health to the CMA is true, they could not have done what they did in 2000 and capped the price of the tablet, it would have been ultra vires.

Now I want to come to scheme M because it reinforces the point that you can have a scheme for generics, even

though you are part of the PPRS.

The second point is scheme M. In my respectful submission, the CMA is equally lacking in the decision in transparency about scheme M. We need to go to tab 17 and tab 16. I'll focus on tab 16. What happened, in April 2005, two new voluntary schemes were introduced. These documents are dated June 2005, I think they may have come into being in April 2005. But 2005, two new schemes were introduced. Scheme W, for wholesalers, and scheme M for manufacturers.

Scheme W is a scheme for wholesalers and it's in very similar terms to scheme M, but they are two different schemes. Again, I just make the point, just make the point that we now have two schemes. You have a scheme for a generic manufacturer and you have a scheme for a generic wholesaler, and if it is right that when the Act refers to "I no longer have the power" if you're a member of a scheme, it would mean that if I am a member of scheme W, but I also manufactured generics, a Secretary of State would lose all power over my manufacturing.

THE CHAIRMAN: Scheme W is wholesales?

MR BREALEY: Wholesalers.

THE CHAIRMAN: Can a manufacturer be a member of a wholesaler's scheme?

MR BREALEY: You can join both schemes. It's the same words, but if one looks at tab 17, paragraph 4, you can join both schemes. Again, I make the point that these are voluntary schemes, so you could voluntarily become a member of scheme W - and now I enter all the consensual arrangements about wholesalers - but I also manufacturer generics and I say "Yah-boo" to the Secretary of State, you can't regulate it.

What I want to concentrate on is scheme M, tab 16, because this is the context in which the Department of Health regulated the price of the Teva tablet.

So new long-term arrangements for reimbursement of generic medicines. I'd like to take the Tribunal to the relevant bits of scheme M.

Tab 16, paragraph 2, "Objectives":

"The objectives of the scheme are that it should ..."

Again it gives the objectives, but secure value for money. This the fourth bullet: "Secure value for money for the NHS".

This is a voluntary scheme for generics outside the powers to control the prices. But one of the objectives is to secure value for money for the NHS.

We have membership, and if one goes to paragraph 6:

"Arrangements for membership of each scheme are

covered by voluntary agreements under section 33 of the Health Act 1999."

This is a scheme M. The 2005 scheme is the same as the 2010 scheme, but we see that it is underpinned, it is underpinned by section 33 of the Health Act 1999. This is a voluntary scheme envisaged by section 33.

"All companies supplying generic medicines are able to join the relevant scheme. Those that decide not to shall be subject to a statutory scheme under section 34-38."

What the Department of Health is saying here is that you're a generic manufacturer, "If you become part of my scheme, this scheme, scheme M, I will not have the power to regulate you under section 34".

Paragraph 7:

"Section 34 governed the price that may be charged for NHS medicines and the level of profit. Section 37 allows for financial penalties."

Then:

"These sections shall not apply to members of voluntary schemes."

Again, we would say what the Department of Health is saying here is: "If you're a member of scheme M, we won't regulate the price under section 34."

Eight:

"No manufacturer will be exempt from the statutory scheme if it fails to join the voluntary scheme."

The voluntary scheme. It's not saying that: "I will not regulate you under 34 if you're a member of the PPRS."

That would be ridiculous, because you're no longer securing value for money for the NHS.

THE CHAIRMAN: I mean, these comments are made in the context of companies joining scheme M or scheme W, not joining the PPRS.

MR BREALEY: No, but what --

THE CHAIRMAN: You're saying by extension that means the same thing?

MR BREALEY: It's to everybody. It's to all pharmaceutical companies who happen to manufacturer generics, and will not be controlled under section 34 and want to enter into a consensual relationship with the Secretary of State for generics, but the Secretary of State is saying to these manufacturers: "if you do not become a member of the scheme, we will continue to regulate you under section 34," as indeed the Secretary of State did in the 2000 regulations, capping the price of phenytoin.

The point, if one just goes back to tab 2, to the statutory scheme, and to pick up a point that the professor made, what assists me in my interpretation of:

is it the manufacturer or the product, if one goes back to section 35, right at the bottom of subsection (6):

"This is a statutory scheme:

"The scheme may prohibit any manufacturer increasing any price for the supply of any health service medicine covered by the scheme."

So we get, we already get, in section 35, medicine covered by the scheme, and it makes perfect sense, but paragraph 8, we'll go back to tab 16:

"No manufacturer will be exempt from the statutory scheme if it fails to join the voluntary scheme."

Then, if I could go on, we get compliance, and the companies, the paragraph 12, compliance with the scheme:

"Any company that fails to comply with the scheme or fails to provide information required under the terms of the scheme membership will be required to leave the scheme. That company shall then be subject to the terms of the statutory scheme."

So you're a manufacturer of generics, if you breach, if you don't comply with the scheme, you can be asked to leave and then you'll be subject to section 34 and the Secretary of State will exercise its price control powers.

Then I would like to go to paragraph 21, just to show that under the voluntary scheme, the schemes

allowing freedom of pricing, you're not being regulated. That's just the first line.

Now we come onto a critical part of the scheme M, and this is under the heading, over the page, "Setting the category M drug tariff for generic medicines". So we've got freedom of pricing. What I'd like to emphasise is paragraphs 28, 29 and 30. This is the context in which the Department of Health intervened as regards the Teva tablet price.

So again, there is the power under section 34 to control the price, "you join this scheme, you will have freedom of pricing," but "wherever possible, the department will allow changes in market prices to be influenced by existing market mechanisms. This means that where there is effective competition in respect of any given generic medicine, then the Department will not interfere in the operation of the market for that medicine." So we will not interfere.

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

Under the scheme, so Teva is no longer -- Teva becomes a member of scheme M, it is a member of the PPRS and scheme M, it is no longer subject to the statutory scheme, section 34, because it's become a member of this scheme. However, if the Department identifies a price increase that it does not like:

"It may intervene to ensure that the NHS pays a fair price for the medicine concerned."

THE CHAIRMAN: I'm just getting a little bit confused about the chronology. Just sticking with Teva for the moment, what you're saying is that they were subject to the statutory price scheme which you described.

MR BREALEY: Yes.

THE CHAIRMAN: Which capped the price of Phenytoin.

MR BREALEY: Yes.

THE CHAIRMAN: They're not here to explain, of course, but then they volunteered to join scheme M.

MR BREALEY: Yes.

THE CHAIRMAN: What actually happened they therefore got away from the statutory price scheme.

MR BREALEY: Correct.

THE CHAIRMAN: What happened to the price then?

MR BREALEY: The price actually went up. We shall see that. The price went up.

THE CHAIRMAN: Quite a lot.

MR BREALEY: Quite a lot, yes, to £113 for a pack of 28.
THE CHAIRMAN: So that was existing market mechanisms allowing changes in market prices?
MR BREALEY: I think the CMA and Teva under section 26 notice, it's in the decision, the market mechanism went a bit awry. It kept on --
THE CHAIRMAN: The price went up quite a lot.
MR BREALEY: It did to £113 which is basically 300 for the pack of 84 -- (overspeaking) --
THE CHAIRMAN: At the 2005 prices, presumably. Right. Then you're saying because of this voluntary arrangement, it came down again? I'm not arguing about the detail, it's just that's the sequence of events.
MR BREALEY: It is the sequence of events, it is in paragraph 47 of our skeleton, but you're right, sir that's the sequence of events.

But the important point is - and we'll come onto this in a moment - that the tablet went into scheme M, category M, the price was going up and up and up, and the Department of Health saw it going up and up and up, and intervened, and would have intervened under paragraph 28. Because it can call somebody in, and it refers to "Intervene to ensure that the NHS pays a fair price for the medicine concerned."

I'd also, just in passing, refer to paragraphs 29

and 30, because the Secretary of State in this scheme is telling everybody to allow the consideration of prices and reimbursement, it will look at various costs.

"Analysis of the direct and indirect manufacturing supply costs, profit margins."

And then 30:

"In its examination of the reasonableness of the costs, the company will have such regard to such factors as trends in previous prices reported by the company and other companies for the same product, any special features, any ratios inferred from the company's non-generic business."

So if one looks at the third, there is a clear implication there that the company can have a non-generics business, ie a brand, and a generics business, but it is looking at a wide variety of factors, including comparables, in order to determine fair price.

THE CHAIRMAN: We're going to hear quite a lot about fair prices.

MR BREALEY: Yes.

THE CHAIRMAN: That is the Department of Health's fair price, you are saying.

MR BREALEY: Yes, and that is what the market perceived as a fair price. I'll move on because I don't want to

leave myself short of price.

Paragraphs 33 and 42 refer to entry into the scheme, and exit essentially from the scheme, but the same point is made that "if you're not part of the scheme, we will regulate you under section 34."

So that is the context --

THE CHAIRMAN: Presumably paragraph 42 is relevant as well, is it?

MR BREALEY: I do have that in my note, yes. Yes, the exit from the scheme.

MR LOMAS: Mr Brealey, sorry, just to clarify one point. In relation to paragraph 28, "The Department may intervene to ensure that the NHS pays a fair price."

Are you saying that there are two mechanisms by which it can intervene? It can intervene, if you like, commercially and simply say, "We'd like to have a discussion about this", and if that is not productive, its only stick is to eject them from the scheme and to apply the statutory measure?

MR BREALEY: Mm.

MR LOMAS: Thank you.

MR BREALEY: Yes, that must be the -- you get a phone call, which is what happens, "I don't like the price, it's got to come down." And then you enter a process of dialogue, but the dialogue is always in the context of

"I, the Department of Health, can ask you to bring it down under paragraph 28, because that is the powers that I have under the scheme you signed up to," and, "if you still don't play ball, I will eject you from the scheme and I will regulate you under section 34."

That is scheme M, and that is the actual context, this is 2005, and Teva got the call in 2007.

PROFESSOR WATERSON: Just to be clear, scheme M and category M, what's the relationship between those two? Are all category M products in scheme M and vice versa?

MR BREALEY: I think you can be in category M but not in scheme M, but you can, if you're in scheme M, you have to be in category M.

I think that's right, but I'll double-check. I'm told, we'll come back, but I think if you're in scheme M you would be in category M, because scheme M is dependent on the price being in category M, and being a competitive price. So the category M is essentially the price where the drug tariff price is there because of an element of competition. So that is what category M is all about, and that's why Mr Ridyard, in his expert report, when he refers to the generic AEDs that I referred to this morning, he says are particularly relevant, because these are in category M and are supposed to reflect a competitive price.

But I think you can be subject to category M and not be in scheme M.

THE CHAIRMAN: Better be clear about that before we finish.

MR BREALEY: I'm told by Ms Bacon I'm right, and if she tells me I'm right, I'm right.

THE CHAIRMAN: I might hold you to that Mr Brealey.

MR BREALEY: So that is scheme M.

Now I want to refer to the intervention by the Department of Health, so Mr O'Donoghue has pointed out, it's in our skeleton at paragraph 47, that price did go up, it was £113 in October 2007, but that, remember, is for a pack of 28. We say it was precisely the type of situation that paragraph 28 envisaged, and the nature of the call-in is explained by Mr Beighton. He will give evidence, but I do want to, just for the record, go to bundle B, tab 1, just to see what he says, and Mr Hoskins will obviously ask him questions about this.

It is tab 1, paragraphs 4-8. The tablets fell within category M. This is paragraph 5:

"During 2007, the drug tariff price of the tablets increased. The price increase prompted the DH to intervene. I do not recall the precise dates, but to the best of my recollection, in or around October 2007, Teva was contacted by an official from the Department of Health who requested a meeting with Teva. The meeting

was called because the DH wanted to discuss the pricing of the tablets. I attended that meeting, recall that we were told by the DH, wanted the price of the tablets to be reduced. The DH also told us if Teva did not cooperate, they had the power to bring the price down itself, but would prefer to do it with our cooperation."

The Department of Health has consciously decided not to come to the Tribunal and to dispute this version of events. We'll have to see what Mr Beighton says on oath, but at the moment we have radio silence from the Department of Health.

"It was my understanding that DH had a range of different powers to regulate prices of medicinal products supplied in the UK, including generic products such as the tablets, which it could use to bring down the price, and that is what I understood the DH to be referring to when it said it could use its powers to bring down the price of the tablets.

We identified a reduced price for the tablets, I do not recall the precise price that we tabled to the DH officials, but I do recall they wanted us to implement a phased reduction for the prices of the tablets ultimately to a lower level.

The price reductions were subsequently implemented. It was my understanding from my dealings with the DH at

the time that the DH was satisfied and if it was not happy with the revised prices it could intervene again. The DH did not contact me again in relation to the pricing of the tablets."

We've seen that the price of the tablets is comparable to other AEDs. But that is the evidence that will be before the Tribunal, and we will see what the CMA does with it.

The Department of Health has simply not engaged in this fact-finding process, and it gets worse. So if I go back to the decision, I said I would revisit paragraph 3.479 at page 186. If we have that to hand, but also go to J2, tab 64, that's J2, tab 64, remember I referred to the passage in the decision where, again it is hearsay because the CMA is being told by the Department of Health, but the Department of Health is apparently saying it did not actually set Teva's revised price or negotiate this with Teva. Rather, the DH asked Teva whether there was something Teva was able to do about the price of the tablets.

I'd like to focus on the word "used" because we get a sense from this paragraph that the DH is meekly asking Teva whether there was something that Teva could do about it. So not having the whip hand, but Teva having the whip hand. We will meekly ask "Is there something you

can do about it?"

We say that is flatly contradictory to Mr Beighton's evidence, but it is actually a inaccurate record of what is actually said in the notes of the interview. So if we go to J2, 64, and at page 7, paragraph 31, so this is not confidential, what the notes of the interview actually say is:

"The CMA asked whether it would be fair to say that the DH was happy with the price of £30 per pack."

That's for the 28.

"The DH said it did not have on file any documentary evidence regarding its discussions with Teva about the price of Teva's phenytoin."

So it has no documentary evidence.

"The DH official, we don't know who it is, who had handled discussions with Teva had now retired. However, it was unlikely that there had been a negotiation as such. It was likely that the official in question just asked Teva whether there was something it was able to do about the price of tablets."

Now there is a world of difference between what is stated at paragraph 3.479, "Rather, the DH asked Teva whether there was something Teva was able to do about it", and the speculation that is happening in paragraph 31. We don't know, but we think it was

unlikely there would have been a negotiation.

Whereas in the decision, we're being told "Did not actually set or negotiate."

These are the sort of -- you know, when I said this morning, I'd be very careful how things are put in the decision, and there is a lack of objectivity. I don't say that lightly, but that is not a fair description of what actually the notes of the interview said. Some unknown person is saying, "It is unlikely there would have been a negotiation", not saying as a fact "There was no negotiation."

Just before I move on, I think this is the -- yes --

THE CHAIRMAN: Read 34 as well, presumably.

MR BREALEY: Yes.

THE CHAIRMAN: The word "happy" comes up again.

MR BREALEY: What I would ask the Tribunal to note is paragraph 2 as well, where the CMA is saying to the Department of Health, "You may have to provide a witness statement."

THE CHAIRMAN: I was going to ask you about that. I mean, what reliance are you asking us to place on this note?

MR BREALEY: Well, I --

THE CHAIRMAN: Sorry, what weight are you asking us to --

MR BREALEY: Zero. Absolutely zero. The reason for that is that it is speculation by somebody -- what evidential

value is it, really, that someone can speculate in 2015 as to what happened in 2007?

THE CHAIRMAN: If the Department had intervened, we could ask them.

MR BREALEY: Yes.

THE CHAIRMAN: If the CMA had provided the Department of Health with a witness statement and the ability to cross-examine, you'd be a happy man, Mr Brealey; is that right?

MR BREALEY: Well I'm always happy, but -- happier.

THE CHAIRMAN: I'm using "happy" as a term of art.

MR BREALEY: Yes, I mean clearly there is a factual issue as to whether the Department of Health insisted on there being a fair price, and there is an issue as to how the tablet price came down. As I say, the market saw this coming down, and if the Department of Health had come along and adduced -- and the CMA had a witness, there could have been a much better informed debate as to what went on. But at the moment, you only have the witness statement of Mr Beighton who says that the price came down in the light of the threat of the Department of Health exercising its powers.

Then you have a note of a meeting, which in any event is evidentially pretty flimsy, but the CMA actually misrepresents what the note says, because it

says in the decision there was no negotiation. Actually, what the unnamed department official says 10 years later is that it was unlikely there would be negotiation.

We have never been given a reason why the person who was in this meeting could not be called, the note says they've retired. Well, retired people always give -- there is no reason why retired people cannot give evidence. But it gets even worse. So we can put the -- so remember we've got 479 saying "DH told the CMA that it did not negotiate this with Teva."

Can I put bundle J2 away and pick up bundle G2.

THE CHAIRMAN: Just before we do, while we've got the decision in front of us, is it correct that paragraphs 480 to 483, the statements are all drawn from this meeting note; is that correct?

MR BREALEY: Um --

THE CHAIRMAN: If you look at the footnote reference.

MR BREALEY: Footnote reference, 543 --

THE CHAIRMAN: They seem to be direct quotes.

MR BREALEY: I think that's right, yes.

THE CHAIRMAN: Thank you. Perhaps you can look that up over lunch.

MR BREALEY: G2, this is the last point I'd make on the Department of Health's intervention. This is tab 110.

Remember that the CMA is telling the reader that the Department of Health has told it that there was no negotiation.

THE CHAIRMAN: I see, there's a great black square.

MR BREALEY: I think that's because it is another product. So if we go -- this is from someone called [✂] who is in the -- you see that. He's the head of medicines analysis. [✂]. He crops up quite a lot. He is quite vociferous, as far as I can work out. So the last page, one will see that this is [✂] and you'll see that everyone is on first name terms, so --

THE CHAIRMAN: Yes, that's the way it works these days, Mr Brealey.

MR BREALEY: The way it works these days. But he raises the issue of the phenytoin tablets. And [✂] he says -- that's on the second page -- "Well can you give me the numbers?" We know what the -- if it is cost plus six for capsules, what would it be for tablets?

Then we get [✂]. The bit in black is a product which we don't -- I think there were two products, so this is something we don't need to worry about. Then we've got phenytoin underneath. So here they're doing about what numbers can we crunch in for any potential overcharge for tablets? And he says:

"[✂] - see below for our assessment of the cost impact note, there is an issue with the counterfactual with phenytoin tablets, as you will see ...

"Phenytoin.

"This is a little trickier. It is less clear what we should take as the pre-hike price, as it started at about 20p ... back in 1991 and rose gradually to £1.69 ...then rising fast to £113 ... then falling to £30 over the course of next year (as per negotiation with Teva)."

So we don't know whether it was a kind of the godfather Don Corleone-type "I'll make you an offer you can't refuse" type negotiation. Putting that to one side, the serious point is that what [✂]is telling the CMA is, as per negotiation with Teva, and that is contrary to the impression that is given in the decision at 3479.

THE CHAIRMAN: This paragraph underneath the black rectangle is referring to capsules or tablets?

MR BREALEY: Tablets.

THE CHAIRMAN: Because that's the counterfactual?

MR BREALEY: Yes, so what is obviously going on is that [✂], the Head of Medicines Analysis, is asking the CMA to look into other things, and we've got two products here. We see this from the very last paragraph on page 3:

"I understand there's been some correspondence from DH with OFT on another product ..." Blanked out.

So then [✂] writes back to [✂] and says, "Well about the tablets, what do you -- you know, give me some numbers for the potential overcharge."

And [✂] says, "Well there's actually an issue with the counterfactual." This is the top of the e-mail, 2013, "Because there's an issue with the counterfactual with the phenytoin tablets."

It is trickier, it's less clear, what should it be, and he also refers to it falling to £30 as per negotiation with Teva?

Again, one is looking for some sort of corroboration for the note of the meeting, which is an inaccurate reflection of what was said at the meeting, but what the CMA was told by [✂] is contrary to what is represented there.

I'll make a --

PROFESSOR WATERSON: It may also be useful to note the last paragraph of that first page, where it appears at that stage at least to have been significant substitution.

MR BREALEY: Yes, you're absolutely right. That's consistent with Professor Walker's evidence which is that the tablet -- I mean, clearly you might get a prescription for tablet and capsule, but he says the

two are identical.

If we are right and, in my submission, the evidence is all one way that there was an intervention by the Department of Health to force the price of the tablet down, in the context of a regime which is designed to ensure a fair price, but if we are right on that, it would be startling if the CMA could proceed against Teva and say, "You are guilty of exploitation, you are guilty of an abuse of a dominant position by excessively pricing the price of the tablet."

If we are right that the Department of Health did intervene to force that drop, it would put article 102 on its head if the CMA was to say, "Well, in the face of you being threatened with statutory powers, you nevertheless exploited your dominant position."

And the CMA has not gone after Teva with the tablet price, and if it would be wrong for the CMA to proceed against Teva as regards a tablet price because on no view could it be called abusive, it is then difficult to see why Pfizer should also be guilty of exploitation and an abusive price by benchmarking the capsule to the tablet if the tablet is a valid comparator.

So if Teva is in the room in 2007, comes out, "I've just been forced to reduce the price to £30", the Department of Health are happy with that, that's what

they wanted. Let's assume that's how it goes, and the CMA the next day say, "Well you're still guilty of an abuse of a dominant position", in my submission, it would be a cast iron defence to say, "I'm not abusing my dominant position because I've just been told to bring the price down to £30."

If that is true, it would be a cast iron defence, why should it be if Pfizer was in the room next door and was to price the capsule at £30, or the equivalent price, the very next day --

MR LOMAS: Mr Brealey, can I clarify three very short points?

MR BREALEY: Of course.

MR LOMAS: First of all, is Teva the only supplier of tablets?

MR BREALEY: No, we'll see that other manufacturers have come in at the same price.

MR LOMAS: Secondly, were patients stabilised on Teva tablets in the same way or stabilised on capsules?

MR BREALEY: There's no evidence either way, but I would assume that certain patients are stabilised on capsules and stabilised on tablets, but there's no evidence to that.

MR LOMAS: Thirdly, is there any evidence, because I'm not sure I've seen it, in relation to the cost structure for

the Teva tablets?

MR BREALEY: Marginally, there is, in our notice of appeal, we have said that the price -- just on this, the capsule versus tablet, it is exactly the same molecule so you've got exactly the same 100 milligrams. All that's different is the mode of delivery. So the question I think you're putting to me, sir, is what's the cost of a capsule compared to the cost of a tablet? We, in our notice of appeal - and Mr O'Donoghue is going to tell me where it is - we say that the actual cost of manufacturing a tablet is slightly less than the manufacturing a capsule.

THE CHAIRMAN: That's fairly intuitive, isn't it, given that a capsule is a separate container?

MR BREALEY: Yes.

THE CHAIRMAN: Can I just ask you, while we're on this point, my colleague asked some time ago that, if you like, the carrot was to join scheme M, the stick was statutory price regulation if you didn't. I suppose the question arises and that would be by means of asking the company to leave the voluntary scheme, expelling them, I think, has that ever happened and is it a realistic threat?

MR BREALEY: That I'd have to check over lunch. It must be a realistic threat because when one looks at scheme M,

scheme M is littered with references that if you do not comply, you can be asked to leave. So my immediate reaction to that, it must be realistic because otherwise why would the Department of Health be putting it in? I mean, it would be very strange --

THE CHAIRMAN: Nice to put some flesh on the bones of that argument, I think. So maybe think about that. Yes.

MR BREALEY: But ultimately, the scheme is we would like to do this on a consensual basis rather than to force you. If you know that you can be forced to do something, you tend to do it on a consensual basis.

THE CHAIRMAN: Depends how rational you are. I think that my final question - and I don't want to interrupt your conclusion on this - but no, you carry on.

MR BREALEY: Sir, on the point on the costs, it's page 45 of our notice of appeal, footnote 184.

THE CHAIRMAN: Thank you.

MR BREALEY: Footnote 184, page 45:

"Based on internal estimates, Pfizer estimates that the API raw material, packaging, labour, overhead costs, associated with production of 50-milligram phenytoin tabs which it produces in South America are around ..."

Then there's a figure, percentage "Of the levels associated with the capsules in its Freiburg facility."

So page 45.

THE CHAIRMAN: Yes, what I was going to ask you was, in this note of the meeting, which you've said we should attach zero weight to, there is comment that it was unlikely that the Department would have assessed costs for value because it didn't. I mean, that's the burden of it. Are you saying we should attach any weight to that?

MR BREALEY: Well again, if I am -- can I say zero weight, it's flimsy weight. You cannot hang somebody, you can't fine someone £84 million and have a conclusive finding of infringement which is going to be used in a civil trial on the basis of a note of evidence where the Department of Health is simply not coming to the Tribunal and saying, "We don't have the resources." Because we could cross-examine the relevant person as to whether they had the resources. And also, you could say: look, if Parliament gives the Department of Health the power, it's irrelevant whether they think they have the resources or not, you have the power.

You have the legal ability to control the price. Scheme M, as we saw, paragraph 29 and 30, says that's what we're going to do. We're going to ask you for the costs of other products and -- what Mr O'Donoghue has given me, yes, paragraphs 29 and 30. They represent to the world that they have that power and will do so.

Again it comes back - and I'll finish - it is a very

strange theory of harm to have, as a supplier of a product offering a price, that person has the extreme power, the legal power, to control my price, and I get fined because that person says, "Well I haven't got time to do it," and they're the customer.

After lunch, I'll quickly go to how Pfizer benchmarked and then we'll get onto the law.

MR HOSKINS: Can I just give you one reference before lunch which is in response to Mr Lomas's second question, which is: "Were patients stabilised on tablets?" I think the position is dealt with references in the decision, paragraph 5.507, where it tells you that tablets had the same as capsules and NTI, non-linear pharmacokinetics and that continuity of supply was followed. So I think that hopefully answers your question, 5.507, page 413.

THE CHAIRMAN: Presumably you will be putting that to Professor Walker.

MR HOSKINS: I'll be putting all sorts of questions to all sorts of witnesses.

THE CHAIRMAN: I imagine you will be. That's one you might remember.

I think you can take it that it is common ground between us that we are conscious that the Department of Health is not represented in the Tribunal.

MR BREALEY: I'm grateful. I don't know whether that's a convenient moment.

THE CHAIRMAN: Very good. Very good timing, we'll meet again at two o'clock.

(1.04 pm)

(The Short Adjournment)

(2.00 pm)

THE CHAIRMAN: Mr Brealey, please continue.

MR BREALEY: Thank you sir, I'll speed up a little bit.

The next topic is the how Pfizer benchmarked against the tablet. I'll do that quite briefly because I'm sure Mr Hoskins is going to take support to one of the documents, and then I'd like to go to the law on unfair pricing, and then, probably after the tea break, I'll try to do as much as I can on the section 26 notices on continuity of supply.

Dealing with how Pfizer benchmarked against the tablet, first of all can I just go to the decision at page 96, where this is the chronology of events relating to the price increase, so the CMA and the decision gives about a dozen, I think it's 11, bullet points which it says is the key evidence.

THE CHAIRMAN: I've got one little green marking. You're not going to read that, are you?

MR BREALEY: Which is the green marking?

THE CHAIRMAN: It's a company name.
PROFESSOR WATERSON: Don't tell him, Pike!
THE CHAIRMAN: It's a company name. It's in the second bullet point. I'm sure you'll treat that with the seriousness it deserves.
MR BREALEY: I beg your pardon turning my back. I'll take it that that is not confidential until I'm told otherwise.
MR BAILEY: I'm sorry that is not correct. The identity of the company has always been confidential as both appellants have been well aware.
THE CHAIRMAN: Can we perhaps just carry on without mentioning the company name for the moment, please, Mr Brealey?
MR BREALEY: Right, okay.
THE CHAIRMAN: I don't think it is central to your case.
MR BREALEY: I'll have to -- I want to mention the name. Can I call it Mr T? I'll call it Mr T. What we'd like to do -- the serious point is that there are a dozen bullet points there that the CMA says is key evidence and I would like to put a third bullet, a fourth bullet, and a fifth bullet in that summary. The third bullet should read, so this is extra bullets, because in my submission, what is being portrayed in this chronology doesn't give the correct picture. The third bullet, in

my submission, should read:

"T, Flynn and Pfizer considered it was valid to benchmark the price of the capsule against the tablet."

So:

"T, Flynn and Pfizer considered that it was valid to benchmark the price of the capsule against the tablet."

That is a key piece of evidence.

The fourth bullet should read:

"T, Flynn and Pfizer considered that the DH had forced down the price of the phenytoin tablet."

So:

"T, Flynn and Pfizer considered that DH had forced down the price of the tablet."

The fifth bullet should read that:

"T, Flynn and Pfizer considered that the phenytoin tablet price was the value attached to 100 milligrams of phenytoin by the Department of Health."

The fifth bullet:

"T, Flynn and Pfizer considered that the phenytoin tablet price was the value attached to 100 milligrams of phenytoin by the Department of Health."

They should be right up front, and they're not even mentioned at all. I'll just go to a few documents in G1, which supports those three bullets. As I understand it, I want to mention T, so I'm going to mention T and

Flynn here. If we go to bundle G1, tab 9, so as the Tribunal will have picked up, Pfizer -- so this G1, tab 9. Throughout this period, 2009, ten, 11, there were two companies that essentially approached Pfizer to do the sort of deal that we see in the decision.

This is a document about how you would take Epanutin capsules into the generic market, so this is a meeting held between T and Pfizer on 29th January 2010, and I just want to go to page 4, where T refers to the tablets. That's the last paragraph. Also to go to page 6, which I think I can read out, it is not confidential, the very last lines of page 6, we got the box Epanutin to phenytoin caps:

"Phenytoin tabs, 100mg currently sits at 25.50 invoice price in a full line of a DT of £30 so the figures would appear to be in the right area of discount."

So we've got the parties looking at how they're going to market --

THE CHAIRMAN: The DT is drug tariff?

MR BREALEY: Yes. Of course, the £30 is basically the £90 because this is for a 28 pack, and the capsules are in 84. But there we have the proposal from one market player talking about benchmarking the capsule to the price of the tablet.

On the T proposal, could I go to tab 33? I think this document, is slightly out of sync, out of chronology. Tab 33. Again, this shows the mindset of the market participants at the time. This is tab 33, G1. This, I believe, it's an undated document, but it's been put at tab 33. I actually believe that it's relevant to the T proposal because one sees at the bottom, "T would need an exclusive distribution", so this is in the context, I believe, of the T proposal. This is before Flynn come on the scene.

Again, the Tribunal will see, this is a Pfizer document, I believe, this is a Pfizer document reacting to the T proposal. We see situation, the reference to the price of the tablets, and I've got two passages that I'd like to emphasise. It's two-thirds of the way down. We see here:

"The Department of Health [DH] last year" -- so kind of puts it in time --

"Reduced the category M price of phenytoin tablets to £30. The previous price was £110. This indicates the value of this medicine to the NHS."

So --

THE CHAIRMAN: It also gives you a date, doesn't it? It's last year.

MR BREALEY: Yes, absolutely. I don't believe this, as

a lawyer, I believe Mr Hoskins can ask Mr Poulton. I think this is a Mr Poulton document. But this indicates the value of this medicine to the NHS. Again, we have a legal test that what is the economic value to a purchaser, and here we have Pfizer in response to the T proposal saying, "This indicates the value of this medicine to the NHS."

Over the page, questions and answers, a third of the way down:

"What impact will this have on the DH in category M or category C? The launch of the generic phenytoin capsules will remove category C from the equation and it will become a category M product in the same way phenytoin tablets are category M. The DH has set the DT price for the tablets at £30. In this proposal we are recommending a drug tariff price of 25.50 for the 100mg capsules, 15 per cent less than the DT for phenytoin tablets. Clearly this is a higher charge than the current category C price of the brand, but is less than the price that the DH wish to pay for phenytoin, ie, £30, 28 tablets."

Again, this can all be put to Pfizer, but this is a contemporaneous document about the T proposal and Pfizer, believing that it was the Department of Health that reduced the tablets to £30, and believing that that

is the price the DH wished to pay for phenytoin. It should have been a bullet point. The CMA should -- they can reject it, whatever they want to do with it, but they should at least refer to it. So that's the T proposal. Could I go to the Flynn proposal as there were two proposals to genericise Epanutin. So this is the subsequent proposal, as the Tribunal knows. Tab 16. Tab 16, this should be referred to in the decision. This is Flynn, I don't believe any of us -- is this confidential?

"Epanutin proposal June 2010."

We turn over the page, sold at a loss, unable to change the price of a branded product due to the PPRS, so we know that under the PPRS it's difficult, if not impossible, to change the price, once it's there, it's there.

"... must continue to be available to patients. This explores the ways ..."

The next slide again refers to the capsules and the tablets. Then I'd like to emphasise the slide over the page again, which is "Phenytoin capsules potential prices generic."

"DH would be concerned if price rose too much. Teva would be forced to drop price from circa £100 per pack to £30 for phenytoin tabs. It is suggested that the

price is pitched at half of the price for phenytoin tabs initially."

So we have here Flynn stating to Pfizer that DH would be concerned if it rose too much, Teva were forced to drop the price. That was the market intelligence. That's a contemporaneous document. Let me just finish this. The Department of Health would be concerned if the price rose too much. Teva were forced to drop the price, so that is the contemporaneous document that at the time it was believed that Teva were forced to drop the price, and suggested that the price is pitched at half the price of phenytoin tablets. And Mr O'Donoghue reminds me that in G1, 21, right at the bottom, it is stated that:

"Flynn recommends that a restrained approach is taken and the price should be set at 50 per cent of the tablet price."

At G1/21 at the bottom, it is the second page, the parties were recommending a restrained approach at 50 per cent of the tablet price. Thank you.

THE CHAIRMAN: Where does it say that?

MR BREALEY: Right at the bottom, sixth page, apparently. 3 pages in.

THE CHAIRMAN: Yes, I have it. That wasn't the price finally fixed on, was it, by the way? 50 per cent

discount was not --

MR BREALEY: No, that's not what -- no. Certainly, as I said earlier on, the Pfizer price was less than half.

THE CHAIRMAN: Yes. Yes. But you're only supplying one customer.

MR BREALEY: We were only supplying one customer, but we are competing with other pharma companies and we are pitching the capsule to Flynn at less than half the price that the tablet has been sold at.

THE CHAIRMAN: Right. Are these other prices that you quoted to us at the beginning, were they the price to the pharmacy, or were they the price --

MR BREALEY: The price to the NHS for six months. So what it costs the NHS for six months of treatment.

THE CHAIRMAN: Okay. So your price to Flynn was not what the NHS pays?

MR BREALEY: No, no.

THE CHAIRMAN: I think we understood, it is just that I was getting a bit worried.

MR BREALEY: That is our price to Flynn, then you can work out what price that Flynn can -- we don't, as you've seen, and we cannot, we cannot dictate the price at which Flynn sells.

One last document and then I want to go to the law on unfair pricing. Go to tab 23. But this morning,

when I was going through the prices, I think it is relevant because Pfizer was found to have infringed for charging prices to Flynn. I did also mention the Flynn price, and one sees --

THE CHAIRMAN: Yes, you did, yes.

MR BREALEY: One sees the Flynn six-month price is less than a lot of the others.

The reason I said tab 33 was probably the Steve Poulton document, although he doesn't say in his witness statement, is that this is an e-mail from Steve Poulton, it sets out very similar the financials, it references the tablet and the capsule, and again this is 8th March 2010, two-thirds of the way down. If this was a lawyer, this would be -- this is:

"The Department of Health, DH, reduced the category M price, so the DH reduced the category M price in 2008 to £30."

So this is not a negotiation. The market perception is the DH reduced the category M price to £30. The previous price was 110.

This indicates the value of this medicine to the NHS.

THE CHAIRMAN: What you're telling us is that's what the market thought.

MR BREALEY: Yes.

THE CHAIRMAN: That's what Pfizer thought.

MR BREALEY: Yes. And that's relevant, and it is relevant because anybody in business, any economist, anybody in business, they launch a product and they have to decide what the price is. And of course, they'll look at their costs, but they'll also look at comparable products. If you think you've got a fantastic product, you'll look at a comparable product and you might charge a premium. If you don't think the product is as good, you might reduce the price by reference to the comparable. But nearly every single company in the whole wide world, when it is pricing its product, will look at what the market is prepared to pay. And that is why, when we come into At the Races in a few moments, that is why the Court of Appeal emphasised in spades the relevance of economic value to a purchaser. Not what the cost is, but the economic value of a product to a purchaser.

That is an extremely important point in this appeal, that when normal companies pitch a product, they will be looking at comparable products, the same products, and trying to work out what is the relevant price. And for the CMA just to say they are irrelevant considerations, comparable products are irrelevant, is in my respectful submission an error of law. It is an error of law because it is a relevant consideration.

MR LOMAS: Mr Brealey, are you saying that the subjective intent of the Pfizer people is relevant to whether there was a breach of article 102?

MR BREALEY: No, of course not, as you know, sir, abuse is an objective concept and therefore it is relevant in the sense that the CMA, in working out whether it is an abuse, actually will look at the subjective intentions, it'll be the first to say so. Ultimately, it is an objective question. Even an abuse, the competition authority will look at the subjective intentions of a party to work out whether objectively it was an abuse. Clearly it is relevant to any fine.

THE CHAIRMAN: If there was a document by Mr Poulton that said, "We are entirely unrestrained as to the price we can charge, I suggest we charge the maximum", you would say that would have been quoted against you, as evidence of -- from the other side?

MR BREALEY: The CMA, I think, mention about 30-odd times the word "fleece", "supernormal", it picks out every single phrase that is prejudicial to Pfizer when it looks at the documents in G1. You only have to read the skeleton, the decision. You get "fleece" taken out of context. Nowhere does the CMA give credit for Pfizer believing that this was the economic value to the Department of Health. That's why I need to refer to

this, to make sure that those bullet points on page 96 are inserted.

Mr O'Donoghue reminds me that it is an objective concept, which we've seen, but if you have the market believing that the price is a fair price, then it becomes objective. So it is not just Pfizer, T comes along, Flynn comes along, and at what point does it become objective? We have at least three people, contemporaneous evidence, saying the relevant is the benchmark, that is the tablet. So it is not just Pfizer's subjective view, it is T's subjective view, it is Flynn's subjective view, and at some point that becomes objective. That's how you test objectivity, not just one person but various people in the market believe.

THE CHAIRMAN: Three is still a bit on the low side, I would say.

MR BREALEY: Well, it would be interesting to see how many people the CMA refer to. It ignores, as we've seen, it ignores the price that the DH pays to other manufacturers for very similar products.

I'm also reminded, J19, page 6, the tablet price was the price that NRIM thought was fair price. That's paragraph 45. So paragraph 45:

"NRIM noted that the price increase of phenytoin

capsules was most likely in line with the price of similar and comparable dosage form of phenytoin caps. As noted, if we compare like to like the price of phenytoin capsules versus 84 tablets, which in fact makes phenytoin caps 20 per cent cheaper than the phenytoin tablets."

So this is paragraph 45, J19, it is the NRIM telling the OFT -- well, it considered the benchmark price was there.

So we've got to four.

I'd like now to turn to the law on unfair pricing. As I said earlier on, clearly we can have kind of two or three days on the law of unfair pricing.

THE CHAIRMAN: Nothing would give me greater pleasure, Mr Brealey.

MR BREALEY: I actually think that's true.

THE CHAIRMAN: At my age, you can't take chances. I think we might forego it though, don't you?

MR BREALEY: What I'd like to do is just concentrate on where the Tribunal can get a steer for the importance of comparables, and that's why I emphasise the price of AEDs as normal.

Just for good's sake, we should first go to -- actually if we get 2 bundles out, that's United Brands, C1, and Attheraces at B1. So C1 and B1. This is the

authorities bundle. So C1, United Brands, that's at tab 3B, and B1 is tab 4, Attheraces.

Again, just for form's sake, I need to highlight the passages in United Brands and I know the Tribunal knows it. If we have open C1 and go to page 299, and if we also have B1 open at tab 4, that's the Attheraces, Court of Appeal, starting at paragraph 114. So United Brands, as we know, it was also a discriminatory pricing, United Brands was charging different prices to where you were based in the European Union, and the decision on discriminatory prices was upheld. We see that at the top of 299, paragraph 232.

Then you get the analysis on unfair prices. That was ultimately annulled. But at 301, we get the famous passage --

THE CHAIRMAN: It was a commissioner's finding, wasn't it?

MR BREALEY: I beg your pardon.

THE CHAIRMAN: A commissioner's finding was annulled.

MR BREALEY: Yes. The commissioner's finding was annulled.

The relevant paragraphs that are cited time and again are paragraphs 249-253.

So 249:

"It is advisable to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap

trading benefits which would not have reaped if there had been normal and sufficiently effective competition."

That gives you a sense that that is referred to in AKKA/LAA, it is giving you a sense of you actually are looking at what the market is bearing because if the market will bear it, you're not exploiting anybody. That's the marketplace.

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

We know that that is basically the test, what is the economic value?

251:

"The excess could inter alia [and it is inter alia] be determined objectively. It was calculated by making a comparison between the selling price of the product in question and its cost of production which will disclose the amount of the profit margin."

We know from Attheraces and subsequent tests, that is not the only test. That's not just the test for economic value.

252, this is essentially the passage the CMA latch onto:

"The question to be determined of whether the difference between the costs actually incurred and the

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

I'll come back to that in a moment and then we've got 253 over the page:

"Other ways may be devised and economic theories have not failed to think up several selecting the rules and determining whether the price of a product is unfair."

I want to leave United Brands and go on to Attheraces, but a bright line point about paragraph 252. This is not some sort of statutory test. It's not taking first of all a green pill and working out costs and then having a choice of taking a blue pill or a red pill, which is it in itself excessive or by reference to comparable products? When one reads the decision, when one reads the defence and the skeleton with the greatest respect, one gets the feeling that this is some sort of statutory test, and it's not.

THE CHAIRMAN: It is routinely recited, when courts have to deal with this sort of issue.

MR BREALEY: It is and this is why we're here. We're not saying ignore it, but what we are saying is there are many ways of determining whether a price is excessive.

THE CHAIRMAN: I appreciate that, but if the courts of equivalent status, successor courts, recite these passages over and over again, does that give them some kind of statutory nature?

MR BREALEY: It certainly gives it some force, but then one has got to work out how you're interpreting. I mean, for example, you take a monopoly, take the collecting society cases, that paragraph 252 is not really applied to those sorts of cases. You don't look at the costs first and then ask whether in itself. You don't even look at comparable products. You're looking at other markets and other Member States, as we'll see in AKKA/LAA. So the notion that this is the last word in it, as we'll come to explain in a moment, one has to treat it with a degree of caution.

THE CHAIRMAN: You would say take these general pronouncements in the context of the case.

MR BREALEY: Absolutely, sir, and that is particularly the case in the Athens Airport case. I would emphasise that in the Athens Airport case.

I've referred to those paragraphs. Can I just go to the Court of Appeal Attheraces, to mention two points? Again, I'm trying to concentrate the submissions at the moment on whether it is right to shut one's eyes to comparables. This is all I'm trying to work out at the

moment, whether the CMA has made an error by shutting its eyes to comparables.

Paragraph 114 of Attheraces. We get the passage that I've just cited, so we can actually put United Brands away.

THE CHAIRMAN: They call it a key passage.

MR BREALEY: A key passage.

THE CHAIRMAN: It's obviously got some kind of status.

MR BREALEY: Of course, I mean, undoubtedly it does have some sort of status, but I do ask the Tribunal to note, at paragraph 115, where the Court of Appeal says "Please don't read the passage too literally. That's what I'm submitting.

THE CHAIRMAN: You would ask us to take that on board, would you?

MR BREALEY: I would ask the Tribunal to take a cautionary note of what the Court of Appeal has said about that passage in United Brands. Do not read it too literally as if it is a statute. You look at the cost of production and then you can look at it in itself, and then that's the end of the whole exercise and I don't do anything else.

So that is paragraph 115. Do not take it too literally.

Note also paragraph 172. Because the criticism from

Mr Roth as he then was, was that the judge -- this at the bottom of 172 -- was taking a mechanistic approach to pricing. Again, we shall see the Court of Appeal agreeing with the criticism that Mr Roth made of the judge's approach, but I put those two bits together. This is my first point to make on United Brands from Attheraces. Do not read the passages too literally, do not adopt too mechanistic an approach. Those are important -- it is important advice when we get to AKKA/LAA.

The second bit I want to get from Attheraces, again on comparables, is that the Court of Appeal does say, in my submission, that the judge was wrong not to look at comparables.

So if we go to paragraph 172, we see there that Mr Roth's main criticism was the judge took a mechanistic approach and then, I'm sure the Tribunal knows it, you have an analysis of costs. We'll by-pass that, but that is the mechanistic approach, look at paragraph 181, about costs.

His second main criticism is at 186 and that is one of the key issues there about economic value. So his first is mechanistic approach to cost, economic value, 186. Then, this is where I'm getting to my main point, paragraph 198, we see that Mr Roth criticised the

judgment on two other grounds. So this is in the context of economic value. The first was for failing to have regard to the relevant range of comparators available on pre-race data, which contradicted the finding that a price significantly in excess of cost plus is excessive and unfair. The comparators cited by Mr Roth were, and he goes on to cite comparator A, B, C and D.

199:

"Although Attheraces objected that the comparators were not relied on, it appears from the judgment that the comparators point is not a new one."

Then the next sentence is important:

"The significance of the comparators is that in none of these cases was the price to be paid for the pre-race data determined on the cost plus basis."

We then get the Court of Appeal referring to Mr Roth's criticism that the judge failed to have a look at comparators. The Court of Appeal emphasises the significance of the comparators, which is that elsewhere the price was not just referring to cost plus but the value that people attached to it. And at paragraph 203, conclusion:

The Court of Appeal states “we are in broad agreement with Mr Roth's submissions criticising the

judge's approach to the issue of the excessive unfair price."

We know from 203 to 218, the Court of Appeal cautions against using competition law to price regulate, and at 218:

"in particular the judge was wrong to reject BHB's contention on the relevance of the value of the pre-race data to Attheraces in determining the economic value of the data and whether it was excessive and unfair."

So the Court of Appeal, when one reads this -- obviously we're going to come back to this in closing with the Tribunal, but when one reads it, you're looking at the value of the pre-race data to the purchaser, and one of the criticisms that in my submission the Court of Appeal accepted was the judge refused, or declined, to look at the significance of the comparators. And the significance of the comparator was that the prices paid for the data elsewhere was not just on a cost plus basis; it was greater than that.

We would say you look at the other AEDs in this case, what is the value that the NHS, the Department of Health, is placing on the AEDs that I mentioned this morning? Just to shut one's eyes to that, to be wilfully blind to that sort of evidence, we would say is an error of law. And that is supported, in my

submission, by the advocate general and, in a more iconic way, the CJEU in AKKA/LAA which is obviously the most recent word in excessive pricing.

MS BACON: Just on a housekeeping matter we have noticed that the version of the Advocate General that is in the Tribunal's bundles, and in fact everybody's bundles, which was taken from the curia website is incomplete. Some of the paragraphs appear to have been mangled. Because none of the electronic versions have the full version, it appears we've spoken to the registry of the court this morning and we've got the original version which is complete and I would just hand that up and I would suggest that we work on this version of the Advocate General.

MR BREALEY: Well I can't because mine is marked.

THE CHAIRMAN: That's terribly kind. I have my own copy as well, but any more copies.

MS BACON: Yes, if your copy has --

THE CHAIRMAN: I was sent mine by the Advocate General.

MS BACON: Yes, exactly. That will be this version which is the right one. The other versions seem to be wrong. So shall I send up two more, two copies?

THE CHAIRMAN: By all means. (Handed) We could use them as comparators, perhaps.

MR BREALEY: We've finished Attheraces we've finished United

Brands, I'd like to go to AKKA/LAA, C3, tab 39A. Thank you for the Advocate General.

To pick up a point, sir, that you made about the passages in the United Brands, the Advocate General is clearly interpreting United Brands in this case. Tab 39A. Again, I do want to look at the pharmacy evidence, so I'm going to take this as quickly as I can, given the time, but obviously I need to deal with it also in some detail.

I'll take, if I can the Tribunal to the topics and then the paragraphs which I think are relevant.

This is the Advocate General's opinion. If we start at paragraph 15, under the heading "Analysis and introduction". So we have seen in United Brands the reference to two limbs. We see in paragraph 17 the reference to "the first step". So that equates to the first limb and the paragraph over the page at paragraph 21, the second step, which broadly equates to the second limb.

What the Advocate General does in the first step the first limb, is say you consider everything. In looking at the economic value, you don't rule anything out. You're not forced to do anything. You don't rule out anything. There's a big difference.

So the first step, that's paragraph 17.

Paragraph 18:

"The court has acknowledged there may be different methods of determining whether the price is excessive."

And 18 and 19 goes through the different methods. Clearly, sometimes you can't have just a cost plus basis. So I mentioned 17, 18, 19 and 21, because when we get to paragraph 35, general remarks, or I should say paragraph 33, when we get to paragraph 33, he is referring to the first step. So we see that from the first line of paragraph 33. So again, just to try to get the roadmap from where he is going, it is not always clear. Paragraphs 17-21 refer to two steps. Paragraph 17 refers to the first step.

"The different methods of determining whether a price is unfair."

Paragraph 19, you will see expressly refers to comparators. Then, when he deals with the second question at paragraph 33, what he says following is relevant to the first step. Again, I'm just at the moment - and I may have to deal with this more in closing when everyone has had a chance to have their say, we'll look at this more in the round - I'm trying to work out with the Tribunal the question of comparators.

So if I go to paragraph 35 and 36, I'm going to

emphasise 36 because the court endorses what the Advocate General says at paragraph 36.

"It can be safely stated that at the current stage of legal and economic thinking there is no single method, test or set or criteria which is generally accepted in economic writings or across jurisdictions for that purpose. Different authorities, as well as lawyers, economists, have suggested a number of methods of analysis as well as a variety of criteria, tests or screens to that end. However, in point of fact, each of those methods reveals some inherent weakness."

Now, when we come to the court, we shall see the court - and this is at paragraph 37 - endorses what the Advocate General says there. And why is that important? It is important for this reason: the CMA, as we know, they do adopt a quite a mechanistic strict approach. They say, "I'm going to look at one limb, I'm going to look at the cost, look at the profit margin and then I'm going to look at is it unfair in itself." That's all they do. I know they then go on to do a bit more, but that is what they say they can do.

What the Advocate General is saying at paragraph 36, there is no one single test. There are inherent weaknesses in all of them, and it would be very odd indeed if the Court of Justice was saying to the

Competition Authorities "Although your 'in itself' test has an inherent weakness, that's all you have to do. That is the single criterion you can latch onto." In circumstances where the court endorses what the Advocate General says here, there is an inherent weakness."

That's why I will come onto just more than that. And if there are comparators out there, and you are wilfully blind to those comparators, that is an error of law, which we say was endorsed in the Court of Appeal in Attheraces.

So 36, no single method or test. I'll speed up. I'll ask the Tribunal to -- obviously you have read it.

Paragraph 43, after the Advocate General says you look at comparators, 43, combining different methods.

"In the absence of an ubiquitous test and given the limitations inherent in all existing methods, it is in my view crucial that in order to avoid or minimise the risk of errors, competition authorities should strive to examine a case by combining several methods among those which are accepted by standard economic thinking, and which appear suitable and available in the specific situation."

In other words, if, in a specific situation, you have comparators, what price the purchaser is actually paying in the market, you don't just shut your eyes to

it.

"It seems to me that those which can be found in the court's case law may serve that purpose."

So it actually refers to the practice of the UK Competition Authority choosing, not shutting its eyes to just one method. Again, we'll probably deal with this in more detail in closing, but I would ask the Tribunal to note paragraph 54:

"Regardless of the specific situation in a given case, the methods applied and the other indicators examined must give the authority a sufficiently complete and reliable set of elements which point in one and the same direction."

So in other words, what he's saying there is that really you should be looking at all different sorts of things and you've got to have a degree of confidence that these different methods are pointing in the same direction. The reason for that, he comes on to explain, is that excessive prices is a value judgment. What is excessive to one person is not excessive to another. So you are at risk of getting things wrong unless you consider more than just one thing.

THE CHAIRMAN: Can I just take you back to paragraph 17, because it is referred to in paragraph 54, and just ask you whether you agree that it is correct to define as

the benchmark price that the price which the undertaking would hypothetically have charged had there been effective competition in the market? Do you think that's the right way to look at it?

MR BREALEY: Well in many circumstances the answer must be yes, because that refers, I think, back to paragraph 249 of United Brands.

THE CHAIRMAN: Which was the starting paragraph.

MR BREALEY: Yes, so that --

THE CHAIRMAN: Abuse means doing what you couldn't do in a competitive market.

MR BREALEY: Correct. That's what I think he is referring to there. In our case, whether -- the Teva tablet, we say the Department of Health intervened and actually imposed a price.

THE CHAIRMAN: I think the CMA take the view that the benchmark price is cost plus 6 per cent.

MR BREALEY: Well, if that's what they do, yes.

THE CHAIRMAN: That's why I'm asking you whether the Advocate General would take a different view, do you think?

MR BREALEY: I am in absolutely no doubt that the Advocate General would take a different view to the way that the CMA has analysed article 102 in this case.

THE CHAIRMAN: That's not quite what I asked. What I mean

is, would the Advocate General look for a counterfactual competitive price from various sources, or would he hone in on cost production to start with?

MR BREALEY: Well, when he's looking at what hypothetical charge had there been effective competition in the market, in my reading of that, he's just not looking at the cost reduction, he's looking at what is available in the market, comparators.

THE CHAIRMAN: That's hypothetical.

MR BREALEY: Hypothetical, or factual.

THE CHAIRMAN: "Would have been", it says.

MR BREALEY: Would have been, yes.

THE CHAIRMAN: It gets rather circular this, doesn't it, because the assumption is that this is not a competitive market; this is a market characterised by a dominant position so it is quite hard to find what the competitive price would have been in a competitive market?

MR BREALEY: I understand the point.

THE CHAIRMAN: You understand the dilemma.

MR LOMAS: Can I just clarify something?

MR BREALEY: Yes.

MR LOMAS: Are we agreed there needs to be a benchmark price?

MR BREALEY: Not in all cases, no.

MR LOMAS: Right. Does there need to be one in this -- is essentially what you're saying that the benchmark case -- sorry, the benchmark price in this case should be set at the level of the comparators?

MR BREALEY: Yes.

MR LOMAS: Okay. So there is no excess, then?

MR BREALEY: In our case, no. Pfizer priced at less than some of the comparators.

THE CHAIRMAN: We're still talking about the law.

MR BREALEY: Yes. Paragraph 17:

"The first step is to determine whether there was an excess. A significant difference to the price actually charged in the relevant market and the price which the undertaking would hypothetically have charged had there been effective competition in the market."

In my submission, all that is, if one goes back to United Brands, the court is trying to work out whether a company has exploited some sort of market power, and trying to work out what the price would have been in a competitive market.

THE CHAIRMAN: That's really all you're saying.

MR BREALEY: Yes. That is a benchmark, what it would have been.

THE CHAIRMAN: You have to start somewhere in this analysis.

MR BREALEY: You do. And what, in Attheraces the Court of

Appeal does is look at the actuals, so the price actually charged -- I mean, essentially what you're doing is taking the price charged and, we say, looking at similar prices for similar products and working out whether that is excessive overall. It's not -- at the end of the day, although the law is complex in the sense of what is a value judgment, in my submission, it's actually quite easy. In AKKA/LAA, what they did, they looked at the price that was being charged and then looked at the price that was being charged in other Member States for a similar service.

THE CHAIRMAN: Different geographical markets.

MR BREALEY: Different geographical markets.

THE CHAIRMAN: This is not then the same question as market definition for finding of dominance. It is a different question.

MR BREALEY: It is a different question, yes. But the simplicity of it is that, as the Court of Appeal says, you look at the economic value that the purchaser attaches to something. Not just cost plus. The economic value to the -- that's the ratio of the Court of Appeal in Attheraces.

THE CHAIRMAN: I won't anticipate, but the point being made against you is that in this case the purchaser arguably has no choice, so it is difficult to know what value the

purchaser does attach, but that will no doubt be developed by the CMA.

MR BREALEY: Correct, we say that it's not made out on the evidence because they do have a choice. But again, I come back to - and this is why I emphasised before lunch - if the purchaser has set a price that tablet manufacturers charge in the marketplace, and that under the scheme is supposed to be a fair price, and assume that my product is very, very similar to that product, the Advocate General --

PROFESSOR WATERSON: I'm getting a bit confused now about whether you are or are not distinguishing between a benchmark price and the value of the product. To me, these are two different things because you don't have the benchmark here. Is that a reasonable position to take?

MR BREALEY: You could use the word "benchmark price" for a comparable. You could use the benchmark price for what is the lawful price. What is the fair price? So you could -- so you look at the actual price and you look at the benchmark which is a fair price. Sometimes you can determine that fair price by looking at what is happening in the market, what the purchaser is paying for the same or similar products. Is that a fair price? Yes, it is, because that price over there, they're not

dominant, they are -- it's another product, and there is no exploitation of market power, and that is a fair price, a benchmark price for the product in question. So you --

THE CHAIRMAN: So a benchmark is something that you make comparisons with?

MR BREALEY: Correct.

THE CHAIRMAN: Just in plain language. I'm not sure plain language really applies here, but you've got to start somewhere.

MR BREALEY: You've got to start somewhere. So what I'm saying is, well yes, that's what he's saying, you've got to start somewhere, and very often you'll be looking at what is the price for a same or similar product in another market. I say well the most obvious comparator in this case, in our case, is what the Department of Health was prepared to pay for 100 milligrams of phenytoin.

MR LOMAS: Mr Brealey, is that consistent? Because in the passage you picked up later, I'll give you the reference, 43 and 54 and so forth, what I understood you to be saying is the Advocate General is saying that the CMA is wrong to rely just on cost plus because you should be looking at a basket of measures to try to decide your benchmark price.

MR BREALEY: Mm-hm.
MR LOMAS: But what you were just saying is "I'd like to select one particular comparator and define my benchmark price around that." Isn't what the Advocate General saying here that the responsibility for the NCA is to use a variety of methods to come to a reasonable benchmark price of which costs plus may not be the only one, and then to compare that with the actual price in the market?
MR BREALEY: Okay, and I'll go with you, sir, so far but that's not what the CMA have done.
MR LOMAS: I understand that's your submission, yes.
MR BREALEY: That's exactly what they've not done.
THE CHAIRMAN: Apart from phenytoin tablets, and the cost of production, what else should they have been looking at?
MR BREALEY: Well -- I don't know where they have had gone -- oh, these.
THE CHAIRMAN: Okay, the other AEDs. They are all on the UK market. What about the overseas market?
MR BREALEY: Well then you look at the overseas market, but the Advocate General and AKKA/LAA says you can look at the overseas market but then - and it burdens on the CMA - you've got to work out whether there are differences between the overseas market and that's why you get a lot of reference to the PPRS here. So when you're looking

at overseas markets, you've got to factor in that there may be different purchasing power, different standards of living, different regulation, different all sorts of things. So if you're going to look at other markets, and the CMA do, they don't actually do the job that the Advocate General says you must do.

THE CHAIRMAN: Okay. Continue.

MR BREALEY: That's why we would say, again, the most obvious comparator in this case is what the Department of Health fixed under the scheme for 100 milligrams of phenytoin. Then you look at that and then you look at what is it prepared to pay for other AEDs that treat epilepsy, focalised and generalised. Well they happen to be actually more expensive than the price which Pfizer charge or Flynn charged. And then you think, well, is this -- and this is excessive -- this is why I said at the beginning, this -- what they've done is price regulate. Because if you take the view that cost plus is not the be all and end all, as the Court of Appeal says, you look at the price for phenytoin 100 milligrams, you look at the price for this, you ask yourself the question: is the price that Pfizer charge such an outlier that it can be explained by some sort of exploitation?

PROFESSOR WATERSON: My difficulty with your argument is

that none of these products is supplied in competition with each other.

MR BREALEY: Well the answer to that is that the law says that they don't have to be. The law is quite clear that in order to be a valid comparator, they do not have to be in the same market. And I think you already mentioned this morning, sir, that actually the tablets could be in competition with the capsule. Certainly, I mean, Mr Hoskins can ask Professor Walker about it, the extent --

MR HOSKINS: Sorry, but that has not been raised in the notice of appeal. Too late. Too late.

THE CHAIRMAN: It has not been raised in the appeal?

MR HOSKINS: It is not challenged that tablets were in the same market. The only market definition challenges that NRIM was in the same market. It has not been challenged that tablets have --

THE CHAIRMAN: We'll get onto markets in due course.

MR BREALEY: I'm not saying they are in the same market. I have said that you have seen some degree of substitution. You've seen Professor -- I don't have to prove, as a matter of law, that they're in the same market. But it is completely different from saying that they are a comparable product. I have Professor Walker saying that the tablet and the capsule are essentially

identical. We've already seen that you can take them both together. You can take 100mg of the capsule, 50 -- sorry, 100 of the tablet, 50 of the capsule. You can take them together. But the law says you do not have -- they don't have to be in the same market.

MR LOMAS: Mr Brealey, isn't there some confusion on this - and I think it is very complex on the authorities - that you can use the comparators for one of three purposes. You can use them to help you decide what your benchmark is, you can use them to try and decide whether the difference in your benchmark and your price is excessive, and you can use them to decide whether or not it is unfair.

MR BREALEY: Well yes, but the question is, and you get it from United Brands, what actually is the difference between excessive and unfair?

THE CHAIRMAN: Unfair is in the treaty.

MR BREALEY: Correct. Excessive is in the United Brands and then it also refers to unfair. So if you actually read the passage in United Brands, when it says, "excessive and unfair," actually what is it talking about?

The essential point is they don't have to be in the same market, they have to be comparators, just as in Attheraces, what other people were paying in Ireland is not the same market as what was being asked for the

purchaser in the UK.

THE CHAIRMAN: I think the reason the market issue has come in is that there's an observation, I think, by Sir Christopher Bellamy in Napp is that our attention should not be diverted away to products that are not in the same markets as the one where the abuse occurred. That's probably the origin of this issue. Maybe you're going to deal with that.

MR BREALEY: Well I don't believe that Sir Christopher was saying that, but it's just patently not correct.

THE CHAIRMAN: I think he said it but he may not have meant it.

MR BREALEY: May not have meant it, but it is patently not correct. You just have to look at the facts of AKKA/LAA.

That is exactly, AKKA/LAA. You're looking at what shops are paying in one Member State, and legal monopoly and in order to try and work out whether that is unfair, you're looking to see what shops are paying in another Member State, that's not in the same market, which is also a monopoly.

THE CHAIRMAN: Have you reached a place where you'd like to pause?

MR BREALEY: Yes.

THE CHAIRMAN: Or are you galloping towards some conclusion?

MR BREALEY: Yes. I'll finish AKKA/LAA and then I do need to -- If you just give me five minutes and then I can finish this.

Just for the Tribunal's note, we have comparators, I would ask the Tribunal to note paragraph 40, in particular, 63. So 63, "Contrary to the view," et cetera. He goes on:

"It is indeed crucial in this context to take into account the following two factors which in my opinion could affect the economic value of the service provided by AKKA/LAA. The capacity and willingness of AKKA/LAA's customers to pay for that service received."

So again, a willingness to pay. That is part and parcel of economic value. What the Department of Health is prepared to pay for 100 milligrams of phenytoin.

On comparators, paragraph 85, looking at the purchase power of the customer. Again, paragraph 90, willingness to pay.

I'll finish AKKA/LAA by going to the last section, which again is a cautionary note, and this is paragraph 103 to 112.

Now again, this is in the context of the CMA doing what we say is a rigid mechanistic approach, a blue pill or red pill. Cost of production in itself shutting your

eyes to everything else.

103. If you just adopt a very rigid, strict approach, you could end up with type one errors, because you will be condemning something which actually should be permissible. So there was a real risk, if you just adopt very narrow approach of getting the wrong result. And he's saying that is particularly so in the case of unilateral conduct.

104 is important, and this is why all the methods that you choose should point in the right direction:

"it must be acknowledged that it is often difficult for dominant undertakings to estimate in advance with a sufficient degree of likelihood where the line between legitimate competitive price and a prohibited excessive price may be drawn."

Again, that's why I took the Tribunal to how -- well, four players, regarded the tablet price as a comparable price.

105 is that the price has got to be significant persistently and I'll end with paragraph 112:

"On the one hand an authority should intervene under 102 only when it feels sure, regardless of the limitations and uncertainties surrounding the calculation of the benchmark price, the difference between that price and the actual price is of such

a magnitude that almost no doubt remains as to the latter's abusive nature."

So yes, you might say well there was a big price increase, but when you actually look at the price of Trileptal or you look at the price of Keppra, all the other AEDs that perform very similar functions to phenytoin, and you look at the phenytoin tablets, can you really be sure that, when you're looking at the price, can you really be sure that that is abusive in nature.

Again, my submission is you do look at comparators, if they are there, and it is an error of law simply to be wilfully blind to them. And that's what one gets from the Advocate General in AKKA/LAA, and I won't have time after the break to go to the court, but the court does endorse what the Advocate General says at paragraph 36, and what you get from that is the court saying you've got to be careful because they all have inherent weaknesses, and the CMA can get no comfort from the court saying well there's an inherent weakness in just taking a cost plus and in itself.

THE CHAIRMAN: There is an Advocate General's opinion in United Brands, but nobody seems to refer to it ever. Are you putting to us that the AKKA/LAA court's judgment and Advocate General's opinion taken together are at

least equal help to us in -- as United Brands court judgment in deciding what the law is here?

MR BREALEY: Well they're of -- obviously they're of equal status --

THE CHAIRMAN: I don't mean --

MR BREALEY: -- but clearly the Advocate General in AKKA/LAA is the very first real examination --

THE CHAIRMAN: Discussion.

MR BREALEY: Discussion of United Brands and, as Mr O'Donoghue rightly points out, the Advocate General was not followed in United Brands. But clearly they're entitled to their weight, but Advocate General in AKKA/LAA is the first real exposition of what United Brands means, and he is interpreting United Brands. And I do, again, emphasise paragraph 37 of the court cautioning these have inherent weaknesses. And the CMA should be extremely slow just to adopt one method, and that's it, without looking at these. Then I'll --

THE CHAIRMAN: Right. We'll break for ten minutes.

(3.18 pm)

(A short break)

(3.30 pm)

THE CHAIRMAN: Mr Brealey, we're one hour into our three-day discussion of the law, but you're going to curtail it, are you?

MR BREALEY: I know. I'm sure we're going to have more debate.

THE CHAIRMAN: You can probably take it that we are.

MR BREALEY: What I do -- I do take from United Brands and AKKA/LAA is that if the comparables exist, and they don't have to be in the same market, if comparables exist, it is wrong for the authority to be wilfully blind to them. In particular, where the court on AKKA/LAA has expressly endorsed paragraph 36 of the Advocate General to the effect that a simple narrow approach will have an inherent weakness. So if you just take what the CMA does, the first limb, cost, second limb, in itself, and that's it, if you read the CJEU in AKKA/LAA, as I say one should do, the court is saying there is an inherent weakness in that approach which would steer you to looking at other methods in order to satisfy yourself that the price actually is unfair.

And if you have valid comparators there, and you shut your eyes to them or are wilfully blind to them, that is an error of law. That's what I'm trying to extract from AKKA/LAA.

There are three cases that the CMA relies on in the skeleton. There is authority for the proposition that you can just adopt the narrow United Brands approach which is limb one, cost, red pill in itself, and ignore

everything else. That is the Albion Water case, the Athens Airport case, the Scippacercola case, and the National Grid case.

THE CHAIRMAN: Could we refer to AKKA/LAA as the Latvian Copyright case, it's so much easier?

MR BREALEY: Yes, anything.

THE CHAIRMAN: Introduce it to the generalcommunity.

MR BREALEY: Yes, so the Latvian Copyright case.

THE CHAIRMAN: Something like that. AKKA/LAA could mean anything, couldn't it?

MR BREALEY: Well I have given it to the -- I have written it down now, but yes, the Latvian Copyright case.

THE CHAIRMAN: Thanks.

MR BREALEY: Can we refer to the Scippacercola case as the Athens Airport case?

THE CHAIRMAN: Well that was my point, I think.

MR BREALEY: In reverse order, and I'm not going to go to National Grid and Scippacercola, the Athens Airport case. National Grid, just so Mr Hoskins knows where I'm coming from on this, National Grid with the greatest respect is an astonishingly bad point.

MR HOSKINS: That's very kind. [Laughter]

MR BREALEY: I think it's an astonishing thought.

THE CHAIRMAN: I think we can leave the greatest respect out of it, can't we?

MR BREALEY: Because it concerns -- the National Grid case is about a counterfactual. When one reads National Grid, it's all about counterfactuals. And it is as if someone, with the greatest respect has plonked in a benchmark and come up with it, but it is a benchmark. But when the Court of Appeal is talking about a benchmark, it's talking about a counterfactual, what would be the state of competition in the absence of the agreement or conduct in question? It may come to that in closing, but that's my point on that.

On the Athens Airport case, that is a case where you have to look at what the court said in context. It was a complaint, the complaint was about that the commission should look at comparators, it went to the general court, it went to the main court, and we say that the relevant passage that Mr Hoskins relies on in the Athens Airport, the main court, is actually against him. And I emphasised in the passage the word "must", and I emphasised in the relevant passage "in the order".

Now why do I emphasise those? Because essentially what was being submitted by Mrs Scippacercola, what was being emphasised there was that you had to apply United Brands in a very rigid order, look at cost, and then comparables. The submission essentially was a very mechanistic rigid application of United Brands and we

say that actually the court -- well when the court rejects that, it is actually in our favour rather than his.

Before I go onto the pharmacy evidence, I would just like to go to --

THE CHAIRMAN: You're not going to tell us about Albion Water?

MR BREALEY: Albion Water, very quickly.

THE CHAIRMAN: I'm not encouraging you to, but if you want to --

MR BREALEY: Well can I, because I think it is actually -- we do it in three or four minutes. We go to bundle A2. I'm not going to go obviously through all the facts. Bundle A2.

THE CHAIRMAN: As you may know, Albion Water runs through the Tribunal.

MR BREALEY: Bundle A2. There's Albion Water one, Albion water two. Two is tab 15. It's paragraph 250, page 79 that Mr Hoskins relies on. It relies on this for the proposition, so tab 15, A2, paragraph 250, page 79.

Page 79, paragraph 250. We know what the facts were, Welsh Water, monopoly, carriage, Albion Water wanted to supply water through the pipe to the paper mill and the question was about access price. And we also know from Albion Water that primarily it was -- you

calculated on a basis of cost plus, but I think this is the first case that the CMA rely on in support of this proposition that all they need to do is to do cost plus and then in itself, and that's it. So this is the proposition they tried to get from it.

So paragraph 250, 251:

"Was the first access price unfair in comparison to competing products?"

Because what is said right at the end of this very lengthy piece of litigation is, "Okay, you've also got to look at competing products."

So 252, and we know this from the Latvian Copyright case, we know this from many other cases, that in order for a comparator to be valid, this is paragraph 252, page 79, it has to be sufficiently similar. So it doesn't have to be in the same market, it has to be sufficiently similar.

But in this case, there were no comparators. And that is a very important fact. We agree with the authority, it is difficult to identify suitable comparators to act as a yardstick. So they did look at cost, the cost, which is actually how the Water Act says you should do it, and over the page is where the CMA try to distil this proposition that all they need to do is cost plus and in itself.

We see at 256, "It is therefore impossible to compare the level of the common carriage charged by Welsh Water with that of direct competitors because there are none."

So there were no comparables in that case, and therefore, as the Advocate General said in the Latvian Copyright case, "Well you're forced to fall back on something" which is here cost plus.

Paragraph 255 is what the CMA say, "Well that's all we're entitled to do" because they are in itself or when compared to an alternative not a cumulative requirement, in my submission, that simply doesn't give the Competition Authority the green light wilfully to ignore comparators. It is a completely -- Lord Carlile is not saying in that paragraph, "If there are valid comparators, if you are paying a price for a similar or identical product, you can ignore it."

I would test that proposition by the following, which is that if at the end of this litigation, so you've got Welsh Water and you've got Albion, and the question is, is the access price a fair price? And ultimately, you've got to get a fair price. What happens if, in Albion Water, somebody else comes along and says, "I also want to supply water to that paper mill"? It would be absolutely nonsensical in Albion

Water 3, if there's a now a debate about another party wanting to use the common carriage, supplying that water to that paper mill for the tribunal to turn round and say, "Well although we've spent the last 3 years working out what the fair price is for Albion Water, we don't have to take that into consideration at all."

But that is the extreme proposition that the CMA is putting forward in this case. So I just say it again. You've got Albion Water wanting to supply the water through the pipeline, the whole debate is about what is the fair price. Let's assume that either the tribunal sets the price or a regulator endorses it, so this is now the price between Welsh Water and Albion, and somebody else comes along, and says, "I would also like to supply water through that pipe" and the Competition Authority says, "Well I don't need even to look at the price that was set by the tribunal or endorsed by the regulator."

If that went to the Court of Appeal, we'd say we'll look at Attheraces. It was a relevant consideration. It would be an error of principle wilfully to shut one's eyes to that comparator price. And that is the difference between us and the CMA on this. It is a question of principle, if there are valid comparators out there, are you entitled simply to ignore them?

THE CHAIRMAN: But you're also asking us to take these various pronouncements in these judgments as in their context and not to take them too literally.

MR BREALEY: Absolutely, and it is -- excessive pricing as we know, as we've been told, it is complex, it is a value judgment, and one has to take into consideration relevant considerations. And if the price of phenytoin, whether it's in a tablet form, is a relevant consideration, the Tribunal might decide against us, the tablet is completely irrelevant, it's a tablet rather than a capsule, therefore it is not a valid comparator, end of story. But if it is a valid comparator because it is the same substance, same milligrams, exactly the same treatment, and it is a valid comparator, it should be taken into consideration. Our submission is as simple as that.

That is what I wanted to say on the law. As you say, sir, we'll come back to it.

Mr O'Donoghue is going to deal with fines so I've got to leave him a little bit of time, so I'll try and finish at -- I'll try and sit down at quarter past.

But I want to just deal with continuity of supply. I could take all afternoon on it, so I've got to kind of just pick out some points.

Continuity of supply, obviously the CMA uses it

quite a lot throughout the whole of the defence and the decision. It goes to the market, whether NRIM forms part of the same market. It even goes to abuse because the CMA say that everyone's completely dependent on the Flynn product as opposed to both products.

And it will probably be in closing, but I will want to take the Tribunal through the pharmacy evidence in some detail, but for the next half an hour I'd like to give the Tribunal a flavour and this is just at the end of the day, this is opening.

If I can deal with the continuity of supply principle as follows. Although it is in our skeleton, I would like to emphasise the MHRA guidelines, and they are H2/32.

I don't know whether I can ask whether the Tribunal would consider sitting a bit earlier tomorrow. I'll flag it.

THE CHAIRMAN: Well, what do Flynn say about that?

MS BACON: I was going to raise that. I have a lot of ground to cover tomorrow. I am going to do my best not to repeat anything that has been discussed today. We do have some distinct points on the law as well as background issues, such as market definition and dominance, and you'll have seen that our case on that is put in a slightly different way from Pfizer, so I do

need to go over some of those details. But I then need to come onto a major part of my submissions, in which we have a case that Pfizer doesn't advance, which is the ROS analysis, and that is rather technical.

The reason I want to cover it substantially in opening is that there is a lot of quite difficult technical material there which I wanted to show you before the relevant witnesses get cross-examined, so you will have a flavour of what the contours of the dispute are. For that reason, I am wondering if we could maybe, either or both, start early and sit late. I'm very much in your hands, but I am conscious that I have a lot of ground to cover.

THE CHAIRMAN: But you were going to cover it during normal hours, as it were. What you're worried about is that your time is going to be eaten into; is that right?

MS BACON: No, I'm worried about getting through it in normal hours, irrespective of whether it is eaten into. If we carry on with Pfizer's submissions tomorrow, then there's going to be even more of a problem.

THE CHAIRMAN: Well you were happy with the timetable before.

MS BACON: Yes.

THE CHAIRMAN: Yes. So what has changed?

MS BACON: No, I was happy with it, but now I've obviously

done my submissions.

THE CHAIRMAN: You didn't fix it, but you're happy with it?

MS BACON: Yes. In the way of things, one drafts one's submissions and then one thinks well there is quite a lot here.

THE CHAIRMAN: So having heard Mr Brealey, you now think you want more time? Is that what you're saying?

MS BACON: I am saying that there are a few issues that we need to cover tomorrow which go over some of the same ground because we've got a distinct position and I'm also very aware that there is a lot of material on the ROS analysis.

THE CHAIRMAN: I am speaking for my colleagues, I'm happy to go on a bit after 4.30 today, if that gives you more time and Mr O'Donoghue time to present.

MR BREALEY: Yes, I'm very grateful.

THE CHAIRMAN: You then want us to start early tomorrow anyway?

MS BACON: Well I was going to suggest either starting early or sitting late, or both, whichever is more convenient to the Tribunal.

THE CHAIRMAN: Well we're public servants, we'll do whatever the case requires. We're willing to start at ten tomorrow and to go on until towards 5 o'clock today, if that's helpful. And the CMA can also ask for more time,

if they feel they need it, having heard both these learned counsel.

MR HOSKINS: I'd like to say less, but that's probably optimistic.

THE CHAIRMAN: So much the better.

MR HOSKINS: No promises.

MR BREALEY: I'm grateful. I said, I think, tab 32. Can we just go to the NICE guidelines at tab 28 just to identify them, because these do crop up quite a lot. H2/28, page 24, is where one sees them. This is general information about pharmacological treatment. This is a paragraph in a fairly lengthy document.

The relevant paragraph is 1.9.1.4 at the bottom.

"Consistent supply to the child, young person or adult with epilepsy of a particular manufacturer's AED preparation is recommended, unless the prescriber (in consultation with the child, young person, adult and their family or carers) considers that this is not a concern."

So that was the guidance, consistent supply to the person of a particular manufacturer's AED is recommended unless the doctor considers that this is not a concern. So this was not just geared to phenytoin, this was geared to all AEDs, but the advice was, "We recommend you stick with the particular manufacturer's AED, unless

you, oh doctor, do not consider it a concern." That was the extent of the NICE guidelines.

Then we get to tab 32, which is -- this was, it is -- so NICE guidelines were in force when the Flynn tablet was launched. Then we get the MHRA guidelines, November 2013.

You will have seen, this is set out in the decision, but we get the background, and we see the category 1, category 2, category 3. So what the MHRA guidelines do is, for example, for category 3, they water down the previous guidelines because that's now not so much of a problem.

You then have category 2, and then you have category 1, which contains phenytoin.

What you have to do is again read this in its context. You see the two lines above category 1, that essentially you're looking at the category 1 for the solubility and absorption, but this advice is to help prescribers decide whether it is necessary to keep using a supply of a specific manufacturer's product. So the guidelines are there to help prescribers, doctors, to decide whether it is necessary. So there is still that discretion in the doctor, knowing the patient, whether it is necessary to stay with a particular brand or product.

So it is not mandating anything, it is advice to help them decide whether it is necessary.

Then we get advice for the healthcare professionals, so if a patient should be maintained, so if, then you should write out the prescription by brand. So if that doctor thinks it is desirable that the patient should be maintained on a specific manufacturer's product, then the doctor will write the prescription by brand.

The additional advice for pharmacists: if the prescription is written by brand, then the pharmacist should dispense the brand. And the important words are, which don't -- just do not feature sufficiently in the CMA's case on the pharmacy evidence, "Usual dispensing practice can be followed when a specific product is not stated." That is the last line of additional advice for pharmacists.

So the advice to pharmacists is when the prescription is written openly, generically, pharmacists can adopt usual dispensing practice, which we all know means they can adopt the cheapest version of the product, or they can take NRIM or Flynn. But that is when the CMA and the decision say, "Well the pharmacists followed the MHRA guidelines" and that you get this in the section 26 notices, well the question is, what does that actually mean?

And that is what, if some of the pharmacists were here, you'd be asking them. Because following the MHRA guidelines when a prescription is written generically, well, you can follow the guidelines and dispense either NRIM or Flynn, because the pharmacist is specifically told that, "Usual dispensing practice can be followed when a specific product is not stated."

Those are the guidelines. And it is quite important, when one looks at the section 26 pharmacy statements, to bear this in mind.

That's the first thing I wanted just to emphasise, what actually is the extent of the guidelines. The doctor has the discretion to decide whether to prescribe by brand, if the doctor prescribes from a generic point of view, the pharmacy can adopt either the Flynn or the NRIM.

The other point which you'll have picked up from the skeleton, but it is still an extremely important point, is that notwithstanding the NICE guidelines and the MHRA guidelines, over 90 per cent of prescriptions are written generically. Indeed, it increased. So as we say in the skeleton, in early 2012 it was 60 per cent, and when NRIM was launched, it went up to 90 per cent.

So rather than more doctors prescribing by brand, then actually more doctors, when the second generic came

along, they prescribed generically.

Again, one gets a sense sometimes from the decision that there is, you know, a massive medical problem with switching, well, clearly the advice has got to be, you know -- the advice is there and there is a concern. But, you know, we're here before the Tribunal listening to the evidence, and the evidence on the prescribing side is that 91 per cent of prescriptions were written generically. Which means that, at face value, the doctors did not deem it necessary to prescribe by brand. So when Mr Hoskins gets up and talks about the NTI and everything, clearly that is a concern. But one has to accept that the doctors have exercised their professional judgment and have written the prescription generically.

So with that, those two points, the what actually do the guidelines say and what is the prescribing evidence, we then turn to the pharmacy evidence. I think we need just to go to the decision. There are two passages in the decision that the Tribunal should be aware of. The first is, in my note, 439. Yes, it is page 199 of the decision.

So again, why am I taking the Tribunal there? So this is 439, page 199. We've got the guidelines which say the pharmacist can adopt usual dispensing practice,

we've got prescribing evidence. So 439:

"The CMA has focused its analysis on pharmacist dispensing behaviour."

The question of fact, this is, focused its analysis on pharmacist dispensing behaviour.

"Although it is prescribed as such as consultants and GPs who write prescriptions, the large majority of descriptions of phenytoin sodium are open, and so pharmacists have in effect a choice as to which type of phenytoin sodium capsule, the focal product, or Flynn product, or NRIMs they dispense to a patient. As such, the key substitution decisions in this case are taken by pharmacists."

So a key substitution decision could be taken by the doctor, but the doctor has regarded, at least by writing the prescription as generic, the doctor has looked at them and said well they are substitutes. So the prescribing evidence is that they are substitutes. But the CMA is concentrating on now on the second, the lower down, the pharmacy evidence.

So it is important to see that the CMA is focusing the case on pharmacists, and the other paragraph to look for -- it is a footnote, actually, at page 221, footnote 666. We've seen that it depends on the pharmacist's behaviour. What does that mean? It is

dependent on the interpretation placed on the guidelines by the pharmacists. You see this at footnote 666. So while technically the MHRA guidance only required pharmacists to maintain the continuity of supply when a specific formulation was prescribed, the evidence set out below shows that in practice, pharmacists, including Boots and Lloyds, interpreted the guidance as "Emphasising the importance of maintaining continuity of supply in all cases where a patient has been stabilised regardless of whether the prescription specified a particular formulation."

So it is quite an important point of fact which is buried in footnote 666. So the CMA's -- the edifice of this part of the case, it realises it can't get home on the prescribing evidence, the prescribing evidence would tend to suggest the two are substitutable. It is reliant on the pharmacist's behaviour, not only is it relying on the behaviour, it is relying on how the pharmacists have interpreted the guideline, something which is obviously not in Pfizer's control, and then it sets out at 4112, essentially to 4125, the section 26 notices.

So these paragraphs, 4112 to 4125, are absolutely key to the CMA's case on continuity of supply, and whether NRIM and Flynn are in the same market, and

whether somehow the Department of Health is completely dependent - completely dependent - on Flynn.

4112 is important. This is the CMA's case that it says it gets from the section 26 notices.

"Eight out of the ten pharmacy groups contacted informed the CMA that in the period April to November 2013, they followed the continuity of supply rather than commercial incentives when determining which phenytoin sodium capsule product to dispense. These pharmacists were sufficiently concerned by the risk of therapeutic failure that they did not view the Flynn product and NRIM's product as substitutes. This is consistent with what would be expected based on applicable clinical guidelines at the time."

So we know - and I don't have time to go through it - we know that when NRIM was launched, both Boots and Lloyds bought substantial quantities of the NRIM product.

THE CHAIRMAN: We're happy for these names to be read out, are we?

MR BAILEY: The position is that the identity of the pharmacies has been identified as being confidential and that's why it is highlighted in green.

THE CHAIRMAN: I know that. That's why I'm asking.

MR BAILEY: So the answer is no, it is not meant to be read

out in court at the moment.

THE CHAIRMAN: Is that understood and agreed, or not?

MR BREALEY: I'll have to take instructions on that. I find it extremely difficult to believe that the names of these pharmacies should be kept confidential.

THE CHAIRMAN: Has the CMA been in touch with these companies to see whether they object to their names being --

MR BAILEY: Yes, the CMA did an extensive process of contacting all the third parties asking for representations on confidentiality and they have maintained the representations they made earlier in the administrative process, which is a similar approach adopted by all parties in preparing confidentiality.

PROFESSOR WATERSON: Can we simply call them two of the largest pharmacy companies?

MR BAILEY: Yes, that seems like a sensible solution.

THE CHAIRMAN: Quite honestly, we know what you're talking about. You can refer to the paragraph, but I think in deference to commercial interests of third parties, they don't like their names being dragged through other people's processes. If we can manage without identifying the names, I think that would help.

MR BREALEY: Very well, although --

THE CHAIRMAN: It means you have to stop and think, which

is --

MR BREALEY: Well it is just another example of the inadequacies of a section 26 notice.

THE CHAIRMAN: Yes, well that's a point you can make, but what you're talking about is their interests, not the CMA's interests.

MR BREALEY: These people -- that a company can be hung on a statement by somebody who actually wants their name to be withheld, is a -- anyway, I won't waste time on it.

THE CHAIRMAN: It is not being withheld from us, just withheld from the outside world. We will take a view on that when it comes to the judgment stage. I think for the moment, hold the ring, please.

MR BREALEY: I'll try and find --

THE CHAIRMAN: Otherwise I'll have to clear the court.

MR BREALEY: Of course and we had -- it is a nightmare. It's a nightmare. But it's wrong in principle.

So B and L, then --

THE CHAIRMAN: I think if you start from the end of the alphabet and work downwards, you can refer to the paragraph numbers as --

MR BREALEY: Two very large pharmacies bought substantial quantities of the NRIM product clearly taking the view that they were substitutable. In closing we'll go through some of the documents.

I want to just test this proposition, that eight out of the ten pharmacy groups kept with this continuity of supply, and were not concerned with any commercial incentives. That's essentially what is being said. That pharmacy X has looked at the guidelines, only going to stick with one brand, and no commercial incentives at all.

So I'm reluctant to go into private, so I will try -- so, one pharmacy, if one goes to G2, tab 121.

THE CHAIRMAN: So all the pharmacies you're going to talk about are within the eight --

MR BREALEY: Within the eight. I should say, as we say in the skeleton, the ten account for less than 50 per cent of --

THE CHAIRMAN: They're the largest but -- (overspeaking) --

MR BREALEY: They're largest, but still less than 50 per cent of the UK market.

So this --

THE CHAIRMAN: This particular pharmacy.

MR BREALEY: This particular pharmacy is dealt with in the decision at 4.122, so hopefully the name has been expunged. 4.122.

THE CHAIRMAN: Yes, got that.

MR BREALEY: So this is what the CMA say happened. So in the context of 4.122, this pharmacy is only concerned

about the continuity of supply not commercial incentives. This particular pharmacy at 122, explained it has always been able to source its requirements from Flynn and parallel imports:

"However it also explained that if its pharmacists were presented with an open prescription for phenytoin, it would seek to ensure continuity of supply rather than be influenced by any financial incentive by checking."

Right. Remember that when NRIM was launched, discounts were given by Flynn and by Pfizer, two large pharmacies did look at financial incentives because the NRIM product was cheaper, and that is why they switched. One of them had their superintendent, that was sanctioned. It was okay to switch, and they looked at commercial incentives and they chose the NRIM product because it was cheaper. This document at 121 is all about financial incentives. So the third page in, this particular pharmacy --

THE CHAIRMAN: There's an awful lot of confidential stuff in here. Are you going to just --

MR BREALEY: I'm not really sure that this is confidential.

MR HOSKINS: It is Flynn's confidentiality. It is marked in light blue. Flynn's confidentiality, most of this, it's marked in light blue.

MR BREALEY: Right. So can I refer to this? Thank you. So

I'll keep the pharmacy out of it, but we can read the text.

THE CHAIRMAN: Good.

MR BREALEY: So:

"I've been offered phenytoin caps at £52. Can you please have a look at this and confirm if you're in a position to match the price?"

Then you get an e-mail chain still trying to ascertain if this is parallel import or NRIM. On page 1, see the e-mail below, we see a generic pricing offer from NRIM.

I've asked the Tribunal to read this when it can. It is clearly, this particular pharmacy, there is a risk that this particular pharmacy is going to switch to NRIM unless Flynn reduces the price. Halfway down page 1:

"How likely is it that the pharmacy would be able to fulfil all their needs with parallel imports or be able to switch all patients to a generic?"

And remembering that two pharmacies -- it is a bit like Voldemort, he who must not be named -- two pharmacies have already switched all their patients, basically.

MR BAILEY: I hesitate to rise, but I've spoken to the CMA. My understanding of the position is that insofar as the identities of the pharmacies are identified in these

documents, no objection is being made for them to be referred to in court. However, third party was not consulted in relation to their identity in the public version of the decision, which is why, for example, you see the various highlighting at the moment.

THE CHAIRMAN: CMA's decision?

MR BAILEY: Well, the CMA, for the purposes of this appeal, has not gone back over the redactions that have been made in relation to the decision itself. Insofar as it will make it easier, the identity of the pharmacies can be referred to now insofar as they are contained in the trial bundles.

THE CHAIRMAN: I'm grateful to you, Mr Bailey. I think that would make it a lot easier. Yes, please. So Mr Brealey, we can release you from your self-imposed --

MR BREALEY: My Harry Potter World.

THE CHAIRMAN: It was getting a little bit obscure.

MR BREALEY: It was.

THE CHAIRMAN: Thank you. That's not a general release.

MR BREALEY: Okay. So the Co-op does write to Flynn saying, "I've been offered this reduced price."

The important point is that the CMA, although we put the CMA on notice of this at the oral hearing, it does not feature in the decision.

MR HOSKINS: I'm sorry. That's just not right. It's

page 210, footnote 621.

MR BREALEY: I'm sorry, it is a long day. It does feature in the decision but the CMA does not engage, does not engage with this point at this hearing. I take that back. It does.

THE CHAIRMAN: Note 621.

MR HOSKINS: Footnote 621. We've also dealt with in the skeleton argument, I believe.

THE CHAIRMAN: You'll have your chance.

MR HOSKINS: Absolutely.

MR BREALEY: Two points. It does not deal with it at this hearing, but also, and this is the section 26 point, as far as I'm aware, the CMA never go back to the Co-op and ask them the obvious point: "Would you have switched had you not got the better price from Flynn?" Because the obvious inference from that is "Had you switched all your supplies to NRIM, you would have switched the patients?"

This is an instance of the inadequacy of the section 26 statement. This is an instance of, to quote the words in paragraph 4112, the Co-op actually being quite concerned about commercial incentives.

PROFESSOR WATERSON: This is, of course, July 2013, before November 2013.

MR BREALEY: Yes. And one of my points is that when one

reads the section 26 notices, one does not know whether it is pre or post-2013, very often. It is something that needs to be tested.

I will move on to another pharmacy. There is more to be said about the Co-op, but let's go to -- the point is, the CMA don't go back to the Co-op and ask them about these commercial incentives.

Can I go to Day Lewis, which is -- if we go to bundle I. So bundle I1 is the section 26 notices. Tab 36. So the only documents I think we need at the moment is the decision and bundle I. So this is Day Lewis. In the decision, we've got paragraph 4.119:

"Rowlands, Day Lewis and the Co-op all informed the CMA that they did not purchase NRIM's product during April-November 2013, all being concerned about the risk of therapeutic failure."

Then we have -- and this is the biggest quote at 4.121. So the reader looks at this summary of the pharmacy evidence and you get a massive quote from Day Lewis at 4.121.

Now, in bundle I1 we go to tab 36 and tab 37. Again, I'm trying to tease out of the Tribunal the robustness of the section 26 statements. So we go back to 4.119 and there you see at 4.119, Day Lewis footnote 673, so this is paragraph 4.119, Day Lewis at

673, that is document 00649.1. So that is, Day Lewis told the CMA "Did not purchase NRIM's product. All being concerned about the therapeutic failure."

That document, 649.1, is at tab 36. This is from a [✂], who is the company secretary.

"We have been purchasing from ...

"The manufacturer is Flynn.

"NRIM did come out with 100mg caps at the time but buying them meant we would lose our discounts from Flynn if we did not buy all strengths of their products, hence stuck to the Flynn brand."

This is 2014. We'll come on to that. So 5.1:

"We did at one point buy the NRIM product but because of losing the discount deal for other strengths if we did not buy all strength of the Flynn product, we stopped using this brand and have stuck to Flynn Pharma."

THE CHAIRMAN: It is not clear whether they have bought or whether they are speculating.

MR BREALEY: It is not, but the first point I'd like to emphasise is that the document that the CMA rely on clearly -- actually, I don't think it is any -- it is the next response that they rely on. It's at tab 37. But one would have thought that there would be some probing by the CMA of the two inconsistent statements

because we here have Day Lewis essentially making two section 26 inconsistent statements. The one at tab 37 is the one that is essentially quoted in full at 4.121.

So [✂] writes the first one on 2nd July 2014. He's the company secretary. He then comes back and says that:

"Our lawyers, Charles Russell, have subsequently been in contact with your colleague [✂], agreed to extend the original deadline ..."

Then he says:

"Having researched the matter in more detail, it transpires that Day Lewis never purchased any NRIM phenytoin sodium hard capsules. The buyer, who is himself a pharmacist ..."

And this is the bit that is then quoted in the decision.

But [✂] is not giving evidence; we don't know. He certainly never retracts the fact that discounts were a factor. Now, even if one takes the second statement at face value, what is the evidential value on it?

Well, I'll take the following points. First is that [✂] doesn't actually say that part of the decision not to buy NRIM was the discounts. It may have been too. But if he was in the box here, we may have been able to put to him: "Well, actually, had the discounts

been sufficient, you would have done it." Maybe, maybe not. We don't know.

But the second point is his section 26 statement is based upon hearsay upon hearsay. It's made by [✂], the company secretary, who relies on a conversation he had -- presumably this is now in October 2014 -- with an unnamed buyer which in turn relates to a conversation between the buyer and an unnamed person from the superintendent's office. And that conversation relates to something that took place over one year previously. So it's hearsay upon hearsay, and it's not contemporaneous.

THE CHAIRMAN: This is the second letter, the 6th October letter. Is that a reply to a formal section 26 notice?

MR BREALEY: I think it is, because it is "Thank you for your letter of the 8th", enclosing a further notice under section 26.

THE CHAIRMAN: No, was the July letter a response to a section 26 notice?

MR BREALEY: It was, yes.

THE CHAIRMAN: So it's not clear to me why two notices were needed.

MR BREALEY: Well, it seems that in certain cases the CMA did go back. It got a response. There are July section 26 responses, and a few weeks later the CMA went

back and asked more questions. But the first section 26 notice is not referred to.

When we get to the second 26 notice. As I say, it's hearsay upon hearsay relating to a conversation which took place over one year previously. Again, I remind the Tribunal of Lord Carlile's comments that these section 26 notices have to be treated with a degree of caution.

Third, there is a reason given, and this is the paragraph 9 over the page, a reference to the reason about it being -- sorry, yes, it is. It's the last paragraph. There is an issue as to bioavailability.

Well, again, we would want to test this with the pharmacist because again, Professor Walker's view is that the two NRIM and Flynn capsules are bioequivalent, but if that is the reason, well then, it's not necessarily a good reason.

Also, this is a point that applies to quite a few of these pharmacy statements. The CMA, in this section on the pharmacy statements, treats it rather as a point in their favour that a pharmacy only purchases one brand. So here we have [✂] saying, "Well, we only buy Flynn. We don't buy any NRIM."

The original reason was because of discounts. Now, it's because of the bioequivalence. One has to remember

that by this time -- and we don't know whether it is basically pre-or post -- but by this time NRIM has, say, a third of the market, and that's being generous to the CMA. A third of the market.

Let's assume NRIM has a third, parallel imports have a third, and Flynn has a third. We know from paragraph 1.4 of the decision that there are a 48,000 patients takings phenytoin. 48,000 patients taking phenytoin. So on a one-third split. You've got whatever it is, 16,000 patients in the UK taking an NRIM capsule, and if this is to be believed, and this pharmacist is only buying Flynn, it must be turning some patients away from its chemist or it is switching them to the Flynn capsules.

MR HOSKINS: I'm sorry to rise again. It is the last sentence of item 9 on tab 37.

MR BREALEY: Yes. I'll come to that. If a patient -- well, there are 48,000 patients, and a third -- so we've got 16,000. He says:

"if a patient was already being prescribed a preparation that was not manufactured by Flynn then that preparation would be ordered locally specifically for that patient."

Correct. Now, is he talking about where the patient was being prescribed by brand, or is it generic?

"If the patient was already being prescribed a preparation that was not manufactured by Flynn, then that preparation would be ordered locally."

But if it is pursuant to the guidelines we've seen -- we saw the guidelines -- if the prescription is by brand, then of course you would expect, pursuant to the guidelines, that you would order it locally. If it is generic, then under the guidelines you can dispense anything. Either the NRIM ...

Okay, we've got two lines from somebody, and can one say for certain that this is, in all circumstances, if a patient was already being prescribed?

THE CHAIRMAN: You're saying it is "being prescribed", not "is taking".

MR BREALEY: Correct, correct. So it is a thoroughly bad point for Mr Hoskins to stand up. That's indicative of what we're faced with.

So, can I go to Morrison's. Again, we get the decision at 4.112. This is one of the eight out of the ten pharmacies who had no commercial incentives, were only concerned with giving the brand that were already taken. So the bit for Morrison's is paragraph 4.116:

"Morrison's pharmacies also focused on ensuring continuity of supply ... would only be dispensed in limited circumstances."

So focused on ensuring continuity of supply, explaining that NRIM's product would only be dispensed in limited circumstances. It gives the quote.

Now, there are two section 26 statements. The first one is at tab 45. The quote is in the second statement, so the first section 26, as I say, is at tab 45. I'll do Morrison's and then I'll let -- I think the Tribunal will get a flavour of it. This is the first statement, which is not referred to.

Just to speed up, if we go to question 5, which is "Do you purchase or have you purchased phenytoin hard capsules?"

So two-thirds of the way down:

"From our work as pharmacists, options are to fulfil using any manufacturer available. However, this is a product where patients' doctors like to remain on the same brand, as (...read to the word...) differences can occur. As with all descriptions, if the product is written as a brand, then we would have to supply the brand. If written generically, we can supply either."

Now, that paragraph is not referred to in the decision. One goes over the page to paragraph 9, at the bottom:

"Unless the patient specifically requests, or is already on a specific brand, we would issue whatever

that patient medication record selects. This would usually be the cheapest option available from ... also depends on bioavailability of the product (...read to the word...) medication."

So, you know, it depends, but can you say -- and this is the first one -- can you say that these two passages support paragraph 4.112? And the answer is quite clearly no.

Question 15. Again, the CMA, at 15, doesn't refer to the reply at 15. At the bottom, so this is almost at the end -- sorry, not 15. I beg your pardon. It is 14. I don't know if you have it; it is on the left-hand side:

"Pharmacists follow advice/guidance, have up-to-date knowledge on medicines. Pharmacists must take into account which brand that patient is to maintain the same bioavailability."

Again, the advice is, from Professor Walker at least, that the NRIM and the Flynn capsule are bioequivalent. Over the page, question 15:

"Your purchasing decisions are determined by doctors' professional judgment who would take the most up-to-date guidelines."

So your purchasing decisions are determined by a doctor's professional judgment. That could mean, "Well,

if it's written from a generic point of view, then we can issue either."

So we would say that, looking at this first section 26 statement, it's actually supportive of the pharmacists adopting the cheapest version.

We then go to the second response at tab 46. So the CMA comes back to the pharmacist. I don't have time to go over the rest of this in any detail, but we start three pages in. So one sees annex 8, "A Notice Under Section 26 of the Competition Act". So again, none of this is signed by anybody.

What the CMA do is ask a further question, and this is at the bottom:

"Having carefully considered your response the CMA wishes to obtain further information on Morrison's policy on the need to take account of which brand the patient has been stabilised on to maintain the same bioavailability."

It goes and asks two questions.

"In what circumstances would you dispense the NRIM product?"

On the top, this is the bit that is cited by the CMA: of all the two section 26 notices, these would be dispensed if the patient was already on. And that is the bit the CMA rely on.

You then go down the page: "Does Morrison's purchase Flynn 100mg? Please explain why Morrison's made the decision to purchase and dispense NRIM's product including all of the factors it had considered. If a prescription is written generically, the wholesaler sends in the cheapest option available to us. This would usually be the case unless the prescription or patient specifically requires this to be overridden and a specific brand ordered."

That is just not in the decision. That's why I said this morning -- and I don't say this lightly -- there is a degree of a lack of objectivity in the way that the CMA has portrayed the pharmacy evidence.

Again, they repeat that in the answer to question 10.

The last point I'll make on this, and then Mr O'Donoghue can ... We've got the Alliance data. So remember that what the CMA is saying about Morrison's here is that the NRIM's product would only be dispensed in limited circumstances.

So if we can go to the reply, that's at bundle A, tab 4. The CMA have -- so this is in our reply, if you go to tab 4.

THE CHAIRMAN: What page?

MR BREALEY: I'm sorry, sir. It is basically the very last

page of the reply. Sorry, yes, tab 4A. So this was our reply.

Again, I make this submission in the context of paragraph 4.116, where the CMA is telling the reader that Morrison's would only dispense NRIM's product in limited circumstances. In limited circumstances. Then they give a reason, which we have shown, that is completely inconsistent with other answers.

Then we look, and the CMA had the wholesale sales of the 100mg phenytoin sodium. We look at that graph, and we see how it starts buying more and more of NRIM and less and less of Flynn. The only explanation is that Morrison's the chemist is switching the Flynn patients on to NRIM. That is the hard data.

So if one takes the Durkin and the Tesco line, which is "Oh, CMA, be very, very careful what you do with notes of interviews", we would say section 26 notices, because it is based on hearsay. Look for corroboration. The corroboration actually is completely inconsistent with paragraph 4.116.

I could go on more, and there are other stories to be told on this pharmacy, but I will do it in closing. But the whole edifice of the case in this section is on continuity of supply, and we say that edifice is on very, very shaky ground. Really, the CMA should be

referring to sales data like that and accepting that Morrison's must have switched.

THE CHAIRMAN: Okay.

MR BREALEY: That's all I have to say, sir. I will hand over to Mr O'Donoghue, who is going to, I think, deal with fines in 15 minutes, and then Miss Bacon can have her --

THE CHAIRMAN: That's a challenge, if ever there was one.

Submissions in Opening by MR O'DONOGHUE.

MR O'DONOGHUE: Sir, it is difficult, and I think we've technically moved beyond the graveyard slot at this stage.

THE CHAIRMAN: Please carry on.

MR O'DONOGHUE: I'll be as brief as I can. I'm conscious fines is really more for closing. I want to sketch some of the more broad outlines of some of the points we wish to touch on. Can I ask you to look at what the CMA did in the case of Pfizer. I think Flynn's fine is done on a somewhat different basis, and I think Miss Kreisberger will be addressing you on that. So the best place, I think, to pick this up is at table 7.1 of the decision, which is on internal page 445. There, sir, you'll find the various steps which you'll be very familiar with.

Now it is unclear to me, some of the steps are

marked confidential, so I'm not going to read those out. So you see the relevant turnover then the 30 per cent starting point, a 10 per cent uplift for aggravation. Therefore a 100 per cent uplift for specific deterrence, and you will see the two figures there which are not confidential, there is a debt of about £67 million, so £67 million for deterrence alone, and then no further adjustments, and then a final figure of just over £34 million.

Now, the total fine is unprecedented in CMA fining history, short though it is. The 30 per cent multiplier, I can only find one other case where that has been imposed, which is Galvanised Steel Tanks. The 400 per cent uplift for deterrence is unprecedented both as to the 400 per cent figure and as to the £67 million actual uplift. So on many, many levels, this is entirely unprecedented. Now, I did mention one case where the 30 per cent was used, Galvanised Steel Tanks. And just to put this in context, it is a 7-year cartel involving all but one player in the industry, and three of them were most serious cartel behaviours, price-fixing, bid rigging and market sharing by way of customer allocation, and one of the directors of one of the defendants pleaded guilty to a criminal offence.

So what the Tribunal is being asked and actually in

very explicit terms, is that this case of unfair pricing is as bad as a cartel of that kind.

Now, in my submission, that submission only needs to be stated to see that it cannot possibly be correct.

For the CMA to have any chance of justifying this extraordinary penalty, the case, in my view rationally, has to sit at the extreme end of intent. Now, what we see in the decision is the CMA has hedged its bets and it has said intentional or negligent. It was of course open to the CMA to impose an aggravation factor of 10 per cent for an intentional infringement. They didn't do that. Under the previous OFT guidance it was also open to the CMA to impose a mitigation of 10 per cent if the infringement was negligent as opposed to intentional.

So we see within the guidance whether something is truly intentional as to opposed to merely negligent. It can have some bearing in terms of aggravation.

Now the elephant in the room, in my submission, is that their template for pigeonholing this fine is a horizontal cartel. We're led to believe, in respect of the 30 per cent, it is as bad as that kind of conduct. In my submission, it really is apples and pears. The cartel infringement is obviously the most obvious pernicious type of infringement. You don't need

to be an accomplished expert to find out that is a concern.

We're really at the other end of the spectrum; the least legally certain, the most difficult and complex area, I think, of all of competition law, and we're led to believe that these are close cousins or at the same end of the spectrum. And in my submission, that is an impossible position to sustain.

In a sense, the case law is extremely revealing. This, to my knowledge, is the first case finding a standalone excessive pricing. There has been zero enforcement within the United Kingdom and at European Union level for more than 15 years in respect of unfair pricing. The Scandlines position in Attheraces were generally thought to have effectively killed off this area of competition law.

You have economists, including the CMA's chief economist, telling the world at large and in their publications that this is an area which should either not be subject to intervention at all, or certainly not subject to fines. And from my own personal experience of advising in this area for more than a decade, I cannot recall a single example in the last decade where I've ever been asked by a company to advise whether the price is unfair. Now, contrast that to a cartel. It is

not really a sustainable comparison.

That is at a high level of aggregation, to suggest that unfair pricing is in the same ballpark as the cartel, is completely unsustainable.

Now, add to that the CMA's test in this case. So we are led to believe from the decision that a return on sales of more than 6 per cent is either abusive or at least very, very suspect. And that, too, is entirely unprecedented. In fact, in the decision at paragraph 719, the CMA says Pfizer never even looked at costs at the time it decided its price. The suggestion that, in pharmaceutical markets, people are routinely engaged in costs plus pricing is completely unsustainable.

Then one gets to, finally, a comparison with the case law --

THE CHAIRMAN: So you mean, by that, that you wouldn't have expected them to have looked at their costs because that's not how they set their prices?

MR O'DONOGHUE: It simply isn't how it works. You've got uncontested evidence from Flynn that for each and every one of their products, cost plus is simply not the basis on which they approach pricing. What you're looking at in each and every case is comparators. That's how people price in this market. So this decision, it is

unprecedented in terms of cost plus, and there is clear contemporaneous evidence that neither Pfizer nor Flynn -- nor, I would suggest, anyone really active in this industry -- considers pricing on the basis of cost plus at any stage.

So if that is the metric of condemnation, it is not a metric which has any resonance in the actual market that the CMA is considering.

Now, just to wrap up a couple of things in the case law -- and I'll be done very, very quickly -- there is literally a handful of cases in 50 years of enforcement finding unfair prices. And none of those cases, as I have submitted, concerns a pure standalone unfair pricing allegation. In fact, there is a pretty consistent theme in the cases which have been brought, and they are primarily in the nature of exclusion cases, or in the context of EU law, market partition cases, or both.

Now, United Brands, sir, you'll be very familiar with this. It was a discriminatory pricing allegation, exclusionary price allegation, and a partitioning case. And the exclusionary -- or the unfair pricing abuse, which was number 4, was essentially the corollary of the other three abuses. And I won't take this up, but the Commission said -- and this is at page 15 of the

Chiquita decision which is in E1/1:

"The marketing policy of United Brands had resulted in the segregation of the markets in question."

Sir, you will remember this very clearly. In fact one of the real issues in that case was the green bananas clause which prevented arbitrage. So in fact the real issue in that case was a contractual clause and the unfair pricing was essentially a corollary of that, and of course ultimately it was annulled. That's United Brands.

You had Mr Brealey's submissions on Albion Water, which I won't go back to.

Let me say a couple of things about Napp, which is the Tribunal's main precedent in this area, and that's at authorities bundle A1.

Again, it was primarily in the nature of an exclusionary case. There was the predatory pricing to the hospital segment which led to follow-on prescriptions in the community segment. The hospital segment was the gateway to the community, the ratios were about 10/90. Napp strategy, which had been successful, which was if you can lock the gateway, that then protects the community market. So it was primarily an exclusion case, not an exploitative case.

At paragraph 364, very revealingly, the OFT as it

then was -- this is the judgment -- said that it would not have pursued the exploitation aspect of their case but for the presence of exclusion. Indeed, the tribunal said that it would be artificial to regard the abuses, exclusion and exploitation as unconnected, and that's paragraph 517.

THE CHAIRMAN: It doesn't necessarily mean the OFT would never pursue an exploitation case; it just means that in this case they saw it as the natural adjunct to the exclusion.

MR O'DONOGHUE: I accept that, but there are a couple of points. First of all, a case in which there was both exclusion and unfairness, as a corollary, must, by definition, be worse than a case where there was merely one type of abuse. To the extent of the analogy in this case, I would certainly accept that if Pfizer or Flynn were engaged in conduct to exclude NRIM, Teva, all the other AEDs, that would make the case worse, but the absence of that factor when one is trying to calibrate this infringement, it must mean that Pfizer is in a better position, and certainly not at the cartel end of the spectrum.

So if one compares this to the few precedents we have, this, in my submission, is by far the most benign, if I can call it that, of the infringements that have

been identified. That must matter in the context of fines.

In my submission, for this case to have any chance of justifying this unprecedented fine, both in terms of absolute amount of constituent components, it has to be at the level of some form of super intent.

Now on that point, we have, after several years of administrative proceedings and litigation, the CMA's case essentially amounts to, in my submission, one e-mail, which is supernormal profits. The second e-mail they have milked to death is the so-called fleecing. That really is quite misleading. We have made very, very clear in all our submissions, and one can see this clearly from the e-mail, that that related to an accusation by third parties that Pfizer would be accused, wrongly, of fleecing the NHS. It is quite wrong, in their skeleton argument, to see that extracted yet again. They could put this to Mr Poulton, but if one compares the totality of evidence, particularly in G1, value of medicine to the NHS, it really is quite distortive and misleading to cherry-pick on one, one and a half, e-mails to make that the lynchpin of their case.

The Tribunal will have to form a balanced view of the preponderant evidence. The evidence, in our

submission, is extremely clear. Here were companies at the time who had a loss-making product. They had decided to exit the PPRS. It is common ground that was a legal decision. It is common ground that there had to be some price wise. Everybody was scouting around for a benchmark price at the time, and Pfizer, NRIM, the T company and Flynn and, we would suggest, Teva, everybody saw the tablet price as the instinctive measure or benchmark of value to the NHS. It was effectively a regulated price. It was a price reduction. It was set by a regulator who is unique in that it is also the customer.

This is not some sort of argument which a lawyer or economist, many years after the fact, has come up with. The contemporaneous documents are replete with evidence of reference to the tablet both as a benchmark and as a benchmark of value. So this really is evidence of a high quality.

I mean, one way to test the CMA's fine is to put yourself into the shoes of Pfizer or Flynn in 2012. So there was market intelligence from all corners of the market that the tablet was the distinctive value-for-money benchmark. If the CMA's case is to be believed in terms of the unprecedented fine, Pfizer and Flynn should have entirely ignored the contemporaneous

and clear market evidence, and they should instead have addressed their minds to the one thing that the decision says they didn't address their minds to: costs plus 6 per cent. I would suggest that is an entirely unreal and actually unfair perspective.

The final point I want to make, and I'm conscious of the time, Mr Brealey has addressed you on the powers of the Department of Health. The Department of Health, as I said, is unique. It is a regulator and a customer. I'm not aware of any other market where the regulator is also the customer. They had a suite of formal and informal powers available to them, ranging from the fireside chat to statutory regulation. At no stage in relation to pricing, prior to running off to the CMA, did they approach Pfizer for any discussion of that kind.

We suggest that is significant, certainly in the context of fines, because having seen the regulated Teva price sticking for many, many years, having seen an absence of any dialogue with the regulator and customer -- and this is a regulator and customer that my client is in continuous dialogue with -- the silence from the Department of Health was eloquent. The first we heard of this -- so the chronology is that the Department of Health ran off to the CMA on

28th September 2012, and that was a matter of days after the new generic product had been launched.

The first discussion Pfizer had with the Department of Health in relation to the price was in January the following year. We suggest that is a significant and important and, in my submission, mitigating factor in the context of fines. So we will come back to that. That is the main issue in fines.

There is one final point I wanted to raise before I sit down. It is in relation to ground 4 of our appeal. We have set out eight or nine pages in our skeleton, a series of legal and factual points in relation to ground 4. Those points have not been responded to in the CMA skeleton. There isn't a single reference to our skeleton in relation to ground 4 in the CMA's skeleton. We will be expecting a response on Wednesday. We will deal with that in closings when we get that response.

THE CHAIRMAN: Thank you. Before you sit down, can I ask you, in relation to the deterrence uplift, who do you think the CMA are trying to deter?

MR O'DONOGHUE: Well, sir, it is a good question because one of the realities of this case is well, deterrence for who? So we know in relation to the United Kingdom there is new legislation which, on any view, plugs the

so-called gap in relation to generics. So there is nothing to deter there. If the idea is to deter the branded, there are already schemes for that. If the idea is to deter Pfizer and the world at large outside the UK, then we're slightly baffled, because in many of these countries out of the United States, unfair pricing is not illegal. In all European countries there are regulatory price controls and profit gaps of a similar nature to those in the United Kingdom. So if one is considering deterrence in this market, whether of Pfizer, Pfizer Inc, or the world at large, you have to rationalise what is the pre-existing regulatory framework by which prices and profits are capped? You essentially have to calibrate and put that to one side because there is nothing to deter there.

In my submission, candidly, the deterrence here is that the CMA saw a big target in the form of Pfizer Inc and that is used as a sort of lever to impose an extraordinary fine, both in terms of the 400 per cent uplift and in terms of £67 million just for deterrence. It is truly extraordinary.

THE CHAIRMAN: Right. Well, that concludes Pfizer's opening.

MR BREALEY: Thank you, sir.

THE CHAIRMAN: I think that concludes proceedings for today.

We will meet at ten o'clock tomorrow.

(5.06 pm)

(The hearing adjourned until 10.00 am the following day)

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