IN THE COMPETITION APPEAL TRIBUNAL

Case No. 1274/1/12/16 (IR)

Victoria House,
Bloomsbury Place,
London WC1A 2EB

17 January 2017

Before:

PETER FREEMAN CBE, QC (Hon)
(Chairman)

(Sitting as a Tribunal in England and Wales)

BETWEEN:

(1) FLYNN PHARMA LIMITED
(2) FLYNN PHARMA (HOLDINGS) LIMITED Applicants

- and -

COMPETITION AND MARKETS AUTHORITY Respondent

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HEARING OF
APPLICATION FOR INTERIM RELIEF

A P P E A R AN C E S

Ms Ronit Kreisberger and Mr Tom Pascoe (instructed by Macfarlanes LLP) appeared on behalf of the Applicants.

Mr Rob Williams and Ms Jennifer MacLeod (instructed by CMA Legal) appeared on behalf of the Respondent.

Mr Brendan McGurk appeared on behalf of the Department of Health

Mr Robert O'Donoghue and Mr Tim Johnston (instructed by Clifford Chance LLP) appeared on behalf of Pfizer Inc. and Pfizer Limited

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THE CHAIRMAN:CHAIRMAN: Good morning everybody.

Ms. Kreisberger.

MS. KREISBERGER: Thank you, sir. I appear for Flynn Pharma and just to introduce today's line up, we have Mr. O'Donoghue for Pfizer, Mr. Williams for the CMA and Mr. McGurk for the Department of Health.

Sir, before I turn to our application there is just one matter of housekeeping, which concerns the confidentiality of the decision. We are obviously at a very early stage because this hearing takes place before our notice of appeal is lodged, the decision is still confidential.

THE CHAIRMAN:CHAIRMAN: You have not even got a case, Ms. Kreisberger.

MS. KREISBERGER: We do not have a case. One of the issues that arises is that we do not have a non-confidential version of the decision. We have liaised with the CMA on this issue and have agreed to tread very carefully as far as references to the decision today are concerned. So the suggestion is if I am proposing to take you to a particular passage from the decision, that I announce the passage and pause, if there is any concern as to third party confidential material in the section being referred to.

THE CHAIRMAN:CHAIRMAN: Most of the decision is non-confidential, am I right?

MS. KREISBERGER: That is correct and much concerns our own confidential material in any event, which we are in a position to take a view on.

THE CHAIRMAN: Well, I would like the discussion to be as open as possible. That would be my preference.

MS. KREISBERGER: Understood. I am grateful, sir.

THE CHAIRMAN: While you are on housekeeping, we have the whole day. I do not want to go over into a second day, but I am willing to sit for as long as is necessary today, but I hope we can deal with this fairly promptly. If I feel things are going nowhere, I shall adjourn and give everybody a chance to cool down, but we will see how we go, shall we?

MS. KREISBERGER: I am grateful.

THE CHAIRMAN: Otherwise it will be the normal timetable, we will go on until 1 o'clock, we may have a break in the middle, and we will sit back after lunch if we need to.

MS. KREISBERGER: Thank you, sir. I will take matters at a brisk pace.

THE CHAIRMAN: Not too brisk.

MS. KREISBERGER: Brisk but considered. Application by MS. KREISBERGER

MS. KREISBERGER: Sir, if I may, I would outline the five points that I was going to cover this morning and hope to get through them this morning and then go on to develop those points.

THE CHAIRMAN: I was going to say you can take it that I have read the papers.

MS. KREISBERGER: I am grateful. So the five areas we propose addressing this morning are the directions themselves, what it is that Flynn would be compelled to do if implemented, and particularly the relevance of Pfizer's position here and what that means in terms of price regulation. I would then propose to say just a few words about the test for interim relief. I am grateful for the indication you have read the papers, so I think that can be dealt with quite briefly.

THE CHAIRMAN: I have also read our own rules.

MS. KREISBERGER: Thank you, sir. I can deal very briefly in that case with what it is the Tribunal needs to be satisfied of and really say a few brief words on what are the overriding considerations in our submission of preserving the integrity of Flynn's appeal, to ensure its effectiveness and protecting Flynn from irreparable harm.

Then I propose to move on to the merits of the case and, sir, you will be very familiar with the test, it is a very low hurdle, so we propose saying little on this, but we do need to correct the impression given by the CMA in their response that implementing the directions would in some way simply be to uphold the law of the land. We say it is not so, it is a highly controversial decision on many levels and we will therefore address a few comments on that, sir. Plainly these are not matters for the Tribunal to resolve today, but it is really not to leave the Tribunal with the impression that the decision in some sense represents accepted wisdom, given in particular the direct interference in price, which hangs over Flynn.

THE CHAIRMAN: Are you saying there is any accepted wisdom in competition law, Ms. Kreisberger?

MS. KREISBERGER: I would not presume to make that submission, but if there were, excessive pricing is certainly not an area for it and this decision departs from those authorities which we do have, in quite unusual ways, which if I may I would like to take you to briefly, as I said, to give a flavour for our position on this decision, which is so far from accepted wisdom.

THE CHAIRMAN: Carry on.

MS. KREISBERGER: Thank you, sir.

Then moving on to the balance of convenience, which is really the meat of today's application. The Tribunal will not be surprised to hear that the fact that damage to Flynn is irrecoverable, irreversible and substantial is at the front and centre of our submissions on this, and that the directions are also unworkable. This proposes a direct interference in price with no guidance at all and if I may I will take you to some relevant passages on that, sir.

Finally on balance of convenience, I will say a few words on the patient detriment on which the CMA now seeks to rely. My client is of course sympathetic to these issues, but they do not in this context militate against relief. If the CMA's objective were to bring prices down fast, it were well within its gift to expedite matters, but it is not for the CMA now to say we should sacrifice the integrity of Flynn's appeal and resolve these issues on an interim basis against Flynn in the interests of haste.

The final topic for today for my submissions is the cross-undertaking and that concerns in particular its impact and issues raised about the correct beneficiary.

THE CHAIRMAN: Can I just be clear, it is your job to convince me to grant this relief. You are not entitled to this relief, you have to convince me that I should exercise the Tribunal's discretion to grant it. Are we at one on that?

MS. KREISBERGER: We fully appreciate that, sir, and we say we do that on these facts quite easily.

Sir, if I may direct you to page 489 of the decision. Those are the directions.

Sir, I appreciate you will have read these, but just to recap, at paragraph 1(b)(i) Pfizer is required to reduce their input prices charged to Flynn within 30 working days of the decision, so that sets a deadline of 23 January. Then at (1)(b)(ii) is the first limb of the directions which applies to Flynn and that is the first step price reduction by Flynn, the same deadline is set for that, 23 January, and that is for stock which has been purchased from Pfizer at existing prices. There is then a second step at (iii) and that imposes a cut-off date of 7 April as the long stop, or rather more rapidly, within two days from purchase of the newly priced product from Pfizer, Flynn must introduce a second revised set of prices. These are to its NHS list prices. So it is a two-step price reduction based on existing prices from Pfizer and revised prices from Pfizer, which will apply from 23 January and Flynn has two days from sale of that stock.

Then we have some guidance in paragraphs (c) and~(d).

THE CHAIRMAN: Just before you get on to that, on your first date, that is next Monday, is it not?

MS. KREISBERGER: That is right.

THE CHAIRMAN: What do you understand that if you comply with these directions Flynn would have to do? I understand about the Pfizer supply price and the existing stock, but in relation to Flynn's price what do you understand that you would have to do?

MS. KREISBERGER: Well, we are in the dark, sir, in terms of where price needs to go and that is a key plank of our application.

THE CHAIRMAN: I understand that, but you must have made contingency plans on the possibility that you do not get the relief. What is your client planning to do on Monday?

MS. KREISBERGER: What we are able to do -- and I may just look to those behind me to confirm this is right -- is on the step 1 price reduction there are numbers in the decision on which those price reductions could be based, so Flynn would really have no option but to rely on the numbers put forward by the CMA in the decision, so that means the CMA's assessment of Flynn's costs allocated on a basis that Flynn neither recognises nor understands --

THE CHAIRMAN: I understand that, but just so -- I am just trying to explore what --

MS. KREISBERGER: Using those numbers, that is right, sir. So at least on step 1 the CMA has put its case, so Flynn can take those numbers, it does not agree with them, and it can set prices based on the value set out in the decision.

THE CHAIRMAN: So it is not physically and practically impossible to comply with the directions?

MS. KREISBERGER: It is not practically impossible to implement step 1, subject to all the points that I will come on to, but I do not think that is what you are asking me at this stage, but it is physically possible.

THE CHAIRMAN: If you then did that, that is prima facie compliance with the directions and I think you are obliged to tell the CMA what you are doing, follow up any requests -- no doubt Mr. Williams will address me on this, but in a sense it is then over to the CMA, is it not, to say "Well, is Flynn complying or not?", so the question of whether it complies with the direction is in play, it is a question that is in play. You are not automatically going to be liable for breach of anything; as far as you are concerned you have complied with the directions --

MS. KREISBERGER: That is correct.

THE CHAIRMAN: -- and the situation goes forward --

MS. KREISBERGER: That is correct.

THE CHAIRMAN: -- until you buy some more stock.

MS. KREISBERGER: Until we buy some more stock, or until the cut-off applies, until we run out of existing stock.

THE CHAIRMAN: I have the figure of three months' stock in my head. I do not know where I got that from, but is that what you have?

MS. KREISBERGER: That is right, that is in the evidence. We would say two to three months is about right.

THE CHAIRMAN: Right, sorry. I interrupted you, go on.

MS. KREISBERGER: But of course that does not take us very far because Flynn genuinely considers itself unable to implement limb 2 based on revised input prices and I will come on, if I may, to address you on that issue, sir.

THE CHAIRMAN: So it is not a situation that actually confronts us until about March, what you have been saying?

MS. KREISBERGER: That is correct. We think March is about right, two to three months, so that is correct, in terms of physical ability to implement.

Coming to (c) and (d), Flynn is told to have regard to the decision, but for the avoidance of doubt at (d) we see:

"Nothing in these directions, or the decision should be taken to mean that the parties are precluded from earning a profit margin greater than the reasonable rate of return adopted by the CMA for the purposes of establishing cost plus in this decision."

That is the 6 per cent return on sales figure that is advanced in the decision. So the directions acknowledge that that figure is not part of the directions.

Now, Pfizer have described these directions a mess. I do not think we would demur from that. The position we are in now, and, sir, I think this is precisely what you have in mind, is that it is right that this may be deferred until March, but given that Pfizer has not applied to suspend the directions, we will be in a world where we have to address limb 2. That seems clear. We assume that Pfizer will be complying with these directions and reducing their input price by 23 January.

Now, I will address you more fully on the difficulties Flynn faces in coming up with a price that is to comply with these directions based on a revised input price. We say that being told to have regard to the decision in those circumstances is irrelevant because Flynn is left in an analytical vacuum in those circumstances.

There is another issue that Flynn may face. We say that when prices come down -- if prices come down -- they cannot later go up, or there is a risk that they cannot be put up given market realities and I will come on to address you on that. This means that if Pfizer later took the view, following a successful appeal, that they should put their prices up -- we simply do not know, that may be one outcome -- Flynn takes the view that it would not be able to pass those price rises on, so that could put Flynn in a very difficult position if it was unable to cover its own costs of supply. So that is one issue that Flynn may face and we just raise that now.

THE CHAIRMAN: I am not sure you put that in your reply, have you?

MS. KREISBERGER: No, we did not specifically draw attention to the fact -- we have been dealing with a very abbreviated timeline and it became clear to us just as we were lodging our reply that this was Pfizer's position. We understood that from their observations.

THE CHAIRMAN: You are suggesting that if Pfizer put their price back up that you would be unable to pass that on? Really?

MS. KREISBERGER: Oh, well, we have put in the evidence in terms that we think if the price comes down Flynn would not be able to put the price back up and I will be --

THE CHAIRMAN: I understand that, but I thought that assumed that you would at least be able to pass on the input price.

MS. KREISBERGER: We do not see any distinction because we think that the price which Flynn charges to its wholesalers and the list price, one will not be capable of raising that price, even if this appeal is successful because frankly the market will have moved on. Now, I do not know what view -- Flynn cannot know what view Pfizer might take --

THE CHAIRMAN: It is all speculation.

MS. KREISBERGER: It is all speculation.

THE CHAIRMAN: I think we should move on.

MS. KREISBERGER: These are the issues that Flynn may face and these are risks that cannot be excluded at the interim stage, I think that is the point.

THE CHAIRMAN: There is a sort of threshold of plausibility that you have to get across I think.

MS. KREISBERGER: And we appreciate that, but, sir, I will take you to the evidence on Flynn's assessment of how the market will sit, which is really a function of who is in the market and who is competing and there is nothing groundbreaking --

THE CHAIRMAN: Is that not covered by the decision and we said we cannot get into the merits of the decision?

MS. KREISBERGER: It certainly is covered by the merits of the decision and it is a very significant area of dispute between the parties and the CMA.

THE CHAIRMAN: Will be.

MS. KREISBERGER: It will be, absolutely. I mean it will be central in our notice of appeal. So these are matters that cannot be preempted now at this interim stage, the risks cannot be excluded. These are areas of factual dispute which will be vigorously fought over and, sir, I will take you to the evidence we have put in at this stage, obviously rather rapidly.

That was all I was going to propose to say about the directions themselves. Unless you have any further questions on those, I was going to move on to the test for interim relief.

THE CHAIRMAN: I think you should move on.

MS. KREISBERGER: We have set out the test in our application, so you have it for your note. It is at paragraph 36 to 38 of our application for interim relief. The Tribunal will be very familiar with this test.

The starting point is of course the Tribunal's power to give interim relief under rule 24 and the CAT guidance which is at page 39 of the guidance. But the Tribunal has laid down specific guidance on the test in the leading authorities of *Genzyme* and *Napp*. They are cited in the Tribunal's guidance and they are particularly apposite of course because they are also drug pricing cases.

THE CHAIRMAN: Slightly different facts.

MS. KREISBERGER: That is right, but for the purposes of the interim -- setting out the principles, of course they --

THE CHAIRMAN: Also the law has changed a bit. Are you going to tell me about that?

MS. KREISBERGER: I may be coming on to that, sir, but you may have questions, but it might be helpful to have *Genzyme* in front of you, which is at tab 9 of the authorities bundle.

Sir, the Tribunal's analysis begins at page 24 of that case and conveniently we do not need to turn up *Napp* because the Tribunal cited the relevant passages from *Napp*. I draw to your attention paragraph 38 from *Napp* which is just over the page on page 25, where the Tribunal said:

"In that connection, it is important to emphasise that a principal purpose of interim relief is to preserve the integrity of the appeal and in particular to ensure that as far as possible, taking into account the other interests involved, the applicant does not suffer serious and irreparable damage pending the hearing of an appeal which may yet succeed."

We say that is the starting point for the test. Perhaps another way of putting it, in the words of the President when he opened the hearing in *Genzyme*, is that:

"An applicant should not be deprived of the fruits of a potentially successful appeal by reason of a mandatory order that takes effect before that appeal can be heard, so long as there is a prospect of that appeal being successful."

We say that principal consideration is what should inform the Tribunal's approach. So yes, it is for us to persuade the Tribunal that interim relief should be granted, but that this is the prime consideration.

THE CHAIRMAN: This is all about jurisdiction, whether we have the power to grant.

MS. KREISBERGER: It is about the power, but the Tribunal also specifically laid down the principles which it says should be applied to these cases, so, sir, if you have paragraph 79 on page 26:

"In most cases the Tribunal's approach, combined with the specific provisions of the rule [as it then was] involves asking five questions ..."

So the first of those five questions relates to the merits, are they at least prima facie entirely ungrounded, you have that.

THE CHAIRMAN: If it helps you, I think the threshold on the merits is fairly low and that you probably satisfy it. I have not heard the CMA, but I do not think you need to labour the point, Ms. Kreisberger.

MS. KREISBERGER: I appreciate that. Just so that you have it, sir, very clearly on the balance of convenience, that is (iii) and (iv) over the page:

"Is the applicant likely to suffer serious and irreparable damage if relief is not granted and what is the likely effect on competition or relevant third party interest of the grant or refusal of interim relief."

That is the balance of convenience.

THE CHAIRMAN: Yes, that is the balancing exercise. That goes to discretion.

MS. KREISBERGER: It does, it does. We say here not only do we satisfy that, but we are in quite an interesting, perhaps unusual situation where both limbs of the balance of convenience in fact point in one direction and that is because this is not -- I will develop this in later submissions, but this is not an exclusionary case. So what one saw in *Genzyme* is --

THE CHAIRMAN: It is a harm to consumers case.

MS. KREISBERGER: It is, it is, but the effect on competition is relevant because lowering price might have the unintended consequence of deterring generic entry. Sir, I will take you to it, but it is in our evidence that Flynn anticipates there may be future generic entrants. Now, NRIM said in terms that when the price was low that was a disincentive. So our case is relevant both to effect on Flynn, which is abundantly clear, but also effect on competition, which is why regulators --

THE CHAIRMAN: I think you are being quite ambitious, but go on.

MS. KREISBERGER: I hope to persuade you of this point as we go through, but I flag that that is a secondary point. The principle point is the balance of convenience, the effect on Flynn, which is very clear and it is effectively common ground.

Just moving on in *Genzyme*, sir, as you have rightly pointed out the facts were different, it was a margin squeeze bundling case, the facts are well-known, but the Tribunal went on to consider balance of convenience at paragraphs 88 onwards, page 29. I am going to deal with this very briefly, but it is worth noting that the Tribunal found first of all that the loss was financial, it was first of all financial, that is at paragraph 89, but the Tribunal went on at

paragraph 91, on page 30, to find that what *Genzyme* would have had to do is introduce a new price, establish and invoice separate prices for home care separately from the drug and supply third parties at the new price. Those were the three elements to the action required of *Genzyme* and the Tribunal characterised that action as *Genzyme* having to substantially modify its business policy. It says at paragraph 91:

"That would require a major change in its business operations."

Halfway down the paragraph:

"These changes, it seems to me, would amount to a major upheaval in *Genzyme's* business in addition to the loss of revenue."

THE CHAIRMAN: That is on the facts of that case.

MS. KREISBERGER: That is on the facts of that case. I will go on to show that in our submission the conduct required of Flynn is more intrusive, not less intrusive, so it is an interesting barometer.

Then what the President said there is:

"It seems to me that I cannot exclude the risk that *Genzyme* might find itself in practice unable to re-establish the previous arrangements even if it were to win the appeal."

Which included as to price. "I cannot exclude", so it is the inability to exclude the risk that weighed heavily in his consideration.

The last paragraph of *Genzyme* I was proposing to -- sorry, sir, there are two more paragraphs. There is paragraph 98 which I should bring to your attention while we are on *Genzyme*. Halfway down the Tribunal refers to "preserving the integrity of the appeal" and they say:

"This applies also to preserving the integrity of the OFT's decision. The Tribunal should be prepared to intervene if not to do so would run a real risk that the decision would be without practical utility, even if the appeal were unsuccessful."

The CMA make much of this, but we say that does not apply here. Our submission is competition, as it exists now should be preserved and there is no detriment to the practical utility of the appeal if price regulation is deferred in the event of an unsuccessful appeal until after the Tribunal's determination.

Then lastly, paragraph 130, the final sentence of that paragraph there --

THE CHAIRMAN: Sorry, before you get on to that, are you really equating competition with pressure from third party competitors, or is there some other aspect of competition, namely the consumer detriment, which is just as powerful although it is different in excessive prices cases?

MS. KREISBERGER: I am focusing on the structure --

THE CHAIRMAN: Because *Genzyme* was a case where there was a third party competitor whose interests in affected by the decision, clearly, and whether to comply with it or not. I do not have this situation here, although no doubt I will listen attentively to what you say about management of generic entry, but the main essence of the case is the excessive prices charged indirectly to consumers. That is a competition detriment.

MS. KREISBERGER: That is right. Well, that is right, it is a consumer detriment.

THE CHAIRMAN: I began my competition career with *United Brands*; it is not strange to me, I have to say.

MS. KREISBERGER: Well, *United Brands* was a case in which there was exclusion, sir, as you will know. Their strategy --

THE CHAIRMAN: But also the higher prices of bananas.

MS. KREISBERGER: But the strategy was designed to exclude a rival, so you will be well familiar with the fact that the economic consensus and consensus amongst competition authorities is tread very carefully if there is not a structural problem. The easy case is a rival is being excluded by some form of pricing strategy involving high prices --

THE CHAIRMAN: The CMA will say they did tread very carefully, that is why they took such a long time.

MS. KREISBERGER: Well, we say this is a precisely -- they certainly took a long time, we would agree with that, but this is precisely a matter for the Tribunal's consideration. It cannot be dealt with at this stage --

THE CHAIRMAN: But that is the merits.

MS. KREISBERGER: -- but it is relevant to balance of convenience. It is relevant to balance of convenience because --

THE CHAIRMAN: I can see that you have things to argue about on whether the CMA has established that facts demonstrate an infringement of the law; okay, that is what the appeal will be about, no doubt. But the principle of applying Article 102 to excessive prices which do not have a direct exclusionary effect is not really in doubt, is it?

MS. KREISBERGER: We do not say that --

THE CHAIRMAN: I do not put any weight on consensus of economic opinion. I take that as a challenge, not as an established truth.

MS. KREISBERGER: I will bear that in mind. We say economic consensus is relevant, but of course we are not challenging the existence of this box of abuse, this category of abuse, of course that exists, but if I may come on when I address you on the merits to explain why we

think this decision is, put at its lowest, untested; put at its highest, in terms that Pfizer have mentioned in their observations, it is highly controversial.

THE CHAIRMAN: Okay.

MS. KREISBERGER: But perhaps if I may turn to that in just a moment. Just before we put *Genzyme* away, the final point on balance of convenience and how the Tribunal approached it in that case, is the Tribunal's conclusion set out in the final sentence at paragraph 130, which is that:

"The absence of financial redress on the part of *Genzyme*, if its appeal were successful, is an important factor which makes it incumbent on the Tribunal to act in a way that strikes the balance on as minimal a basis as possible. That is what I have sought to do."

Again it just echoes that the principal consideration here was the absence of redress for *Genzyme*. Now, that is a fact that applies equally here, that there is no difference between *Genzyme* and this case.

THE CHAIRMAN: On as minimal a basis as possible? That is what you want me to do, is it?

MS. KREISBERGER: Well, on these facts we say that simply means -- well, there the minimal basis referred to Healthcare at Home, so it was to prevent exclusion of a competitor. So it was effectively taking the interest of two undertakings.

THE CHAIRMAN: And the prevention of the exclusion of the competitor benefited consumers.

MS. KREISBERGER: That is right, but we certainly do not accept that --

THE CHAIRMAN: No, but you have to argue that.

MS. KREISBERGER: Well, we will argue in our appeal, as you have rightly said, there will be a great argument about whether the CMA has made out its case based on pure financial overcharge and that will be a hard fought issue. But we say at this stage the risks that we are setting out for you today cannot be excluded, and it is highly relevant to the analysis that there is no undertaking, there is no rival company, no rival business that says "We will be prejudiced by this", and the detriment that the CMA has referred to is not such as should tip the balance and I will come on to deal with that, but we say the case law is very clear. The determining factor is irreparability of harm to Flynn and on the facts of this case, which we will address, it is not off-set.

THE CHAIRMAN: Well, irreparability is interesting and possibly you have given a lot of a thought to that, but it is not actually the test any more, is it? The Tribunal's rules do not refer to irreparability.

MS. KREISBERGER: The Tribunal's rules do not, but the guidance still refers to *Napp* and *Genzyme*. Perhaps if we could turn that up if that would be helpful.

THE CHAIRMAN: Yes. We have a change in the law, do we not?

MS. KREISBERGER: But not such as to invalidate this case law. That is still --

THE CHAIRMAN: Well, we of course read *Genzyme* very very carefully, we have enormous respect for our own decisions, but the actual formulation of the rule has changed from the rule that the President in *Genzyme* was adjudicating on and applying.

It is a point that might be in your favour so I am a bit surprised that you are not taking it. The test now is significant harm not significant irreparable harm.

MS. KREISBERGER: The test is significant harm, so it is a weakening of the test.

THE CHAIRMAN: Well, it might be if you can convince me. But from what you are saying you appear to be taking the line that it is exactly the same.

MS. KREISBERGER: We are not going to take the point that there is some different threshold because we think that we meet the threshold by some distance, so the question of whether there is significant harm will be informed by the fact that it is irreparable and it is common ground that it is irreparable. There is no debate between the parties because there is no protection for Flynn.

THE CHAIRMAN: Well, part of it is irreparable. As I understand your argument, you have the loss that you might suffer if the directions are complied with up to trial and then you have the question of whether you could put your price back up again if the arguments you are going to deploy are successful and you win. It seems to me the nature of the damage falls into two parts.

MS. KREISBERGER: But all of that damage is irreparable. We have no redress, there is nowhere for Flynn to seek compensation from. So it is right that it will change.

THE CHAIRMAN: But you have argued that the damage is substantial because you will not be able to put your price back up, right?

MS. KREISBERGER: Well --

THE CHAIRMAN: That is disputed and that is not covered by the lack of a cross-undertaking from the CMA.

MS. KREISBERGER: I think perhaps if I could deal with this when I turn to balance of convenience, but we say that any harm sustained by Flynn, both up to and assuming a successful appeal and following an appeal because of changes in the market, are irreparable in the sense that there is no redress, there is no claim that Flynn can bring to claim losses in the event that its prices are found perfectly lawful.

THE CHAIRMAN: Right, that is a hit, but you can, according to the CMA -- not that they would want it -- go back to something approaching your previous prices and the damage would then be brought to an end so far as you are concerned.

MS. KREISBERGER: That is right, but --

THE CHAIRMAN: I only suggest it because you raised the point that you could not put your price up.

MS. KREISBERGER: In any event all of this ticks the significant harm box and as is set out in *Genzyme*, these are risks that cannot be excluded at this stage and should not be on an interim basis. But perhaps if we could turn to the balance of convenience in a moment?

THE CHAIRMAN: Yes.

MS. KREISBERGER: Thank you, sir.

I was just going to say a final word on the test before I move on, really just to preempt a point the CMA might make. They made it in their response. We do not know if they maintain this point. We really do think it is a bad one, which is that the CMA attempts to introduce a new principle by reference to judicial review case law and that is a principle that they say there is a strong presumption against interim relief. I was not going to spend much time on this, sir, except to say it is completely contrary to the *Genzyme* test I have just set out for you, which focuses on irreparable harm to the undertaking, the applicant. As I said, these judicial review cases of *Monsanto* and *Factortame* pre-date *Genzyme* and *Napp*, but one finds no mention of them in the Tribunal's case law, or in the Tribunal's guidance in relation to the new rule.

THE CHAIRMAN: This is all in your reply, I have read this.

MS. KREISBERGER: It is, it is. So we simply maintain those submissions. We think that would be a subversion of established principle. I will say no more about that. We say the principles are clear. The primary considerations are to preserve the utility of the appeal and to protect the applicant from serious harm.

So if I may turn to the merits, taking account of your indication, for which I am grateful, that we can assume that the hurdle is met.

THE CHAIRMAN: Well, subject to anything else I hear, but that --

MS. KREISBERGER: Given that I am on my feet first --

THE CHAIRMAN: The hurdle is rather low and your case has to be -- although we have not seen your case yet -- your case has to be not entirely ungrounded. Mr. Williams?

MR. WILLIAMS: Sir, if it helps, we are not going to say that the merits threshold is not met in this --

THE CHAIRMAN: I think it would be much more fruitful if we concentrated on the discretion aspect rather than jurisdiction.

MS. KREISBERGER: Then if I may just make a brief point without taking you to the decision.

THE CHAIRMAN: It is very tricky this because it is very important that possible consideration of the merits does not colour this decision. There is quite a lot in your application about the merits, there is quite a lot in Pfizer's submissions about the merits. We are trying to put that out of our minds if the jurisdictional threshold is satisfied. Then we get on to practical matters.

MS. KREISBERGER: But, subject to one point, the CMA contends -- and it is a contention made against us -- that it is relevant to the balance of convenience, as we understand their submission, I am paraphrasing, that they have looked at matters carefully and that the decision should be implemented now. They say that is relevant to the exercise of the Tribunal's discretion. They say in terms it is in the public interest to uphold competition law. It is in the public interest. But we say that that is premature --

THE CHAIRMAN: Competition authorities tend to say that sort of thing. I seem to remember saying it myself at one stage.

MS. KREISBERGER: But whether the implementation of this decision would be upholding competition law is a matter for the Tribunal's consideration based on our appeal.

THE CHAIRMAN: All this is very circular.

MS. KREISBERGER: It is circular, it is circular. So we say this: no assumptions should be made against us. We say you have our submissions in writing. We say this is a controversial case, it is untested.

Sir, you asked me about pure overcharge cases and relevance of economic consensus. If perhaps I could just say this. We say that the decision is, at its lowest, untested; at its highest contrary to authority, setting aside economic consensus, contrary to authority and case law in this particular regard -- we say that in multiple respects, but this principal way, which is that the CMA has disregarded every sensible benchmark put before it. Now, because it is accepted that competition authorities should tread carefully before interfering in prices, interfering in market dynamics, deterring entry, dampening incentives, every benchmark needs to be looked at carefully, objectively and taken account of as appropriate. It is not appropriate to say "We will ignore this product because it was excessively priced" without meeting the burden of proof on it to show that product was excessively priced -- I obviously have tablets in mind here -- or when a particular analysis is put forward in a statement of objection as relevant, when criticisms are made of that analysis in response --

this was an analysis of internal profitability -- rather than engaging with those criticisms the CMA simply said "Oh, actually that is no longer relevant, we ignore that". That is not how an excessive pricing case should be approached. One sees in a case like *Napp* that one looks at a range of benchmarks and one takes them all into account.

So all we say at this stage -- we are of course not asking the Tribunal to reach any views, we are simply setting out our stall, but the contention advanced by the CMA that this is in some sense upholding the law of the land is not a consideration which should weigh in the Tribunal's approach to balance of convenience. It is not a relevant consideration. It is all highly contentious and that is a matter for another day.

So that is all we would say on the merits, unless --

THE CHAIRMAN: I do not want to hear any more on the merits.

MS. KREISBERGER: Understood. Sir, if I could then move on to balance of convenience.

The question of serious harm to Flynn, we make four points on serious harm. The first is that the harm is irreparable, as already discussed. The second is that the harm is substantial. The third is that the harm is irreversible, that is the pricing issue. The fourth is that the harm lies in asking Flynn to do the impossible, in particular in relation to step 2 and that is contrary to legal certainty.

So dealing with each of those four points in turn, as we have said, the principal and overriding consideration in my submission is irreparability of harm. It is common ground that if the CMA interferes in Flynn's prices now, based on this particular decision, and that interference proves to have been unlawful, Flynn will be left without a remedy for losses suffered from implementation of the directions until determination of the appeal. There is no financial redress if Flynn's appeal is upheld. As I have shown you, sir, that was a consideration that weighed heavily with the Tribunal in *Genzyme*.

Now, we are unable to say what the magnitude of Flynn's loss will be because we do not know where prices would go.

THE CHAIRMAN: Unable to say?

MS. KREISBERGER: We are unable to give you a number on magnitude of loss because we do not know where Pfizer's prices are going, so we cannot possibly begin to calculate, even if we could do that.

THE CHAIRMAN: I will ask Pfizer this no doubt, but have there been any discussions between the parties as to what Pfizer's compliance with the directions might entail? They are Flynn's only supplier. Is that not a little bit curious?

MS. KREISBERGER: Pfizer's prices will simply be a matter for Pfizer and we have said clearly in the evidence, which I can take you to, Flynn's approach, in the ordinary way, in the usual course of matters, would be to pass on any cost reduction, any reduction in the cost of goods would be passed on to its customers, so Flynn will --

THE CHAIRMAN: Let me ask another question. How much notice would your client expect to get of any change in Pfizer's supply price?

MS. KREISBERGER: May I take instruction on that?

(Pause).

What has been pointed out to me is that this is not the ordinary course of events. The parties are all under considerable pressure to work out what this decision means and, sir, you will have seen how weighty a decision that is in length. Plus in the normal course of events there may be a negotiation about price charged to Flynn, but clearly that cannot take place here, so Flynn would not expect to be informed in advance. It will simply have to apply the price that is mandated under the directions. There is no scope for negotiation, therefore Flynn would not anticipate having any discussions. It will simply have to implement the price put on the table. That is the very nature of these directions.

THE CHAIRMAN: I wonder. I mean if the price is so uncertain, as you say it is, because you cannot comply with the decision because you do not know what the decision means, then presumably there is scope for negotiation as to what the right price would be.

MS. KREISBERGER: I will be corrected if I am wrong, but I do not understand the position to be that Flynn would presume to negotiate with Pfizer over price in these particular circumstances.

THE CHAIRMAN: So Flynn would take whatever price Pfizer decided in the light of the decision.

MS. KREISBERGER: That is the position.

THE CHAIRMAN: That is clear, is it? Because this is quite important.

MS. KREISBERGER: It is also worth bearing in mind that Flynn is a small pharmaceutical company. There is limited scope for negotiation in any event, but in these exceptional circumstances it will simply pass on the price reduction.

THE CHAIRMAN: Okay. But your real difficulty is not in relation to Pfizer's price, it is calculating your own uplift, is that correct?

MS. KREISBERGER: That is correct, yes. You have it, sir, that is the issue.

THE CHAIRMAN: And you have to do that by next Monday.

MS. KREISBERGER: By next Monday, on the point that we opened on, Flynn has no option but to simply take the values in the decision, it has to do that, so that is all it can do by next Monday. I am just about to take you through some of the issues that do apply to limb 1 and limb 2, but Flynn will do that by Monday, if it has to.

Now, we said the harm is irreparable and that is common ground, but the harm is also substantial and I do not just mean in terms of the magnitude and that is where we began this discussion.

THE CHAIRMAN: You said you cannot give me a figure of the magnitude. I mean supposing it took nine months to bring this to trial, it would be of assistance if your clients could produce an order of magnitude estimate.

MS. KREISBERGER: What we could do -- if I may just take instructions.

(Pause).

We are unable to produce anything on a revised input price because we do not know what that input price would be. The best that Flynn could do at this stage, and I think this is where I may -- well, this will be Flynn's material. If I just take you to it, sir. If you turn up the decision at page 343, there is a table in the centre of that page, table 5.18, headed "Flynn's excesses on Flynn's products, September 2012 to June 2016" and if you look at the excess review row ... so these figures are all confidential so I will not read out the figures, but if you read across from "excess revenue" there is a total figure there. That is what the CMA says is the excess --

THE CHAIRMAN: That is four years.

MS. KREISBERGER: -- over that almost four year period.

THE CHAIRMAN: So I divide it by four, take a big pinch of salt and I have some idea of the sort of figure we are talking about.

MS. KREISBERGER: You have it, but caveated by the fact that it will overstate the position because it is based on current input prices.

THE CHAIRMAN: Of course it is nine months not a year, and the incentives on everybody to bring the case forward quite speedily will be quite strong.

MS. KREISBERGER: We calculated it on a monthly basis so we have a figure based on a per month calculation. As I say, it does not take account of input prices and variations in return --

THE CHAIRMAN: But that is your excess.

MS. KREISBERGER: But that is the CMA's case.

THE CHAIRMAN: Okay, that is helpful, thank you.

MS. KREISBERGER: So just coming back to the question of harm to Flynn being substantial, as I said, aside from the question of the magnitude of the financial loss that we have just been looking at, the substantial impact of the harm would be the modification to Flynn's business policy and that would be the changes very obviously that Flynn would have to implement as to price, but also what we would describe as a radically different approach to cost allocation.

Sir, if I could ask you to turn up Mr. Fakes' first witness statement, which is in volume 14 of Flynn's hearing bundle, at tab C. Turning to paragraph 7(b), which is on the second page, Mr. Fakes, director of Flynn, says that:

"As regards common cost ..."

So this is turning to the question of cost allocation:

"As regards common cost the CMA's approach essentially seeks to allocate the common cost across Flynn's entire portfolio by reference to a number of different sales volume mechanisms, that is per pack, per defined daily dose, or per capsule or unit."

So it is a volume cost allocation methodology. He goes on to point out that:

"Flynn's sales of products across its portfolio vary significantly from day to day ..."

This is a commodity product, it fluctuates:

" ... and there could be peaks in demand for different products depending on a wide variety of different circumstances. It is not therefore possible for Flynn to determine its common costs and apply these on a forward looking basis to each and every product."

In other words one might be able to look at past volumes but one cannot predict how volumes are going to change, they are fluctuating daily, so then how does one go about allocating costs on a volume basis. It simply does not work. It is a methodology that has been constructed without reference to the realities of this marketplace.

So Flynn says it is not possible to determine its common costs and apply them on this basis and Flynn has never done it in this way.

If I could then just take you to the continuation of Mr. Fakes' evidence on the same point. He gives some more detail in his second statement, which is in volume 2 of the hearing bundle at tab J, page 6, and it starts at paragraph 19.

In paragraph 19 Mr. Fakes deals with the CMA's contention that one does not need to worry about this because common costs are flat and Mr. Fakes says it is not whether common costs have increased or not which is the issue, it is this volume allocation methodology that is the problem:

"As far as I am aware from my experience in the industry, no pharmaceutical company allocates its common costs by reference to pack volumes. Such a methodology is simply unworkable. Generic companies such as Flynn typically have a portfolio of products, a large portfolio, and incur few product specific costs. Given that sales volumes fluctuate from time to time, the practical difficulties of accurately apportioning costs which themselves also change from time to time by pack volume are therefore chronic and intractable."

He then goes on in paragraph 20 to explain that:

"Flynn measures performance by reference to gross margin earned on particular products."

That is common with other generic companies. They look at gross profit margin across the entire portfolio and then halfway down that paragraph Mr. Fakes says:

"Obviously the directions would require Flynn to take a radically different approach to pricing by allocating its common costs by reference to pack volumes which would affect not only the way in which Flynn prices phenytoin capsules, but also the way in which it calculates prices for the rest of its portfolio, which could significantly impact on profitability across the entire product portfolio."

He explains in paragraph 21 that this means that the significant impact will be more general. There will be a decline in profitability, depending on the level of reduction in the input price. He says:

"I cannot estimate the precise amount of that impact because I do not know what level of reduction Pfizer may put through. However, this will inevitably mean that Flynn cannot so easily or readily continue to invest in products and projects that it might otherwise have done, for example Flynn's therapeutic antibody programme, new generic products or new indications for existing products."

Then he goes on to give some specific examples of savings achieved through Flynn's initiatives to the NHS.

So the point, sir, is that this is a substantial interference in it Flynn's business policy and in its commercial freedom to allocate cost, to set prices.

THE CHAIRMAN: You are not saying here that they cannot make sense of it and they cannot actually do this, you are saying that if they do it it will have a substantial impact.

MS. KREISBERGER: They are saying both, but here we are focusing on if they are forced --

THE CHAIRMAN: If they cannot do it there is not going to be any substantial impact.

MS. KREISBERGER: They are going to have to do something, which we will come on to, but --

THE CHAIRMAN: As I understand the CMA's argument against you it is that this is all very interesting, but it is essentially the reasoning by which the CMA came to the view that the price was excessive and you have to take that into account in setting the price.

MS. KREISBERGER: The current price.

THE CHAIRMAN: But what the CMA are about interested in is a reduced price. I will not say how you do it is your affair, but that is what it boils down to. They will then see if that is sufficient and if they do not like it they will presumably let you know about it, but in the meantime how you calculate it is your affair. You are putting forward two propositions, one is that you cannot calculate it, which I am having some difficulty with because I think it must be possible, even if you do not agree with it, to go through the motions and indeed that is what you are saying you are planning on doing anyway if you do not get the relief you seek. Then you are saying that "Well, if they do do it, it is a really substantial change because it means a wholly different approach to calculating profit, looking backwards instead of forwards and we just cannot do it", but that is what you are going to have to argue at the trial presumably, about whether these directions make sense, because that will come up in the main action.

What we are talking about here is the interim, what is going to happen in the interim?

MS. KREISBERGER: Sir, precisely. In my submission you have put the point for us rather powerfully. These are precisely --

THE CHAIRMAN: I am delighted to have been of service.

MS. KREISBERGER: We are very grateful. These are precisely the sorts of issues we should not have to grapple with at the interim stage. These are real concerns. It is, with respect, in our submission not good enough for the CMA to say "You have just got to bring your prices down and how you do it is a matter of no concern to us, we are not a price regulator, it is not for us to guide you through. We may fly the plane, we do not know how to land it but you figure it out". That is not, with respect, good enough. If there is to be direct interference in our prices prior to the Tribunal scrutinising this decision, it should be a consideration in the mix, and an important one in our submission, that we do not know what to do.

THE CHAIRMAN: They are in a very difficult position, are they not? If they had done what you are suggesting and acted like an economic regulator and stipulated exactly to the nearest penny what the price should be, you would be criticising them for interfering in business freedom and acting like an economic regulator. They have tried to -- I have no doubt they will say -- steer a middle course between setting out the principles of excessive pricing, the

considerations they have taken into account and what you should take into account. They have not actually told you what price you have to apply, they have left that to you.

MS. KREISBERGER: But, sir, these are not issues that should be resolved against us on this interim basis. It is a very real issue that you have a decision based on a methodology that we say is impractical, unworkable, we cannot figure it out, but we are being asked to reduce prices on --

THE CHAIRMAN: No, no, you said you can figure it out but you would rather not figure it out.

MS. KREISBERGER: Well, we will have to do something because we will be in breach of the directions. I am unable to tell the Tribunal what it is we will do at that stage.

THE CHAIRMAN: Well, we may hear from the CMA as to what they think a breach of the directions will be, and I would be interested to hear that, but go on.

MS. KREISBERGER: If I might take instructions on one point.

(Pause).

We are unable to take it much further than this, except we do not -- in our submission Flynn should not be put in a position which is invidious, which is we are being forced to bring down price. But it is not just simply a failure by the CMA to tell us to the decimal point what our prices should be, it is the adoption of a methodology that we say and we will put evidence in to the Tribunal on this in the appeal, that shows that methodology to be meaningless, arbitrary and unworkable, not used by anyone in the industry and we say that that should not be -- if they are asking for interim relief, at the very least it should have been on the basis of something that is comprehensible. It should not be for Flynn to sort it out on an interim basis, to come up with a price that we then say we think we will be stuck with for the future. So this is real meddling in the market, without guidance --

THE CHAIRMAN: I am concerned about this because it does invite me to get into the merits when I am also being told I should not be in the merits.

MS. KREISBERGER: The way to avoid it is to suspend the directions, it is the directions that bring this into play, and Flynn should not be put in the position of being told we are not allowed to attack the decision -- we are told in the directions to have regard to the decision, but, as I have already described that, it is an analytical vacuum. We do not know what that means.

THE CHAIRMAN: Supposing the CMA had actually set a price, coupled with all the other reasoning, then what would your position then be? Your position would then be that it is still very damaging, does your client substantial harm --

MS. KREISBERGER: That cannot be recovered.

THE CHAIRMAN: -- which you cannot get back, but at least you would know where you are.

MS. KREISBERGER: Yes. We say simply it is another consideration which shows that these Directions cannot be implemented and it is relevant to the exercise of your discretion.

THE CHAIRMAN: You keep saying they cannot be implemented --

MS. KREISBERGER: Sensibly.

THE CHAIRMAN: -- but that is not quite right, is it? They can be implemented, they are not going to be implemented in a way your clients are happy with. That is a different point.

MS. KREISBERGER: My clients certainly will not be happy with it, but there is a question of -- there is an important principle of legal certainty here as to whether it is appropriate for the CMA to insist on price regulation at this stage, without having given any clear guidance. That is relevant to the exercise of your discretion.

You are right, our principal position is that the harm is irreparable and in any view we would be making that submission and we think that is the determining factor, but it is also relevant that we are being asked to implement directions.

I should say this has put my client Flynn under considerable pressure prior to lodging of the notice of appeal. They are having to grapple with a lot and the CMA refused even to defer this issue by a short period of time, thereby placing Flynn under more pressure.

So we say --

THE CHAIRMAN: How far have we got? You are doing very well, but how far have we got, I mean in terms of time?

MS. KREISBERGER: I am grateful, sir. In terms of time I would say I will probably take us to 12. I think it is slightly different to gauge just because we have jumped ahead so I might be able to save time on some topics.

Just stepping back for a moment, we say that the substantial effects are not just the unworkability, just to be clear, and not just the irreparability, but also the compulsion to modify business policy and that is where we started, that it is not just that it is unworkable, it is the fact that we are being asked to adopt a different approach to cost allocation, and the CMA's response to this is "No you are not, you are just being asked to bring the abuse to an end". I am not sure that does merit a response, but if it does, Flynn must be put in a position where it can measure its price against the allegation of abuse and it is the CMA's rejection of every proposal Flynn has made about how to go about measuring profitability that puts it in this position and that has a substantial impact on Flynn's commercial policy. It is an interference in its freedom to conduct its business as it sees fit.

Finally, I was not proposing to take you to the case law on financial loss. It is set out in our reply. As we say there, we think these are exceptional circumstances, but in any event the case law makes clear that the concern with financial loss is that it can be compensated, it is compensatable, and here it is not.

I then move on to my point 3 of the four types of harm and that is the irreversibility. We have touched on this. Sir, if I could just take you to the evidence, it is in Mr. Fakes' second statement, which is in volume 2 of the hearing bundle at tab J, page 2, paragraphs 6 to 8. That is where Mr. Fakes sets out his crystal ball gazing, it is his anticipation of how the market will look, but it is an informed assessment based on his experience and he says -- the point made against us is that "Well, you increased price when you entered the market", well that was market launch of a general generic product in September 2012 and key difference -- the CMA said "There is no reason why you cannot raise the price again, so if it is found that our decision is unlawful you can just raise prices and things can go on as if this decision had never been made" and Flynn says that is simply not the case. In paragraph 6 he says:

"The CMA's prediction does not reflect market reality. The environment is now very different from September 2012 when the only phenytoin sodium capsules were those manufactured by Pfizer, which could be sourced by Flynn or Parallel Trade. Since April 2013 we have NRIM in the market."

He explains why he anticipates that NRIM will match Flynn's price if Flynn implements the directions, but will not later put prices up. He disagrees with the CMA's market definition which puts Flynn and NRIM in different markets, even though they supply precisely the same products --

THE CHAIRMAN: Back in the merits.

MS. KREISBERGER: -- phenytoin capsules.

But the evidence before you, sir, from Flynn is that Mr. Fakes regards NRIM as a direct competitor.

"I do not accept the CMA's case about the principle of continuity of supply."

And Mr. Fakes gives some examples as to why, he illustrates that. The first one is (a):

"The products are essentially the same."

The second is that NRIM gained customers. I mean these are facts, it is an objective fact that NRIM took Boots and Lloyds away from Flynn. Then the third point is that NRIM has in fact grown significantly since it launched and Mr. Fakes gives some figures there.

So based on his experience he says at paragraph 8:

"I would expect the pricing of the NRIM product to be re-evaluated following any reduction in the NHS list price. If Flynn subsequently sought to increase the price, I would not expect NRIM to follow suit because their objective is likely to be to take additional share from Flynn by having a lower price."

So it is just a commercial strategy, they might stay low and take custom away from Flynn:

"I also believe that it is possible that other generic companies will launch a phenytoin sodium capsule in the UK which would again change the market environment and prevent us from any subsequent price increase after the Tribunal has heard the appeal."

So that is Mr. Fakes' evidence that once they go down they cannot be brought up in this market environment. Certainly if there are more generic entrants one would normally see a downward pricing spiral.

THE CHAIRMAN: Just to get this right, your client's damage would be irreversible because market conditions might have become more competitive and there might be more entry; that is your argument?

MS. KREISBERGER: Our submission is that they have become more competitive since Flynn's entry because of the entry of NRIM, yes. So in September 2012 Flynn did not face a rival phenytoin sodium capsule. It does now.

THE CHAIRMAN: There is not any evidence from NRIM, is there?

MS. KREISBERGER: Before you today. There is of course in the decision evidence concerning NRIM.

THE CHAIRMAN: There are people saying what NRIM says, but there is no direct evidence.

MS. KREISBERGER: What we do have actually in these papers --

THE CHAIRMAN: Mr. Williams, sorry?

MR. WILLIAMS: I was only going to make the point that I think Ms. Kreisberger was about to make, sir, which is that there is a document --

THE CHAIRMAN: In the decision?

MR. WILLIAMS: No, as part of Flynn's application. If Ms. Kreisberger does not take you to it, I was going to do that.

THE CHAIRMAN: Let us go to that, shall we?

MS. KREISBERGER: It is in the hearing bundle, it is at tab A3. This relates to the point about unintended consequences to the competition as well.

THE CHAIRMAN: Ah yes.

MS. KREISBERGER: So it is page 10 of tab 3 and this was a confidential response by NRIM to an information request from the CMA in March 2014. Towards the bottom of the page, the penultimate paragraph, final sentence, or last couple of sentences, dealing there with phenytoin sodium:

"Until 2006 no company in the UK ..."

MR. WILLIAMS: Sorry, I think this might be one of the documents we need to be cautious about.

THE CHAIRMAN: This is confidential.

MS. KREISBERGER: Sir, if I could ask you to read the last two sentences of that.

THE CHAIRMAN: The last two sentences of the penultimate paragraph.

MR. WILLIAMS: On which page, sorry?

MS. KREISBERGER: Page 10. I think it is fairly uncontroversial. I do not think there is any commercially sensitive material there.

THE CHAIRMAN: We will obviously have to consider this in detail.

MR. WILLIAMS: Sir, while you are in this document and to avoid taking up more time later, would it be sensible for me to ask you to have a look at the passage I was going to ask you to look at later on.

THE CHAIRMAN: I think we can probably come back to the document.

MR. WILLIAMS: I will do that.

MS. KREISBERGER: So that we say is relevant because NRIM clearly correlates prevailing prices in the market to incentives to enter for generic companies.

So the timing there was after -- I was going to make my next point by reference to that document, which I have already indicated to you, which is that this is a case where both preserving the integrity of the appeal and preserving the competitive process, which often point in separate directions, as in the *Genzyme* case, here in fact point in the same direction because an unintended consequence of lowering price might be to dampen competition rather than stimulate it, to dissuade --

THE CHAIRMAN: So the high price is pro-competitive in your submission.

MS. KREISBERGER: Well, this is precisely how competition is supposed to work: prices attract entry.

THE CHAIRMAN: Sometimes, not always.

MS. KREISBERGER: But we have evidence from a third party that it was when prices -- sir, I am acutely aware of the need not to get into the merits, but I think this perhaps falls just on the right side of the line, to observe that when we talk about high and low prices, prices for

epanutin before Flynn's acquisition of the drug were loss-making and that is common ground, so of course there was an increase in price and we see that that increase in price stimulated entry, and Flynn fully anticipates future entry.

THE CHAIRMAN: It is all a matter of judgment and degree, is it not?

MS. KREISBERGER: Without doubt. But we are put in this position by having to grapple with the directions because we are speculating as to what may happen, but again, at risk of labouring this phrase, the risk, the risk cannot be excluded that these directions will have the unintended consequence of dampening competition and deterring generic entry.

Now, we accept this is an area of factual dispute. The CMA disagrees. That is a matter for trial, we cannot begin to determine that now, but the evidence before you cannot be disregarded. It is before the Tribunal and that is Flynn's assessment of the position, so it militates in favour of suspension.

My last point on implementation of the directions I think has largely been dealt with and this is the fact that Flynn is in difficulty, shall we say, in implementing in particular step 2. I think we have covered this in some detail already.

THE CHAIRMAN: I think you have.

MS. KREISBERGER: I think I would just observe that it is relevant that the CMA has itself had great difficulty in answering the question of what is a reasonable margin, what is a lawful price on their view. They had not reached a view internally on that over a year after opening their investigation. I am not sure I need to take you to the evidence on that, sir. I could give you the reference for your note. It is in Mr. Firth's statement at paragraph 18. I think that was July 2014. The investigation was opened -- you have the chronology, sir, but the investigation was opened in May the year before.

We are told by the CMA that Flynn should simply determine the appropriate price as it does in its ordinary course of business. That is at paragraph 61 of the CMA's response. But exactly that is the problem, it is being asked to determine price in a way which it would never normally do in its ordinary course of business and it is this sort of result which really leaves companies with no clue as to what the lawful price is, it is precisely why excessive pricing cases have a high burden of proof on the competition authority and this is something we will develop in our notice of appeal very specifically in relation to the question of benchmarks, and it is precisely why many of the decisions show that intervention or striking down of price is lawful where multiple benchmarks point in the same direction. Now, that substantive issue, that is a fight for another day, but it does underline the reasons why there should be no interference with price on an interim basis at this stage.

Those are my submissions on balance of convenience on Flynn's side. I then need to address you, sir, on the CMA's claims as to detriment.

We make the following points and I hope I can deal with this briefly. You will have seen that Flynn has offered a cross-undertaking, even though there is precedent in the case law for there being no obligation to do so, but Flynn has willingly offered this. This is not asking the Department of Health or the NHS to fall back on civil remedies, as was the case in *Genzyme*. As already discussed, the competitive process points in the same direction and, sir, I think I have covered that at length in my submissions.

So the final point on the CMA claims as to detriment concern the claims as to patient harm.

THE CHAIRMAN: Just before you do, the CMA do not like your cross-undertaking and I think the Department of Health does not like it either. Are you going to address that?

MS. KREISBERGER: I was, yes. That was going to be my very final area, the cross-undertaking.

THE CHAIRMAN: Carry on then. Do not let me disturb your flow.

MS. KREISBERGER: I am grateful, sir. Just addressing the claims as to patient harm, Flynn is of course sympathetic to these concerns but it does not accept that its prices are unlawful; if its prices are not unlawful there is no entitlement to lower drug prices. Otherwise interim relief would never be ordered in a case such as this, because it is always the case, of course it is the case that the money could be spent elsewhere within the NHS, of course that is right, but that is not an answer, it is not even an argument one sees made in the other cases. That cannot be the answer.

We say on the facts of this case, as we have brought out in our reply, this is not a consideration which should weigh at all with the Tribunal and that is in the specific context of the CMA's delay here. Over four years have elapsed between the complaint and the decision. You will see we have set that out in the reply. It is not right for the CMA to now object to its decision being subject to scrutiny to the ordinary process of appeal in this Tribunal before implementation on the basis that a few extra months -- sir, I was grateful for your indication of nine months -- that that time period would be --

THE CHAIRMAN: We are always hopeful.

MS. KREISBERGER: We are certainly grateful for that on our side. The suggestion that an extra nine months or so will be catastrophic should not in our submission be taken seriously in the context of the four years that have elapsed since the complaint.

THE CHAIRMAN: But it is not a game, is it, where they have a certain time and you have a certain time.

MS. KREISBERGER: It is not a game but --

THE CHAIRMAN: On your submission we are all engaged in a common purpose here, to benefit patients.

MS. KREISBERGER: But it is the case that -- and of course we support that and reaffirm that, but the timing is wholly of the CMA's own making. Flynn has pushed and pushed through this process for answers, answers as to what is an acceptable price, and it has looked for a swift resolution of these issues and it has not got it, so my contention is not that it is a game, but that the timing is of the CMA's own making and it is not for the CMA, having we would say dawdled over the last four years, to now say "Well, it all must happen quickly such that you must give up your essential right to have your appeal heard before we meddle in market prices, we have to have direct price interference now notwithstanding the four years that have elapsed", we say the Tribunal should approach that submission with some caution, in our respectful submission, and we do say -- and this is not our primary argument but we just mention that the suggestion of catastrophe should perhaps be put in context. We are sympathetic and we appreciate the money could be spent elsewhere, but --

THE CHAIRMAN: But are you saying that we should never take into account the fact that money spent on excessive prices cannot be spent elsewhere? I do not quite follow why that is completely irrelevant.

MS. KREISBERGER: We do not say it is completely irrelevant, but we say it is not an issue that should off-set the clear categories of harm I have set out for you, sir, and that is because on the facts of this case the CMA has only been able to point to limited and unspecific detriment -- I mean the percentage points raised in the evidence are in the order of 0.2 per cent of budget to about half a percentage point. These are just giving a little perspective --

THE CHAIRMAN: I think there is a bit more to it than that, because we are talking about the amount of discretionary spending in individual commissioning groups' budgets and -- I do not want to make their case for them, but there is clearly an amount of money which is significant which could be spent on one patient that is spent on another.

MS. KREISBERGER: Of course and that will always be the case, but what we say here --

THE CHAIRMAN: But the fact it is always the case does not mean we should not consider it, surely?

MS. KREISBERGER: It certainly did not dissuade the Tribunal from its decision in *Genzyme* --

THE CHAIRMAN: No, but they weighed everything up in the balance, as I will do.

MS. KREISBERGER: They did, taking into account as their principal objective that the integrity of the appeal should be preserved. Now, the integrity of the appeal is that that militates in favour of preserving prices which we say in my submission are perfectly lawful --

THE CHAIRMAN: And the integrity of the decision and you are saying it does not matter, effectively, when the decision takes effect provided you have a chance to attack it.

MS. KREISBERGER: It will be a short delay. It will be a short delay and Flynn wishes at this hearing to indicate firmly its hope that nine months or so is achievable.

THE CHAIRMAN: If you were to get the relief you seek, what is your incentive to proceed quickly?

MS. KREISBERGER: Flynn has put in the evidence that commercial uncertainty has been highly detrimental to its business. Flynn would be more than happy to have a hearing date set down, if that were -- I hesitate to mention it because procedurally we have not put our notice of appeal in --

THE CHAIRMAN: Yes, you are in a slightly awkward position here.

MS. KREISBERGER: -- but the team has made inquiries of the Tribunal, it has been confirmed that there is availability in the autumn term to set down a hearing and Flynn would frankly like nothing more than to have this all dealt with this side of Christmas.

THE CHAIRMAN: So you are saying it will be the same for you whether you get the relief or not, you still have the same incentive to proceed quickly?

MS. KREISBERGER: Flynn lays down its marker now --

THE CHAIRMAN: We may hold you to this.

MS. KREISBERGER: I can say without any reservation, Flynn asks for a hearing of this matter on an expedited basis. It may be that the CMA are not content with that.

THE CHAIRMAN: You had better bring your appeal first before you start asking for directions.

MS. KREISBERGER: But we would certainly be hopeful for an appeal in the autumn term. So that should off-set any issue -- one is looking at a short extra delay against the principle --

THE CHAIRMAN: It also limits the damage to your clients.

MS. KREISBERGER: It does. So that is a clear submission that Flynn is looking for an expedited resolution to matters which should off-set any concerns about extra delay.

THE CHAIRMAN: I hear what you say.

MS. KREISBERGER: I am grateful, sir.

Sir, you will be pleased to hear that I am coming to my last topic, which is the cross-undertaking, and just turning it up it is at --

THE CHAIRMAN: I wonder if we might -- I think we might just take two minutes out and come back in five. All right?

MS. KREISBERGER: I am grateful, sir, yes.

(12.00 pm) (A short break)

(12.10 pm)

THE CHAIRMAN: The cross-undertaking.

MS. KREISBERGER: Thank you, sir. The draft order with the cross-undertaking is at hearing bundle 2, tab F, and the cross-undertaking is over the page. Sir, can I assume you have had an opportunity to read the cross-undertaking?

THE CHAIRMAN: Several opportunities.

MS. KREISBERGER: I am grateful, sir. In that case I can turn to the points made against us.

THE CHAIRMAN: Yes.

MS. KREISBERGER: Unsurprisingly we say there is nothing in those points. Our overriding answer to this is that simply it is not unusual for the NHS to be protected by a cross-undertaking in these terms. In the patent infringement sphere, in the patent court this happens all the time. The NHS in general, or the Department of Health, is generally not even referred to by name, but there will be a cross-undertaking by the originator who has secured an injunction to keep the generic out and it is assumed that the Department of Health can claim for losses as a result of the price being kept up on that basis, but in some cases the Department of Health and the NHS is specifically referred to.

Now, sir, I must apologise, we refer to a case *Warner-Lambert v Actavis* in our reply. I see it did not make its way into the authorities bundle. We have copies here which we will hand up now. (Handed).

Sir, it is just a short point.

THE CHAIRMAN: You are not expecting me to read this as I listen to you, are you?

MS. KREISBERGER: Certainly not. I was just going to pull out for your attention a sentence in paragraph 8. Mr. Justice Arnold had made the point that the Department had initially declined to attend the hearing. It is an interim hearing and the judge said:

"After I had repeatedly made clear through the parties that it would be assisted by its appearance the Department relented and on the afternoon of the third day of the hearing instructed counsel to appear. I am grateful to the Department for its assistance. The value of the exercise is illustrated by the fact that contrary to what had been indicated in an email, counsel informed me that he was instructed to request that

if relief was granted Warner-Lambert's cross-undertaking in damages should be extend to the Department and the NHS."

So that simply illustrates that in that case that was the form of undertaking anticipated. Similarly, sir, if I could ask you to take the authorities bundle again and turn up the *Napp* case at tab 7, paragraph 24 on -- the pages are not numbered. It is the third sentence of paragraph 24 referring to *Napp's* undertaking:

"... to reimburse the Department of Health for losses caused to the NHS by the suspension of the directions if *Napp* loses its appeal."

THE CHAIRMAN: In terms acceptable to the director.

MS. KREISBERGER: That is right, sir, but there is no suggestion in that case, and neither the CMA or the Department of Health have suggested otherwise, that those terms were anything other than a reference to those parties.

It would be entirely extraordinary -- it is in the ordinary course. Our starting point is that if there were no cross-undertaking in damages, as was the case in *Genzyme*, for instance, the Department of Health would fall back on its civil remedies and would have to bring a claim for damages in the usual way and often does and one often sees these cases. There is no suggestion that there are some complicating factors associated with beneficiary and, as I have set out, it is perfectly usual for the cross-undertaking to be in these terms. Flynn has no objection to the beneficiary being either or both the Department of Health and the NHS and if the cross-undertaking is to be amended to refer to the NHS, Flynn has no issue with that at all.

So we do not think this is a convincing objection to the wording of the cross-undertaking and certainly the parties have not put forward any undertakings in other cases in different form, different formulation. It is perfectly standard wording.

The other point made against us is that there will be all sorts of difficulties in ascertaining the lawful price. We do not demur from that.

THE CHAIRMAN: Well, what is being said is not that there are difficulties in obtaining the lawful price, but that it presupposes that that is what we will do and you do not know that.

MS. KREISBERGER: We certainly will not be any worse position than we are today. We anticipate that there may be useful guidance in the Tribunal's judgment in this case. We do not think that the difficulty in ascertaining a lawful price is a reason for not granting the relief sought because it is precisely our submission that there are all sorts of difficulties in asking us to set a lawful price now.

THE CHAIRMAN: Okay, but supposing we approach the substantive appeal in a way that you have not anticipated and decided it entirely differently, but still adversely to your client's interests, are you saying that your client would go along with any reasonable order that the Tribunal would make at that point?

MS. KREISBERGER: Without question. I mean subject to appeals one would simply be --

THE CHAIRMAN: Maybe a cross-undertaking in those terms might be more fruitful, because that would get you round the lawful price point, would it not?

MS. KREISBERGER: Well, I am not sure that the wording does not cover that. "Such part of the purchase price as is attributable to the non-implementation of the directions and unfair", it seems to us that that will take into account any findings that the Tribunal makes as to how one should go about determining --

THE CHAIRMAN: They say that would involve us making a finding on whether the price is fair or unfair.

MS. KREISBERGER: The current prices, yes. It is hard to see how the Tribunal would not determine whether -- current prices are either excessive or they are not, so to make a finding of abuse the Tribunal will have to make a finding as regards current prices.

THE CHAIRMAN: Well, look, that is not to argue now.

MS. KREISBERGER: The short point and the essential point is that we do not think that one should get into these nuances at this point in time. The key issue here is the NHS and the Department of Health are protected against any losses, they will be reimbursed, that is provided for in terms.

THE CHAIRMAN: Well, they are protected against any financial losses on your submission, but there is another point that I think they will no doubt make which is that during the period up to the trial -- and we have no guarantee that it will be as speedy as you say, we may go on to the Court of Appeal, heaven forbid, and it might be quite a lengthy period, and then the damage to patients will have taken place and cannot be remedied just by providing more money to the NHS in a later financial year. I think that is the argument. What is your view on that?

MS. KREISBERGER: Well, as we said, of course if our appeal is successful there is simply no entitlement to lower prices, so it would be pre-deciding, pre-determining the issue here, so that is our primary response. The entitlement to lower prices does not arise unless our prices are unlawful and we say they are not.

As regards the specific issue in relation to patients, we have set out that we do not think the CMA is entitled to say effectively "We are not entitled to have this decision reviewed, we

are not entitled to our appeal being heard before price regulation is implemented", it does not now lie in their mouths to say that given --

THE CHAIRMAN: Sorry, with the greatest respect that is not what we are talking about. What we are talking about is whether, when this case comes finally to be decided and let's suppose hypothetically that you lose, at that point you have to honour this cross-undertaking and what is being said -- I do not want to put words into the Department of Health's mouth, but what is being said is that by that time the damage will have been done and money paid in that financial year will not be able to be used by the commissioning group to put right the harm to patients that occurred because money was spent on your drug and not on another one. That is the argument.

MS. KREISBERGER: We understand the argument but of course that will be --

THE CHAIRMAN: What is your answer to it?

MS. KREISBERGER: There will be an off-setting gain in the year when the money is returned.

THE CHAIRMAN: By which time the harm may have taken place and be irreversible, to use your word.

MS. KREISBERGER: Well, the NHS is making decisions all the time about where to allocate resources. There is no evidence here about the specific detriment. Of course it is a permanent allocation of resources around needs. All we can say to that -- all we can say is -- as I said, the principal response is we may win and so --

THE CHAIRMAN: But, sorry, that is inviting me to get into the merits of the appeal. I am being absolutely neutral as to whether you might win or lose.

MS. KREISBERGER: Sir, with respect, it is not. Sir, with respect it is simply setting out that that is an outcome. We are not asking you to determine it, it is an outcome.

THE CHAIRMAN: That is a possible outcome, yes.

MS. KREISBERGER: Coming back to *Genzyme* and where we started, the principal objective is to avoid serious and irreparable harm to the applicant during the duration of the appeal, so these are --

THE CHAIRMAN: Also to preserve the integrity of the decision as well as the appeal process.

MS. KREISBERGER: We agree and we do not think there is any damage to the integrity of the decision. That is a formulation, that is a phrase constructed with a particular rival being excluded in mind. The decision, if correct --

THE CHAIRMAN: So the principles in *Genzyme* were constructed with the particular facts of the case in mind, is that what you are saying?

MS. KREISBERGER: No, no. The principles are laid out, but when they refer to preserving the integrity of the decision, the Tribunal had in mind explicitly, as set out in the judgment, that that meant preserving Healthcare at Home on the market.

THE CHAIRMAN: When the principles referred to the permanent change of the business model of the applicant was that with regard to the special facts of the case, or was that a general principle?

MS. KREISBERGER: That was a finding on the facts of the case, but the principle that is relevant to your determination, sir, is that if directions occasion a substantial modification to business policy and freedom to price, that is a factor which is not only relevant, it was the determining factor in that case.

THE CHAIRMAN: Determining in that case and relevant to other cases is what you are saying?

MS. KREISBERGER: It applies with greater force on the facts of this case because there they simply had to split out two components and come up with a separate invoice. Here we are saying we would have to go about cost allocation in an unfamiliar and unworkable fashion and doing that will impact on profitability of our products across the board, so the repercussions go beyond phenytoin, it goes to the heart of Flynn's ability to price its products as it sees fit. This is a substantial -- I mean, with respect, this is not an extreme submission. On the facts of this case --

THE CHAIRMAN: There is an awful lot of respect flying around.

MS. KREISBERGER: Well, we make these submissions with this set of facts in mind and we think these are considerations which should weigh heavily in the exercise of the Tribunal's discretion.

On the specific point as regards patient detriment there will be a boon the following year if we are wrong and if our appeal is not upheld, but as I set out, sir, the exercise for the Tribunal is whether it is in a position to exclude particular risks at this stage. We say the Tribunal is not in a position to exclude the risk that the price can be brought back to original levels if this decision were found unlawful and, at risk of repetition, we say it is the irreparability of this harm that is the determining factor, should be the determining factor in the exercise of the Tribunal's discretion. The Department of Health is protected as far as financial harm is concerned; Flynn is without redress.

Sir, unless I can assist you further, those are our submissions.

THE CHAIRMAN: I think that is fine. You will be able to reply later on.

MS. KREISBERGER: Thank you, sir.

THE CHAIRMAN: Mr. Williams.

MR. WILLIAMS: Sir, we were not sure whether you would find it of assistance to hear from me next or from Pfizer, so that I can --

THE CHAIRMAN: I think I would prefer to hear from you and then I thought I would hear from Pfizer if they are willing to address me and then anything that the Department of Health wants to add, I will hear also. Submissions by MR. WILLIAMS

MR. WILLIAMS: Sir, I am going to summarise the six main points we make in opposition to the application and then I will develop them, recognising that we have covered some of the material in the course of Ms. Kreisberger's submissions.

The first point is that the legal and the policy framework of the Competition Act is that appeals in relation to penalty do have suspensory effect but that otherwise appeals do not have suspensory effect, so that means in the language of injunctions that the status quo is that the directions should be given effect and it is for Flynn to displace that status quo. Flynn says in the course of its reply that fundamentally it is entitled to have its appeal determined before it changes its prices and actually that is the opposite of the position under the Competition Act.

In our submission that is the right framework for interim relief in this sort of context because the CMA has made a decision in the public interest. Obviously that decision is contested, but there cannot be any disagreement that the purpose of the decision is to further the public interest and that is a factor which ought to weigh in the balance in the present context.

The second point is that there is no disagreement before you that the effective threshold for the grant of interim relief to Flynn is that it has to show that the implementation of the directions will cause it serious and irreparable harm and that harm has to be proven on evidence on this application, and if Flynn shows that harm then one gets into a balancing exercise, but until it has shown that harm there is nothing to balance.

THE CHAIRMAN: Can I put to you what I put to your colleague, which is that the current version of the rules do not mention irreparability, they just talk about significant harm. Are you saying the Tribunal's previous interpretation stands despite the change in the law and the rules?

MR. WILLIAMS: If you like, it might help to go to rule 24. I was going to go to it a bit later, but we can go to it straightaway, sir, if that would help you. I think it is in the authorities bundle, tab 3.

THE CHAIRMAN: Rule 24.2, is it not?

MR. WILLIAMS: If we could just start at 24.1:

"The Tribunal may make an order on an interim basis (a) suspending in whole or part the effect of any decision which is the subject matter of proceedings before it."

So that is a rule which on the face of it is directed at exactly the sort of case that the Tribunal is dealing with today. Then at sub-paragraph 2:

"Without prejudice to the generality of paragraph 1, if the Tribunal considers that it is necessary as a matter of urgency for the purposes of preventing significant damage or protecting the public interest, the Tribunal will give such directions as it considers appropriate."

So paragraph 1 deals specifically with interim orders. Paragraph 2 is a more general power to give such directions as are necessary as a matter of broad discretion and so -- and it is expressed to be without prejudice of the generality of paragraph 1. So a question does arise in this context whether the operative rule for the purpose of this application ought to be the specific rule in paragraph 1, or the general rule in paragraph 2. In circumstances where there has not been any disagreement between the parties as to what the principles ought to be, we did not think it was necessary to get bogged down in that. It is right to say that the rest of rule 24 goes on to say:

"The Tribunal shall exercise its power under this rule, taking into account all the relevant circumstances."

So the considerations that are identified relate to the rule as a whole, which raises a question as to whether some of them might be more important in the balance under one rule rather than another.

What we say overall is that one can understand the reason for introducing a general rule in the form of paragraph 2, so as to give the Tribunal the maximum flexibility to deal with a range of cases and if I could give the example of the *Ryanair* case, with which you are no doubt familiar, sir, where rule 24.2 or the predecessor thereof was used to stop the clock in a Competition Commission investigation, so there is value in a general provision of that sort, but the fact that the rules now establish a lower threshold as the basis for that more flexible rule does not mean in our submission that the Tribunal ought to take a more generous approach, or to lower the threshold for the grant of interim relief in the context of the statutory framework as I have described it to you, which is to say that the policy framework of the Act is that decisions other than as to penalty should not have suspensory effect.

THE CHAIRMAN: Is there any difference between you on this?

MR. WILLIAMS: Well, as I say, I think we have both approached this on the basis that for this sort of application, whether it is under 24.1 or 24.2, one is looking at the need for serious and irreparable harm really as the launchpad for the application.

THE CHAIRMAN: So you are saying that the formulation in the *Genzyme* judgment stands and we should apply it?

MR. WILLIAMS: Yes, that is right, sir, and in fact *Genzyme* is then to some extent, although not completely, reflected in sub-paragraph 3, so for example in sub-paragraph 3 you have urgency, that is obviously in *Genzyme*, "effect on the party making the request", that is in *Genzyme*. You then have the effect on competition if the relief is granted. In *Genzyme* there was a more general formulation about the effect on third parties, but I do not think there is anything between us as to whether that is of significance or not. It is probably a matter of how broadly one construes the idea of the effect on competition. Then you have the existence and adequacy of any -- so one has a framework within the rules now which looks a bit like *Genzyme*.

THE CHAIRMAN: Yes and the reference to undertakings as to damages is a product of the 2015 rules I think, is it not?

MR. WILLIAMS: I think that is right, because in the past cases one sees a debate as to whether the Tribunal is even entitled to consider that.

THE CHAIRMAN: Okay, but it is clear that some of these concepts, urgency, damage, they come up at different stages of the analysis.

MR. WILLIAMS: Well, that is right. You mean generally or in the present context?

THE CHAIRMAN: In the present context. You are content with the approach, are you, under which we would first of all examine whether we had jurisdiction to give this relief, to use the former President's words, and then we would examine whether we should exercise our discretion to grant the relief and we have to look at some of the same concepts in each stage of the analysis.

MR. WILLIAMS: Yes. I think in order to submit that you had no jurisdiction I would probably have to submit that rule 24.2, which contains the significant damage threshold -- I would need to submit that that is not in play at all because that is the lower threshold and you will have seen that we do submit, for example in relation to step 1, which is the urgent matter, as you have identified, sir, that actually that is a very self-contained point which involved setting one-off prices and we say actually query whether that even really reaches the threshold of significant damage, but I think given the way in which the application had been developed I think -- the main submission I would may make is that there is an effective

threshold of serious and irreparable harm to Flynn, before one gets to weighing the other side of the balance.

THE CHAIRMAN: Flynn have said that the harm is irreparable, so we have to stick with that.

MR. WILLIAMS: Exactly, that is the way they have put the application, sir.

THE CHAIRMAN: Okay, all right.

MR. WILLIAMS: So the essential submission we make in relation to serious and irreparable harm is that Flynn has not shown as a matter of evidence that the directions will or even probably will cause it to incur serious and irreparable harm in any sense which is consistent with the authorities which I will show you briefly.

The third point I think, sir, has already come out in the course of your exchanges with Ms. Kreisberger, which is that although it is common ground that the interim relief is reserved for cases of urgency, actually once one recognises that all that has to be done by next week is step 1, that puts a different complexion on the question of urgency. The steps that need to be taken by 23 January, as I have said, are very limited steps in relation to run-off sales of existing stock which are of very limited significance for Flynn's business going forwards and that is no doubt why the main emphasis of Ms. Kreisberger's submissions was on step 2, which, as you have indicated, sir, probably does not really arise until March.

So we say actually seen in that light urgency takes on a very different complexion and that is certainly a very different picture from that painted in the original application, which is that Flynn has mere days to take business critical decisions.

THE CHAIRMAN: Mr. Williams, they still have to work out what their uplift would be on the current stock and they say that is very difficult.

MR. WILLIAMS: Well, what they have to work out is a price which will bring the infringement to an end, as found by the CMA.

THE CHAIRMAN: Which they say they cannot tell from the decision.

MR. WILLIAMS: I do not think Ms. Kreisberger does say that today actually, sir. I think what she accepted in the course of exchanges with you is that certainly in relation to step 1 the decision contains findings in relation to Flynn's current cost base and in relation to a reasonable rate of return, which enabled them to set a price which they consider would accord with the CMA's findings.

THE CHAIRMAN: So they could do it but they would rather not?

MR. WILLIAMS: Undoubtedly they would rather not, but I think one has to separate out different issues. The first point that Flynn makes in its application is that the directions are too legally uncertain to be given effect and they simply cannot do anything and I think in

the course of her submissions Ms. Kreisberger accepted that as regards step 1 in particular that submission does not hold because, as I say, there is a benchmark in the decision which establishes cost plus and which the CMA has found represents economic value in relation to the capsules at current Pfizer input prices and Ms. Kreisberger accepted that they can set the price in accordance with those findings. So as regards step 1, unworkability, in our submission it has fallen away really.

THE CHAIRMAN: So are you suggesting we should adjourn the whole business until March?

MR. WILLIAMS: I am not, sir, because we have submissions which are in my submission dispositive of the application in relation to step 2 as well.

THE CHAIRMAN: Okay, let us hear that, but I mean one option would be just to say this is all premature. I am not saying I am thinking that, I am just saying that is a possibility, if what you say is right.

MR. WILLIAMS: Well, I think the point I am making is that there is no urgency in step 1. The urgency as it is put in the application is with reference to the 23 January date and the point I am making is that those steps do not involve serious and irreparable harm. Then as far as step 2 is concerned the issue is this really: step 2 will involve Flynn setting a price on the basis of the new Pfizer input price. The complaint is that Flynn is not in a position to set that price because the decision does not make sufficiently certain findings in relation to what the step 2 price ought to be for Flynn to be able to give the decision effect. I will deal with that shortly, sir, and in our submission there are findings in the decision which are relevant to step 2 and it is simply not right to say that the step 2 decision will be made in a vacuum, but as regards step 2 that will of course need to take account of the revised Pfizer price, which Pfizer has not set yet and will be set on 23 January, so, sir, it is extremely difficult to see what findings the CMA were supposed to make in relation to step 2 and what the price ought to be in advance of Pfizer making its own decision as regards the 23 January date.

The criticism is that there is a defect in the directions as regards step 2. We say there is not and that the directions are in accordance with the authorities in relation to what a competition authority ought to do in a case like this, but actually just at a practical level it is not clear what else they were supposed to do.

Those points all go to serious and irreparable harm to Flynn and unless it crosses that threshold, in our submission there is no prospect of the Tribunal granting interim relief.

The fourth point concerns the other side of the balancing exercise and the point is that if interim relief is granted and the appeal fails, there is clear evidence before the Tribunal of

harm which is both serious and irreparable to the NHS, to its patients and to the wider public interest and specifically the evidence is that by denying the CCGs, the clinical commissioning groups, the cost savings that will flow from the implementation of the directions, there will be a direct and commensurate impact on the scale of services and the range of services which CCGs can provide for -- I have down here something like a year. Sir, you have said nine months --

THE CHAIRMAN: Well, I am an optimist.

MR. WILLIAMS: Then of course one would need to factor in time for a judgment. So in my submission a reasonable benchmark is about a year. As you have said, sir, that leaves to one side the prospect of any onward appeal.

This is at a time of extraordinary financial pressure on the NHS. So the short point is that patients who could have been treated with the proceeds of savings from phenytoin will go without care for the duration of the appeals and I think the upshot of your exchanges with Ms. Kreisberger is that evidence is uncontested actually.

The point we make about that is that it is not financial harm, it is harm with a human cost which cannot be reversed or reimbursed and it is not capable of being addressed through a cross-undertaking and it is not addressed by Flynn's undertaking and the only point actually that is really made against this is that it took the CMA something over three years, three and a half years, to reach a decision and in our submission that just is not an answer to the point at all because it does not contest the harm, it does not contest its significance and if there is a single determinative point in the application before you, sir, it is that point, that that harm is non-financial harm, it is not capable of being addressed through a cross undertaking and it outweighs any harm that Flynn relies on in support of the application.

THE CHAIRMAN: That is harm to patients that takes place arguably over the next nine months that is not going to be put right by money given to the NHS or its purchasing bodies in a year's time, or two years' time, or three years' time?

MR. WILLIAMS: Yes, sir.

THE CHAIRMAN: Right, so we are talking about medical harm.

MR. WILLIAMS: Yes, we are talking about what I have called the human cost of patients who need care going without care.

THE CHAIRMAN: What do you say to the argument that that happens all the time and that when the NHS sues for damages, it accepts that that is a problem anyway and all it ever gets is money, so that is in the nature of the beast?

MR. WILLIAMS: Well, it is true, sir, that during the course of any infringement where money is taken out of the NHS and is paid to a party infringing competition law, it is true that the sort of harm we are talking about arises in those cases too. The point today is that the Tribunal is being asked to grant interim relief, it is being asked to make an order which will bring this state of affairs about, so one cannot generalise and say this kind of harm is a fact of life because the Tribunal is being asked to make an order which will cause that harm.

THE CHAIRMAN: Where am I in the scheme of analysis? Am I doing the balancing here, or am I -- I am weighing up the damage to competition, or third party interests if the relief is granted, is that right?

MR. WILLIAMS: Yes. So the point I made a moment ago is that in our submission Flynn does not put anything, or anything material in the balance, whereas the harm which I have just described is uncontested.

THE CHAIRMAN: Right, and I can take harm to patients of the kind you have described as consumer detriment for competition analysis purposes, can I?

MR. WILLIAMS: Well, it is the -- there are --

THE CHAIRMAN: That is not normally what you get.

MR. WILLIAMS: No, but it is the consumer harm which is identified in the decision as flowing from the infringement.

THE CHAIRMAN: So the consumer is the NHS acting as a proxy for its patients, is it? The consumers are the patients, or the consumers are the purchasing authority, or what?

MR. WILLIAMS: It depends in what sense you are using "consumers", sir, I mean --

THE CHAIRMAN: We are always searching for the consumer because that is what the policy is there to protect.

MR. WILLIAMS: The clinical commissioning groups -- the complication in this case is that --

THE CHAIRMAN: They are the customer.

MR. WILLIAMS: Yes --

THE CHAIRMAN: So who is the consumer?

MR. WILLIAMS: -- the complication in this case is that different decisions are made by different parties and there is not a single purchaser in the ordinary sense. There is the prescription issued, there is then a dispensing decision made and it is the CCGs that foot the bill and the drug is then used by someone else, so --

THE CHAIRMAN: If we took a patient in, I do not know, Nailsworth where your Gloucestershire CCG might -- the result of their efforts might have an effect on that patient, I mean to take the analysis, the patient is the consumer, the CCG is the customer, the

prescribing doctor comes in somewhere and the administering pharmacist comes in somewhere.

MR. WILLIAMS: Yes.

THE CHAIRMAN: This is not rocket science, we have discussed this in other cases, but in terms of fitting it into the standard competition analysis it is always a little bit complicated, is it not?

MR. WILLIAMS: It is complicated and it is right to say that the persons affected on the account of the harm I have given are not patients using phenytoin, those patients will continue to receive the drug, so it is harm to --

THE CHAIRMAN: And they would receive it either way?

MR. WILLIAMS: That is right, so the --

THE CHAIRMAN: The price to them -- they are indifferent to the price.

MR. WILLIAMS: Yes.

THE CHAIRMAN: Because they do not decide it. So is the pharmacist, is that right? No, the pharmacist is affected by the price.

MR. WILLIAMS: In principle the pharmacist would be affected --

THE CHAIRMAN: The prescribing doctor is not --

MR. WILLIAMS: -- but for continuity of supply.

THE CHAIRMAN: Prescribing doctor prescribes according to clinical guidance and medical knowledge and is price blind; that is right, is it not?

MR. WILLIAMS: That is right. Most prescriptions are open prescriptions. The prescribing of phenytoin to adhere to the policy of continuity of supply really follows decisions made by the pharmacist.

THE CHAIRMAN: I am not getting into the merits of the case, I am simply trying to examine the mechanics of how this harm fits into the competition analysis.

MR. WILLIAMS: Sir, you are right to say that the harm which arises is not harm to ultimate consumers of phenytoin, the harm which arises is harm to the clinical commissioning groups in not being able to use resources in the way they think is most appropriate to fulfil the purposes of the NHS, harm to patients who do not receive treatment and the broader harm to the public interest that arises as a result of both of those.

THE CHAIRMAN: And you are saying that is enough to fit in the *Genzyme* category of harm to competition, or relevant third party interests?

MR. WILLIAMS: It is serious and irreparable harm to third parties affected by the grant of interim relief.

THE CHAIRMAN: Okay.

MR. WILLIAMS: So the fifth point, which I will come to at the end, is that in addition to that non-financial harm the terms of the cross-undertaking are not sufficiently robust and effective to deal adequately with even the risk of financial harm. We accept that there is no absolute rule that there should be a cross-undertaking, but it is undoubtedly another factor in the balance and indeed now expressly so under the Tribunal's rules.

The sixth main submission is a point which has not really emerged in the course of Ms. Kreisberger's submissions, but it is that there is a still further point militating against interim relief which has actually been made very powerfully by Pfizer in its intervention ostensibly in support of Flynn and that is that in the circumstances of the present case the grant of interim relief to enable Flynn to continue to charge current list prices for phenytoin would create a further injustice by increasing Flynn's profits still further at the expense of the NHS and that is because the supposed basis for Flynn claiming interim relief is that it cannot and should not be required to reduce the list prices which it sets for the NHS, but Pfizer has not applied for interim relief, it is going to be putting its prices down and that has, on the face of it, obvious implications for Flynn's profitability.

Pfizer suggested this issue can be addressed by Flynn holding funds on escrow and in our submission that is a non-starter because the only party to benefit from it is Pfizer and Pfizer has not made an application and it has not been volunteered either.

So we say in circumstances where Pfizer is reducing its prices there really can be no question that the benefit of that price reduction should flow to the NHS in the form of reduced prices from Flynn and in that regard Flynn's response to the escrow proposal is significant because it appears to say that when Pfizer reduces its prices, Flynn will or may put its prices down in any event and I think it might be worth going to this now, sir, rather than save it up for later.

MS. KREISBERGER: Would it assist in just clarifying Flynn's position?

THE CHAIRMAN: There is a certain amount of ding dong here.

MS. KREISBERGER: It just may expedite matters just to be clear what Flynn's position is so --

THE CHAIRMAN: Well, I have not heard Pfizer yet, so I would like to hear what Pfizer says about what they are going to do and what their escrow proposal actually means and then I suggest that we could hear -- I have not heard Pfizer yet, I just wonder whether on this point it might be a good idea if we did. Would that make it easier for you to respond if you heard what Pfizer said?

MR. WILLIAMS: Well, the point I am making now does not actually depend on Pfizer's response, so maybe I will just show you this, sir, I do not mind.

THE CHAIRMAN: Okay, you carry on.

MR. WILLIAMS: Sir, it is Flynn's reply bundle, I think they call it volume 2, and it is Dr. Fakes' second statement at paragraphs 22 and 23. In 22 it just outlines Pfizer's proposal. 23:

"Flynn has considered this but it does not consider this to be appropriate or workable. In the normal course of business were Pfizer to reduce its input prices ..."

I am not sure what the significance of "in the normal course of business" is there, but:

" ... Flynn would look to pass on all or as much as possible of that reduction to our customers by reducing its selling prices by an appropriate amount. Flynn is not comfortable with the proposal that it should charge its customers a price based on a higher input price than it is actually paying and simply retain that increased differential."

THE CHAIRMAN: That is a very worthy sentiment, is it not?

MR. WILLIAMS: Right, but what it seems to say is that once Pfizer's prices come down Flynn would expect to reduce its prices and --

THE CHAIRMAN: I think that is putting to one side all the difficulties they would have in working out what the reduction should be.

MS. KREISBERGER: Sir, I am just concerned that there will be a debate about hypotheticals, so I think I should just be clear. Flynn is making clear in that section of the evidence that it will simply pass on any reductions in the input price. That is why it does not think the escrow proposal is necessary or workable. The necessary implication of all of Flynn's submissions are that that means that prices will not go back up if the appeal is successful.

THE CHAIRMAN: That is a different point. Okay.

MR. WILLIAMS: The point is simply that Pfizer's prices are going to come down and I think Flynn is saying that as a result Flynn's prices will come down and there is no application for an order restraining the directions against Pfizer --

THE CHAIRMAN: I've got that point.

MR. WILLIAMS: -- so it is not really clear what the purpose of the application is in that sense, because the purpose of the application is to say, "Well, we should not be required to put our prices down", but as I read those circumstances they are saying that in circumstances where Pfizer is going to put their prices down then Flynn's prices will go down anyway.

THE CHAIRMAN: I think the point is that under your directions they would have to go down more.

MR. WILLIAMS: I am not sure what the point being made is, but the point I am making, sir, is simply that this cascading effect on Flynn's prices, it appears is going to happen anyway because Pfizer has not applied for interim relief.

Sir, I will now move to flesh those submissions out a bit. I am mindful of your comments --

THE CHAIRMAN: Is this a good moment, before you put the flesh on the bones, whether we might stop and reconvene promptly at 2 o'clock?

MR. WILLIAMS: Yes, sir.

THE CHAIRMAN: Maybe even 5 to 2. Why not. Thank you.

(12.55 pm) (The lunch break)

(2.00 pm)

MR. WILLIAMS: Sir, I am going to now, as I said before lunch, flesh out those opening submissions under five headings. First of all, I am going to go back to the directions and make some observations on how they work, secondly I will have a few observations about the legal framework for interim relief, I am then going to deal with the alleged harm to Flynn, fourthly I will address the non-financial harm to the NHS CCG patients if the directions are not given effect and then finally I will deal with the cross-undertaking.

Sir, you made it clear before lunch that the merits of the decision are not for today. I think you can take it as read that any appeal will be strongly resisted, but I do not need to cover that today, but by the same token the Tribunal obviously cannot proceed on the basis that there is strong putative appeal which is the way Mr. O'Donoghue puts it for Pfizer. The low merits threshold cuts both ways.

THE CHAIRMAN: I think the Tribunal is proceeding on the basis that the claim is not entirely ungrounded.

MR. WILLIAMS: So what I do want to do though is look at the directions and just to pick up a few points that may not have come out of Ms. Kreisberger's submissions this morning.

Pfizer says that the directions -- the directions are at 489 of the decision. Pfizer says in its intervention that the directions are composite and inseparable directions and it is true in the sense that the directions against Flynn interlink with those against Pfizer, as you have seen, and, as I was saying before lunch, once it is recognised that Pfizer is going to comply with the directions, there is no sustainable basis on which Flynn can avoid reducing its prices too, but as a matter of law there are separate directions against the two parties because the decision is legally characterised as distinct legal decisions and directions as against each party and that is reflected in the application. If you look at the draft order at reply bundle F, which you perhaps do not need to do now, you have probably seen, sir, that the

application is only to suspend the directions against Flynn, there is no application -- Flynn as the appellants, but the appellants in these putative proceedings. There is no application to suspend the directions as against Pfizer and so the composite nature of the directions does not mean that an application for interim relief by Flynn has any impact on the directions as against Pfizer.

In the course of Ms. Kreisberger's submissions, sir, you separated out really the two issues which arise in relation to the directions: first of all, are they unworkable, can they be given effect, are they too legally uncertain; and, secondly, is it said that implementing the directions will cause harm? Now, at the moment I am only going to deal with the first of those issues, I will come back to the second one.

I will try to take it reasonably quickly, sir, but what you can see really is that 1(a) is the essence of it, the infringement has to be brought to an end, and this direction is exactly what the CMA is empowered to do under section 33 of the Act. We have copies of that, because it did not make its way into the authorities bundle, if that would be of assistance. (Handed).

You can see 33.1, sir, says if the CMA has made a decision that there is an abuse, it may give "such directions as it considers appropriate to bring the infringement to an end", so there is obviously an exercise of discretion in relation to the form of those directions.

THE CHAIRMAN: So it would have been within the authority's power just to have issued 1(a)?

MR. WILLIAMS: It would have been within its power, but --

THE CHAIRMAN: Then it would have been criticised for being too vague.

MR. WILLIAMS: Well, I will come back to that point, sir, but I think two diametrically opposed criticisms are made of us at the same time and sometimes --

THE CHAIRMAN: It is not unusual in litigation I have found.

MR. WILLIAMS: -- in the same paragraph. Yes. But you are right, 1(a) is the essence of it and what the remainder of the directions do is two things: first of all they put a practical timeframe on the implementation of the directions and, secondly, they deal with the fact that Flynn is reselling a product which it buys from Pfizer at prices which have been held to infringe competition law and in practical terms, as you have seen, that means that the Flynn directions have to operate in two stages. There is a new price for existing stock and then there is a new price in relation to stock purchased from Pfizer at the new Pfizer prices and that is -- this is what one sees in the three stages. You have seen the direction against Pfizer at 1(b)(i). At 1(b)(ii), I think probably the points on this were teased out in the course of your exchanges with Ms. Kreisberger this morning, which is to say this is only dealing with the position in the short-term, it is dealing with a run-off of existing stock and the period has

to be short because it is dealing with stocks that are going to run out within a matter of months. So whilst the CMA is entitled to require that the infringement is brought to an end promptly, 30 working days being the applicable period here, its significance for Flynn is limited because it is an inherently short-term price which has no real significance in terms of the market thereafter.

THE CHAIRMAN: It is clear, is it, that it is open to Flynn to change its NHS list price, there is no point about that being impossible to do as a matter of mechanics? It is one thing I meant to ask Ms. Kreisberger and I am sure she will deal with it in her reply.

MR. WILLIAMS: I do not think any point is taken about that.

THE CHAIRMAN: No. You just notify a new price, is that right, and then it becomes the list price?

MR. WILLIAMS: I think the CMA's position is that once a view has been formed of what the price ought to be, that practical mechanism is not complicated.

THE CHAIRMAN: I seem to recall something in Flynn's application that these are not the prices that Flynn charges to customers, these are the NHS list prices.

MR. WILLIAMS: Sir, I will deal with that point. The point that they raise in that regard is to say "Well, actually the price that we set is a price for our wholesale customers and that is not the same as the list price", so they say --

THE CHAIRMAN: So you have the wholesale discount.

MR. WILLIAMS: -- is it clear that this leaves room for the wholesale margin, to which we say the answer is yes, it is clear.

THE CHAIRMAN: Okay.

MR. WILLIAMS: As I said before lunch, I think once one understands the limited significance of step 1, I think the argument on urgency does take on a different complexion.

1(b)(iii) then deals with step 2 and there are alternative dates, either two days after they sell new stock, although, as Ms. Kreisberger clarified before lunch, that is likely to take them until at least March in practice, and failing that a new long stop date which is four months after the decision and so Flynn may hit the long stop, or it may run somewhere close to it. What this means in practice is that Flynn really has months, months to consider the step 2 price, even after it knows what Pfizer's new price is and you raised the question as to whether there is or has been dialogue between Pfizer and Flynn, but even if there has not been dialogue there is a significant period between Pfizer's new price coming into effect and the step 2 price in practice coming into effect.

The adequacy of the period is reflected in the fact that in 2014 -- and there are findings in the decision about this but I think they are pure points of fact -- Pfizer put up its prices to Flynn in February 2014, backdated to January, and Flynn followed with its own price reduction in April which took effect from May. So the timeframes under the directions correspond fairly closely to that practical precedent.

THE CHAIRMAN: Is that a matter of chance, or is that something the CMA had in mind?

MR. WILLIAMS: I am told -- perhaps I had better take instructions before I answer.

(Pause).

Sir, the CMA says it took into account parties' representations but it was aware of this and there was also the stock point which was a point that Flynn specifically made to the CMA in its comments on the draft penalty statement. I do not know if you need to see that, sir, it is behind our submissions, paragraphs 3.3 and 3.4.

THE CHAIRMAN: I have read it.

MR. WILLIAMS: So I was only going to take you to two more directions, which you have seen already. 1(c) is "have regard to the content of the decision" and I will pick that point up in a minute when we look at *Microsoft*.

Then 1(d) is important, it says:

"For the avoidance of doubt nothing in these directions should be taken to mean that the parties are precluded from earning a profit margin greater than the reasonable rate of return adopted by the CMA for the purposes of establishing cost plus in the decision."

So that is specifically cost plus 6 per cent and that applies to both step 1 and to step 2.

So the criticisms that are made of the directions really boil down to two points: first of all, it is said, in particular in Mr. Firth's evidence, that the directions are contradictory and secondly it is said that they should be more specific. Ms. Kreisberger did not develop the first of those points this morning so I was simply going to refer you back to our submission.

THE CHAIRMAN: I think she said it was quite hard to apply (c) and (d) and to know what the upshot was.

MR. WILLIAMS: In that case I will deal with the point.

THE CHAIRMAN: If you would.

MR. WILLIAMS: So there is no contradiction between the findings for this reason: the CMA found that a 6 per cent return was generous to Flynn at Pfizer's current prices for a number of reasons: its role in the supply chain, the level of returns and so on. There is a discussion in chapter 5 of the decision -- it is sufficient for us to look at 5-210 and 5-211, which I could ask you to read.

(Pause).

THE CHAIRMAN: Yes.

MR. WILLIAMS: Essentially the CMA is saying "Well, we might have found that a lower return would be reasonable but we have not, we have adopted 6 per cent as the reasonable rate of return", and then you can see in 213 and the table following that that "Cost Plus", with a capital C and a capital P, is calculated on the basis of cost plus 6 per cent.

Once you have seen that, sir, if you could turn then on to page 354, paragraph 5-260 and then read those three paragraphs towards the bottom of 354 up to 5-262.

(Pause).

THE CHAIRMAN: Yes. Economic value, yes.

MR. WILLIAMS: So an explicit finding that the economic value is cost plus the 6 per cent, which you just saw in paragraph 5-213. That is a reference back to 5-213. Then in the next paragraph it says in 5-263:

"These findings do not establish the upper limit of what they may legally charge, however their prices must have a reasonable relationship to these levels."

So that is really just saying in as many words that Flynn's prices must bear a reasonable relationship to what we found is the economic value of the products. Then based on what you said this morning, sir, I am not going to invite you to turn up *United Brands*, which is in the authorities bundle, at tab 15, paragraph 250, but all that does is say in as many words what *United Brands* paragraph 250 says, which is that the prices must bear a reasonable relationship to the economic value. So there is absolutely no contradiction in the findings Mr. Firth identifies. Then if there were any doubt about it, Pfizer says in paragraph 9.3 of its reply -- I would ask you to take this out. It is Flynn's bundle 2, tab H.

THE CHAIRMAN: Did you say Pfizer or Flynn?

MR. WILLIAMS: Pfizer. So Flynn says it is all very unclear, but it is perfectly clear to Pfizer.

Could you read paragraph 9.3 down to the word "acceptable".

THE CHAIRMAN: The one that begins "The directions are frankly a mess".

MR. WILLIAMS: Yes. I did not want to read that out, sir.

THE CHAIRMAN: I have now read it onto the transcript for you.

(Pause).

So you do not say how much a reasonable relation to costs would be over and above the percentage you have identified in the decision; that is the gist of what you are saying?

MR. WILLIAMS: Yes, the gist of what I am saying is that Pfizer understood that cost plus 6 per cent is not an absolute cap, which is what the decision says in as many words. So the point

made in Flynn's application is the decision contradicts itself because on the one hand cost plus 6 per cent is said to be generous but on the other hand it is not a cap and it is perfectly clear to Pfizer that the decision and the directions are not saying cost plus 6 per cent is a cap.

THE CHAIRMAN: But they do make criticism --

MR. O'DONOGHUE: Sir, that is not accepted and I will tell you why in due course.

THE CHAIRMAN: What is not accepted?

MR. O'DONOGHUE: That there is clarity and an absence of contradiction.

THE CHAIRMAN: Right.

MR. WILLIAMS: All I am saying at the moment is that this submission says that they understand that we are not imposing a cap of cost plus 6 per cent, which was the criticism made by Flynn.

THE CHAIRMAN: Yes. It is a paragraph of Pfizer's observations which is fairly impolite about the directions, I have to say.

MR. WILLIAMS: It is impolite, that is right.

THE CHAIRMAN: I do not mean that pejoratively, I mean it does not like them. It is not complimentary of them.

MR. WILLIAMS: No, no, I was not suggesting this is a blessing of the directions as a whole, I was making the narrow point about is cost plus 6 per cent a cap, which was the contradiction alleged by Flynn.

THE CHAIRMAN: Okay, take the narrow point.

MR. WILLIAMS: The other points made in this paragraph are "this is an acute form of price regulation under competition law" and then it says in the next sentence "the CMA appears to have recognised it is wrong for it to act as a rate setting agency", but then it goes on to say "but the CMA conspicuously fails to say how much would be acceptable", which is an example of the competing submissions that I referred to earlier on, sir: on the one hand we should not be setting the rate, but on the other hand we should be more specific.

What I wanted to do now was just ask you to take out *Microsoft* at tab 19 of the authorities bundle, sir. This really goes to the question as to whether it is a proper part of the CMA's function to specify a price in directions of this sort and really there is one paragraph of key relevance, but I will just give you the context. Paragraph 3 sets out the nature of the abuse found in the decision in 2004. Paragraph 9 sets out the directions and you can see the relevant direction at (a), to make a product available on reasonable and non-discriminatory terms.

The decision is then appealed and there is an application for interim relief referred to at paragraph 12 which we will look at a bit later on. You can see then from the paragraphs that follow, in particular 20 and 21, that there are then periodic penalties imposed on the basis that *Microsoft* has not properly complied with the directions. *Microsoft's* complaint is reflected in -- you can see the first two and a bit lines of 71:

"Before *Microsoft's* obligations had been made specifically specific ..."

Then 74, first line, "failed to specify positively what *Microsoft* had to do to comply with 5(a)." So it is a situation that is very closely analogous to the present case where the complaint is about the specificity of the directions required to bring an abuse to an end.

If I could just ask you to look briefly at 85 as we go past, that says:

"In accordance with the settled line of authority, the operative part of the decision must be read and interpreted in light of the grounds of that decision."

So really that goes to the point about paragraph 1(c) of the directions simply making explicit what would be the position anyway, that is to say in giving effect to directions a party to an infringement the decision has to have regard to the content of the decision, so that is not introducing any new obligation.

Then at 95, this is really the key finding on the allegation I just showed you. Perhaps if you just read it to yourself, sir.

THE CHAIRMAN: This is about reasonable remuneration rates and whether they are clear enough. Yes.

MR. WILLIAMS: Yes. The important part is "It is not for the Commission ..." at the bottom of page 14.

(Pause).

THE CHAIRMAN: It is a slightly different factual base, is it not?

MR. WILLIAMS: It is, but it is dealing with -- the context of the criticism there was you cannot impose a penalty because you have not fleshed this out enough and the point of principle that is made is it was not for the competition authority to specify what you needed to do to bring the abuse to an end anyway, that is a matter for you.

THE CHAIRMAN: But you are not at the stage of enforcing the CMA's decision, or trying to impose penalties or anything like that; you are simply looking at the point about specificity.

MR. WILLIAMS: Yes, but it is right to say -- what this says is:

"It is not for the Commission to impose upon the parties its own choice from among the potential courses of action which are in conformity with the treaty or the decision imposing behavioral remedies such as the 2004 decision."

So that is the underlying infringement decision, rather than the subsequent enforcements. So that really goes to the point that it is not actually a necessary or indeed -- well, it is just not a necessary part of the finding of abuse or the directions consequent there on to specify exactly what conduct is needed to bring the abuse to an end.

So it really follows that the guidance given to a party whose prices have been held to be excessive will be the substance of the findings made in support of the infringement finding and that is what Flynn has in this case.

So that now brings us to the question of what is the significance of the decision at step 1 and step 2. It is right to note that the CMA's findings bear most directly on the new step 1 price because that decision relates to Flynn's current cost base, which includes the current Pfizer prices, and the decision was published on 7 December. Obviously the work that was done in relation to it went back a bit a few months before that, but broadly speaking both the direct and common costs considered in the decision will remain a relevant benchmark at step 1 and I think as Ms. Kreisberger accepted in her submissions, that is because there are findings, specific findings, as I have shown you, as to what is the economic value of the product at current input prices and it is probably for this reason that the arguments have put more weight on step 2 than step 1 and I did make the point before lunch which is that step 2 concerns Flynn's price set with reference to an input price set by Pfizer which has not been set yet, which obviously has implications for how far the CMA could in the decision have been expected to specify what the price might have been, but Flynn goes further than that and it says there is no hint in the decision as to what the position might be at step 2 and it describes it as a vacuum, and that is not right. You have already seen direction 1(d), sir, which says there is no decision that the rate cannot exceed 6 per cent.

Secondly, the common costs considered in the decision remain broadly relevant at step 2 because what changes at step 2 is essentially the direct costs rather than the common costs.

Thirdly, one has to look at the CMA's reasoning and I am not going into the merits, I am just explaining what the finding was. The CMA found that 6 per cent was a reasonable rate of return for Flynn at current Pfizer prices, having regard to a number of considerations, including the high levels of return that that gave Flynn in absolute terms because the returns took into account the high input costs from Pfizer.

Now, I am not going to put a gloss on the decision and say what it says, but the reason is relevant to step 2, where Flynn will perform the same task as it does at step 1, but it would on the basis of the same rate of return make lower returns, so it simply is not right to say that the reasoning has no application at all to step 2 and that Flynn is in a vacuum, and, as I

say, there were in any event limits on what the CMA could do at step 2 in advance of Pfizer setting its prices.

So we do not accept that there is any basis for criticism of the directions and we do not accept that Flynn is in a vacuum either, but ultimately of course it is for Flynn to set its own prices.

I will just finish off with the point that I have already shown you - that bit of the Pfizer submission where they criticise us at the same time as not being for specific enough but also say we should not act like a price setting agency and really the same contradiction is found in different parts of Flynn's submissions.

Paragraph 52 of the application complains that the CMA has not specified the scale of the price reductions or the lawful rate of return and in the reply, paragraph 23, Flynn says that it should not have to self-regulate, but at the same time paragraph 30 of the reply complains that the directions are back door price regulation. So we do not accept any of those criticisms, but what we say is that the criticisms cannot both be right. If we should not be acting like a price regulator, which is a point we agree with, then it is hard to see how we can be criticised for failing to specify an effective regulated price.

So the objections made to the directions on grounds of legal certainty are not legitimate. They are also workable and I will come in due course to deal with the contention that they will cause Flynn significant harm in terms of the impact on its business practices.

Sir, I think as we covered before lunch, the broad legal framework is essentially common ground.

THE CHAIRMAN: I think you need to move on a bit because it is important that we hear the other parties and that Flynn has a chance to reply to what you have said.

MR. WILLIAMS: Understood, sir. I was just going to cover four points on the legal framework.

The first point is a point I opened with and I will not labour, but it is the fact that it is a relevant consideration that the decision has prima facie been reached in the public interest and we say that that consideration is taken into account in the public law injunction context and it is relevant here too.

We have cited the *Monsanto* case. I will make a few brief observations about it. I do not think I need to take you to it, sir.

THE CHAIRMAN: No. I am not sure you really need to address me on this in the light of what you have put in your written submissions. I think I understand what you are saying. I mean, is it the CMA's position that, having taken a decision, you regard that decision as, if

you like, valid unless struck down on appeal, so not provisionally valid subject to confirmation on appeal, that is really what you are saying?

MR. WILLIAMS: That is our position, coupled with the fact that whilst the decision is going to be challenged it is a decision which has been based on an assessment of what is in the public interest.

THE CHAIRMAN: Yes, okay.

MR. WILLIAMS: I will just deal quickly with the points Ms. Kreisberger makes in her submission.

She seeks to distinguish *Monsanto* for a number of reasons. It is important to note though I think that -- one of the reasons Flynn seeks to distinguish it is because they say they have offered a cross-undertaking which makes this different from the general public law scenario. It is just important to note that in *Monsanto* that was a case that was principally about an affected third party because *Monsanto* challenged the grant of a permit to its rival and *Monsanto* was a case in which a cross-undertaking was offered to protect the third party's interests, but the court said that the undertaking was not adequate because of difficulties in assessing damages for the purposes of the cross-undertaking. That is 117.3(b) of *Monsanto*.

The second topic is the issue of burden of proof in relation to serious and irreparable harm and this is quite important. I think what I am going to do, sir, is take you as quickly as I can through two or three cases and not read out extensively from them.

If you could turn to tab 16, sir. This is the *Cambridge Healthcare* case and it is a case about the withdrawal of a marketing authorisation for a medicine. You can see at paragraph 109 it says:

"The immediate operation means the complete withdrawal from the market ..."

So it is a very strong case on the face of it because the product is completely withdrawn from the market, a stronger case than the present one. They say in 110:

"The risk therefore exists that if the contested decision is annulled that it will be difficult for CHS to recover the market shares it held."

Then 111 is the paragraph:

"CHS merely pleads difficulties in recovering market shares and has not demonstrated that obstacles of a structural and legal nature would present doctors from prescribing such medicinal products again."

So it is not enough to raise the prospect of the harm, one has to identify the reasons why that harm will materialise, reasons of a structural and legal nature demonstrated on the basis of evidence.

Flynn relies on paragraph 113, but that paragraph only goes to whether harm is reparable or irreparable, it does not go to whether the harm is serious and irreparable. I just wanted to ask you to note paragraphs 120 and 121, which are not relevant to the burden of proof, but they are relevant to the approach of the balancing exercise.

(Pause).

Sir, I am not suggesting that that authority is irrevocably binding on you in the way that you approach the balancing exercise, but we do suggest it is in accordance with the way we say the Tribunal ought to approach it in this case, ie that the interests of public health should be given precedence over economic considerations.

I will just then ask you to note a few paragraphs in *Microsoft*, which is at the next tab. If you could pick it up at 240 and 241, 241 in particular.

(Pause).

So the harm must be demonstrated with sufficient probability and, sir, we do not accept the idea that the Tribunal should proceed on the basis that if it cannot exclude a risk it should treat the harm as established. The harm should be proven on evidence.

In similar vein, I will not ask you to read them now because it is a passage -- it is a full page -- 290 to 292, the same point is made here, which is that if a party is going to allege that its business practices are going to be irrevocably changed then it is going to have to adduce evidence to support the irreversible nature of that. That is in particular 292, but notably what it says in 291 is of course the obligation to bring an abuse to an end requires you to change your behaviour, it cannot be the case that any change in your behaviour is a relevant change to your business practices.

Then finally tab 18, sir, when you have made your note. This is *United Phosphorous*. This is a case where the use of a particular active substance in I think herbicides was prohibited and interim relief was sought and there is a useful discussion at paragraphs 32 through to 35. 34 in particular sets out the general principle which you have also seen in *Genzyme* that financial loss will not be regarded as serious and it will not be regarded as serious and irreparable harm unless the applicant's existence is imperilled and then that principle is applied by analogy at 35 to reductions in market share. Really the point that comes through 35 is if you are relying on serious and irreparable harm short of being removed from the

market, you still have to provide evidence that really puts the harm you are alleging on an equal footing with a case of disappearance from the market. If you see paragraph 35:

"You can only put this on an equal footing with the risk of disappearance from the market and justify an interim measure if the irremediable effect on market share is of a serious nature."

So the point is serious means serious, not any change in business practices.

Now, it is an issue, sir, that some of the issues raised in relation to serious and irreparable harm and the impact on prices are, as Ms. Kreisberger has noted, bound up with issues that will be considered on appeal, but our main submission is that that does not dilute the obligation on Flynn to adduce persuasive evidence that the harm is likely to materialise and one cannot proceed on the basis that the risk cannot be ruled out because otherwise it would be enough for an applicant to say "We were going to deal with this on appeal" and that would get you through the serious and irreparable harm --

THE CHAIRMAN: So your position is that the applicant must establish to a reasonable standard, the balance of probabilities, or whatever you say, that these risks are real and what they are saying is that "On the contrary, if the risks are established prima facie then we must not exclude them. If we cannot conclude them, then we should accept them".

MR. WILLIAMS: It is very difficult to work out what is meant by established prima facie there. Is it enough that they made a reference in their evidence that they consider the risk is material? I think it is fair to say if the Tribunal was going to grapple with the reality of that risk it would need to look at issues which were dealt with in detail in the decision, because it is all to do with the interaction of NRIM's prices and Flynn's prices. Faced with that difficulty the submission I make is that you have to look at the quality of their evidence and whether you are satisfied that it discloses a sufficient probability of the harm arising, to use the formulation in *Microsoft*, and in our submission the evidence is insubstantial. What one has here are clinical guidelines the effect of which is that dispensing pharmacies do not, or are advised not to switch patients from, for example, Flynn's product to NRIM's product and vice versa and that point filters through the analysis of the market and competitive harm and all the rest of it. Now, we are not asking you to reach conclusions about that today, of course we are not, but if Flynn is going to take that on it is not enough for it to say in passing in its evidence "Well, this is all in dispute", otherwise the gate would swing open to serious and irreparable harm straight away.

THE CHAIRMAN: Well, as you say, it is a fairly fundamental point.

MR. WILLIAMS: Yes, sir.

The third point you have seen, which is the relevance of financial loss in the context of serious and irreparable harm and the point is just that under ordinary principles it does not constitute serious and irreparable harm, one needs to take it further, and it is only in exceptional circumstances that financial loss short of obliteration will constitute serious and irreparable harm.

The last point is the relevance of the reasoning in *Genzyme* where it deals with the risk that interim relief will jeopardise the competitive outcomes which the decision is intended to bring about and Flynn submitted to you, Ms. Kreisberger submitted to you this morning this is not in point, essentially because *Genzyme* was an exclusion case and this is not an exclusion case.

It is obviously right to say that the exclusion of a competitor is a strong case of irrecoverable harm and this is not an exclusion case, but the harm identified both in the decision and in the evidence before you, sir, is another type of strong irrevocable harm, which is harm to the NHS and to its patients at a time of strained financial resources and I just want to show you the decision just to show you that this is the harm found in the decision. If you could turn to 5.394, this was in the context of the discussion of abuse and the assessment of whether the relevant prices are unfair in themselves. That heading is on page 376. Again, I am not going to ask you to read it now, but 5.394 and following are all about the sort of harm that we say that interim relief will perpetuate. 5.395:

"You have to look beyond the immediate customer and take the interests of end customers into account."

5.396:

"CCG budgets are finite and legitimate demands will always exceed their capacity."

5.399:

"As a consequence of these increased costs CCGs have needed to commit extra money from their constrained budgets."

And so on. So this is the harm that follows from the exploitive abuse found by the CMA in this case and so it is simply not right to say that *Genzyme* is all about protecting against the risk of an exclusion of a competitor, what it is about is risking the integrity of the decision by failing to prevent the harm which the decision is intended to prevent against and that here is the very harm which is discussed and set out in CCG's evidence.

THE CHAIRMAN: We were talking about this earlier. The essence of what you are saying, based on this part of the decision, is that money spent on this product, arguably excessively, cannot be spent on anything else at the time when that money becomes available under the

NHS's budgetary system of controls and therefore it is not available to be spent on something else and therefore a patient that might need something else does not get it, or does not get it to the same extent. That is the argument.

MR. WILLIAMS: Yes, I am saying that and that is a relevant harm for the --

THE CHAIRMAN: And you are saying that is more than financial loss, that is --

MR. WILLIAMS: Yes, I am also saying it is the very harm against which the decision is intended to protect. So it goes into the balancing exercise as dealing with affected third parties, it is in the public interest; it is also for present purposes the harm to competition against which the decision is intended to effect. So for all of those reasons it is fundamental to the balancing exercise, sir.

THE CHAIRMAN: So providing good or improved public health is one of the objectives of competition policy. That is the proposition. In the sense that if it does harm and it is competition relevant, then it must be within the bounds of what competition policy is meant to bring about.

MR. WILLIAMS: Well, the harm arising in the context of this abuse is exploitation and the consequences of the harm are as you have just set out to me, sir, so it is harm to competition --

THE CHAIRMAN: I am trying to get at whether there is anything special about health harm that is different from say not having as many types of coffee on the supermarket shelf or something like that.

MR. WILLIAMS: I think the point is that it then plays out in two ways: it falls within the category of the harm to competition against which the decision is intended to protect, but it also involves, as I was putting to you before lunch, sir, the human cost and that has a particular significance in the balancing exercise because then it is non-financial harm.

THE CHAIRMAN: And you would say that is harm that I can take into account in weighing the balance?

MR. WILLIAMS: Absolutely, sir, yes. You can take into account affected third parties and the public interest, as well as the harm to competition, and --

THE CHAIRMAN: I thought I could take all relevant circumstances into account.

MR. WILLIAMS: Well, yes, sir. But I think the point is that this point fits into any of those boxes, which are established to be relevant considerations in the context of your decision, sir.

THE CHAIRMAN: Right. I hope I get it in the right box.

MR. WILLIAMS: I think our point would be it fits into all of them but it does not matter which box it goes into, it is the quality of the harm and the weight of the harm.

THE CHAIRMAN: I see, go on.

MR. WILLIAMS: So *Genzyme* is relevant for that reason.

I also want to deal very briefly with the reasons why the tribunal found that there was serious and irreparable harm on the other side of the scales in *Genzyme*. I think you have this point, sir, so I will not labour it. The infringement in *Genzyme* is described at paragraph 33 of the judgment and it involved bundling and margin squeeze and so the directions -- if it is useful to look at it we can do that very quickly, sir.

THE CHAIRMAN: What is the paragraph again?

MR. WILLIAMS: 33. It says "The alleged abuse".

THE CHAIRMAN: Yes.

MR. WILLIAMS: The directions are then at paragraph 45 and if you look on page 13 it is 396 point 2 and it involves unbundling prices and supplying to third parties. That is what is then picked up at paragraphs 91 and 92 of the judgment in terms of the onerous nature of the change to the business practices. In our submission it is just a very different case from this case. *Genzyme* was being required to reorganise its business in that case and to adopt a different supply model, as opposed to simply just to move the price, so it is a very different case.

Coming then to the harm to Flynn, in our submission the financial harm on which Flynn relies does not qualify a serious and irreparable harm. There is no suggestion anywhere in Flynn's case, or no serious suggestion that their business is in jeopardy, so that core scenario of serious and irreparable harm does not arise, and this is connected to the second main point which is that Flynn is explicitly permitted under the terms of the decision to make a return on its costs and in practice that means there is no real risk of the financial harm to Flynn crossing the line into serious and irreparable harm and --

THE CHAIRMAN: They just make less money than they otherwise would, is that what you are saying?

MR. WILLIAMS: That is right, sir. I will come to this point in a minute, but the decision is not dealing with any other product, it does not require Flynn to change its products or the way it sets its prices for any other products. The decision and the directions are about phenytoin capsules and you already have the point that step 1 in itself has extremely limited consequences.

THE CHAIRMAN: When I asked this morning how great the financial harm is estimated to be, would you disagree with the view put forward by Flynn as to how we should approach that?

MR. WILLIAMS: We would agree that gives you an order of magnitude number.

So for the reasons I have just given, this is not an exceptional case in which financial loss constitutes serious and irreparable harm, it is firmly a case on the other side of the line and so it is really in that context Flynn has sought to argue that its losses are non-financial in other senses.

Some of the evidence is extremely thin, an example being the suggestion in paragraph 21 of Dr. Fakes' second statement that there may be some impact on other products and projects and really the point we make about that is the evidence does not establish any concrete consequence for Flynn's business, it does not even establish that there is a real prospect of such a consequence, so the Tribunal cannot really attach weight to speculative comments on what might happen, the Tribunal has to be satisfied that there is a sufficient probability of the harm.

Really Flynn makes two main points and the first is the irreversible effect on market pricing, in particular it is said because of the interaction with prices set by NRIM. Now, the point is disputed for the reasons I covered in outline a few moments ago. It really comes back to findings which are set out in detail in the decision, but at the heart of it there is the clinical guidance relating to continuity of supply. So it is material to ask what does Flynn actually say about this in its evidence, given that this is an issue which has been covered in detail during the course of the investigation and obviously Flynn has had an opportunity to set out its stall.

So the issue was first addressed in Dr. Fakes' first statement at paragraph 13. I will not ask you to look at it now, but it really just says "Well, I actually disagree with the CMA" and reasons of substance are not given at all in the first statement. It is only in the second statement at paragraph 7 that Dr. Fakes makes any specific points at all about this. So I think you do need to look at this, sir. It is tab J, paragraph 7. Towards the bottom of page 2 Dr. Fakes says:

"I do not accept the case that the continuity of supply means that the prices are not constrained, given following facts regarding NRIM's acquisition of customers."

Three points are then made. The first is not a point which really goes to continuity of supply at all, it is just the point about the nature of the products, what they are intended for. The second point refers to 4.180 of (c) of the decision, so I do need to just show you that, if I may, because it is positively relying on a paragraph of the decision. It is on page 242 and

you can see the point is at (ii) this is potentially third party confidential so I will not comment on any of it, but (ii) you have to read in the context of (iv).

THE CHAIRMAN: November 2013 is the date of new guidance.

MR. WILLIAMS: The MHRA guidance.

THE CHAIRMAN: New guidance, more stringent guidance, or was it the same guidance said in a more stringent way?

MR. WILLIAMS: The content was the same. It does seem -- perhaps I will take instructions.

THE CHAIRMAN: A reemphasis of the guidelines.

MR. WILLIAMS: The content is the same but it had an impact. You can see at (iv) that there was a reaction to it, which is directly relevant to the point made by Dr. Fakes in (b). So (b) is really a very partial story.

Then there are some purported market share numbers at (c) which the CMA has not seen the workings underneath those so it is difficult to comment on those.

THE CHAIRMAN: The fact is when I say I am not going to the merits of the case, for a patient that is not currently on this Pfizer manufactured product it is open to a prescribing doctor to prescribe generically and it is open to a pharmacist to supply NRIM's product.

MR. WILLIAMS: It is open to them --

THE CHAIRMAN: The continuity of treatment --

MR. WILLIAMS: -- but there is this guidance.

THE CHAIRMAN: There is, but that relates to people who are already taking the Pfizer manufactured product. The difficulty, as I understand it, is in switching a patient from one manufactured source to another.

MR. WILLIAMS: Yes.

THE CHAIRMAN: So for a patient who has not taken such a product before, assuming this type of product is thought suitable -- that is not necessarily the case -- then in principle another party's product could be supplied; that must be right?

MR. WILLIAMS: But the product is not prescribed for new patients. So I will get the exact reference for you --

THE CHAIRMAN: That is because it is "end of life" product.

MR. WILLIAMS: That is right, sir.

THE CHAIRMAN: Okay, that is helpful.

MR. WILLIAMS: We can perhaps get you a reference for that, but that is the shape of it.

THE CHAIRMAN: That is merits and we do not really want to go there.

MR. WILLIAMS: No. I think the point I make is it is merits, but one has to look at what is the evidence being advanced in this application and that is the sum total of it, sir, and in our submission it is not seriously grappling with the reasons that have been set out as to why NRIM's product is not expected to exert a constraint on Flynn's product. In circumstances where that is the harm, the alleged irreversibility of the prices is being advanced to you as a core plank of the serious and irreparable harm which interim measures are needed to protect against. Sir, you have to look at the evidence and form a view about where it takes you and in my submission it does not take you very far at all.

I think 3.43 in the decision says that phenytoin is not prescribed, or is not prescribed for very many new patients.

So that is one issue. The next issue is what is NRIM expected to do. Even if NRIM does reduce its price when Flynn reduces its price, would you expect it to stay down at rock bottom levels even if Flynn puts its price back up? I am just going to show you another extract from the document Ms. Kreisberger showed you this morning, which is bundle 1, A3, pages 16 and 17. Question 7 on page 16 is about NRIM sets its prices, retail and wholesale prices, and so there is a discussion which -- I am not trying to omit things but for reasons of time I will not read out anything. The paragraph I wanted you to look at, sir, is the penultimate paragraph on page 17. You can no doubt look at this in context in due course, but you can see what NRIM says about the way it sets its prices, and that is not surprising in circumstances where there is a lead product and a rival product.

So what are the prospects that if Flynn reduces its prices and then seeks to put them back up, what are the chances that NRIM will stay at rock bottom? Well, if it wanted to price at rock bottom relative to Flynn it could do that now, but it does not.

So really it is all speculation, sir, is our point, and there really is not evidence that establishes any kind of probability of this serious and irreparable harm.

THE CHAIRMAN: So you would say they are normal, rational, profit maximising businessmen --

MR. WILLIAMS: That is not a bad place to start in thinking about competition.

THE CHAIRMAN: Not these days.

MR. WILLIAMS: The other point I just want to cover very briefly is the prospect of new entry. This is really a throwaway reference in Dr. Fakes' second statement to the possibility and it seems to be another thing which you are being asked not to exclude.

THE CHAIRMAN: I had some difficulty with the proposition, as you may have gathered, but go on.

MR. WILLIAMS: Yes. I think the important point to make is that any kind of new entry is going to involve a practical timeframe and if I could just ask you again to look at the decision at 4.264 -- perhaps I should just put it in context: 4.261.

I do not think here we are dealing with the same hot potato as we were earlier on around NRIM, but 4.261 indicates that we are talking about the prospect of new entrants and if I could just ask you to look at the practical timeframes in 4.264 and 4.266.

(Pause).

THE CHAIRMAN: The argument being put to us -- and you are saying it is just speculation -- the argument is that if the NHS list price is reduced as a consequence of your directions, generic manufacturers will be less likely to enter the market.

MR. WILLIAMS: And the point I am making, sir, is that what we are talking about here is the period between now and the appeal, so one has to look at the prospect that the directions taking effect is going to suppress likely new entry.

THE CHAIRMAN: There was some point also about the longer term, whether the price could be put up again and if it could not then that would damage the prospects for new entry in the future. I think that was --

MR. WILLIAMS: I think that comes back to the irreversibility of the price position which we looked at a few moments ago.

THE CHAIRMAN: And the fact that irreversibility is a bad thing. Have I got that right?

MS. KREISBERGER: Yes, sorry, sir, since you gave me a pause -- I was a bit slow to leap up a bit earlier, I wonder if I could just correct something, I apologise for doing it now but whilst you have the NRIM document fresh in your mind, Mr. Williams did not take you over the page, that same paragraph, which is relevant I am afraid, so I would just ask that Mr. Williams read it, or we all look at if it is confidential. Your attention was directed to the last two paragraphs of page 17. If you carry on page 18, the highlighted text in square brackets ...

THE CHAIRMAN: Okay. Rational, profit maximising businessmen.

MS. KREISBERGER: Exactly, sir.

MR. WILLIAMS: The point is -- anyway, I think you have the point, sir. I think the submission I am making now in relation to entry is what is the prospect, given the sort of timeframes that are involved, that the effect of the directions between now and the determination of the appeal is likely to suppress new entry and again it is really pure speculation, there is no evidence of substance and it does not look very practicable at all, sir.

THE CHAIRMAN: Just before you go on from that, presumably the CMA would welcome new entry?

MR. WILLIAMS: Right, I mean it is not --

THE CHAIRMAN: Would it? I ask the question at large.

MR. WILLIAMS: What I have shown you are the findings of what is the prospect of new entry for the purpose of assessing whether there is a constraint on Flynn's prices, so the CMA has reached that conclusion.

THE CHAIRMAN: That was my next question: would new entry in fact offer a constraint on Flynn's prices and if so how?

MR. WILLIAMS: It comes back to the market definition, sir.

THE CHAIRMAN: So if you are right, then it does not, and if they are right, it does. Must do. Although the effect has to work its way through to the NHS list price and that has to come down presumably.

MR. WILLIAMS: So if there was new entry would it constrain Flynn's prices? Well, it really depends on how Flynn reacts to the existence of the competition and obviously what the decision looks at is what impact have NRIM's prices have on Flynn's pricing and it concludes that they have not had a material impact.

THE CHAIRMAN: You are saying that may or may not happen but it is all speculation and it is in the future anyway.

MR. WILLIAMS: I am very conscious that you have said you are not going to get into the merits for reasons which we fully appreciate. What I am saying --

THE CHAIRMAN: I think even this brief discussion demonstrates it would be most unwise.

MR. WILLIAMS: One has to look at the quality of the evidence advanced to say that serious and irreparable harm is advanced and you then have to take a view when you look at the balance as to how much weight to give that evidence.

THE CHAIRMAN: Right. Can I put NRIM away now?

MS. KREISBERGER: Thank you, sir.

THE CHAIRMAN: How are we doing for time, Mr. Williams?

MR. WILLIAMS: I am not far off actually, sir. We have covered really my submissions about harm to the NHS and so I've got to get to the end of the harm to Flynn and then I have a few points on the cross-undertaking.

THE CHAIRMAN: Okay.

MR. WILLIAMS: So, sir, the other point to note in relation to the irreversibility of the price increase is Dr. Fakes' evidence at paragraph 22 and 23, which I showed you before lunch

and the point I made, was if it is right to say that Flynn is going to reduce its prices in response to Pfizer's price reduction, then it is not in any event the case that the directions are going to bring about a state of affairs that to some degree would not happen anyway, as a result of the inevitable effect of the directions working their way through the supply chain and so to the extent it is being said that the directions will generate serious and irreparable harm the directions as against Flynn, if and when Pfizer reduces its prices Flynn would have to reduce its prices anyway then it is not right to say that the directions are generating incremental harm. In short, Flynn is seeking interim relief against the prospect of something it is going to do anyway.

Pfizer has not addressed you yet in relation to its proposal so I will not say anything about that for now. Our broad point, as I have said, is that it is a measure which is intended to prevent harm to Pfizer and in relation to which there is no application, nor is it being volunteered.

The second type of non-financial harm alleged by Flynn is a change to its business practices or operations and, as I showed you in *Microsoft*, there needs to be evidence to demonstrate that the steps taken will be irreversible.

The CMA does not accept that the directions have implications for Flynn's wider business as has been suggested. The change in price required relates only to a product for which Flynn has been held to be dominant so that it has a special responsibility in setting its prices. Flynn does not need to change the whole of its business, or the prices of any other products, or the way it sets those prices and it does not even need -- it is not being directed to do a specific cost allocation exercise and the reason I say that is that the decision contains allocations of common costs at recent volumes, which are a relevant benchmark both for step 1 and step 2 and given that the step 2 price is likely to come into effect between now and April, the analysis in the decision is likely to remain pertinent because what changes at step 2 is the direct costs rather than the common costs. Obviously Flynn has to consider the decision when setting the step 2 price and it may or may not decide to do its own cost allocation exercise, Flynn has to decide that, but it is wrong to say that the decision is requiring Flynn to change its business practices other than by eliminating the excessive price.

THE CHAIRMAN: That is a counterintuitive point, is it not? What you are saying is that the decision arrives at a judgment that a particular price is excessive by using a methodology which is in part based on ascertaining costs and a rate of return on top of that, but in order to comply with it you do not have to use the same methodology, you can use whatever

methodology you like provided you end up at more or less the same figure. Is that actually what you are saying?

MR. WILLIAMS: No, no, what I am saying is that the decision contains an analysis of common costs based at recent volumes, so if one is looking at the cost base one will have element 1 which is the new Pfizer input price, element 2, a calculation of common costs, an allocation of common costs, and together those will make up the relevant costs base.

THE CHAIRMAN: There are very few direct costs other than the supply price, is that agreed? Yes. So allocation is a very important aspect of this if you are going to get the cost base right, as it were.

MR. WILLIAMS: It is important, but the point is that the decision contains a recent benchmark.

THE CHAIRMAN: So you are saying if they follow that for the next nine months they will not go far wrong. Can they rely on that?

MR. WILLIAMS: I do not want to put a gloss on the decision, sir, but I think the idea that they are being forced to carry out some new and wide-ranging exercise which will filter down into their prices for every product in their business, I mean it is just not correct, sir. No one is directing them to set prices for any other product on the basis of any other methodology, or to require any change in relation to the setting of those prices.

The specific point made by Dr. Fakes is that allocation based on pack size is difficult because of the variations in volume on a daily basis and in our submission even if Flynn does choose to do a cost allocation exercise, that does not make the methodology unworkable. Volumes may fluctuate for the purposes of any cost allocation exercise and as in any regulated context, Flynn is not going to be held to a standard of superhuman foresight, so the fact that volumes may change is not in itself a fatal objection to the application of the directions.

THE CHAIRMAN: The point I made earlier to Ms. Kreisberger was that whether or not Flynn were complying with the directions would be a matter for the CMA to assess, is that correct?

MR. WILLIAMS: Yes. As you have seen, the machinery of the directions requires them to notify the prices.

THE CHAIRMAN: Yes. It would be a little unusual if the CMA were to invoke procedure for enforcing directions pending an appeal, would it? Or would it not? It depends how blatant the breach was, I suppose you could say.

MR. WILLIAMS: I could take instructions on that if you want me to, sir.

THE CHAIRMAN: No, I do not think I do actually. I am just trying to think what the situation would be in practice.

MR. WILLIAMS: So on the other side of the scales then - so to round that submission off, Flynn's evidence does not articulate a cogent or persuasive case of serious and irreparable harm. We say they do not establish serious and irreparable harm and therefore they do not pass the threshold test, but even if you do not go that far, sir, what they have put forward merits very limited weight in the balance.

In contrast, we have already considered the nature of the harm which will be occasioned to the NHS, its patients and the public interest in the event that interim relief is granted and the appeal fails. You have the witness statements. I do not think I need to take you through them. You have clearly got the essence of the point and also the point that it is not financial harm because a patient that needs treatment this year does not benefit from the NHS being reimbursed next year.

Really that evidence, as I have said, is uncontested and the only points that are made against it are that the duration of the harm is short. We disagree. A year or so of patients not receiving the care they require is clearly material and it is not really clear to us why a reduction in public services for a year is regarded as tolerably short, but that period is too long for Flynn's financial losses to last and that is all before one takes into account the possibility of appeals.

The second point that is made is that the CMA is somehow not entitled to say that these are time-sensitive needs because its investigation took three and a half years and really there are a number of responses to that. First, the harm in question is harm to the NHS and its patients, it is not harm to the CMA and in our submission it does not make any sense to say that the harm to the CCGs is not significant because it took the CMA some time to investigate their complaints. That is a complete non sequitur. The fact that the CCGs have been overpaying for the duration of the investigation is a reason why the direction should be given effect, not a reason why they should be suspended.

Secondly, whatever the position was until now there is now a final decision that there has been an abuse and it can and should be given effect.

Thirdly, we say that the criticism is bogus anyway because it implies the CMA was not concerned about producing its decision as quickly as it reasonably could. Of course the CMA wanted to produce its decision as quickly as it reasonably could, its purpose is to bring to an end the consumer harm identified in the decision which I have shown you, but at the same time it had to produce a carefully considered decision which dealt with two

infringements, not one, not just the case against Flynn, and it had to deal with the case put by both parties and it is now going to be tested on appeal and there is obviously a balance to be struck between doing a thorough job and getting the job done as quickly as possible and really there is nothing in the history to suggest that the Tribunal should now regard the CMA as really disinterested in bringing the infringement to an end as soon as possible.

THE CHAIRMAN: So you say that is just a prejudice point?

MR. WILLIAMS: It is pure prejudice, but, as I say, once one acknowledges that the harm is to other parties it falls away completely.

THE CHAIRMAN: And the other aspect that you mentioned at the beginning, the -- I think Flynn's view was that the NHS is always going to be short of money, there are always going to be hard choices and that is the nature of healthcare.

MR. WILLIAMS: The answer to that, sir, is that it is a separate question whether you should now make an order which visits further harm on the NHS. I mean it is true to say --

THE CHAIRMAN: So things are bad but I should not make them worse, is that what you are saying?

MR. WILLIAMS: Exactly, sir.

Finally then, the cross-undertaking. I do not really have much to add to the submissions we set out in writing. Overall in relation to this, again we do not say that it is determinative in and of itself, but in the absence of a cross-undertaking which provides effective protection for the parties in question we say that weighs heavily against the grant of interim relief.

We do not accept, as I say, the analogy with claims for private compensation. What one is dealing with here is losses that would arise from the grant of interim relief, not in any event, so it is a false comparison in our submission.

The key points are, as you have seen, we do not accept the premise of the cross-undertaking, which is that a lawful or useful counterfactual price will necessarily drop out of the Tribunal's ruling. The issue on appeal is not to determine the lawful price and the undertaking should not pre-judge the terms of the Tribunal's judgment and of course insofar as the Tribunal's judgment does not produce a specific counterfactual benchmark price for the purposes of the cross-undertaking, the serious risk is that the undertaking will just trigger additional costly and complex competition law litigation and --

THE CHAIRMAN: Well, we might just send the whole thing back to you to have another go.

MR. WILLIAMS: Right, well -- yes.

So the other points are that the beneficiary of the cross-undertaking is the NHS rather than the CCG. So Ms. Kreisberger's point is that quite often cross-undertakings are adopted in

this form. I obviously cannot speak for the position generally, Mr. McGurk will address you on behalf of the Department of Health in a minute, but all we are saying is that on the face of it the undertaking is not in favour of the entities which will actually suffer the loss, which means that some further -- well, first of all it is not by its nature effective to prevent those entities from suffering the loss, so query whether the money will find its way back to the right people. Secondly, to the extent that it is going to do so, that depends on the Department of Health taking on some sort of role as the administrator of Flynn's cross-undertaking.

THE CHAIRMAN: The problem here is that it is every purchasing authority that would potentially have to be compensated.

MR. WILLIAMS: That is right.

THE CHAIRMAN: It is a little different from *Napp* say or *Genzyme* where the numbers of relevant authorities were fewer and possibly more ascertainable, I do not know, I am speculating, but that is what is being said, is it?

MR. WILLIAMS: That is what is being said in favour of this approach?

THE CHAIRMAN: It is what is being said about the impracticability of --

MR. WILLIAMS: Giving it to the CCGs?

THE CHAIRMAN: Well, yes, a cross-undertaking that tried to identify every purchasing authority that had been arguably harmed by the excessive pricing would be quite impractical.

MR. WILLIAMS: Yes, but that is the point we are making, that actually trying to establish a practicable arrangement which gives effective protection to the parties that are actually affected is difficult. Whatever one is putting in place is a proxy for what one really needs and we say that is a disadvantage of the arrangement because you are potentially creating financial losses which then need to be compensated --

THE CHAIRMAN: And the fact that the Department of Health has to do that if it is claiming damages for breach of competition law or common law is interesting but not decisive.

MR. WILLIAMS: It is beside the point because, as I say, there is a difference between claims they may choose to make when they have no choice and losses that would flow from an order of this Tribunal, because these are avoidable losses in the sense that the Tribunal does not need to make the order.

THE CHAIRMAN: No.

MR. WILLIAMS: Then very quickly, the undertaking does not in any event cover the excess wholesaler margin which is applied to Flynn's price and which is also inflated by the higher level of Flynn's underlying price.

THE CHAIRMAN: So the wholesalers get their benefit anyway?

MR. WILLIAMS: That is right, but from the CCG's point of view there is uncompensated financial loss because Flynn is only taking responsibility for its bit.

THE CHAIRMAN: And there is something about interest on damages, which is a very small number of words but a rather large subject.

MR. WILLIAMS: That is right. Interest is the other missing element.

Finally, in the context of all these difficulties our written submission did not address the quantum of the sums involved which you considered with Ms. Kreisberger this morning. There is not evidence from Flynn as to the extent of its resources relevant to that quantum. You have seen from our submissions how much money roughly Flynn had in the bank -- I do not know if you have that number in mind, sir.

THE CHAIRMAN: I have it confidentially in mind, thank you.

MR. WILLIAMS: You have also seen -- I am not sure that number is confidential but I am being cautious. You have also seen the sorts of sums that might be involved under the cross-undertaking and we merely register concern that the extent of the potential liabilities is a large sum relative to the sum you have seen in our submission.

So those are my submissions, sir.

THE CHAIRMAN: Thank you.

Right, we now come to those parties who are not parties, but who have submitted observations. I think it would be appropriate to hear Pfizer first, if that is all right.

MR. O'DONOGHUE: Sir, would this be an appropriate moment for a break for the transcribers? I am in your hands really.

THE CHAIRMAN: Are you suggesting we should break?

MR. O'DONOGHUE: I am in your hands, it may be an appropriate moment.

THE CHAIRMAN: Perhaps I should congratulate you on your recent elevation before we break. I do so now.

MR. O'DONOGHUE: Sir, I am very grateful. Technically there is still the opportunity for Her Majesty to change her mind, but in a nominee capacity.

THE CHAIRMAN: Provided she remains on the throne I am sure she is most unlikely to.

Perhaps we will have five minutes, yes, thank you.

(3.20 pm) (A short break)

(3.32 pm) Submissions by MR. O'DONOGHUE

MR. O'DONOGHUE: Sir, I have three points to make. It should not take more than ten minutes. The first point is that Pfizer has always believed and still believes that it set a lawful price in 2012 and therefore we entirely welcome the suggestion from Flynn, well received I think by the Tribunal, that this might be expedited to the extent it reasonably can. For our part we are very keen that this is determined as soon as reasonably possible.

THE CHAIRMAN: Well, I like to expedite all cases and this seems particularly deserving of it.

MR. O'DONOGHUE: Sir, we entirely agree.

Now, sir, we have set out, perhaps with more enthusiasm than is required at this stage, some views of the merits.

THE CHAIRMAN: "Enthusiasm", that is a rather weighty word I think for what your submissions contain.

MR. O'DONOGHUE: We entirely accept, sir, that at this stage you cannot get into the detail, we entirely accept that at this stage the hurdle is low, but, sir, for your reference it would be relevant to have regard to the strength of the prima facie case at the interim measures stage and, sir, for your reference that is *Genzyme* paragraph 80 and *Napp* paragraph 38. Sir, we are not at that stage.

The General Court often has the luxury of having the application for annulment and the application for interim relief at the same time and therefore in a case like *IMS. Health* there is quite detailed consideration of the merits of the main appeal because they had the full application before them. Now, you do not have that, therefore you cannot realistically deal with it, but we do insist that this decision is deeply flawed and we will make those points in due course.

Now, sir, the two points I think you really wanted to hear me on was first of all, briefly, the directions and second this escrow proposal which nobody seems to like.

THE CHAIRMAN: I think what I want to hear from you is why you are not asking for interim relief yourself.

MR. O'DONOGHUE: Well, sir, we have focused on the preparation of the notice of appeal. Our objective is to get that determined as expeditiously as possible. We did not want to get sidelined into interim measures. To some extent we have been, but we are anxious to get on with all of this and to have it determined as soon as possible.

THE CHAIRMAN: Yes. Where does that get us in terms of the wider argument? I do not want to -- why do you not say what you want to say and I will pick you up as you go along. That is probably the best way to proceed.

MR. O'DONOGHUE: Sir, I am grateful. On the directions we entirely stand by the submission we make in our written submissions that they are frankly a mess.

THE CHAIRMAN: They are a mess that you can comply with.

MR. O'DONOGHUE: Well, sir, one can always set a price and we will have to do that on Monday, but it does not mean that it is the right price, it does not mean that it is a relevant price and it does not mean that we can insure ourselves against the risk of undershooting or overshooting.

So the sequencing of how these directions came about is important in my submission and Mr. Williams rather glossed over this. Sir, if you can open paragraph 9.3 of our written observations, which you have seen -- the other thing which is frankly a mess is my bundle, but I think it is in H.

THE CHAIRMAN: That is all right, I have yours. Is paragraph 9 you say?

MR. O'DONOGHUE: 9.3 and internal page 5. So the sequence here is important. As we set out there, the statement of objections said in plain terms that a 6 per cent return in sales is the maximum rate and Pfizer understandably made the submission in response to that point "Well, this is a pretty acute form of price regulation". Then we got the directions in draft form in the draft penalty statement and instead of the directions reflecting the maximum rate position as set out in the statement of objections, there was, as in these directions, a failure to specify any particular price. Now, the bit that Mr. Williams did not read is the quotation set out at the bottom of the page which is our response to the DPS and we said essentially Look, you cannot have it both ways. If you want to say that there is a maximum 6 per cent return on sales, have the courage of your convictions and engage in proper price regulation by setting a rate, but you have not done that.

Now, what we see in the decision is that in the directions at least this maximum rate position no longer appears and in fact they go out of their way -- perhaps if we turn to this, this avoidance of doubt paragraph in the directions. They go out of their way to say for the avoidance of doubt it is not 6 per cent. That is at 1(d).

THE CHAIRMAN: It is not necessarily 6 per cent is what they are saying. They are saying it should not be taken to mean the parties are precluded.

MR. O'DONOGHUE: This is in the context of the statement of objections, which said --

THE CHAIRMAN: But the statement of objections -- you presumably replied to the statement of objections.

MR. O'DONOGHUE: We did.

THE CHAIRMAN: And they must have listened to what you said, must they not? It is one up to you, is it not?

MR. O'DONOGHUE: If that was all that occurred that would be correct.

Now, there are two problems with these directions because of course 1(c) tells us that we have to have regard to the content of decision when setting the supply prices. Now, if one goes back a few pages to 462, it is footnote 1412, there it says:

"The CMA considers that a 6 per cent return on sales is the maximum reasonable rate of return that should be considered reasonable for phenytoin sodium capsules."

I apprehend that is a hangover from the statement of objections and if, as one is told in paragraph 1(c), you have to have regard to the decision in understanding the directions --

THE CHAIRMAN: Well, are you going to take me to 5(c), 4(b)(ii)? What page is that?

MR. O'DONOGHUE: Well, there, sir, we have a far more detailed treatment of why 6 per cent is the applicable rate. The point I want to mention in this context is that here it is described as a maximum.

THE CHAIRMAN: But I just want to check, what page is that? It does not give a page reference.

MR. O'DONOGHUE: I will try and locate that. I am told it is 5.85, I am grateful.

THE CHAIRMAN: 5.85?

MR. O'DONOGHUE: That is where it starts. So essentially this is the longhand version of "Well, should it be return on capital?", "No, we think it should be return on sales", and then "What is the percentage" and "We think it should be 6 per cent", I think that is all common ground. But the point I want to make later in the decision which I have taken you to --

THE CHAIRMAN: This is 5.86. "The primary method" -- this is not confidential I think.

I am not getting into the merits, I am just following up your point.

MR. O'DONOGHUE: If I can briefly explain the scheme. So they looked at two return measures, one is return on capital employed, the other is return on sales, and for reasons that do not matter they opted for return on sales as the primary measure, so that is the methodology for return. Then the question is, well, what percentage of return on sales should one have regard to and that is 6 per cent and again the details of that do not particularly matter, but what I want to highlight is what in my submission is an inconsistency between saying in 1(d) that 6 per cent is not necessarily the maximum and footnote 1412 which suggests actually that it is.

THE CHAIRMAN: But the footnote refers to a discussion in the text of the decision and it is presumably the full discussion that one should look to, not just a footnote.

MR. O'DONOGHUE: Well, the footnote does use the word "maximum" and we are told we can have regard to the content of the decision and this is the content of the decision and in my submission --

THE CHAIRMAN: Are you saying the text does not include the word "maximum" but the footnote does and that is a hangover from the statement of objections, or what are you saying?

MR. O'DONOGHUE: Yes, that is my submission. In a sense, that is one point. Now, the other point is that at, for example, 5.440, there is other content in the decision which talks about the historic prices in 2012 and then there are other parts of the decision dealing with the prices in other member states. So if one is having regard to the content of the decision it is frankly unclear as to where exactly this 6 per cent fits as a supposed guide and that is why we said and we still say these directions are a mess.

Now, you put this to the CMA this morning and said "Well, it might be useful to have some guidance on the price", or --

THE CHAIRMAN: Is that what I said?

MR. O'DONOGHUE: -- what might be the indicators. Now, it was perfectly open for the CMA to say "Well, actually we think 6 per cent is the cautious level", it was equally open to them to say "We think something between 6 per cent and another percentage is in the range", but they have not said any of that and they still say to the Tribunal and to us "Well, this is all clear enough". With respect, it is not.

There are essentially two possibilities. One is that we overshoot and, as you say, sir, there may be a separate procedure for dealing with that infringement; the other is that we undershoot and we are entitled to impose, even under these directions, a maximum lawful price and if we pitch the level too low through a lack of guidance, that clearly would be irrecoverable and it would also frankly be unnecessary.

So the guidance in these directions, in my submission, is manifestly insufficient.

Now, Mr. Williams mentioned *Microsoft*. Of course that is entirely different, for two reasons. First of all, the obligation in the underlying decision was to give access to interoperability information. The General Court actually overturned the Commission decision because the Commission delegated the pricing element of that decision to a trustee. So the price of that information was not a part of the Commission decision in that case, whereas in this case, on any view, it is. Now, what we will have to do by next Monday at the latest is set a price, but we wish to lay down a very firm marker that that price is not

accepted as being the correct price or necessarily a relevant price and we will have to enter whatever reservations are appropriate.

So to answer your question, sir, yes, we can and will set a price because we have to, anybody can set a price, but we do not accept for one second that it is the lawful and correct price and these directions essentially give us no useful guidance whatsoever.

THE CHAIRMAN: But you are nonetheless going to do it.

MR. O'DONOGHUE: We will do it.

So that is the directions. Then, sir, on the escrow. I suspect, sir, this point simply does not arise because the sequencing was as follows, that having received Flynn's application and having understood that their priority was not to change the retail price at all if they could avoid that, we thought that in circumstances where Pfizer was not seeking interim relief and would be changing the supply price, that the only possibility of holding the ring in circumstances where Flynn would not change its retail price would be to have an escrow for the upstream price.

THE CHAIRMAN: Otherwise they would get a windfall.

MR. O'DONOGHUE: Indeed. In fact an interim measure of that kind would not be a proper interim measure because it would not conserve or preserve the status quo ante, it would improve the position of the applicant and we have not included this in our submissions but in the *Arriva and Shires* case, the Luton bus station case, Mr. Justice Roth refused interim relief on the basis that by effectively awarding the tender to the applicant he would pre-judge the question of whether they would have won at all so they would get more by way of interim relief than they might by way of final relief, so the windfall point went in a similar direction.

Now, we understand that following this submission Flynn's position now is that actually what they really care about is the margin and --

THE CHAIRMAN: I thought they cared about patients, Mr. O'Donoghue?

MR. O'DONOGHUE: About?

THE CHAIRMAN: Patients.

MR. O'DONOGHUE: Them too. And if, as they have said, they will reduce the price in circumstances where Pfizer reduces its supply price then it may be that this suggestion is no longer relevant.

But one final point to respond to Mr. Williams' point, we are not an applicant for interim measures, that is clearly right, but in the same way as the Department of Health has suggested a condition should be imposed in the context of the cross-undertaking, we as an

interested party are entitled to suggest to the Tribunal that if interim measures are awarded, the condition we have suggested may be worthy of consideration and there is nothing in rule 24 -- in fact the Tribunal could ex officio, as it did in *Genzyme*, suggest a condition as a condition of getting interim measures, so as a jurisdictional matter there is nothing wrong with a non-applicant for interim measures suggesting that a condition is appropriate and necessary --

THE CHAIRMAN: An escrow condition is what you are talking about.

MR. O'DONOGHUE: -- and in my submission in fact if this were to be a lawful interim measure something of that kind, if a windfall issue arose, would actually be essential.

Sir, one final point, not by way of submission, but really to assist the Tribunal, you have heard a lot of backwards and forwards on what cannot be excluded and the legal test. Sir, for your reference in the *IMS Health* interim measures proceedings an appeal was made to the Court of Justice against the grant of interim measures and one of the grounds for appeal was that the president of the court at first instance as it then was had erred in law in applying the test based on it cannot be excluded. Now, that appeal point was dismissed but, sir, it may be useful for you to see what the Court said on that particular point because it has been dealt with.

Sir, those are Pfizer's submissions.

THE CHAIRMAN: Thank you. Cheerful note on which to end, thank you.

Now, the Department of Health. Thank you for attending and thank you for providing information. Submissions by MR. MCGURK

MR. MCGURK: Thank you for giving us the opportunity to attend and make representations, sir.

I wish to make two brief sets of submissions. First of all, on the question of benchmarking and the relationship between the price of the Teva's tablets and the impact that is said to have had on the pricing of Flynn's capsules -- benchmarking for short because we do not accept there was benchmarking -- and secondly the scope and adequacy of the cross-undertaking. I do not propose to be more than 15 minutes, sir.

Before I make those submissions I just wanted to make this point, and in light of Ms. Kreisberger's observations about the confidentiality arrangements, sir, you may already have the point that the Department of Health does not have the benefit of the decision itself. As we understand it the CMA is still in the process of redacting the decision it has provided in confidential form to the applicants and Pfizer and my point is not in any way to criticise the CMA, rather it is to simply point out that we may be able to give you rather less assistance today than we might have done had we had the benefit of that decision.

Now, I understand that we will be notified by the CMA in due course when a non-confidential version becomes available and it may in due course be necessary to give reasonable undertakings to join and see a confidential version, but that is not a matter for today.

THE CHAIRMAN: We are nowhere near that stage, yet.

MR. MCGURK: No.

Sir, my first set of submissions are on benchmarking, what has been described as benchmarking. Sir, nothing at all may turn on this. The Department's concern is that some of the observations that have been made by Flynn, and in particular Pfizer, may lead to a misunderstanding about the relevance of the price of the Teva tablet.

THE CHAIRMAN: But these go to the merits of the appeal, do they not? I mean I agree it could potentially be an interesting point, but the way in which the CMA did or did not assess the excess price is not something I have to worry about today.

MR. MCGURK: Well, if the circumstances --

THE CHAIRMAN: There may be another occasion when we are very interested but I am not sure where it is going to get me today.

MR. MCGURK: It is not going to be of any relevance to your decision, I just wanted to very shortly say the Department of Health never agreed to the price that the Teva tablet was ultimately reduced to and it never indicated that it could be used as benchmark for another manufacturer's product. I will say no more than that.

THE CHAIRMAN: I think that is enough on that.

MR. MCGURK: Turning then to the cross-undertaking, I want to make three brief sets of submissions under the following three subheadings: first I want to address the irreparable harm to patients, second I want to address the inadequacy of the undertaking as a matter of scope, and third I want to consider the burden that the undertaking imposes on the DoH, but more particularly look at the consequences that will follow from the way in which the undertaking is currently set up.

First then the irreparable harm that will be done to patients. Sir, you have the point, you articulated it with Ms. Kreisberger this morning saying you did not want to take words in anybody's mouth, but we respectfully adopt the way you have characterised the harm that would arise immediately and in the injunction period to patients.

Neither Flynn nor Pfizer have filed any evidence nor made any submission which begins to gainsay what you will have read in the witness statements filed in support of the CMA's response by those who speak on behalf of CCGs.

Now, the high-water mark of Flynn's response appears in paragraphs 26 to 30 of their response of 13 January and I wonder if we could briefly turn that up.

THE CHAIRMAN: This is the reply, is that right?

MR. MCGURK: This is the reply, sir.

In a sense Mr. Williams has already made the point about delay made in paragraph 26. Just to echo that from my client's perspective, the CMA's investigation has taken the time it has taken and without any criticism of the CMA, the Department of Health has not had any control over the course the investigation has taken, so the point made about delay here in paragraph 26 is no answer to the contention that the continuation of the existing price in the injunction period will result in irreparable harm to patients. Plainly that harm will continue and is exacerbated by the grant of interim relief.

At paragraph 30 my learned friends go on to make the point ...(Reading to the words)... merits of the case have been subject to judicial scrutiny."

Now, again that contention is not to deny that there will be irreparable harm to patients and the funding of patient care in the injunction period. It is a submission that impliedly suggests, the irreparable harm notwithstanding, Flynn's economic interests should take precedence, or be regarded as overriding.

Sir, with respect we submit that that is not right. Mr. Williams has taken you to *Cambridge Healthcare*, we were going to take you to that, we will not go back to it, you have the relevant paragraphs and he has made the points we wanted to make about the relevance of human harm, or the patient harm that we say will incontrovertibly arise in these circumstances.

THE CHAIRMAN: I think my question to Mr. Williams was whether that was within the scope of the objectives of competition policy as opposed to health policy. I think he told me that it was, but you presumably would agree?

MR. MCGURK: I agreed with his answer that he gave at the time, in particular irrespective of the box you put it in it must be the case, we would say, that it is relevant and must be taken into account in the exercise of your discretion on the balance of convenience here.

You may have had another question which is whether patient harm always overrides and therefore if this point can be taken, the diversion of funds point can be taken, it would inexorably mean that interim relief would have to be refused on every occasion on which it arises and we say we certainly do not make that submission here, we do not need to make that submission here, but there are two factors which demonstrate the acuteness of the harm that is done on the facts of this case. First of all, the Tribunal will take judicial notice of the

severe constraints that the NHS is currently under and, second, the abuse in this case is particularly clear and clean, if I may put it that way, insofar as there is only one form of abuse, namely excessive pricing, and the transfer of the excess price from CCG to supplier is plainly discernible.

So the taking of funds out of patient care we would say for those two reasons is particularly acute in this case.

My learned friend Ms. Kreisberger, in her reply again, prays in aid two points at paragraph 32 and 33. If I could invite you, sir, back into the reply, she says at paragraph 32, "Well, in any event you will be able to bring your damages claim in due course". In my submission that is again no answer to the irreparable harm that is done now and in the injunction period to patient funding.

Secondly, she says at paragraph 33:

"The claim that there is something unusual ...(Reading to the words)... are entirely typical."

And she prays in aid *Napp* and the decision of Mr. Justice Arnold in *Warner-Lambert* . Can I quickly take you into *Napp* at tab 7 of the authorities bundle, sir. It is paragraph 20 and we did not look at it this morning. It was the basis upon which the application, which as we all know was dealt with by consent in the end, was initially supported. The point I wanted to draw the Tribunal's attention to is in the third line from the bottom:

"One of the justifications was the possible inconvenience and suffering caused to patients by hospitals switching suppliers."

So it was not an irreparable harm point as a result of the diversion of funds, it was the consequences of switching from A to B.

Now, the director, as you know he, sir, in this case accepted that there was some force in some of the points raised by *Napp,* the applicant, and that is why the matter was compromised, but in paragraph 22 you see that whereas he accepted, for example, urgency -- this is five lines down. Seven lines down it records that:

"The director rejected *Napp's* arguments that the operation of directions pending appeal would harm or disrupt third parties such as hospitals, patients or competitors."

So in that case it was the applicant praying in aid patient harm. Here it is the other way round, it is the DoH saying there would be a much more serious form of patient harm.

I make the point that the Department of Health did not intervene in that case and one assumes that if there was a risk of irreparable patient harm on the facts of that case, the director would not have taken the point he did as recorded in paragraph 22.

That is all I wanted to say about *Napp*.

Warner-Lambert, patient harm was not an issue in that case in the way it is in this case either. My learned friend Ms. Kreisberger took you to paragraph 8 of the judgment and it is the last few lines in that which are of interest. I preface what I am going to say about paragraph 8 by pointing out that the only offer in town, as is the case here, was an offer to extend the cross-undertaking to the Department and it is recorded the NHS, I am not quite sure what that means, whether it should be NHS England or not, but there it is. There was no offer to extend the cross-undertaking to a whole range of CCGs or hospital trusts and so on.

The judgment records that:

"The value of the exercise is illustrated by the fact that contrary to what has been indicated in an email sent by the Treasury Solicitor on the first day of the hearing, counsel informed me that he was instructed to request that if relief was granted Warner-Lambert's cross-undertaking in damages should extend to the Department and the NHS."

So given that it was the only show in down, given that there was no undertaking being offered to a wider set of NHS bodies, they were going to take it in circumstances where relief was to be granted. That is all we say you can derive from paragraph 8 of Warner-Lambert. It is no answer to the irreparable and immediate harm point to patient funding that we are faced with in this case.

Sir, that is all I wanted to say about --

THE CHAIRMAN: To be fair, in extremis you have said in your submissions that the Department of Health would accept in this case to be the beneficiary of a cross-undertaking, however reluctantly.

MR. MCGURK: There are difficulties generated by making us the beneficiary of the undertaking and if it is the only offer in town it is better than no undertaking at all, notwithstanding the difficulties to which it gives rise, yes, sir.

That was my first sub-submission.

Secondly, I wanted to discuss the scope of the proposed undertaking and there are two aspects to this submission. The first is really a request for clarification in relation to the bodies that will be covered, the losses of the bodies covered under the undertaking.

Now, the main focus in this application has been on the impact on CCGs who operate in the primary care sector and who will reimburse community pharmacies in the primary care sector and thus who bear the direct burden of Flynn's high prices. We put our observations in part to point out the scope of the bodies who may suffer that more direct form of loss. In

the secondary care sector that of course means hospital trusts, as a second category of body, and there are other categories as well, for example you could experience circumstances where private operators providing healthcare services, eg under procurements on behalf of the NHS, may incur additional cost of purchasing drugs for the healthcare that they provide pursuant to those frameworks and then pass those additional costs on to the NHS.

I think we have it from Flynn's reply submissions and what Ms. Kreisberger helpfully said this morning, but I take it that the undertaking would extend to those three scenarios that I have just set out. If I've got that wrong no doubt Ms. Kreisberger shall --

MS. KREISBERGER: It might be helpful to say: yes, that is covered.

THE CHAIRMAN: If it is helpful to say yes, I am glad you are saying yes.

MR. MCGURK: I am very grateful to my learned friend.

THE CHAIRMAN: So the three categories are the primary commissioners, the secondary bodies such as hospitals -- are there any other secondary bodies?

MR. MCGURK: There is the equivalent bodies in the devolved administration.

THE CHAIRMAN: I was going to ask about them. Are there CCGs in Northern Ireland?

MR. MCGURK: There are equivalents. I can't give you the name.

THE CHAIRMAN: So equivalent purchasing authorities throughout the United Kingdom would cover it, would it?

MR. MCGURK: To put it more generically, yes, that is my understanding. If we've got that wrong I will correct it.

THE CHAIRMAN: That is enough for our purposes I suspect.

MR. MCGURK: That was the first point on scope. The second point relates to the measure of loss by which Flynn says any damages ought to be calculated. Can I ask, sir, you to turn into paragraph 35 of Flynn's response to the reply submissions. My learned friends there say:

"Flynn does not agree with the Department of Health's proposals as regards the wording of the cross-undertaking at paragraph 13 of its observations. First the terms proposed are incorrect. Flynn is not liable for the reimbursement price of pharmacies, which includes the wholesaler's margin, but only the price charged to its customers, the wholesalers."

So that is setting out the appropriate measure of loss to be applied if the cross-undertaking is to be sued upon. But again as regards primary care the CCGs' losses just will be based on the sums that they have paid out to reimburse community pharmacies. A measure of loss based on what Flynn sold to the pharmacy risks undercompensating the CCG.

The point that my learned friends make as regards secondary care is fairer insofar as the measure of loss will relate to the prices that Flynn directly charges to hospital trusts. There are no reimbursement issues there. So my point here is that for an undertaking to be adequate it must be of sufficient scope to cover all losses from the outset. Now, if Flynn is contending for a measure of loss based on what it sold the drug for and not what the CCGs had in fact to pay by way of reimbursement then the scope of the undertaking is, in my submission, inadequate from the outset.

THE CHAIRMAN: Okay.

MR. MCGURK: My third point on the undertaking are the follow-on consequences from the burden that is thereby imposed on the Department of Health. For these purposes can I ask you, sir, to look at tab F and the revised wording that forms the undertaking. So it provides:

"In the event that the appeal is dismissed insofar as it relates to the CMA's finding of infringement the appellants should reimburse the Department of Health in respect of any phenytoin sodium Flynn hard capsules sold to the appellant between 23 January 2013 and the final dismissal of the appeal."

This is the important bit we say:

"Such part of the purchase price of the phenytoin sodium Flynn hard capsules as is directly attributable to the appellant's non-implementation of the directions and is unfair within the meaning of Article 120 ... taking into account findings of this Tribunal."

And so on. So it is "such part of the purchase price of the capsules directly attributable to non-implementation of the directions and is unfair."

Now, it is clear that, let us say for example the price is reduced from 54 to a price of 10, that Flynn will not accept that the loss is 44, the difference between those two prices, and they have said as much in paragraph 35 of the response which I have already taken you to. It is clear that Flynn will argue that notwithstanding the adjustment, not all of the difference between the old price and the new is unfair or unlawful and therefore capable of recovery under the undertaking. In my submission the consequence of this is that it will turn an ordinary fact based inquiry as to damages into a hefty competition law trial because we will have to assess the assertions of unfairness and in particular that will likely take the form that notwithstanding we have reduced the price to 10, we could have charged a price of 12 or 13, or a price within the range, and such additional sums having been lawful on a competition analysis cannot be recoverable under the undertaking. That is the first point.

But not only will this approach turn a fact based inquiry as to damages into a competition law trial on the merits, it will also potentially lead to a duplication of litigation. If Flynn's

appeal is dismissed then there may well be a damages claim going back to November 2012 and we say it would be plainly wrong for essentially the same competition law questions to be tried both in an inquiry as to damages and in the context of a follow on damages trial. There is a risk of additional expenditure and there is a risk of inconsistent judgments and therefore the expansion of the inquiry as to damages to the injunction to be discharged is improperly we say.

Now, one way to partially mitigate this would be to follow the suggestion we make in paragraph 13 of our observations, namely the difference should prima facie constitute the loss and if Flynn wants to argue otherwise, they pay the whole loss to the DoH and then they argue for a return of some balance said to constitute difference which was not unfair, but that of course does not get round the risk of duplicity of actions, increased costs and inconsistent judgments.

THE CHAIRMAN: It is getting very complicated.

MR. MCGURK: There it is. We may cover exactly the same ground on a follow-on damages claim as will have to be covered, pursuant to the wording of this undertaking, on an enquiry -- that is the only point I make about that.

THE CHAIRMAN: Right, can I ask you really a point of information, as you are here on behalf of the Department. There is reference in the papers to possible legislation allowing a future Secretary of State to control prices of drugs of this kind in certain circumstances. Is there anything you can tell the Tribunal about the progress of that legislation?

MR. MCGURK: Can I take instructions?

THE CHAIRMAN: Please.

(Pause).

MR. MCGURK: The legislation is in the Lords. It is known as the NHS Medical Suppliers Costs Bill. I think the implication relative to your question, sir, is that if a company is in the voluntary PPRS scheme, one cannot touch the price of any of their products, even if in a voluntary scheme. It will not cover that product.

We could, if it assists provide a very very short note, circulate it to the parties as well, to provide that point of information to everybody, if it would assist. I am not going to do much better than this now and I am told it is complicated. I am in your hands, sir.

THE CHAIRMAN: I think what I would be interested in is whether at some time in the future drugs in this particular situation, namely end of life narrow therapeutic index, unbranded, outside the PPRS could be subject to price control of some kind. I mean that is the question. I do not really need to know the detail.

MR. MCGURK: I understand, yes.
THE CHAIRMAN: If you are going to circulate a note it would have to be pretty quick.
MR. MCGURK: The answer is yes.
MR. O'DONOGHUE: Sir, there is a concern on this side that that issue is very much in the merits of the appeal. My friend, with respect, dealing with this on the hoof -- what he said is not correct.
THE CHAIRMAN: What he said is not correct?
MR. O'DONOGHUE: No.
THE CHAIRMAN: Although his clients are sitting in the court behind him and he has just taken instructions. Would you like to tell me in what --
MR. O'DONOGHUE: This is something we have looked at and what has been said is not correct.
THE CHAIRMAN: I do not regard it as going to the merits of the case, I regard it as a relevant background circumstance as to whether interim relief is desirable or not, okay? Let me be clear about that.
MR. MCGURK: To be clear about the answer to your very last question, my clients say the answer is yes, it would be covered.
THE CHAIRMAN: Yes. I am not getting into the details of what might be involved, or what conditions might have to be fulfilled, I just want to know whether the reference to the legislation means what it says and that is helpful, thank you.
MR. MCGURK: Thank you. For those reasons we say there is no answer to the irreparable harm that will now be caused and in any event there are serious shortcomings in the construction of the proposed undertaking. For those submissions we support the CMA's position.
THE CHAIRMAN: Thank you very much indeed. Right, your chance to reply, we are all ears.
MS. KREISBERGER: Thank you, sir.
THE CHAIRMAN: We have listened to an awful lot of stuff so --
MS. KREISBERGER: I will keep it brief.
THE CHAIRMAN: -- keep it brief, please, but do not please leave out anything you feel you need to say.
MS. KREISBERGER: Thank you, sir, I am grateful.

Reply submissions by MS. KREISBERGER

MS. KREISBERGER: In fact where we get to is that there is really one principal point taken against us and that is the patient detriment point and, sir, it is something you have questioned me on and I want to be very clear as to the nature of our response, the reason

why we say the balance of convenience should not swing against Flynn based on the patient detriment which the parties have cited against us, CMA and the Department of Health.

The first point we make is that if that were the case, if that were the relevant determining consideration, it would be right that one could never get a suspension of directions wherever you have a decision challenging drug prices, and that links back to the point I made earlier, sir, which is it will always be said that more money is better and could be spent elsewhere. There is a preference for lowering prices. The lowering of prices will have an impact on NHS budgets, so a finding in this case on that basis will set a precedent. There is really no way around that. That is our first response.

Our second response is that as a result of our offer of a cross-undertaking, the NHS is effectively hedged. We accept there is some undefined loss, but we accept an impact on budgets, that must be right, but there is a correlative gain. That must also be right. If we lose -- and this only arises if Flynn loses -- if we lose our appeal it is true that the NHS will not have had the relevant differential to spend on patients in 2017, but as a result of undertaking, the cross-undertaking, it will get extra money the following year, which money it would not have had if the directions were not suspended. So if it is right that let's say the 2017 budget is lower, the 2018 budget is higher than it would otherwise have been, so whilst there may be a detriment to patients in the immediate term, there is an off-setting boon directly off-setting in the next year. So on Flynn's approach, applying the arguments we have heard on the evidence, there will be a definable gain based on a suspension of the directions: there will be patients who benefit if the directions are suspended who would not otherwise benefit.

Our third and last point on patient detriment is to draw the analogy with patent infringement claims and this really brings me back to the first point, the presumption that it will never be possible to get a suspension on these arguments because in patent infringement claims interim injunctions are routinely granted -- sir, as you well know, I see from your nodding -- to keep generics out of the market pending determination of the claim.

THE CHAIRMAN: I am afraid my knowledge of patent infringement cases is far older than that, probably completely out of date.

MS. KREISBERGER: Well, the principles apply, so the Department of Health can claim on a cross-undertaking in that context where a generic has been kept off the market, it is later found that the patent would not have stood up, did not stand up, the generic is let on and the Department of Health can claim on the cross-undertaking because prices were kept up, there was no downward spiral through generic entry.

There is no presumption, sir, in those cases that injunctions should not be granted because if the generics come in prices go down -- there is no reason why these points advanced by the CMA would not apply in that context, but they are not, there is no presumption that, irrespective of the merits, an impact on NHS budgets is enough, it is simply not the case. That was all I was proposing to say on that point.

Our second headline point relates to unworkability. Reports of the significance of unworkability have been widely overstated. We stand by all the submissions we have made as regards workability. My point is that the overstatement lies in their significance to the case and in particular your determination of the balance of convenience, because it was said against me by Mr. Williams that limb 1 is perfectly workable and so all our objections fall away in respect of limb 1. Sir, I am afraid that is a quite significant distortion of what we have said. So in case it is not clear, my submission is that Flynn suffers four types of harm: substantial and irreparable harm because there is no compensation, that is common ground, no financial redress for Flynn; irreversible because of market movements; and a substantial interference in its ability to run its own business and determine its own policy, which is a more extreme interference than that that we saw in *Genzyme*. Those three points are our principal arguments. That is our primary position. I made a fourth point and that is where workability sits. We think it is unfortunate, my submission is that Flynn is in an invidious position, but you can take away point 4 and the arguments still stand, our case on balance of convenience is unaffected, and the importance of that is it goes both to limb 1 and limb 2. All those points stand as regards the implementation of the first step of the price reductions that would be mandated.

Sir, I think I will just there make a related but distinct point which is on financial loss. You have heard a lot about the relevance of financial loss. I am not going to take you back to *Microsoft* because I think we have heard a lot about that, but we set out in our reply that the reason why *Microsoft* says that financial loss is generally -- other than in exceptional circumstances -- not regarded as irreparable is because it can be the subject of subsequent pecuniary compensation and the relevant paragraph of *Microsoft* cites a case called *Italian Post* and we have copies of that which we will just hand up (Handed).

Sir, you will be relieved to hear I do not need to take you through the case, but simply draw your attention to page 1516 -- it has been tabbed helpfully. "Paragraph 119 makes clear" -- so that is the case cited in *Microsoft* and it refers to subsequent pecuniary compensation, of which there can be none for Flynn, both in relation to the step 1 price reduction and the step 2 price reduction.

A further and related point on that -- this is again going to the point made by Mr. Williams seeking to downgrade the relevance of our challenge to step 1, which we maintain and maintain vigorously, and that is the magnitude of the loss which we say is financial but also extends beyond that to interference in business. But just so you have it, sir, the magnitude of the loss is not irrelevant, it is actually very significant and, sir, you will remember table 5.18 on page 343 of the decision. We do not read out the numbers, but you had a careful look at the excess revenue figure. I had the impression, sir, that you had perhaps an annual amount in mind based on -- this is almost a four year period.

THE CHAIRMAN: I am in your hands. I am just trying to work out what the next nine months might involve.

MS. KREISBERGER: I am very grateful for that. All I was going to draw to your attention is that a quarter of that figure, and I can take you back to that table if it is helpful, roughly represents step 1, because we are talking about a two to three month time period. So if one takes the figure in 5.18 pro rata --

THE CHAIRMAN: So that is just on a time allocation, is it?

MS. KREISBERGER: Yes. So it is still a big number and it is a very significant proportion of Flynn's revenue. So we do not in any sense say "Well, step 1 is okay". Step 1 is not okay, it simply involves fewer difficulties of comprehension and implementation, but all our other criticisms apply.

The point I was then going to move on to, sir, I think I can deal with very briefly because, sir, I think you have the point, but I do need to respond given the way it was put.

Mr. Williams said that because we would pass through price reductions by Pfizer, this application is redundant. That is not the case.

THE CHAIRMAN: Did he really put it in quite those terms?

MS. KREISBERGER: That was my understanding and if I have erred in paraphrasing I will in any event make clear that the position --

THE CHAIRMAN: You answer what you think he said and I will then work out whether I think that is what he said.

MS. KREISBERGER: Even if he did not I will take this opportunity to make clear that this application is not redundant. There will be pass-through to customers. This means, in our submission, that it is likely that prices will come down for the foreseeable future, but of course Flynn's concern relates to Flynn's margin, so if prices come down, so be it, that is simply a product of Pfizer not applying to suspend and Flynn's usual policy of passing on savings, passing them down the chain to the customers. It would behave in the normal way,

pass-through would happen, this application relates to Flynn's margin. So there are no workability issues about passing on a cost saving, that will be then the world that we are in, a reduced input price.

THE CHAIRMAN: You did make some point about not knowing what the new price would be.

MS. KREISBERGER: We do not know what the new price will be.

THE CHAIRMAN: Once you know what it is you can pass it on, is that what you are saying?

MS. KREISBERGER: Absolutely. The CMA will have a much better idea than us because we only have a non-confidential version of the decision, so we do not know what the costs figures are.

THE CHAIRMAN: I only have a version of the decision that is sent to you.

MS. KREISBERGER: So we are in the dark. The CMA of course will know where the figures come out at on their calculations, so they will have a pretty good idea.

Then on this pass-through point, we have laid down the clear marker that that is what Flynn would do. We do not regard escrow as workable. I have raised that already. Let me set out one scenario to make clear why escrow would not work.

Let us say we win our appeal and the differential between Pfizer's new revised input price and the old price has been put into escrow by Flynn; what happens to that money if we win? We do not want it, Flynn has no interest in having increased margins as a result of this application, but Pfizer would have no entitlement to it if it has not applied to suspend, so there would be funds sitting in escrow which have no obvious destination. It is just an unworkable suggestion, so we raise it to make that clear.

With some trepidation I move on to my next point relating to the 6 per cent ROS upper bound. I have set out where we position the workability issue, so we think it is less important, but things that have been said do require correcting, so I will do it very briefly.

Sir, if it I could ask you to turn up paragraph 5.208 of the decision on page 340 and I do not think there is any confidentiality issue here. It is a conclusory passage, the CMA says:

"In exercising its judgment and taking account of the factors set out above it considers that the allowable ROS of 6 per cent under the PPRS would be a generous upper bound for a reasonable rate of return for Flynn's products."

There is a difference in treatment in the decision between Pfizer's prices and Flynn's prices and you have heard from Mr. O'Donoghue on the confusion there and contradiction, but what is very clear is that the decision does set a cap for Flynn, contrary to what Mr. Williams would have you believe.

THE CHAIRMAN: Well, they go on to say that it is reasonable, as well as a generous upper bound, so they have it both ways.

MS. KREISBERGER: Perhaps, sir.

THE CHAIRMAN: Well, we have not got into the decision and I have no view on any of this, nor should I have.

MS. KREISBERGER: I am grateful for that and I think we have made clear where that sits in terms of our submissions on balance of convenience.

Then I do need to respond to a separate point, which concerns the quality of Flynn's evidence and I make just a couple of points on that. First of all, the evidence which the CMA has put in is no more detailed, no more robust. We do not have specifics on patient detriment, we do not have examples. The evidence is thin.

Now, the evidence on our side we say is robust, but we would urge the Tribunal to approach it in the context of this application which has been brought on at great speed and it has been brought on at great speed because the CMA refused to hold the ring, to agree terms to hold the ring for a short time so that this could be heard after the lodging of the notice of appeal, and given the only point made against us is patient detriment the argument that a few weeks would have made any real difference is a difficult one. So we are in this position because Flynn has been forced to deal with a double track of notice of appeal and this application. Pfizer chose not to and we think it is a bit rich for the CMA to criticise us in those circumstances when that could have been avoided and that is set out in Mr. Firth's statement appended to our application.

In addition we say that our evidence is clear and it is unclear at this stage what more the CMA wants. We have referred to statements from NRIM where they say they approach this on the basis of normal competition effectively. We have set out precisely what Flynn says is the problem and I will not rehearse it, but we have talked about the cost allocation methodology, the impact on pricing, pricing of other products which we say would be impacted by this approach, and Flynn's ability to invest.

They have not contested that evidence save to say it is thin, it is unconvincing, but in fact it stands uncontested and, as I have said, the irreparability of the loss is uncontestable.

Sir, finally I will turn to points that have been raised by Mr. McGurk for the Department of Health. I would like, if I may, just briefly, to take you back -- and I emphasise briefly -- to the *Napp* case in the authorities bundle, which is at tab 7 and Mr. McGurk directed your attention to paragraphs 20 to 23. I do not think that submission takes matters any further, but we would just draw to your attention that at paragraph 20, as Mr. McGurk said, *Napp*

said the result of the directions in that case would mean higher prices to hospitals and the director in the event considered that a four to five months suspension would be satisfactory. Now, given this was an excessive pricing case, the same issues would have arisen in relation to patient detriment as are being raised here. Precisely the same issues arise because it was a case concerning excessive pricing of drugs, and there was no suggestion in *Napp* that there should be no suspension on that basis. So it really directly covers the point. That is at paragraph 23.

Mr. McGurk raised a number of issues about the precise wording of the cross-undertaking. We have not had any alternative proposed wording from either the CMA or the Department of Health. We have addressed the purchaser issue, clearly it is covered by the current undertaking. It is right that Flynn is not going to cover losses caused by other parties, nor should it, and Mr. McGurk objected that it might be wrapped up in a claim for damages by the Department of Health covering other periods.

I think to be clear, Flynn is offering the cross-undertaking as an extra level of comfort. Without the cross-undertaking the NHS would have its usual claim to civil remedies. We offer the cross-undertaking so the NHS has the comfort of financial compensation. It is never the case in a cross-undertaking that one works out at that stage every eventuality and every basis for loss. There will be a factual assessment and if there is also a claim for damages by the Department then it may be that the two proceedings can be wrapped up together quite sensibly. It sounds like a rather efficient way to proceed to us, but none of those points are reasons not to suspend the directions. This is the ordinary approach to claims on a cross-undertaking and in the absence of alternative proposed wording we suggest our wording should stand.

Sir, those are all our points unless I can assist you further.

THE CHAIRMAN: No, I think that is very helpful. Thank you very much. Does anybody else have anything else to say before we depart from this opportunity?

MR. WILLIAMS: Theoretically I might respond to Mr. O'Donoghue, but I am not sure I need to, sir, in that the two main areas he covered were footnote 1,400 and I am not sure based on what you said, sir, that that is an issue on which you are intending to grapple with.

THE CHAIRMAN: I think that point will no doubt emerge in due course but it is not particularly significant for us at this stage.

MR. WILLIAMS: No. In broad terms the answer is the same as the answer I gave in submissions in relation to the corresponding issue on Flynn.

The only other outstanding area was escrow, but my impression is that has petered out now, sir.

THE CHAIRMAN: It has petered out, right.

MR. WILLIAMS: So no on that basis.

THE CHAIRMAN: Right, I think that concludes the proceedings for today. There will be a judgment, I am not giving it now, but it will be very soon, it will certainly be this week, before Monday. Thank you very much.