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IN THE COMPETITION APPEAL

Case No. 1016/1/1/03

TRIBUNAL

New Court,  
Carey Street,  
London WC2A.2JT

25 September, 2003

Before:  
SIR CHRISTOPHER BELLAMY  
(President)  
PROFESSOR PETER GRINYER  
MR GRAHAM MATHER

BETWEEN:

GENZYME LIMITED ("Genzyme")

Applicant

and

THE OFFICE OF FAIR TRADING ("OFT")

Respondent

Mr David Vaughan CBE QC and Mr Aidan Robertson appeared for  
the applicant.

Mr Rhodri Thompson QC and Mr Jon Turner appeared for  
the respondent.

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**PROCEEDINGS**

**DAY ONE**

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1 THE PRESIDENT: Good morning, Mr Vaughan. I think it would be helpful to us if you  
2 would kindly introduce one or two of the principal members of your team sitting  
3 behind you, so we know who have.

4 MR VAUGHAN: Well, the leader of the team, Mr Robertson - I am the mouthpiece for  
5 him.

6 THE PRESIDENT: And behind you?

7 MR VAUGHAN: Then there is Mr Perrot, Miss McMorrow, Mr Johnson, Miss Kelly, Mr  
8 Morland. I think that is really the main ones.

9 THE PRESIDENT: Yes, thank you.

10 MR VAUGHAN: What we have done is to try and produce a sort of outline to save you a  
11 lot of notetaking. We have produced four copies so you can afterwards look at the notes  
12 and see where we have been, as it were, in our voyage.

13 As you will see there, we tend to concentrate on the issues which are raised by  
14 your questions on Monday, and then the issues that lie behind them and at the back  
15 there are various other matters which we will take very briefly and probably deal with  
16 in reply. We have given our cross references to where we make our points on each of  
17 those.

18 THE PRESIDENT: Thank you very much.

19 MR VAUGHAN: Obviously there is a limit to what one can do and say and to try an  
20 concentrate on the main things. There are three things. One is that my friend said he  
21 would make clear what his position is on Mr Evans, that they were going to treat as  
22 confidential things Mr Evans wants treated confidential. I do not think that is going to  
23 affect anyone but we would like to have an assurance, he could not give an assurance  
24 on Monday but we would like to have an assurance on that now in case we can deal  
25 with it, so that we know where we are.

26 THE PRESIDENT: When you say "now" you mean now.

27 MR VAUGHAN: Now, yes, rather than in submissions in reply. I do not know whether  
28 you are in a position to deal with that now?

29 MR THOMPSON: I must confess it was not at the forefront of my mind coming into the  
30 Tribunal, and I have not got instructions to answer the question now. Maybe at the  
31 short adjournment would be an appropriate to provide that.

32 MR VAUGHAN: Yes, well that is helpful, because we do not want a misunderstanding,  
33 because Mr Evans is pretty insistent that his information should not go further, openly  
34 or unopenly as it were.

35 The second thing is we received this morning, in fact it was faxed last night, a  
36 letter from the Treasury Solicitors which, if I can hand that in too, dated 24th  
37 September, that is yesterday. It was faxed to those instructing us at 7.18 last night, and  
38 was onward faxed from them to us at 7.46 this morning.

1                   This has caused considerable concern, because Dr Carroll, do you remember the  
2 meeting?

3 THE PRESIDENT: Shall we just see what it is all about? Can we just quickly skim read it?

4 MR VAUGHAN: You do not need the second bits, it is just the first page. Basically it is  
5 new evidence from Dr Carroll, who is one of the three people who attended the meeting  
6 at the Department of Health, the NASCAG meeting, one of the new people who did not  
7 know much about it. He is basically saying that the whole purpose of the meeting was  
8 to discuss Fabry, and that NASCAG had no authority to deal with anything else.

9 THE PRESIDENT: Just a moment, Mr Vaughan, I have not quite got to the bottom of the  
10 page. [pause] Yes.

11 MR VAUGHAN: Basically it is the inference of that that if Gashay was discussed, which  
12 they accept it was, it was merely incidental. We are not quite sure what the purpose of  
13 this letter is, except obviously to try and downplay the significance of that meeting. We  
14 would really like Dr Carroll to come to be questioned about these matters if any  
15 reliance is placed on this letter at all, because our evidence is very clear, that a  
16 significant proportion of that meeting was discussing Gashay in that way.

17                   I do not know to what extent it is suggested that that is not true. This letter is  
18 not very clear as to what it is meant to go to or why it has been put in anyhow, but there  
19 must be an intention of putting it in. I think if any reliance is placed on this letter we  
20 would like to question Dr Carroll about these matters, either tomorrow or on Monday.

21                   You will remember he was one of the people who attended the meeting. They  
22 asked him questions. He told Mrs Stallibrass that his recollection was rather vague  
23 about the meeting but he had taken notes and we have the notes before us which, in fact  
24 one will see contain a great deal about Gashay. If my friend over the short adjournment  
25 can let you know is he going to place any reliance on this letter, other than just as a  
26 fact, as it were, we would want to cross-examine Dr Carroll. I do not think we need  
27 take a position now, but clearly if my friend is going to rely upon this, as it were, as  
28 showing that our recollection of the meeting was wrong, or our account was wrong,  
29 then we would want to question him.

30 THE PRESIDENT: Well let us see, Mr Vaughan, it may be a point that in one way or  
31 another is somewhat distant from the main issues in the case.

32 MR VAUGHAN: Absolutely. But what I do not want is to have left open a factual issue  
33 which is relied upon against us.

34                   The other matter is really of rather more crucial importance. It relates to  
35 paragraph 2 of our outline submissions. In order to understand that you need to see a  
36 clip of documents. We got the document that is contained there from the Treasury  
37 Solicitors. We got the documents themselves, again I think last night, 6 o'clock last  
38 night they were faxed. There is a problem at the beginning, because if you look at

1 seventh page in, it is the letter we got, they claim confidentiality from our clients and---  
2 THE PRESIDENT: Where is it?  
3 MR VAUGHAN: It is dated 24 September, the long paragraph at the beginning. I can deal  
4 with this, make the point, without actually reading the document, but we are extremely  
5 unhappy about that, you will see why in a moment, and unless you were to rule that it is  
6 confidential - we have not shown it obviously to our clients at the moment, but you will  
7 see it is a document that we cannot not show to them.

8 The history of this matter, you start at the second page, we had been pressing to  
9 make sure that we had everything from Mr Brownlee, and there was a long letter  
10 written of 23 September this year to Mr Perrett, from Mr Munro, and it starts off - I do  
11 not want to read the whole thing - but it starts off on the basis that they were claiming  
12 these were internal documents and therefore they did not need to show them.

13 Then in the third paragraph there is a discussion of a meeting at the Department  
14 of Health which was minuted which we saw of 18 June, 2001 and then following up on  
15 that we asked if there was anything more and they said, "...we disclosed the totality of  
16 the documentary evidence". That is the end of the third paragraph.

17 In fact, they obviously knew about these documents because in fact they go on  
18 to say there was no inconsistency, because this letter was referring to documents  
19 written by Mr Brownlee, not to any notes at the OFT of meetings or DHS officials. The  
20 position was made clear which drew a distinction between the two. Nevertheless, the  
21 last paragraph on the first page: "The result of the point made by you, OFT counsel  
22 requested yesterday morning the position in relation to documentary evidence from Mr  
23 Brownlee be double checked. The case officer handling the case was absent on leave  
24 when the issue has arisen in April, reviewed the file and informed us in fact there were  
25 two emails from Mr Brownlee" Sorry, the point I made before was not right, they  
26 discovered these for the first time then. Mrs Pope drew counsel's attention to three  
27 emails. "We are writing to put the record straight by notifying you of the existence of  
28 these documents. They essentially comprise five emails, two from Mr Brownlee three  
29 from Miss Colley, which were all written in the context of the understanding with the  
30 DHSS described above, that is that things would be confidential, which was our  
31 previous condition for discussions....reviewed the emails conscientiously. In our view  
32 they are fully consistent with the OFT's case on the relevant regulatory structure, and in  
33 particular the operation of the PPRS. Given that position and the assurance that the  
34 OFT has given to the DHSS to meet their concerns between officials we do not  
35 consider it is necessary or appropriate to disclose the documents. If you feel it is  
36 unsatisfactory you are of course at liberty to apply to the Tribunal to seek an order".

37 At the same time there is a letter to Mr Dhanowa on the same terms, the same  
38 date. They were basically saying that they were not to be disclosed because they were

1 consistent with their position. We protested about that in a letter of 23rd September  
2 (last Tuesday) and I do not think you really need to go through it: it relates to the  
3 history, the rather unsatisfactory history about discovery. Then, the last page - the  
4 second one - "We should be given an opportunity to judge the significance of these e-  
5 mails, particularly the context. Mr. Brownlee has now been asked to attend the  
6 Tribunal hearing for questions. Confirm."  
7 Then we got these letters at 6 o'clock last night, these e-mails. These are  
8 confidential, so I cannot read them out loud.  
9 THE PRESIDENT: We will treat them as confidential for the time being.  
10 MR. VAUGHAN: In order to understand this, one has to go to the second page of e-mails  
11 first because, as you know, they work backwards. The long page, the second or the  
12 third page of e-mails, in fact represents what was set out in paragraph 70 of the  
13 decision, that is, under the Pharmaceutical Price Regulation Scheme.  
14 THE PRESIDENT: Is this the one that begins ----  
15 MR. VAUGHAN: "Thank you for your e-mail ..."  
16 THE PRESIDENT: "Thank you for your e-mail ..."  
17 MR. VAUGHAN: Yes. Then, "What does the NHS price cover?", and then from "under the  
18 Pharmaceutical Price Regulation" down to the end of 1 he has effectively quoted  
19 verbatim paragraph 70 of the decision. I have not checked exactly, but it seems pretty  
20 well verbatim.  
21 THE PRESIDENT: That seems to be the source, yes.  
22 MR. THOMPSON: I do not want Mr. Vaughan to take a bad point, but that e-mail was  
23 dated 13th December and these ones were clearly two or three days before that.  
24 MR. VAUGHAN: I do not understand that, because that e-mail is dated the 11th. One of  
25 the problems is, the Government work on different systems. The Department of Health  
26 works on an American system of months and date; the OFT work on an English ----  
27 THE PRESIDENT: Are we in November?  
28 MR. VAUGHAN: No, we are in December, because otherwise the one we are talking about  
29 was sent after the answer.  
30 THE PRESIDENT: Yes.  
31 MR. VAUGHAN: Basically, that one dated 11th December is paragraph 70 of the decision.  
32 Mrs. Pope then sent the one that appears before, which is time dated afterwards. Then:  
33 "Thank you for agreeing to clarify the issues in his absence." Then in the last  
34 paragraph she sets  
35 out ----  
36 THE PRESIDENT: Wait a minute. One is at 12.29 and the other is at - yes.  
37 MR. VAUGHAN: It is later on that afternoon.  
38 THE PRESIDENT: Later on that afternoon.

1 MR. VAUGHAN: This is obviously confidential. I would ask you to read the last  
2 paragraph.

3 THE PRESIDENT (After a pause for reading): Yes. Then  
4 Mr. Brownlee replies - the one at the top - and that, we say, raises very considerable  
5 problems for the Office of Fair Trading because it is completely different.

6 THE PRESIDENT: Just let us read it, if we may.

7 MR. VAUGHAN (After a pause for reading): First of all, he makes clear that he is  
8 answering only from a PPRS point of view and, secondly, he is saying that they have  
9 had no experience of this on a PPRS point of view and, thirdly, they would deal with  
10 each case on a fact by fact basis. So there is no point of principle. So he does not  
11 support that chunk of the decision which suggests as a matter of principle the drug  
12 tariff price does not ever include the delivery to the home. In fact, he rather suggests  
13 the other: that, on a PPRS basis, each case would be case evaluated. He does not deal  
14 at all with the drug tariff position. One of your questions was, "What is the  
15 difference?"

16 THE PRESIDENT: Yes.

17 MR. VAUGHAN: It is a great concern to see that this was not included or anything about  
18 this was included in the decision, because in fact it undermines the inextricably linking  
19 point of the whole case. First of all, we are very grateful for getting this document but  
20 are pretty horrified that here is a document dated after the oral hearing but before the  
21 decision was taken. We were given an opportunity to deal ----

22 THE PRESIDENT: After the oral hearing?

23 MR. VAUGHAN: After the oral hearing. We were given an opportunity, as you will see  
24 from the chronology, which is at tab 1 to our skeleton, on 13th December ----

25 THE PRESIDENT: Which document are you on, Mr. Vaughan?

26 MR. VAUGHAN: Tab 1 to our skeleton.

27 THE PRESIDENT: Your main skeleton?

28 MR. VAUGHAN: Our main skeleton, yes. File 43.

29 THE PRESIDENT: We are going to take a little bit of time to get up to speed with handling  
30 our files. We are in training!

31 MR. VAUGHAN: If I can suggest that it would be helpful if we could have been told at an  
32 earlier stage your system, because then we could cope with your system.

33 THE PRESIDENT: Thank you, the point is taken.

34 MR. VAUGHAN: It is very helpful because Miss Jeffcote gave us the list but we have not  
35 had time to transliterate.

36 THE PRESIDENT: Miss Jeffcote will shout out the numbers if necessary.

37 MR. VAUGHAN: Tab 1.

38 THE PRESIDENT: Yes, we are there.

1 MR. VAUGHAN: Tab 1 of our skeleton.  
2 THE PRESIDENT: The oral hearing of 6th November.  
3 MR. VAUGHAN: Yes, the oral hearing was on 6th November. We made various  
4 supplemental representations. They asked us additional questions arising out of the  
5 oral hearing on the 16th and on the 30th. I think I am right that the 30th one raised Mr.  
6 Brownlee's other e-mail but not this e-mail. Obviously, if we had seen this e-mail we  
7 would have been pretty cock-a-hoop. We had dealt with his other e-mails at that time.  
8 Obviously, we are glad to get it now, but it raises very considerable problems for the  
9 Office of Fair Trading. Mr. Brownlee is above suspicion: he has given proper answers  
10 to these things, but his answers are not incorporated into the decision and they are not  
11 incorporated into the Office's case today. The idea that that is entirely compatible with  
12 their case and therefore there was a reason not to show it to us we find very difficult to  
13 understand and look forward to seeing the argument on why it is totally compatible  
14 with their case in that matter. It is obviously a matter at which they have looked  
15 carefully and came to that view. It was on the basis of compatibility that they claim  
16 they did not have to show it to us. It shows how important discovery is in these cases.  
17 That is our position. Obviously, we will need to ask Mr. Brownlee some  
18 questions about it, but basically it entirely supports our case, even on a PPRS basis, and  
19 it supports the case of Professor Yarrow and Mr. Williams that on a PPRS basis, which  
20 is different from the NHS basis - even on their basis - they would deal with it on a case  
21 by case basis if they had got a case coming up. But, of course, we were under 25  
22 million anyhow at the relevant time, although we were voluntarily under the system  
23 from 1999.  
24 Equally, I am extremely unhappy at the suggestion that we cannot show it to  
25 anyone.  
26 THE PRESIDENT: I think that point needs to be sorted out before the end of today.  
27 MR. VAUGHAN: Yes.  
28 THE PRESIDENT: Because we need to know what we can do with these documents when  
29 we talk to Mr. Fernlea tomorrow.  
30 MR VAUGHAN: Well, certainly you can talk to him, it is under what conditions I suspect,  
31 because they are not confidential from you, I think.  
32 THE PRESIDENT: We have to sort out what the ground rules are today.  
33 MR VAUGHAN: Yes. But as the first one is totally contained in paragraph 70 and it is  
34 very difficult to see why the explanation that Mrs Pope had not understood him  
35 properly - it should have been in the decision, and if it had been in the decision then  
36 they could not have taken the decision in the terms they took.  
37 THE PRESIDENT: What I was just looking for while you were addressing us, Mr Vaughan,  
38 Mr Robertson can probably help me because he knows the decision by heart, there is a

1 point in the decision where the Director says he prefers Mr Brownlee's evidence on a  
2 particular point, I do not know if you can hunt up the paragraph number for me, Mr  
3 Robertson.

4 MR VAUGHAN: I have a computer. Of course, taking the first email with the second  
5 email then it entirely supports our case and Mr Williams and Professor Yarrow on these  
6 matters. If I can give you the reference, our further supplementary written  
7 representation is your file 18, at tab 5. 4844. The reference to the decision is paragraph  
8 82. These further submissions dealt with the Brownlee point and the Brownlee's note in  
9 that matter, and that was a reply to the document that appears at tab 4 in that file. You  
10 will see that the whole thing was dealing with the question of drug tariff includes  
11 delivery, and they were seeking to say that what I was saying was inconsistent with  
12 other things, and we put in our reply to show it was not, but obviously if we had seen  
13 that document ----

14 THE PRESIDENT: Just to see that I am following the argument. We have at the moment at  
15 the end of paragraph 83 of the decision a passage which Professor Yarrow in particular  
16 criticises.

17 MR VAUGHAN: Yes.

18 THE PRESIDENT: Which says that the NHS list price is not intended to cover the cost of  
19 delivering the drug from the pharmacy to the patient's home, and just before that there  
20 is a sentence that says what the NHS price is intended to cover. You are drawing our  
21 attention to the fact that Mr Brownlee's email of 11 December is much more qualified  
22 from a PPRS point of view.

23 MR VAUGHAN: Even from a PPRS point of view, and does not deal with the NHS point  
24 of view at all. You will see in the decision itself they quote the email from Mr  
25 Brownlee---

26 THE PRESIDENT: Paragraph?

27 MR VAUGHAN: It is in 74 with a footnote 98 where we have the difference in the dates,  
28 but it is clear when you look at them it is the earlier email.

29 We saw the earlier email and had to make the best of that. But we did not see  
30 the subsequent email.

31 THE PRESIDENT: So they showed you the 13th---

32 MR VAUGHAN: In fact it is not the 13th, what they call the 13th.

33 THE PRESIDENT: So what date is it?

34 MR VAUGHAN: I think it is the 11th, and the quote, "we are not aware" - sorry, it may be  
35 the 13th. It is 13th, but they did not show us the intervening one, the one which that is  
36 paragraph 70, and the one that is 13.

37 THE PRESIDENT: To do it in sequence, paragraph 70 of the decision is based on the email  
38 of 11th.

1 MR VAUGHAN: Of 11.12.02.  
2 THE PRESIDENT: Which is 11 December.  
3 MR VAUGHAN: Which I think it is the 11th December one.  
4 THE PRESIDENT: Yes. There is then another one from Mr Brownlee on?  
5 MR VAUGHAN: Also on 11th, I think. You will see from other emails that they have this  
6 different system, the American system he works on.  
7 THE PRESIDENT: 11th, Brownlee, which you say was not disclosed.  
8 MR VAUGHAN: Was not disclosed, and then we have the 13th which was.  
9 THE PRESIDENT: 13th, have we got the 13th in this little bundle?  
10 MR VAUGHAN: That is paragraph 74, it is quoted anyhow, we will find the original one.  
11 "We are not aware", is in the earlier one. I do not think there is one of 13th, sorry,  
12 because "We are not aware..."  
13 THE PRESIDENT: I am sorry, Mr Turner, yes?  
14 MR TURNER: It is only that I am familiar with the history, and I know exactly what  
15 happened, and if I may, because time is being eaten up and Mr Vaughan's submissions  
16 are due to last today, I think I can clarify and perhaps Mr Vaughan can come back, at  
17 least on the sequence, if that would be convenient?  
18 MR VAUGHAN: Yes, of course.  
19 THE PRESIDENT: Let us sort out the sequence.  
20 MR TURNER: May I first say that there is not anything sinister about this, just to lower the  
21 temperature and put the points in perspective. What you have here, attached to the letter  
22 of the Treasury Solicitor, are a series of emails that were treated as confidential in  
23 accordance with the Director's rules, or at least---  
24 MR VAUGHAN: Sorry, my friend said he was going to help you on the sequence, this is a  
25 speech.  
26 THE PRESIDENT: Well, just let us sort out the sequence first, Mr Turner. Just tell us what  
27 happened and then we will hear submissions afterwards.  
28 MR TURNER: The sequence of this is that the emails begin, at least the ones that Mr  
29 Vaughan was speaking about with one from Mr Killman was on 12 November, you  
30 have to read them backwards.  
31 THE PRESIDENT: You mean 12 December.  
32 MR TURNER: 11 December.  
33 THE PRESIDENT: I think, Mr Turner, Mr Vaughan, we will leave detailed questions of  
34 sequencing and all the rest of it for the time being. The point that Mr Vaughan is  
35 making is that there is at least an email from Mr Brownlee which, according to Mr  
36 Vaughan, throws some doubt on the decision and the position of Mr Brownlee in this  
37 case. That is the point he is making. Now, we will discuss whether that point is right or  
38 wrong at a later stage.

1 MR TURNER: That would seem sensible, Sir.

2 THE PRESIDENT: In the meantime somebody can sort out, perhaps give us a note, or  
3 something, about the exact sequence of the documents.

4 MR TURNER: To summarise the essence of the point, what one has here is emails that  
5 predate the email referred to in the decision of 13 December.

6 THE PRESIDENT: Very well.

7 MR TURNER: And that that email of 13 December was the one that Mr Brownlee said he  
8 was prepared to allow the OFT to disclose as representing the Department's position

9 THE PRESIDENT: Right, well I think we had better have a little note as to what the  
10 sequence is, because if it was all going on in November and not in December, then that  
11 slightly changes the order of events, but nonetheless, let us not go into it now, but go  
12 into it in due course.

13 MR THOMPSON: I do not want to trespass on your time given that indication, but the  
14 matter is set out quite clearly in bundle 37, tab CB31 where the Tribunal will find an  
15 email dated 27th November, from Mrs Pope to David Kullman, page 321. It is bundle  
16 37, the first core bundle prepared by Taylor Vinters on behalf of Genzyme.

17 THE PRESIDENT: Bundle 37, tab 31 did you say?

18 MR THOMPSON: Yes, CB31. Mr Kullman responded to that email in the terms we have  
19 been discussing so far, but the culmination of that was a formal email dated 13  
20 December, so after the exchange we have been looking at so far and the contents of the  
21 formal response is at pages 323 and 324 and it is that formal response which is quoted  
22 in the decision. That is the sequence of events, and there is no doubt about it.

23 PROF GRINYER: Are you saying that that supersedes the emails we have just been looking  
24 at?

25 MR THOMPSON: Well, Mr Vaughan may wish to make submissions about what  
26 happened, but the fact is there was clearly an internal exchange of emails, or an  
27 exchange of emails between the OFT and the Department, which has been treated as  
28 internal, but the culmination was a formal response from Mr Brownlee in the terms that  
29 appears there. That is what happened.

30 THE PRESIDENT: And Mr Vaughan's point is that before you got that formal response  
31 there is another response from Mr Brownlee, or a statement of some kind from Mr  
32 Brownlee, that is more qualified as to what the NHS list price covers than might have  
33 been thought to have been implicit from the decision. That is the point he is making.

34 MR VAUGHAN: Thank you very much indeed. Anyhow, we will have Mr Brownlee  
35 tomorrow.

36 If we turn to page 2 of our outline. We deal with questions 1 and 9, we have  
37 given them numbers, as it were, but given the cross reference to the transcript, but set  
38 out basically what the questions are. The two first questions seem to us: What

1 determines whether nursing in a particular case provided by NHS, and what is the  
2 current position on the 2.40 companies from the Fresenius report?

3 These questions are dealt with in Mr Morland's third witness statement, which  
4 is 37 CB 1 37 355. Can I take you to that, please.

5 Dealing with the first question first, it is at page 355.14, paragraph 678 of his  
6 third witness statement, 37 core bundle 1 of ours, 355.14.

7 THE PRESIDENT: Take your time, Mr Vaughan, there is a lot of paper for us to manage.  
8 When we are in the new building we shall have it all beautifully on screen.

9 MR VAUGHAN: And counsel will be left floundering, as always. 355.14 the first question.  
10 "I have also considered the position in relation to the factors influencing the decision  
11 regarding who should provide nursing care. The principal factor.." this is Mr Morland,  
12 the Director of Genzyme. "The principal factor is whether there is an established NHS  
13 community support structure in place, such as the Royal Free Haemophilia team, the  
14 NHS EN & PN Support Structures, those found in Leicester and Nottingham, specialist  
15 community teams with intravenous skills at St Mary's. In deciding to use nursing  
16 services outside the NHS, major factors were the lack of NHS resources, for example,  
17 lack of community intravenous skills, the cost/benefit to the NHS and therapy  
18 specialisation of those providing the nursing services."

19 So from him - and there is no suggestion that they put anything else in on this -  
20 basically the NHS looks to see whether it can do it itself, if it can it will, if it cannot it  
21 will go outside in this way, whether to Genzyme or Health Care at Home or whoever:  
22 they will put it out to tender. It is a pure economic decision and a skill decision too, as  
23 one would expect.

24 The NHS is not, as it were, the sink which picks up things which are not  
25 covered by commercial provision: it is the first one they think about and then go  
26 outside for the services if they need to or leave it to other people to do if they need to.

27 THE PRESIDENT: How does this work in the case of Gaucher's disease? If you have a  
28 particular patient who is unfortunately suffering from this disease who needs nursing,  
29 what is the decision-making process by which it is decided that it is an NHS nurse or a  
30 Genzyme nurse or a GH/HH nurse?

31 MR. VAUGHAN: There are some people who have to be treated in hospital, so forget  
32 those. The nursing people are those who need help with cannulation. There is a  
33 disputed number: we do not know what the exact number is who are in this position.  
34 From this, it would seem to suggest that the NHS will do it if it can and if they have got  
35 the skills and if it is economically worthwhile.

36 THE PRESIDENT: If they have not got the skills, does somebody ring up HH and say,  
37 "Will you send a nurse along?" or what happens?

38 MR. VAUGHAN: What happens is, the consultant will give the prescription to the

1 appropriate company and the prescription will be for the drug and just the drug,  
2 because it is a prescription service, not a contractor service. Then the company that  
3 receives the prescription, be it Genzyme, be it Health Care at Home, be it Clinovia will  
4 then provide whatever is necessary. If it is delivery only, they will deliver; if it is  
5 nursing, they will nurse in that situation.

6 THE PRESIDENT: How do they know what to provide? Who tells them what it is they are  
7 supposed to be doing?

8 MR. VAUGHAN: There is discussion with the consultant. They then go and discuss with  
9 the consultant what is required or with the consultant's nursing team.

10 THE PRESIDENT: Perhaps that can just be tied down. Just let me know whether that is  
11 broadly right. What I am understanding at the moment is this. In an individual case,  
12 when - let us call them GH/HH for shorthand - receive a prescription, there will be  
13 some kind of contact between the supervising clinician and his staff and the home care  
14 provider in the course of which it will be decided whether a nurse is coming from the  
15 NHS or is coming from the provider.

16 MR. VAUGHAN: Yes. Obviously, in many cases it will be just as before: when the  
17 prescription is issued, it will be just a repeat of what was previous prescribed so the  
18 whole system goes on as before. However, in a way people want to get people off  
19 nursing if they can in this whole system.

20 There is a third group of people who, as annex 2 shows, do not have a nursing  
21 service at home but who go to the local doctor, the nurse at the local community health  
22 service, and get the needle put into their vein and then get it done in that way.

23 THE PRESIDENT: When we are talking about nursing services, the typical service required  
24 is the administration of the drug.

25 MR. VAUGHAN: Yes.

26 THE PRESIDENT: The infusion itself.

27 MR. VAUGHAN: There are two bits. One is teaching the first time people, getting them to  
28 understand how to do it and building up their confidence. The desire is to get everyone  
29 self-cannulating if you can or their parents - because a lot of these are children. You  
30 get the parents doing it in that system. And thus to keep people out of hospital.

31 Thereafter, it is going once a fortnight when the intravenous system operates to  
32 put the needle in, effectively, and probably sit with the person during the course of the  
33 one hour which it takes to do that and then, presumably, take it out again and put a bit  
34 of plaster on it.

35 THE PRESIDENT: So we are not talking about intensive nursing services.

36 MR. VAUGHAN: It is not intensive.

37 THE PRESIDENT: It is not 24 hour care.

38 MR. VAUGHAN: No, and these people are not in bed.

1 THE PRESIDENT: It is not changing bandages and all that sort of thing.  
2 MR. VAUGHAN: No, these people are not in bed.  
3 THE PRESIDENT: They are living normal lives or more or less normal lives.  
4 MR. VAUGHAN: Yes, which is the great triumph of what is happening. They are kept out  
5 of hospital. One of the documents deals with a thing called Intonate. In the ordinary  
6 way one had to sit there with a bag on a stand, but there is now a thing called the  
7 Intonate which you strap onto your arm and then can walk around with that, so actually  
8 you can be mobile and carry on doing whatever you wish to do.  
9 THE PRESIDENT: So you do not have to sit there for the hour while you are infusing.  
10 MR. VAUGHAN: It is particularly good either for children or people with children,  
11 because, obviously, for young children it is pretty difficult for them to keep still for an  
12 hour in that way.  
13 THE PRESIDENT: Yes, thank you.  
14 MR. VAUGHAN: As far as we know, that is the system. My note says that, first of all, the  
15 consultant looks at local resources, that is when there is a patient who is a new patient.  
16 He either sends it to his own team or to community nurses or he out-sources it to  
17 Genzyme or Health Care at Home, which I think is roughly what I have said. Then he  
18 fills a registration form - this is what I did not say - to request or instruct a nursing  
19 service to be provided. So he tells them to do it.  
20 THE PRESIDENT: It is not on the prescription as such.  
21 MR. VAUGHAN: It is not on the prescription.  
22 THE PRESIDENT: Because HH receives a form from the consultant which says, "Nursing  
23 services, please, for this patient."  
24 MR. VAUGHAN: Yes. Whether it is an instruction or a request, it is done. Basically, that  
25 is our answer to question one. Our answer to question nine (which is our second one)  
26 is the companies mentioned in paragraph 2.40 of that. What has happened is, Mr.  
27 Dominic Moorland with Mr. Vitek Doradra have done their best to try and find out  
28 what is the position.  
29 Annex 1 deals with the position as at the date - in Section A - of Fresenius and  
30 then in B the current situation. So if I can turn it round, I am afraid it comes out very  
31 small, which is a major problem for me, if nobody else, the other ones - you get Abbott  
32 Laboratories, the EN and the IG. These are defined terms in the Fresenius Report, in  
33 one of the annexes to the Fresenius Report. It is 5.5.2, appendix 4.1 of the Fresenius  
34 Report, core bundle 2, Exhibit 38.  
35 THE PRESIDENT: We do not need to go to it now.  
36 MR. VAUGHAN: No. Some of them require a much more intrusive form of nursing than  
37 others. If you are going to have a tube put down into your stomach, most of us cannot  
38 do that for ourselves and would require much more intensive nursing than others.

1 Abbott did EN by tube, so I assume that requires intensive nursing. It was done in-  
2 house. Alpha Therapeutic in-house, IG. IG is an injection, so probably you could do it  
3 yourself if you were trained. Baxter have different things: one by catheter, three by IV  
4 infusion. These were all done in-house, as one will see from the MMC report. Baxter  
5 themselves took the product to the patient at home and then it was administered either  
6 by themselves or through nursing at home. There is nothing in the MMC report to  
7 suggest that there was ny further payment for these, other than the drug tariff price.

8 Novatis - one was by IV infusion. Nutricia is the one you asked about and I  
9 will deal with in a moment. It was with Caremark at the time: they moved it in-house.

10 That was by tube, so that was probably more intensive and only by nursing.  
11 Pharmacia had gone from Caremark to Sunscript and IV treatment. So basically that  
12 was the position then.

13 The current position is the B. You will see that some of the products have  
14 changed. You will see the growth of this whole area of pharmaceutical companies  
15 either doing it themselves or through exclusive distributors, doing it much more  
16 extensively, so the whole system has grown substantially since Fresenius; indeed, on  
17 the basis of Fresenius. The Abbott Alpha Baxter Novatis Nutricia pretty well as  
18 before, but some of the products have changed.

19 There is a column saying, "Service reimbursement." These are the only ones  
20 we have been able to find out whether they are getting any extra reimbursement for  
21 these. No doubt we will look forward to seeing what the Office of Fair Trading tell us  
22 about these things, but for those four no charge to the NHS. We cannot really ring up a  
23 company and ask them how they charge for these things, but we have found out -  
24 sometimes they have told us; sometimes it is on their website.

25 You will see Abbott have no charge. They do this by tube. No charge to the  
26 NHS. So there, Abbott, for example, administered by tube, so you have intensive  
27 nursing in all cases and it is done at no charge to the NHS. The Office of Fair Trading  
28 have said that that is wholly illegal. TKT is Replagal. That is their product for Fabry.  
29 That is done through Health Care at Home on an exclusive distribution system by the  
30 company nurse role. They just do the training. No charge to the NHS. The source, the  
31 Replagal letter.

32 Obviously us both in Fabrazyme and for Fabry and Cerezyme for Gaucher, we  
33 do that at no charge to the NHS and the complaint is made about that by them. The you  
34 go on, Roche, Orthobiotech, Ferring, Biogen, Merck, Wyeth, Rosinius, Gambo,  
35 Grifols, Aventis, Bio Amgen. All these people are doing this and this is by looking at  
36 websites through what we have done. Obviously, it is not complete, but it is the best  
37 we can do in a couple of days.

38 It shows that basically it is a growth area, it is a major aspect of the health

1 service, companies doing this. They do it at no charge to the NHS and they are quite  
2 happy to do it on that basis. But this is what is said to be illegal. If it is illegal for us, it  
3 is illegal for them if they are in any sort of dominant position.

4 THE PRESIDENT: Our general difficulty on this part of the case, Mr. Vaughan, if it is  
5 relevant at all - I do not know if it is relevant yet - we do not really know much about  
6 all these other companies: we do not know whether they are operating in competitive  
7 markets, whether they are dominant, what the exact nature of the service is, what the  
8 charging arrangements are and all the rest of it. It is a bit difficult to draw conclusions  
9 one way or the other on this sort of information, useful though it is to have it set out.

10 MR. VAUGHAN: But that is really our complaint. When we got the Rule 14 notice, in our  
11 defence we complained that they had not done this. We complained at the oral hearing;  
12 we complained in the notice of appeal; we are still complaining. It is their job to do it  
13 properly and we have contrasted with great care and detail - the Competition  
14 Commission looked at all these things - with what in fact has happened. What in fact  
15 has happened is, the Office of Fair Trading - because they define the market in such a  
16 narrow way as home care treatment for Gaucher only - did not look outside. We say  
17 that is a fundamental error. First of all, it is what Mr. John Vickers described as a "zero  
18 one fallacy" - you will find that in Professor Yarrow's report. That is to say if you find  
19 your market you then do not look outside it even if you have the market right. We say  
20 they have the market wrong and they now seem to be going a long way to accepting  
21 that.

22 THE PRESIDENT: So you complain, among other things, of the absence of any real  
23 description of the homecare services market.

24 MR VAUGHAN: Yes, if they had done it they would have seen whether you are dealing  
25 with abuse, justification or penalty or direction that we are doing no different from  
26 anyone else, and we are just performing an ordinary service which a large number of  
27 companies do. If the Office is attacking a large number of services then that is what it  
28 should be doing, not picking off an example, and then hoping the others fall in line,  
29 because the chances are they will not. It will take many years and lots of cases to get  
30 them all in line, I suspect, because they will all say they are different, and nobody is  
31 going to admit to being dominant with this sort of case around. It places us in a real  
32 problem, because whether or not these companies are dominant, they are not going to  
33 help us because they are putting their heads above the parapet. We have found quite a  
34 lot of nice companies who would like to help us but just do not dare because they will  
35 get shot at if we go down in this thing. But it is not our job to define the markets and  
36 look at these things. Anyhow, no doubt the Office, tomorrow, will produce all the  
37 documents we need to know about these things, it is their questions they have been  
38 asked about these matters.

1 THE PRESIDENT: I think Mr Mather has a question.  
2 MR MATHER: Where there is a blank, some of these say "no charge to NHS" others are  
3 blank.  
4 MR VAUGHAN: Yes.  
5 MR MATHER: Does that mean that you have not been able to obtain the information, or  
6 are there any cases in which there is a charge to the NHS?  
7 MR VAUGHAN: No, we find no case in which there is a charge to the NHS. The blanks  
8 are where we have not found things, but again Mr Farrell or Mr Brownlee will be able  
9 to help you tomorrow if the Office cannot help you in the intervening period in answer  
10 to the questions you have asked them to do. This is set out in Mr Morland's affidavit,  
11 321 page 355.12. He says as far as he was aware, this is the date of the Fresenius  
12 report, that is the middle of 355.12, the costs were borne by the company concerned, as  
13 far as he is aware, and no doubt the Office will tell us if that is wrong. Of course, bear  
14 in mind that the Office accept that the Fresenius report is in all intents and purposes  
15 correct. This was in paragraph 9.1, I think, of their skeleton.  
16           3.22 he points out to the growth, "Services may be in-house or commissioned",  
17 and Mr Williams identifies Novo Nordisk is another company using Healthcare at  
18 Home. In fact, if one looks at Healthcare at Home's current website, there is a page at  
19 the very back of this volume, 355.22, the anaemia management. "Healthcare at Home  
20 has significant experience of providing and dispensing home delivery and nursing  
21 support for... The Healthcare at Home sister company ADS Roche runs a  
22 comprehensive nurse training support and home delivery service for their system under  
23 the Healthcare Roche Homecare brand. The Service is rapidly expanding. So you can  
24 see Healthcare at Home continues to support Eprex Direct, a service commissioned by  
25 Ortho-biotech, where patients are supplied with the prescribed Eprex at home on a  
26 regular basis."  
27           So you get a pretty good picture of these things. At some stage in one of the  
28 documents, there is the whole Healthcare at Home website which shows them actively  
29 acting for a large number of companies in this way. Mr Robertson will tell me where it  
30 is so I can let you have the reference.  
31           Then 3.22 at the bottom of that page, 355.12, and that is the point he makes  
32 there. Then Mr Darodra has now made inquiries about Nutricia. File 39 tab CB57, if I  
33 can take you to that, but can you keep open **that** one.  
34 THE PRESIDENT: I am on Mr Darodra, but you want me to go ----  
35 MR VAUGHAN: Yes, can I go back, as it were, keep that one open.  
36 THE PRESIDENT: File 39, CB57, yes.  
37 MR VAUGHAN: I am not going to take time on it, but for your note you will see a lot or  
38 all of their website. Basically they are doing this for them in oncology, haematology,

1 and all sorts of other fields, and they are doing this delivery and indeed, all other  
2 services an acting on behalf of other companies, and some of those Mr Morland has  
3 identified in that column whether they are acting as distributor, or nursing agent for  
4 those people.

5 THE PRESIDENT: Yes.

6 MR VAUGHAN: Mr Darodra made inquiries, this is paragraph 4, 355.13, made inquiries  
7 about Nutricia - you will remember you asked about Nutricia. Nutricia was a company  
8 that had taken it in-house at the time of the Fresenius report, and from Caremark, in  
9 fact, which is exactly what we had done, did do, a little later.

10 Nutricia run a homecare service called "Homeward" and service is provided to  
11 patients who have been diagnosed as having a clinical need for Enterol and Enterol  
12 feeds. Where this service is offered by way of NHS Trust tendering for Enterol and  
13 Enterol feeds service in their local area, companies that offer these products enter the  
14 tender to provide a service". So here is an example of somebody actually - replying to  
15 Mr Mather's question - here is somebody tendering for these services. Then the  
16 successful company gets the contract. I would imagine the service specification would  
17 be a compromise between the Trust and the homecare provider. If a patient would  
18 benefit from the service then a co-ordinator would get in touch with the patient or  
19 organise prescriptions and the delivery of the product. In essence all feeds that are  
20 prescribed on prescription are reimbursed through the NHS normally through the PPA -  
21 that is reimbursement to the chemist. It is made at the full NHS price in the chemist and  
22 druggist at the price in the book.

23 The patient has a choice of where he would like to have that prescription  
24 dispensed, either locally or by the pharmacy contracted to Nutricia to provide such a  
25 service. So they can either go to Boots or Nutricia. Nutricia Homeward employ the  
26 service of a community pharmacy to dispense their prescriptions. It would appear they  
27 do not have a dispensing contract themselves. Patients' ancillaries provided through the  
28 shared care agreements are funded by billing the PCT directly. So the needles and  
29 things like that and tubes come funded. They say they are not under the prescription.  
30 "Could not find out how much the service is costing Nutricia, imagine it will be the  
31 same sort of level as Genzyme Homecare. He informs me that he made further inquiries  
32 as to the nature and payment for the nursing service provided by Nutricia Homeward.  
33 He informed me the do have an in-house nursing team, but nursing is only provided if it  
34 is contracted for by the PCT, services are determined locally by the PCT and not  
35 nationally by the referral centre". That is an example, as it were, of Nutricia now going  
36 out and getting paid for doing this service.

37 THE PRESIDENT: Yes.

38 MR VAUGHAN: And so this is the alternative way of doing it.

1 THE PRESIDENT: If we just jog back to the previous page in Mr Doradra's statement. We  
2 notice in this case there is a tendering procedure, and there seems to be a situation in  
3 which various competing companies bid for the business, and there is a sense in which  
4 at that stage there is competition to provide the service to the Trust. I think what is said  
5 against you in this case is that the Genzyme arrangements do not really admit of that  
6 competitive tendering process, because there is no ability for anybody to offer a  
7 competitive service to provide homecare to Genzyme patients across the pricing  
8 structure.

9 MR VAUGHAN: That is the case.

10 THE PRESIDENT: That is the case.

11 MR VAUGHAN: Absolutely, yes.

12 THE PRESIDENT: So it is interesting to see that in the Nutricia case, there is first of all a  
13 tendering process, and then later on apparently now some kind of independent payment  
14 for nursing.

15 MR VAUGHAN: Yes.

16 THE PRESIDENT: Anyway, that is very useful background, thank you very much.

17 MR VAUGHAN: But it does show that there are all sorts of different ways in which the  
18 whole thing can be done, and it may be because that one is by tube that there is more  
19 intensive nursing than in other cases.

20 THE PRESIDENT: Yes.

21 MR VAUGHAN: Equally they do themselves provide their own nursing services.  
22 Sometimes they send them out, and sometimes by nursing. So if they do it themselves  
23 presumably the do not get paid for that, in that situation.

24 MR MATHER: Could you explain a little more about how the tenders, how the bids would  
25 be expected to differ in that pricing, given that the payment is made at the full NHS list  
26 price?

27 MR VAUGHAN: Well in all cases the payment is made at the full NHS price, even in  
28 Nutricia, so they are paid out at the full price, and as one will see from Mr Brownlee's  
29 email, the one we complain about, that it is up to them what price they take, providing  
30 they do not make excessive profits they can choose their price, and they can decide  
31 what to include in that price. I am told the tendering is for the product not for the  
32 nursing in the Nutricia case, so you tender to the hospital for the product, not the  
33 nursing. But I do not want to deal with that until I know exactly what the position is on  
34 that.

35 MR MATHER: I am sorry, I am still not entirely clear on what varies, what pricing is  
36 varying in the tender? Let us say five companies put in a tender, how will it differ in  
37 terms of price?

38 MR VAUGHAN: It depends how much you want to get the contract, presumably.

1 Presumably everyone's costs are roughly the same, and so there is not all that much  
2 difference in cost terms of a company wanting to tender for that, and assume quality is  
3 roughly the same for the moment. Then it is just up to the company to decide if it is  
4 tendering for nursing services how much it wants the contract really, and is he  
5 prepared, as it were, to tender low or tender high. It depends how much profit it wants  
6 to make on that particular part of the thing. But under the European Rules in the  
7 ordinary event, quality being equal, the lowest price gets it in that situation.

8 THE PRESIDENT: I think that is probably what Mr Mather is driving at, we may have to  
9 ask Mr Farrell tomorrow. We are a bit hazy at the moment in these kind of tendering  
10 situations which are said to be reimbursed at the NHS list price. Is what is going on  
11 some kind of deal of price to the hospital, the price of the drug, or is the tender made on  
12 the basis that so much is for the drug and so much is for the service, so that they are  
13 separately priced - or what?

14 MR VAUGHAN: In the one we have seen, the haemophilia one it was just nursing by  
15 itself, it was just delivery b y itself, sorry.

16 THE PRESIDENT: We know int he haemophilia one there was competition, again there  
17 were several bids, and various companies had various combinations and suggestions to  
18 make.

19 MR VAUGHAN: And there were different products, presumably.

20 THE PRESIDENT: And there were different products, so that appears at first sight at least  
21 to be a competitive market working, so far as any of these markets work competitively,  
22 in a reasonably competitive fashion. The problem with this case is we have one product  
23 and one company and no tendering process, as far as we can make out.

24 MR VAUGHAN: Not at the moment, we will come on to it. You only have one product  
25 and there was tendering then people would ---

26 THE PRESIDENT: Well the OFT's case is nobody else can really tender because they  
27 cannot get the product from you at otherwise than the list price. I think what they are  
28 saying is perhaps at the heart of the case that if you were to offer some kind of ex-  
29 manufacturer price that was lower than the list price then they could get the product,  
30 they could tender in competition and the best man would win. That is the beginning and  
31 end of the case really. However---

32 MR MATHER: Are we assuming therefore that where there are tenders there is a  
33 preparedness to supply at less than the list price?

34 MR VAUGHAN: If there is competition in the product, as it were, and you are tendering  
35 for both then obviously you would tender for an overall price to cover both bids,  
36 presumably. Unless you were asked to divide up your tender you would tender for the  
37 product plus nursing as a bundled tender unless you were asked to---

38 THE PRESIDENT: I think that is what we do not quite know at the moment, Mr Vaughan,

1 and it is probably not useful to speculate as to exactly what happens unless we have  
2 some evidence about it. So the evidence we have got from Mr Morland's third witness  
3 statement is helpful.

4 MR VAUGHAN: Yes, thank you very much. I think basically that is the questions 1 and 9.  
5 Questions 5 and 7, there was a series of questions, 3, 4, 5, 6 and 7, they should all go  
6 together. What we propose to do, you asked us first of all about the position as at the  
7 date when the Act comes into force, and secondly when the agreement comes to an end.

8 It is easier to answer them in the inverse order because we know what happened  
9 when the agreement came to an end, so we are not, as it were in a hypothetical  
10 situation. We have a precise example.

11 All the evidence is to the effect that taking it in-house was better to do. There is  
12 Mr Williams - it was cheaper, it was higher quality, it was consistent with what other  
13 companies were doing, and it was more secure. That was Mr Termeer because he did  
14 not want other companies intermingling and affecting the way in which his product got  
15 to market, as it were, got to the patient, and all the evidence is that way. So there were  
16 considerable advantages to Genzyme doing it. Mr Williams, one will see, says the price  
17 difference is not inconsiderable, if you compare what Genzyme's costs were going to be  
18 as compared with what Healthcare at Home were being paid for that.

19 Paragraph 11, the decision to move in-house was based upon legal advice, that  
20 is to say that there was nothing wrong in terminating the contract or letting it expire by  
21 a flexion of time and then we get to the disputed meeting, as it were. Nobody at that  
22 meeting said "You must not do it, there is something wrong with it".

23 We also know on 5th May what the OFT would have done at that time because,  
24 in fact, earlier they had told us in the interim measure hearings what they wanted us to  
25 do. This ties in with the refusal to supply point. At that stage, in the interim relief  
26 hearing or in the letter before interim relief, which was the 11th April 2001, until the  
27 Rule 14 notice the whole argument was based upon refusal to supply and they were  
28 based upon Commercial Solvents and at volume 24, that reference, you will find all  
29 those matters.

30 They were relying on Commercial Solvents; we were relying on Oscar  
31 Bronner, but the important thing is what they wanted us to do in the interim relief -  
32 when, of course, Healthcare at Home were the complainant - this is paragraph 13 - they  
33 were wanting us to continue, notwithstanding the termination of the agreement by  
34 effluxion of time, to supply on exactly the same terms as before and on the same  
35 financial terms. So they would keep their exclusive distribution agreement, they would  
36 keep the same financial terms and we would not be entitled to distribute ourselves at  
37 all. So they would have a monopoly at that time. Those are the references.

38 If one looks for the moment at volume 24, tab 8A, page 6250, this is

1 interlocutory application by the Director himself, telling us what he wanted to do. At  
2 43 he considered there was a reasonable suspicion that the chapter 2 prohibition had  
3 been infringed by us.

4 THE PRESIDENT: The last sentence of 44.

5 MR. VAUGHAN: That is right, yes.

6 THE PRESIDENT: "The current terms and conditions agreed between Genzyme and HH,  
7 which took effect ..."

8 MR. VAUGHAN: That is right, yes. If he had made that order, we would have been bound  
9 to continue to supply under an exclusive arrangement with Healthcare at Home, not  
10 being able to bind ourselves of that situation in that case. That case was a refusal to  
11 supply case, to remain that until the rule 14 notice.

12 What should we have done on 5th May 2001? The answer is, we should have,  
13 at that stage, maintained the status quo, that is, exclusive distribution to them,  
14 notwithstanding all the evidence that there was cheaper, better and everything else like  
15 that at the time.

16 So his case must be that at that date, first of all, it was a refusal to supply case  
17 and remained that on 5th May 2001 and we would have been bound to continue to  
18 supply. So at that stage that presumably is what the Director says we should have  
19 done, because that is what he asked us to do. Of course, we succeeded in persuading  
20 him that was inappropriate and then eventually he to some extent changed his case or  
21 changed the clothes or the skin in which he presented the case at that stage.

22 THE PRESIDENT: So you say, I suppose, that the decision is now inconsistent in alleging  
23 an abuse by means of exclusive distribution from 1st March 2000 to 5th May 2001.

24 MR. VAUGHAN: Yes.

25 THE PRESIDENT: Whereas in the interim measures proceedings that was precisely what  
26 the Director was contemplating ordering you to do.

27 MR. VAUGHAN: Absolutely.

28 MR. MATHER: The proposed direction could not be read, where it says "under current  
29 terms and conditions" as applying to the pricing rather than the exclusivity aspect.

30 MR. VAUGHAN: No, it included both.

31 MR. MATHER: You do not think that such careless drafting which envisaged that there  
32 would be continuity of supply to HH ----

33 MR. VAUGHAN: First of all, I do not think it is careless drafting. Healthcare at Home's  
34 case was if they did not have the same existing financial terms they would be driven  
35 out of business and that was one of the major rows we had at the time, because they  
36 refused to let us see any documents relating to that. So Healthcare at Home at that  
37 stage - and the Director was accepting this - was saying, "We will be driven out if we  
38 do not have the same financial terms" and we said that was nonsense. But that was the

1 case and that was the basis upon which it was being done, so it included both, very  
2 clearly, to do that. So at that stage they were not worried about the monopoly because  
3 Healthcare at Home had the monopoly: we have the monopoly of product; they had  
4 the monopoly of service provider and would continue to have that until the decision  
5 was taken, which was March 2003. So for the next two years the monopoly would  
6 have remained product by us, healthcare monopoly by Healthcare at Home. We would  
7 have had to pay them what we regarded as the super profit, as it were, they were getting  
8 in this situation, because their case was that they were going to be driven out of  
9 business entirely - not just in this market but entirely - if they did not get this money.  
10 All those documents are there and I am not going to take you through what was quite  
11 an eventful time.

12 It is probably worthwhile reading our reply. There is a long document, which is  
13 Healthcare at Home's solicitor's letter, and then there is our response, which starts at  
14 page 6288, but I do not ask you to look at it now. It just shows quite well what the  
15 battle ground was at the time. So at that stage they had no problems with monopoly  
16 healthcare; they had no problem with us, providing we continued to pay what we  
17 regarded as an exorbitant price; the last thing they wanted was for us to come into the  
18 market at that stage. But, of course, we convinced them that was misplaced, but it  
19 shows what the Director's or the Office's (as he is now called) view was at the time.  
20 Throughout, we repeatedly pointed out the inconsistency of the whole thing and asked  
21 how on earth we were meant to deal with a competition authority which was telling us  
22 one thing and then the other in that respect.

23 That is basically on that date.

24 THE PRESIDENT: Before we leave questions 5 and 7,  
25 Mr. Vaughan, just two comments for you to think about. In relation to all the  
26 advantages that you have summarised in paragraph 10, cheaper for Genzyme and so  
27 forth, in a competitive market where something saves costs or there are efficiency  
28 gains, competition in general will see that those gains are passed on to the consumers.

29 MR. VAUGHAN: Yes.

30 THE PRESIDENT: Here, the situation seems to be that that does not happen: it is Genzyme  
31 that keeps the gains.

32 MR. VAUGHAN: Yes.

33 THE PRESIDENT: That is the sort of background situation in this case.

34 MR. VAUGHAN: Absolutely. That is a factor of two things. One is the drug price is fixed  
35 by the company themselves, as Mr. Brownlee accepts, and it is entirely a matter for us.  
36 Until another company comes along to undercut, then we will keep that price. But it is  
37 also a factor that this is an orphan drug or a quasi orphan drug or would have been if  
38 the legislation had been in place and we have a monopoly. We have a statutory

1 monopoly for ten years over that period.

2 THE PRESIDENT: You would have had but for that technicality.

3 MR. VAUGHAN: Would have but for the technicality, unless somebody came up with a  
4 better product, not a cheaper product but a better product.

5 THE PRESIDENT: Yes.

6 MR. VAUGHAN: That is the whole purpose of this, because nobody, as Mr. Termeer and  
7 the others made clear, the orphan drug legislation in America was critical in bringing  
8 all this development forward. You have got a company like Genzyme, which is a  
9 world class company and a massive company - then we come onto penalties. They  
10 increased the fine simply because we were so big. It is a big company and a very  
11 successful company, a highly innovative company. We took advantage of that. That  
12 was the whole purpose of the whole thing, that we were meant to take advantage of that  
13 and develop things and we are given monopolies in that way. It gets back to the  
14 Bronner point: you reward people for an invention; you must not penalise people for  
15 just getting ahead. The Bronner point is made even stronger in the case of orphan  
16 drugs, where nobody would do any of this unless they had got some sort of real reward  
17 in this way, firstly to encourage people to do it and, secondly, to compensate for the  
18 myriad failures on the way. One has seen the reference to the vast amount of money  
19 that was lost in the cystic fibrosis working, \$200 million. We were working with the  
20 Brompton Hospital, trying to find a solution to that problem. Sadly, that has not been  
21 successful so far.

22 THE PRESIDENT: The comment is in relation to the point you make in paragraph 11 about  
23 the legal advice. I would have thought that it is a bit difficult for us to go into that.

24 MR. VAUGHAN: I am not asking you to do so, but there is evidence that they got legal  
25 advice.

26 THE PRESIDENT: They took legal advice, but we cannot ----

27 MR. VAUGHAN: Before they terminated.

28 THE PRESIDENT: We cannot really, without doing what I do not think we want to do,  
29 which is go into what the questions were, what the instructions were and what the  
30 answer was and all the rest of it, do much except note that that is what happened.

31 MR. VAUGHAN: That is what happened. Also, one has got in mind the fact that Mr.  
32 Johnson, in his statement, said that if he had been told no by the Department of Health  
33 when he had had the meeting he would not have done it, if they had had any objection  
34 at the time. Nobody suggests that that is not right.

35 THE PRESIDENT: Very well.

36 MR. VAUGHAN: Whether or not they had power to tell him no or whatever, but even if  
37 they did not have the power, if they had just frowned at it, he would have thought  
38 again. That is evidence in that way. Certainly, I agree, I do not put it high as a factor,

1 but it was not done willy-nilly without thinking this whole thing through - "We'll  
2 squeeze them out", sort of thing.

3 The Bronner question is paragraph 17-18.

4 THE PRESIDENT: We have got quite a lot of argument on that now.

5 MR. VAUGHAN: That is right, we have got lots. I am not going to take time on Volvo.  
6 Those are the references. I am not going to spend longer than that, except to say that  
7 you will have seen the OFT's decision in Du Pont.

8 THE PRESIDENT: Yes.

9 MR. VAUGHAN: That was published on the same day as we lodged our skeleton and so  
10 we enclosed it as a supplemental skeleton. Interestingly enough, it was a three year  
11 agreement which came to the end by effluxion of time in the same sort of way.  
12 Admittedly, it was not a wanting to take it in house case, but it was wanting to stop and  
13 all the arguments about essential facilities were rejected. It is quite nice to see the  
14 Office understanding General Jacobs and accepting what he said, but basically  
15 accepting what Mr. Justice Laddie effectively said as to what he drew from those cases.  
16 Also, in this case they say  
17 Mr. Justice Laddie was speaking off-the-cuff on an interlocutory basis. Basically, they  
18 are following his line in that case. We say that that is the correct line and the OFT were  
19 right in Du Pont and are wrong in our case. Obviously, there are differences: every  
20 case is different. But there is a large number of similarities, not just the three year  
21 term. We look forward to seeing what the Office say about that.

22 We now go to the question of what we should have done on 1st March, that is,  
23 when the Act came into force. That is paragraph 19. In paragraph 19 we make the  
24 point that it was only in the Rule 14 notice that they make the point that the exclusive  
25 agreement was wrong and we should have terminated it there and then on that date.

26 First of all, that would have been extremely difficult to do because it would,  
27 first of all, be a breach of contract unless we relied upon the Competition Act or the  
28 Articles 81 and 82 and to suggest we were abusing or the agreement was an abuse of a  
29 dominant position or whatever. Obviously, we are not going to do that because we  
30 deny it. So they are forcing us into litigation and a pretty cast iron case by Healthcare  
31 at Home at that stage: we prematurely terminated what was for them a very lucrative  
32 agreement on their case, which was the whole basis on which the company was  
33 succeeding, because without this at that stage they were saying the whole company  
34 would collapse if it was not for this agreement or the favourable terms of this  
35 agreement. So it is a pretty difficult thing, impossible in terms of competition law, to  
36 say that that is what we should have done.

37 THE PRESIDENT: You are saying that was in the Rule 14 notice, that suggestion or  
38 implicit at least in the rule.

1 MR. VAUGHAN: Implicit, yes, because they say exclusive distributions were wrong and if  
2 they were wrong at that stage then they were always wrong at that stage, because the  
3 Act had come into force two years before.

4 It seems to be suggested in paragraph 20 that we should have supplied everyone  
5 who came along, competitors, TKT, everyone, at a price which would then exclude the  
6 cost of the nursing service. We make the point that it cannot be less than the price of  
7 distribution because we say that is already in the drug tariff price. So it is only nursing.

8 We say the cost of distribution is very, very small, taking it round the houses  
9 and taking it to hospitals, if hospitals are part of their case at all. We still have not  
10 heard from them whether they are suggesting hospitals are part of their case.

11 THE PRESIDENT: My recollection of the interim measures proceedings is that the cost of  
12 nursing was even less than the cost of distribution.

13 MR. VAUGHAN: Because there were so few people in terms, but probably on a total  
14 amount - if you took distribution per vial or whatever one might do, it was probably  
15 less, but it is because 160 or something all get distribution and only 40 get nursing. I  
16 think that is a fact of why it was, in total terms, so much less. In terms of cost, delivery  
17 is small per vial.

18 We say at most what we should have done at that stage, if it is right, was to  
19 deduct the cost of nursing that we bore, not the price of nursing that we paid to  
20 Healthcare at Home at that stage. There is evidence of the cost of nursing - this is 22  
21 over the page - in

22 Mr. Williams. In fact, the cost of nursing in global terms is unknown. There is some  
23 evidence about it, but how much nursing was is difficult to tell. Anyhow, if we had to  
24 reduce, as it were, it would have to be taken across the whole spectrum of 180 patients  
25 in relation to the cost of the 40 or so who were getting nursing services. So that it  
26 would be at least one-third of the actual cost that would have to be averaged out over  
27 everyone, because you could not have two prices: one for the drug plus nursing, if you  
28 give nursing, and one for the drug if you only gave delivery. Anyhow, we say delivery  
29 is outside anyhow, because it is included in the drug tariff price. If that happened, that  
30 would become - whatever this figure was - the new list price, because we would have  
31 to pay that to everyone.

32 Then we go on to say that, of course, that creates a real problem because the  
33 direction itself includes no system for which this should be financed or funded by the  
34 Health Service.

35 THE PRESIDENT: This is a point I have not got my head round yet. Why can you not do  
36 what most manufacturers of drugs do and have an ex-manufacturer price that is  
37 different from the NHS list price?

38 MR. VAUGHAN: That is because, first of all, they are not zero discounted price, so that the

1 chemist gets remunerated at the drug price.

2 THE PRESIDENT: Yes, but that is because, as I have understood it, the standard situation  
3 in the industry is that there is normally a wholesale margin, conventionally 12.5%. For  
4 some reason, that does not exist in this case, but why should it not? What would be the  
5 problem of having a wholesale price?

6 MR. VAUGHAN: Then we would deliver it to a wholesaler at 12% below.

7 THE PRESIDENT: Would he come and collect it.

8 MR. VAUGHAN: Who would come and collect it, take it to the chemist, recoup 12.5% off  
9 them and then people would have to get it from the chemist at the list price.

10 THE PRESIDENT: He would do whatever he wanted to do with it, but at least you would  
11 be recouping the cost of the drug, you would effectively have a drug only price, and  
12 other suppliers would be able to get hold of the drug and if they wanted to supply  
13 homecare services they could then tender for the NHS in competition with you. I have  
14 not grasped yet what is the fundamental objection to that from your point of view, other  
15 than that you want to hang onto the distribution.

16 MR. VAUGHAN: For the various reasons we have set out. If we were to give it to AAB or  
17 whatever the other people were, if we were ordered to supply it to a wholesaler ----

18 THE PRESIDENT: At a discount that reflected ----

19 MR. VAUGHAN: -- at a discount and for them to distribute it to the pharmacists ----

20 THE PRESIDENT: An extension of the interim measures idea really: there is a discount off  
21 - this is a list price off which there is no discount.

22 MR. VAUGHAN: Yes.

23 THE PRESIDENT: Because there is no discount, nobody else can get hold of the drug,  
24 which means that nobody else can offer to supply not only the drug but homecare  
25 services. That is the stated problem. We will see whether it is a real problem or not,  
26 but that is the stated problem. One solution to that would be to just loosen up the  
27 pricing structure by offering some sort of discount to third parties.

28 MR. VAUGHAN: If that was so, first of all, that would have to be available to everyone.

29 THE PRESIDENT: Yes.

30 MR. VAUGHAN: Then we come onto the question, if everyone could get it and everyone  
31 could make a lot of money and we were giving away X% of the price to everyone, then  
32 everyone would come in and so the 42 people who wanted to provide nursing services  
33 would all come in and the whole market would become totally fragmented in that way.  
34 This is for a maximum market of 42 people, if we are just talking about nursing  
35 services in that way. It is such a minuscule market. It would mean also that we had to  
36 sell at that lower price ex-nursing, which was available for people who were not  
37 providing nursing, so you could not have two prices. You would have to find a price  
38 that balanced one against the other in that sort of way. That is not what the direction

1 seeks in that way. We are not being asked to do that.

2 We are just acting just like all these other companies, Baxter and these other  
3 people but we are just doing it ourselves and doing it in-house in that way. It is up to  
4 you whether they are zero rated. Under the existing British system, it is up to you what  
5 you charge for the product in this way. We do not accept that the alternative system of  
6 selling it through a wholesaler will be sensible. First of all, we do not need a  
7 wholesaler.

8 THE PRESIDENT: It is not that you would necessarily sell through a wholesaler, but you  
9 would be willing to offer it at some price other than the NHS list price to somebody  
10 who wanted to be active in the market for homecare services, put it that way.

11 MR. VAUGHAN: But then it begs the question as to what they are actually going to do,  
12 because if they are merely delivering to somebody who self-cannulates that will be one  
13 price and if it is to the other people there would have to be another price in that way. It  
14 just creates a major problem. Obviously, we go on to deal with this. It creates  
15 enormous transaction problems. Either it is us financing whoever wants to do it or it is  
16 the health service financing whoever wants to do it, or it is the Health Service financing  
17 what they want to do in their system, through contractual relations and tendering in this  
18 situation.

19 Nobody suggests this case is not about, as we say in paragraph 24, about  
20 excessive pricing. Nobody suggests that the price we charge is excessive, though of  
21 course they are enormous sums, but nobody has suggested they are excessive in any  
22 allegation at all. If it were, then the case would have been a completely different case.

23 On that basis, if what they say we have been doing, that is supplying to the  
24 Health Service ,that is to the hospitals at the lower price, then everyone would have to -  
25 because we certainly would not want to, unless we had to, finance other people's  
26 nursing services in that way. If that were so, then if the Health Service had to fund it  
27 then there would have to be negotiations with each of the 30 different people, and  
28 tendering with all of those people.

29 27, if that were so, the price itself might be a little bit lower, but the NHS would  
30 have to pay more for homecare, because this would become the new price, that is the  
31 price they would be reimbursed at, and so we could not, as it were, supply it to these  
32 people, other than at the drug tariff price in that way.

33 PROF GRINYER: And are you saying that every manufacturer of similar products would  
34 also have to adopt that approach in equity if you were applying----

35 MR VAUGHAN: Every other dominant manufacturer. If you were not dominant you  
36 would not, because nobody could complain. So it would just be a quirk of the market as  
37 to whether you were dominant or not.If you were dominant you had to do this. To take  
38 the example of Fabry disease where TKT seems to be dominant, and has the bigger

1 share of the market we would not have to do it but they would have to do it. They  
2 would have to supply to us. At the moment they have an exclusive arrangement with  
3 Healthcare at Home. That would have to go. We would then be able, if we wanted to, in  
4 theory, buy from TKT product to supply to people in that way, because they would be  
5 dominant, they would have to be selling at off-list price for us in that way. Indeed that  
6 would be the same for all orphan drugs, the 8000 which are automatically dominant if  
7 the OFT is right in its market analysis, and indeed for lots of other drugs, because the  
8 point we make is that if the patient is the dominant factor, if it is a demand led thing,  
9 then there are a lot of drugs where the drug itself is not a dominant drug. The market  
10 share is not dominant, but the patient's own desires may be such that somebody may,  
11 even with a smaller share of the market, become dominant, because a large number of  
12 patients may be completely dependent upon that particular drug, even though they were  
13 competitors in the same illness area.

14 28, they assume that the negotiated tender at Homecare would be more  
15 efficient, but there is no evidential basis at all for that, and we say it certainly is not the  
16 case. Certainly, if there were 30, or whatever the number might be, of people one has to  
17 deal with for these 42 people. We think it is almost certainly going to be higher, the  
18 cost, because if you stripped out the cost of nursing, averaged it out over all the patients  
19 - if you took the cost of nursing for 42 people, and then averaged it out over the 180 or  
20 whatever the number is, which would be the only sensible way you could do it - that is  
21 a third or a quarter less than the cost of nursing, that could lead to a very small  
22 reduction in the price, and then you have all the transaction costs not only for us, who  
23 would be competing in this market, but to Healthcare at Home, and the National Health  
24 Service, and anyone else who wanted to come into this market. As you said, there are  
25 lots of other people in the same position - sauce for us is sauce for other people in the  
26 same position.

27 Then we make the point, which I have really made, about the cost of things.

28 PROF GRINYER: On this particular point, you are talking all along and nursing and nursing  
29 at home being taken out. If in fact you were to take regard of the Homecare services as  
30 an integrated package, which I think the Office of Fair Trading would do, and which  
31 Mr Farrell for instance was suggesting be the case, that figure is going to be much more  
32 like 10 or 12 per cent. according to Mr Williams' figures and others.

33 MR VAUGHAN: It is a higher figure, yes.

34 PROF GRINYER: In which case how does this affect your argument?

35 MR VAUGHAN: Well if you take 10 or 12 per cent. off - take 10 per cent. off, you then  
36 have to find us and other people, all tendering, because obviously we would be entitled  
37 to buy ourselves at the reduced price.

38 THE PRESIDENT: There would then be some tenders, and the NHS would choose the

1 tender on a competitive basis, and every so often the tenders would no doubt come up  
2 again.

3 MR VAUGHAN: Mr Cox says over about two years.

4 THE PRESIDENT: Something like that, and there would at least be a competitive element  
5 in the system.

6 MR VAUGHAN: That is right, yes.

7 PROF GRINYER: Is your argument that the cost of tendering is so high that this will still not  
8 be economic?

9 MR VAUGHAN: Nobody has worked that out, and nobody at the Office has talked about  
10 this or looked at this whole thing. The Office have not got figures for any of these  
11 things in the decision, and there is no suggestion that it is more efficient to do it one  
12 way than the other way. Basically what they are saying is because we discussed the 243  
13 price, the stand alone price, that should be the price at the time. But if one says it was a  
14 bit bigger than what I was saying then you have to analyse to see whether, in fact, it  
15 should be at that different price.

16 One has to bear in mind the fact that the Department and we go back to the  
17 EL95 for a moment, that they are the people who have the power to deal with these  
18 things. If they were unhappy about what was happening, they have ample power to take  
19 action under the Health Service legislation in this matter, and they have not taken any  
20 action in this matter, either against us or any of the other people in the same position.  
21 As EL 95 makes clear they can do it if they want, and they have not, and they have  
22 express, detailed powers to deal with this matter. There are all sorts of reasons why  
23 maybe not.

24 THE PRESIDENT: They are not exactly express.

25 MR VAUGHAN: They are not express.

26 THE PRESIDENT: They are rather general, reserve type powers, if I have understood  
27 correctly.

28 MR VAUGHAN: But they are powers, and the EL 95 was not just a cosy letter written just  
29 for information, it was basically orders to tell people what to do, as the documents  
30 make very clear, and whether it is equivalent to a planning circular or whatever, it does  
31 not really matter, even if in opaque terms, orders are orders in this field, and nobody  
32 would gainsay those. It is pretty clear what would happen if you did in that situation.

33 Basically, in this whole area, what should we have done on that date? First of  
34 all, if they say we should have broken the contract in that situation at that date,  
35 secondly, if we had done that we would have had the repercussions of these other  
36 matters. If we say, well, it could not have been that that they meant, you would have to  
37 say as from the date of the rule 14 we should then have reduced the price when they  
38 made it clear there was a third possible date - we run up into all these other problems,

1 not least that we are an orphan drug producer. So the Government would have to think  
2 very carefully, the NHS, before they forced somebody really doing something really  
3 enormously beneficial, and they were being told what was happening and the new  
4 products which are coming on line, to be told that you could not do this in this area, and  
5 one has something like Fabrazyme, where the nursing has to be - well we are dealing  
6 with Fabrazyme for Fabry's disease, and TKT are doing it for Reprasal. In almost all  
7 cases they require a lot more nursing than Gaucher does. If those systems have to go  
8 for both of us it will cause a real problem for drug producers, because they immediately  
9 get into a wholly new regulator system outside the Health Service. When the Health  
10 Service do not want to act, when the Competition Authorities act in a way that strips  
11 down the monopoly they have been given. We all know that a cheaper drug cannot get  
12 into the market at all unless it is a completely different product, at all.

13 MR MATHER: Could you give an opinion to help me on why they Health Service, in your  
14 words does not want to act. You have explained earlier your view on orphan drugs, just  
15 why the Health Service does not act to reduce prices.

16 MR VAUGHAN: Yes.

17 MR MATHER: But what is your opinion on why the Health Service apparently does not  
18 act to promote competition?

19 MR VAUGHAN: Well I think probably because Mr Johnson and Mr Smith made reference  
20 to the Prime Minister's speech to the Royal Society about the need to encourage - the  
21 United Kingdom and Europe are desperately keen to attract this sort of investment to  
22 this sort of development in Europe, in the same way as America has done. The United  
23 States is doing so successfully, and Europe is hardly doing at all in this whole area.  
24 They want to attract companies to come and produce here, pharmaceutical companies  
25 to come and produce here and provide a healthy environment for the innovation and to  
26 enable people to translate between development of the product, translate that into  
27 production in this country.

28 MR MATHER: That, if I may say so, really goes to the point on pricing, doesn't it, rather  
29 than on distribution systems?

30 MR VAUGHAN: Yes, but if you start whittling away at the price, the remuneration, if you  
31 say you cannot get 2.95, but only get 2.75, whatever these figures might be, 2.50, then  
32 you run into a problem of people not getting what they regard as their proper  
33 remuneration, and the main system is, of course, the Government operating the whole  
34 through the PPRS, and that is where they cut off excessive profits.

35 If somebody is making excessive profits then the PPRS system, all be it  
36 voluntary but effectively compulsory, would take action in that situation.

37 MR MATHER: That is an alternative competition?

38 MR VAUGHAN: Because if somebody is making too much profit, i.e. excessive prices,

1 then they have plenty of powers to deal with that with Mr Brownlee and his teams.  
2 THE PRESIDENT: I find this part of the argument a little difficult, Mr Vaughan. One can  
3 well see the need to encourage orphan drugs and the need to assure orphan drug  
4 manufacturers of a substantial return on investment in a risky business. One question is  
5 whether those considerations are sufficient to justify extending, as it were, the  
6 monopoly, not only over the drug itself, but also over the downstream homecare  
7 services.  
8 MR VAUGHAN: Yes.  
9 THE PRESIDENT: And it is a bit hard to see that civilisation will come to an end as we  
10 know it in the orphan drug field if orphan drug manufacturers are not allowed to  
11 monopolise the distribution. One of the points being made by the OFT is that there is  
12 actually a separate sector for homecare services in which there are companies active,  
13 and the NHS would like to have a choice of which company to use for those sorts of  
14 services, including the possibility of using a provider to provide a range of services for  
15 a range of treatments, Fabry's and haemophilia and so forth and so on which for one  
16 reason or another because of the pricing of Genzyme is difficult or impossible to do at  
17 the moment. That is at least one point you have to address.  
18 MR VAUGHAN: Absolutely, and I come on to this later. But if I can be not thought to be  
19 avoiding the question the reasons why we took it in-house is because we consider it  
20 was cheaper, better, more secure, to do it.  
21 THE PRESIDENT: Why can we not put that decision to the test in the market and see  
22 whether that turns out to be right, or see whether the consumers, the patient, the public  
23 who is paying for all this, cannot get the benefit of any savings that are being made as a  
24 result of competitive forces at work.  
25 MR VAUGHAN: If that is so, then that would have to be the same for everyone, and so  
26 every company who happened to be in a dominant position, and all these 19 companies  
27 we have set out would all have to change their policies in this particular way. If that  
28 were the case, some of those people would have to drop their NHS prices in an  
29 equivalent way, which took a proportionate amount of the cost they were dealing with  
30 at the time. First of all, that would really be, as it were, a Competition Commission  
31 matter, if they were looking at these matters, looking at the industries generally.  
32 THE PRESIDENT: So you say this is really a question of a market investigation for the CC?  
33 MR VAUGHAN: Yes, rather than picking on us.  
34 THE PRESIDENT: Rather than an ad hoc one case---  
35 MR VAUGHAN: And fining us 6 million, or whatever it is for doing the same as everyone  
36 else has done.  
37 MR MATHER: Or could the same route be achieved by a circular, or by a decision of  
38 ourselves?

1 MR VAUGHAN: Yes, absolutely, the EL 95 could be extended in that way. But we do not  
2 see this as being a Competition Act matter in that respect.

3 PROF GRINYER: Is there a difference, because I am certain Mr Farrell, in his evidence  
4 which we will come on to tomorrow, is suggesting there are only two self-suppliers  
5 who are unique in having a uniquely efficacious product like Cerezyme for a specific  
6 disease. So it could be argued that there is competition of some kind in the case of all  
7 the other situations. Whereas, in the case of a product like yours and the other, which I  
8 think was Nova, there is in fact a monopoly and your exclusive distributor, in principle  
9 I would argue - no let me not argue - in principle it could be argued that there was no  
10 difference between an exclusive distribution by HH and you are in an internal vertically  
11 integrated situation. But nonetheless, in each case you have actually got a monopoly  
12 then and not competition at the level of the homecare. So there is a fundamental  
13 difference between you and, say Baxter providing treatment for haemophilia where  
14 there are a number of different suppliers all competing, all tendering, offering different  
15 terms, some bundled, some none.

16 MR VAUGHAN: Of course there is a difference because just being an orphan drug by  
17 itself creates an automatic difference in that situation, but it would create the system  
18 which Mr Aliski rejected entirely the idea that he should be supplying us with his new  
19 Hunter product, or his Replagel, and that he should not have an exclusive agreement  
20 with Healthcare at Home in that way. If that were right then it was the idea that this is a  
21 broad case of general significance, becomes this is a case of minute little significance,  
22 only of relevance to these particular orphan drugs, simply because of the quirk of the  
23 legislation in that way, so it becomes an extremely unimportant case, notwithstanding  
24 the fact that the OFT makes the point that this is a case of wide involvement, and wide  
25 interest to the whole market, when they are talking about the consequences of this  
26 thing, when they attack us for our "rhetorical criticism", or words to that effect,  
27 whatever that means, in this way.

28 So if it is the latter then it is a pin prick of a case in this matter and there is no  
29 evidence that that is a better system, and indeed there is evidence, undisputed evidence  
30 it is a worse system, because we think that we can provide a better service, and if you  
31 take in Replagel, in Fabry, where there are real problems, and there is evidence about  
32 this, in the nursing, and the nursing has to be much more intensive than the Latin "in  
33 fabrith", and in this particular case. So if that is right this becomes just one case of 42  
34 people, and the method of these people getting this treatment in this way.

35 But if we did have a system that stripped out distribution we would be the only  
36 person of all, if we had to lower our price to allow other people to distribute, we would  
37 be the only company in the world, in the United Kingdom world, that was not allowed  
38 to do that.

1 THE PRESIDENT: That is not what is being suggested, Mr Vaughan. What is being  
2 suggested is the precise opposite, that the normal situation in the pharmaceutical  
3 industry is that there is a middleman function of some kind. Here you are vertically  
4 integrated from the top right to the patient's bedside more or less, and the question is  
5 whether, for part of that chain it should be unbundled to allow some competition in the  
6 homecare services sector. That, as a question, does not really undermine the whole  
7 purpose of orphan drugs' legislation or sound particularly revolutionary as a question.

8 MR VAUGHAN: But if you are saying distribution should be taken out, that is distribution  
9 to the patient's home---

10 THE PRESIDENT: You simply have an ex-manufacturer price, you carry on doing it  
11 yourself, and if you are the most efficient everybody else will give up and you will win,  
12 but you will have won on competitive grounds, instead of just winning on the basis of  
13 extending the monopoly downstream.

14 MR VAUGHAN: Yes, but who is going to pay for the distribution in that situation,  
15 because we would effectively be paying our competitors to do the distribution.

16 THE PRESIDENT: No, the normal situation in almost all trades is that most manufacturers  
17 are prepared to allow middlemen to operate at some discount off the list price, it is a  
18 perfectly normal situation.

19 MR VAUGHAN: One knows a large number of manufacturers who do it direct to you, sort  
20 of kitchen equipment, or home domestic equipment.

21 THE PRESIDENT: Some do it direct, it depends, home domestic equipment, fridges and  
22 whatnot may well be delivered, and there may be aftercare services, or aftersales  
23 services or something, it is a very normal situation. But we are looking at the rather  
24 specific circumstances of this particular market and asking ourselves is this a normal  
25 situation? Or is there something in the argument that this is to some extent an  
26 unjustified extension of the monopoly you have over the drug into the downstream  
27 area.

28 MR VAUGHAN: Of course, we dispute the division of the market, but we are no different,  
29 obviously in some ways we are, but we are no different from the vacuum cleaner  
30 manufacturer who comes and delivers the parts and the bags and everything like that to  
31 one's home, and one buys the bags from the distributor in that way, except, I suppose  
32 dominance would be a factor. But that is the way these things work. We are only  
33 dominant because of the quirks of the orphan drug administration and because of the  
34 innovation and the vast investment that was necessary to do in this thing. But if you  
35 were to fine on that basis then that would create a very major problem for anyone who  
36 distributed straight to the home and did not work through distributors, and we would  
37 resent greatly having to act through distributors in this sense. Indeed, we had problems  
38 when we did do it through distributors and we were with Caremark at the beginning

1 before we went to Healthcare at Home, and we ran into problems with them. We have  
2 had some problems with Healthcare at Home, as set out, in this matter, less than with  
3 Caremark, but some problems, and it is accounted in the history of these matters. Of  
4 course, we are accountable for the provision to the patient, and as the manufacturer to  
5 make sure the whole thing is dealt with safely and properly in that way.

6 So basically we say that if you were to go down that line you would create a  
7 very major problem, not just in the drug world, but a very major problem elsewhere in  
8 these sort of fields.

9 Then if one goes over the page on that, if there was a tendering system, then of  
10 course none of us know to what extent the PCTs might decide to do the nursing  
11 themselves. For some it may be impossible, for some not impossible, and none of us  
12 know what in fact would happen in that situation, whether in fact, as Mr Farrell seems  
13 to suggest they would tender it all out or some people may decide to do it and some  
14 not, in a particular case. It is the PCTs who eventually decide, because they are the  
15 paymasters, not the NHS consultants in their particular hospital where they happen to  
16 operate. Some may go one way, some the other. Some may be capable of doing this  
17 themselves, and they may rather do it themselves rather than anything else.

18 31 - of course, none of this discussion we have been having was considered in  
19 the Rule 14, or anything like that. They just simply say "We supply at a lower price and  
20 everything will be all right". They just assume that everything will be better in that new  
21 situation, and there is no evidence that it would be better at all. It would be different,  
22 but not necessarily better.

23 Indeed, at 32, if they were better and equally efficient and equally competitive,  
24 then we would have kept on with them: there was no benefit for us, if all the facts were  
25 different, for bringing it in house in that situation. But we decided to take it in-house in  
26 that situation.

27 At 33, we change from Caremark because they were not satisfactory and we  
28 went to Healthcare at Home because they showed themselves to be capable of being  
29 more satisfactory in that situation. We were entitled to do that. Indeed, we were  
30 entitled to have an exclusive distributor in that situation, because the logic of the case is  
31 that we cannot even have an exclusive distributor in that way. So the logic of the case  
32 in the Rule 14 notice is that we cannot go through an exclusive distributor, so we have  
33 got to supply to everyone who happens to want these things. At the moment there are  
34 us and two others but there may be more if it becomes an attractive proposition.,

35 THE PRESIDENT: The two others being HH and --?

36 MR. VAUGHAN: HH and Clinovia at the moment, but there is no reason why somebody  
37 else should not come along - Central Home Care, sorry, is the last one. They have got  
38 one patient. They are supplying one patient, but it can just go on and on until the

1 whole thing gets broken down and there is no limit to the number of people who might  
2 turn up in order to do it, to get these things. Of course, some people may decided to do  
3 it through a pharmacy and collect their own product in a cool bag and walk it or drive it  
4 home and not need any of these things at all. They are obviously the people who do  
5 not need a nursing service.

6 The direction we have been given and what we should have done right at the  
7 beginning is obscure in the very extreme and the discussion we are having now is really  
8 on the basis of what other directions they might have imposed. That, in our  
9 submission, is not the right basis, the basis is seeing whether the directions were right  
10 or not and were validly based.

11 As Mr. Robertson says, if that had been the case, then the whole evidence  
12 would have been different.

13 THE PRESIDENT: If what had been the case?

14 MR. VAUGHAN: If we had been talking about us selling at an ex-manufacturer's price, the  
15 whole case would have developed in a different way.

16 THE PRESIDENT: It is implicit in the margin squeeze, I think.

17 MR. VAUGHAN: Implicit, yes, but not in the direction.

18 THE PRESIDENT: Not as such ----

19 MR. VAUGHAN: -- in the direction.

20 THE PRESIDENT: -- in the direction.

21 MR. VAUGHAN: Of course, it was only at a very late date that the margin squeeze ever  
22 was suggested before the Rule 14 notice. If you look at the decision, paragraph 3.30,  
23 they in fact rejected the idea that we should be selling it through wholesalers. I have  
24 not read it properly, but what they are saying is, "The abuse is not charging the NHS  
25 the reduced price", they are rejecting the wholesaler and saying it is no part of their  
26 case that we should be acting through wholesalers.

27 THE PRESIDENT: It is not traditional wholesalers, it is middle men providing homecare  
28 services in this particular case.

29 MR. VAUGHAN: However many there may be.

30 THE PRESIDENT: On the evidence at the moment, quite a small number.

31 MR. VAUGHAN: Yes. If one looks at Professor Yarrow at CB22, file 37 ----

32 THE PRESIDENT: Do we need to take it out?

33 MR. VAUGHAN: No, but he relies particularly on that. It is at paragraph 7.2, page 193 of  
34 core bundle 1, which is 37. He develops the argument based upon that.

35 The next question is question 2, which is at the bottom of page 6. This is the  
36 question about whether the abuse ----

37 THE PRESIDENT: This is hospitals.

38 MR. VAUGHAN: -- relates to hospitals. We have always said it is not and none of the

1 abuse relates to hospitals. Obviously we wait to hear whether the OFT now say that it  
2 does. That would seem to be a very considerable change of position from the Rule 14  
3 notice and the decision.

4 THE PRESIDENT: Can I ask a question of fact?

5 MR. VAUGHAN: Yes.

6 THE PRESIDENT: Which you cannot answer off-hand, but perhaps we could have some  
7 impression of what the answer is. In a typical pattern of delivery services, is the  
8 delivery mainly going direct to the patients who are at home or are there circumstances  
9 in which, on one particular delivery, some are going to hospitals, some are going to  
10 patients at home, some are ----

11 MR. VAUGHAN: For us, the ones going to hospitals, we are the only people who deliver to  
12 hospitals and we do that in a bulk system.

13 THE PRESIDENT: But you are only delivering to a very small number of hospitals anyway.

14 MR. VAUGHAN: Yes.

15 THE PRESIDENT: We do not need to know now. You can just give us an impression.

16 MR. VAUGHAN: My impression is that most of the patient ones were dealt with by cool  
17 bags in cars.

18 THE PRESIDENT: It is a separate sort of service - cool bags in cars, you think.

19 MR. VAUGHAN: In cars. We use cars rather than refrigerated vans. That is one of the  
20 major cost savings we have, because they deliver in refrigerated vans, which are  
21 obviously more expensive to operate. They deliver all sorts of things at the same time.

22 THE PRESIDENT: When you say "they", you mean --?

23 MR. VAUGHAN: Healthcare at Home. They deliver. Mr. So-and-So gets Cerezyme, Mrs.  
24 So-and-So up the road gets something else.

25 THE PRESIDENT: So they are going round in a refrigerated van delivering a number of  
26 different drugs and services to different patients.

27 MR. VAUGHAN: Yes.

28 THE PRESIDENT: You are providing a dedicated service for Cerezyme only and now  
29 Fabrazyme.

30 MR. VAUGHAN: Yes.

31 THE PRESIDENT: Which you say you do by motor car.

32 MR. VAUGHAN: By motor car, yes, with drivers. It sounds as though sometimes when we  
33 deliver to hospitals it is obviously sensible to drop off sometimes to a patient who  
34 happens to be living next door.

35 THE PRESIDENT: The hospital deliveries are in, what, a refrigerated vehicle of some sort?  
36 (After a short pause): Sort it out over the short adjournment.

37 MR. VAUGHAN: Yes, thank you very much.

38 MR. THOMPSON: There is a description in the second witness statement of Mr. Walsh at

1 the interim measure stage where he describes the Healthcare at Home system in some  
2 detail: there is a central depot and regional depots. He describes how it works and  
3 how it has been working since May 2001.

4 THE PRESIDENT: Thank you very much.

5 MR. VAUGHAN: So we make our points on that. I will not spend time on that point.

6 Question 6, paragraph 40, "How many providers of homecare services the  
7 particular market can sensibly support." First of all, in 42 we look at the question, first  
8 of all, is it Gaucher only and then, secondly, is it a much wider market? Obviously, for  
9 us it is only Gaucher and Fabry, but for everyone else it is a much wider market. Even  
10 if it was for Gaucher only - particularly if it is for Gaucher only - we are talking about a  
11 very, very small market and we refer to what Healthcare at Home said in Fresenius: it  
12 would be very difficult for a pure service provider to build a profitable business in one  
13 treatment. At that stage, Healthcare at Home was not our distributor. But it is quite  
14 clear even one treatment would not be enough. That would suggest that there may well  
15 be many more people in one treatment than in the tiny numbers we are talking about  
16 here. We say that is the best and only evidence that there is.

17 Then we go on to say that the numbers are so small that almost certainly that  
18 must be right and we set out at 44 the numbers. These are mainly in our appendix 2 to  
19 our skeleton. Then we point out that there are other people competing, distributors  
20 only, the Polar Speed, Mr. Evans, and some doing nursing only and relying upon other  
21 people to deliver, whether they are companies like Healthcare at Home or us or a Polar  
22 Speed type operation.

23 Then 46 is obviously a very important issue. It relates to the question of what  
24 in fact have they really conceded - that the downstream market is, in general terms,  
25 much wider but only made much narrower because of our pricing actions. They say  
26 basically absent our conduct it would be a much wider market, but because of our  
27 conduct it is a very narrow market. We just do not accept that as a matter of law or  
28 fact. It is really defining the market by the conduct and, obviously, to some extent one  
29 is relevant to the other, but we have dealt with that in our reply skeleton and I am not  
30 sure that it is going to be helpful to develop that very much more, though obviously we  
31 rely upon what we said there in that respect.

32 Clearly, they accept now that the downstream market, certainly in ordinary  
33 terms, is much wider. If that is right, then why did they not look at the wider market?  
34 They clearly did not look at the wider market at all, either as part of the relevant market  
35 or at all: all they did was to look at Healthcare at Home and that was it. That was the  
36 only supplier at which they looked and ourselves, obviously. They did not look at  
37 anyone else - none of the Baxters, Abbotts and any of these other people - to try and  
38 find out what was happening. That obviously comes back to the complaint we have

1 always made.

2 We now come to the question of the direction. This is question 10. We set out  
3 the two alternatives that you suggested are the appropriate alternatives.

4 THE PRESIDENT: It is only thinking aloud at this stage.

5 MR. VAUGHAN: Absolutely, yes. That we should reduce our price for non-hospital  
6 supplies to take out the healthcare services at an amount to be determined. We would  
7 presumably be prohibited from providing healthcare services without extra charge at a  
8 reduced list price, so basically we would be charging - the ex-manufacturer comes  
9 later.

10 THE PRESIDENT: A sort of drug-only price.

11 MR. VAUGHAN: A drug-only price in that way. And we had to charge and obtain  
12 financing for the next bit of the service. So if one looks at that. Then the second one  
13 was the ex-manufacturer's type of price and allowing third parties to compete in the  
14 downstream market. But, of course, in both those situations the drug tariff would be  
15 that lower price, so people would be remunerated at the drug tariff price, whatever the  
16 lower price was, and therefore would need - in the first situation ----

17 THE PRESIDENT: The first situation would be drug tariff, but the second situation would  
18 mean that the drug tariff price was the same in the sense that ----

19 MR. VAUGHAN: Then there was a margin.

20 THE PRESIDENT: There was a margin.

21 MR. VAUGHAN: Yes, to allow them to operate. We make the point at 48 that the direction  
22 actually made was neither of those and basically we say that if the Department of  
23 Health wanted either of these things they could have dealt with it. They are the  
24 specialist body with a proper understanding of these matters: they know what the drug  
25 tariff includes; at the moment there is no evidence from any expert on the drug tariff  
26 price. Mr. Brownlee is an expert on the PPRS and makes clear his limited knowledge  
27 about the drug tariff price and what it includes. Anyhow, they have got perfectly able  
28 powers, if they thought it appropriate, and have always had power to take action. We  
29 were not, as it were, a contracted product in EL(95) and we are still not a contracted  
30 product, so the prescription entitles us to be remunerated at the drug tariff price. That  
31 is a price that the PPRS has not reduced because of excessive prices or anything like  
32 that, which it could have done is appropriate. Even though we were below the 25  
33 million, we accept our responsibilities and make these returns to the PPRS every year.

34 THE PRESIDENT: You make a full return, do you?

35 MR. VAUGHAN: We make a full return, yes.

36 THE PRESIDENT: I had the impression that, because you were below the limit, you had a  
37 slightly less detailed return than you would have to make if you were above the limit.

38 MR. VAUGHAN: Yes, but we make a return every year and we are checked every year to

1 make sure that we do not go above the appropriate amounts.

2 THE PRESIDENT: But it is not a detailed breakdown of costs.

3 MR. VAUGHAN: I do not want to answer that now. I will find the answer.

4 THE PRESIDENT: There is a certain amount in the position about it, but the impression I  
5 have got - and put me right if I am wrong - is that above a certain turnover limit there  
6 are quite detailed returns.

7 MR. VAUGHAN: Yes.

8 THE PRESIDENT: You are below the limit at the moment, so you put in a less detailed  
9 return than you would put in if you were above the limit.

10 MR. VAUGHAN: That is right, but if anyone has any problems they can come back to us  
11 and ask for more information. That I think is the basis of it.

12 MR. GRINYER: The transfer price is included in the data that you submitted, is it?

13 MR. VAUGHAN: Presumably so, yes. I just do not know about that.

14 MR. GRINYER: Mr. Johnson is nodding.

15 MR. VAUGHAN: Yes. On that basis, we have explained - this is 49 - why the first is not  
16 workable. That is to say, it is workable but it would not work out properly if we had to  
17 reduce our price on that situation. So if we reduced our existing list price, that would  
18 take down the drug tariff price and would mean that the pharmacies lost out on their  
19 2% that they would recover because of the expensive drug payment that was made and  
20 there is no basis at all in the decision, thinking it would be a better system, either from  
21 a medical point of view - indeed, from a medical point of view we say it would be a  
22 worse system - or from an economic point of view because of all the transaction costs  
23 and all the other things not just for us and Healthcare at Home: we would all have to  
24 compete at every single tender for these things and the Health Service itself would have  
25 to carry out a full public procurement system every time it did anything in this field.  
26 The benefits - we just do not know how many people would come in in that situation.  
27 So you may have 42 different suppliers for 42 different patients.

28 The second alternative ----

29 THE PRESIDENT: Before we go onto that, Mr. Vaughan, I notice we are just ticking up to  
30 1 o'clock and that might be a convenient moment to pause. We will resume again at  
31 five-past 2. Mr. Thompson, what I would suggest is,  
32 Mr. Vaughan completes his submissions and then we sort out the issues over the  
33 correspondence with Mr. Brownlee. We need to sort that out today, I think.

34 MR. THOMPSON: Certainly. I may take further instructions. I will certainly take further  
35 instructions on the Mr. Evans issue.

36 THE PRESIDENT: It is quite difficult at this stage to maintain confidentiality for material  
37 of this kind, but that is not a considered view, it is just a first impression. I look  
38 forward to your submission.

1 MR. THOMPSON: The Tribunal may have got the flavour of the OFT's position from the  
2 correspondence. It is partly that we are holding the ring between a variety of interests.  
3 THE PRESIDENT: I can understand the concerns. One has to ask oneself what one means  
4 by confidentiality. There is what goes into the judgment at the end of the day. It is  
5 pretty difficult to keep things confidential in a judgment. There is what is or is not  
6 referred to in open court. That is another issue. But we have to get to the bottom of all  
7 these things in evidence and the Tribunal is obliged to have a public hearing, so it is  
8 against that background that we have to look at the question of confidentiality.  
9 MR. VAUGHAN: In the nature of the document, it is interposed between two other  
10 publicly available documents.  
11 THE PRESIDENT: The whole context, Mr. Vaughan, you are quite right. Five-past two.  
12 (The luncheon adjournment)  
13 THE PRESIDENT: Yes, Mr Thompson?  
14 MR THOMPSON: I have spoken briefly to Mr Vaughan about the issue of Mr Evans and  
15 Mr Brownlee. In relation to Mr Evans, the OFT is perfectly happy to abide by a  
16 confidentiality assurance, subject to coming back before the Tribunal, or perhaps  
17 before you, Mr President, in the event that some issue arose, but in the circumstances  
18 we are certainly currently happy to give the assurance that Mr Evans seeks.  
19 THE PRESIDENT: Yes, thank you.  
20 MR THOMPSON: In relation to Mr Brownlee, we cannot contact him today, and you will  
21 appreciate that we are essentially protecting the DoH's sensitivities on this matter, and  
22 only secondarily ours. The proposal that I have made, which Mr Vaughan indicated  
23 was acceptable, was that there is a letter which I think you were shown yesterday where  
24 these documents were disclosed to Genzyme. It is the third document in a little pile of  
25 papers that were handed in, and what we were suggesting is there is a sort of what is  
26 sometimes called a "confidentiality club" of the external legal advisers, Professor  
27 Yarrow and Mr Williams. What we were proposing was that we could extend that to  
28 Mr Morland, Mr Johnson and Miss McMorrow, and if necessarily Miss Kelly, that  
29 would be fine, on the same terms that they would only discuss it for the purpose of this  
30 case overnight, and if any variation to that was to be dealt with it could be dealt with  
31 with Mr Brownlee tomorrow morning. I hope that is satisfactory. Mr Vaughan seemed  
32 to think it would be.  
33 THE PRESIDENT: So that will get us through until tomorrow, basically.  
34 MR THOMPSON: Yes and then if any other submissions need to be made, or anything else  
35 needs to be done - I am not sure if we are going to come back to it today, anyway, but  
36 that seemed to be a reasonable way to hold the ring.  
37 THE PRESIDENT: What do you say, Mr Vaughan?  
38 MR VAUGHAN: I am perfectly happy with that as a pro tem way of---

1 THE PRESIDENT: So, for good order's sake we had better identify who is in the  
2 confidentiality ring.

3 MR VAUGHAN: Those of us who were part of the initial offer, as it were, which was the  
4 legal team less - the English legal team, or the Anglo-Saxon English team, and our  
5 experts and Professor Yarrow, and Mr Williams. The extended club is Mr Johnson,  
6 Miss McMorrow, Mr Morland, Miss Kelly.

7 THE PRESIDENT: Is that it?

8 MR VAUGHAN: And that is it.

9 THE PRESIDENT: And everybody understands that that is the obligation.

10 MR VAUGHAN: That is the obligation, yes.

11 THE PRESIDENT: Until tomorrow morning?

12 MR VAUGHAN: Until tomorrow.

13 THE PRESIDENT: Until further order.

14 MR VAUGHAN: Until further order, thank you, yes. We will need to deal with it---

15 THE PRESIDENT: Absolutely.

16 MR VAUGHAN: Obviously it is a thing you will have to deal with in the Judgment.

17 THE PRESIDENT: Absolutely, right, well we will make an order in those terms.

18 MR VAUGHAN: Thank you very much. In return, can I tell you about the delivery. You  
19 asked me about the physical delivery.

20 THE PRESIDENT: Yes.

21 MR VAUGHAN: We have estate cars and drivers who deliver, and all the deliveries are  
22 dealt with by them, both hospital and individual. The only difference is that the picnic  
23 packs, as it were, the sort of things one sees when one is having a picnic, is bigger  
24 when you get to a hospital for them.

25 THE PRESIDENT: It may be your operation is rather small so it does not arise so much, but  
26 are you in some cases delivering to both a hospital and a patient on the same run?

27 MR VAUGHAN: Yes, yes, and obviously, particularly one has the clusters for various  
28 reasons why there tend to be clusters in a particular area, and in some cases there will  
29 be that, but obviously in a way if you live on the way to Manchester or Cambridge or  
30 London from Oxford you will probably get the delivery at that time, if you don't it may  
31 be a special delivery.

32 Sometimes, just to be complete, if the load is particularly big to a hospital, or  
33 something like that sometimes that is subcontracted, but never in the case of an  
34 individual, so there is always one of our drivers goes to an individual. That is the only  
35 time that might happen.

36 THE PRESIDENT: I think I would find it helpful, Mr Vaughan, if someone could just  
37 prepare a short witness statement confirming what you have just told us, and while that  
38 is being done, if you do not mind me asking one more thing. Coming back to our

1 discussion this morning as to how it is decided whether it is an NHS nurse or a GH HH  
2 Nurse. If somebody could just explain that in a short witness statement.

3 MR VAUGHAN: I think Mr Morland has.

4 THE PRESIDENT: He has, that may be so.

5 MR VAUGHAN: I do not think he can go further. He has gone as far as he can go from his  
6 own knowledge.

7 THE PRESIDENT: What I would particularly like to get at is the channel of communication  
8 as it were, between the clinician and the company. I think you told me that there was a  
9 pro-forma that arrived. If you could just perhaps produce one or two, patient details  
10 excluded etc., so we know exactly what goes on.

11 MR VAUGHAN: Well overnight what we will do is overnight, probably Mr Morland is the  
12 appropriate person to deal with this.

13 THE PRESIDENT: Yes, well I am sorry, Mr Morland, to keep asking for more and more  
14 things.

15 MR VAUGHAN: Mr Morland is very resilient.

16 THE PRESIDENT: To dot "i's" and cross "t's" if he will forgive me. Thank you very much.

17 MR VAUGHAN: We had dealt basically with the first possibility and it is the second  
18 alternative, as it were, that is introducing a sort of manufacturer's price. Basically there  
19 are a number of objections to that. If one looks at the Drug Tariff itself there are a  
20 number of these. Can I take you to that?

21 THE PRESIDENT: Yes, we have got the Drug Tariff, yes.

22 MR VAUGHAN: Have you got the September issue?

23 THE PRESIDENT: Cerezyme is not actually listed in this.

24 MR VAUGHAN: The point we make if you go to the website you will find us.

25 THE PRESIDENT: I think we understand why.

26 MR VAUGHAN: Well we do not understand why ourselves, it is just not listed, but it is  
27 listed on the website, if you can get in to their website you will find us, the PPA  
28 database, you will find us - on the database, not on the web.

29 We have said in one of our witness statements that that is the case, nobody has  
30 disputed that. The zero discount products, and there are two groups. One is zero  
31 discount A.

32 THE PRESIDENT: What page are you on?

33 MR VAUGHAN: Page 10, and 11, and then there is list B. List A seems to be those that  
34 are always zero discounted. List B seems to be may be discounted for some but not for  
35 others. So the pharmacy, if it is one of the drugs in this B list and he is not given a  
36 discount, then he has to certify that. But in list A it is always assumed that he will not  
37 get a discount. Under that there are a very large number of products which do not have  
38 to discount from their price. That is because they deliver straight to the pharmacy, they

1 do the delivery themselves, and do not use wholesalers, because if they use wholesalers  
2 then they have to give a discount in that situation.

3 THE PRESIDENT: I am not sure that is quite how I have understood it, Mr Vaughan. As I  
4 have understood it, the normal case is that the manufacturer gives the wholesaler a  
5 discount, say, 12.5 per cent. The wholesaler then sells on to the pharmacist at the NHS  
6 list price, pocketing the 12.5 per cent., and the pharmacist gets the NHS list price back  
7 from the Prescription Pricing Authority.

8 MR VAUGHAN: In broad terms, yes.

9 THE PRESIDENT: In some cases the wholesaler does not in fact keep the whole 12.5 per  
10 cent. discount, but passes it on to the pharmacist, or part of it on to the pharmacist, so  
11 the pharmacist is buying slightly below the NHS list price.

12 MR VAUGHAN: Yes.

13 THE PRESIDENT: In order to avoid the pharmacist being unduly enriched as it were, there  
14 is then a procedure for clawing back from the pharmacists by some averaging  
15 mechanism, to make sure that what the pharmacist gets is what he has actually paid for  
16 the drug and not what he would get if he were reimbursed at the list price. There is  
17 excluded from that clawback mechanism the zero discount drugs which are not  
18 normally discounted as between the wholesaler and the pharmacist. But you cannot  
19 necessarily conclude that these drugs are either delivered direct by the manufacturer to  
20 the pharmacist, or that they do not benefit from a wholesaler's discount. That is my  
21 understanding. I see one or two heads nodding.

22 MR VAUGHAN: Well I need maybe another document from Mr Morland.

23 THE PRESIDENT: Maybe look into that and see whether I am on the right track or not. I  
24 might well not be.

25 MR VAUGHAN: But basically what one has got is a large range including all alternative  
26 medicines which are counted as zero discounting, and quite important things like  
27 insulin, and Fabrazyme is one of those in that list. So if we supplied direct in that case  
28 it clearly would be a full zero discounting, as it were, because we do not discount on  
29 Fabrazyme, but indeed we do not really supply very much to pharmacists in that way,  
30 other than our own pharmacy for them. But there are quite important products.

31 It is described in more detail in the system, in Mr Doradra, we might as well get  
32 it right, as it were.

33 THE PRESIDENT: Would your drug, Cerezyme, come under, I am just looking at zero  
34 discount list A, would it come under "Drugs available only on a named patient basis"?

35 MR VAUGHAN: No. When we originally imported it from the United States, we had a  
36 named patient basis, before we got authorisation to come here, you could then do it on  
37 that basis. In core bundle 1, that is 37, tab 27, page 282.

38 THE PRESIDENT: Yes.

1 MR VAUGHAN: This was created a long time ago, I think, 11th October, 2002.  
2 THE PRESIDENT: Mr Doradra.  
3 MR VAUGHAN: Who is our unregistered pharmacist. He deals with this, paragraph 21,  
4 page 282.  
5 THE PRESIDENT: Yes, that is right.  
6 MR VAUGHAN: It looks as though he does not offer a discount to the wholesaler, and the  
7 wholesaler does not offer a discount at all, so the wholesaler is actually taking it in at  
8 no discount himself, so he does not get a 12.5 per cent. so there is nothing for him to  
9 play with in that case - if the wholesaler takes it in at all, because the wholesaler may  
10 be rather reluctant to take something in for all the other products where makes 12.5 per  
11 cent. to take in no percentages, he may be quite reluctant to do that. So it may be in  
12 those cases there may be some direct deliveries, anyhow, we can check on that.  
13 THE PRESIDENT: Can we check that, because I have not quite understood 21 at the  
14 moment, because the second sentence, "Where on the system does the wholesaler get  
15 any remuneration from?"  
16 MR VAUGHAN: He does not, that is the point, it is done for love if he does it, and there is  
17 not much love in drug wholesaling I suspect, but he makes nothing on it, all the  
18 products he makes nothing and this has been in evidence for a long time.  
19 MR MATHER: So the only remuneration that comes to the pharmacist is in accordance  
20 with the ordinary rules?  
21 MR VAUGHAN: Yes, because if it is an extra high value the pharmacist gets his 2 per  
22 cent. from financing the exercise.  
23 This is the system that is approved and this is the danger, as it were, of trying to  
24 get an equitable answer in an area where none of us have any detailed knowledge and  
25 all on can do is work on the basis of what one is, but there is a very large number of  
26 these zero discounted products where the pharmacist gets nothing. Indeed, in the whole  
27 system is designed where the pharmacist gets nothing out of the dispensing, he gets  
28 payments---  
29 THE PRESIDENT: He gets a dispensing fee, but he does not make a turn on the product.  
30 MR VAUGHAN: He does not make a turn on the product, and the clawback is designed to  
31 average out, so that if he is clever he can make some money on the turn, as it were.  
32 THE PRESIDENT: He might make a bit but he is not supposed to.  
33 MR VAUGHAN: Well it is not wrong to make one, but it is designed on average not to do  
34 that.  
35 THE PRESIDENT: Yes.  
36 MR VAUGHAN: The zero discounted products are what they say. The manufacturer  
37 delivers to whoever and they get no discount anywhere along the line, and it is up to  
38 you, the producer to decide whether it is to be zero discount or not. Obviously in some

1 cases, you will not be one because your main competitor might be offering discounts,  
2 and so there would tend to be things where either everyone goes down the zero  
3 discount line, or there is no real competition in that respect, I suspect, because  
4 otherwise you would not sell anything in the real world.

5 MR MATHER: Some part of the NHS, however, as I understand it, has to agree that it is  
6 zero discount?

7 MR VAUGHAN: That is right, yes, because it gets into the drug tariff as that, and it is the  
8 PPA that agrees that.

9 MR MATHER: And the criteria for that are somewhat elastic?

10 MR. VAUGHAN: They are fairly elastic, but with the economic criteria, obviously, there is  
11 not much competition in the field because otherwise, as we dealt with before, you  
12 would be out of business pretty quickly. If Boots or somebody manufacturing Aspirins  
13 decided to zero discount Aspirins, they would not be in business for five minutes with  
14 all the competitors, similarly with Paracetamol or something like that: there are just so  
15 many alternatives in that field.

16 I must admit, I have never heard of any of these, apart from the ones we are  
17 talking about today. Clearly, obviously, alternative medicines is a pretty good  
18 example. Alternative medicines are things which are medicines but which are not run  
19 of the mill products, as it were. Presumably there is a group of them which are  
20 classified as medicines under the relevant directives and regulations but are not regular  
21 ones. So all of those are zero discount and the authorities accept that that is the  
22 position.

23 I think it is a factual analysis that has to be undergone: are they giving  
24 discounts or not? As, no doubt, it costs the wholesaler quite a lot to distribute every  
25 single package, you are unlikely to send it to wholesalers in that situation. It probably  
26 means you have got to do the delivery yourself to the pharmacy.

27 All these other companies are entitled to do this. If they do the delivery  
28 themselves to the pharmacy, the only thing they can get their remuneration out of is the  
29 price. So the delivery from the manufacturer's door to the community pharmacy on the  
30 high street is from the price: that is where he has got to get his money to do that.

31 MR. GRINYER: Basically, he is not giving the wholesaler his discount and so he can be  
32 putting an excess price, list price.

33 MR. VAUGHAN: He gets the list price, so he gets his delivery cost.

34 MR. GRINYER: He has taken his 12.5% which otherwise would have gone to the  
35 wholesaler.

36 MR. VAUGHAN: It is not a fixed 12.5%: it depends on volume. But he is not taking it, as  
37 it were. There are two systems.

38 MR. GRINYER: In other words, he is not paying the wholesaler.

1 MR. VAUGHAN: He is not paying the wholesaler, absolutely. But what it does show, it  
2 shows quite neatly that the delivery is in the price: the cost of driving from Oxford to  
3 Edinburgh or wherever you are delivering your zero rated good is in the price.

4 THE PRESIDENT: I think we have all understood that the price at which the pharmacist is  
5 reimbursed, the NHS list price, is a delivered price because that is the point at which  
6 the pharmacist is reimbursed: it has been delivered, in the normal case, to the  
7 pharmacy.

8 MR. VAUGHAN: Yes.

9 THE PRESIDENT: You are saying that is even more true in the case of the zero discount  
10 drugs ----

11 MR. VAUGHAN: Yes.

12 THE PRESIDENT: -- because there is no question in the case zero discount drugs of  
13 discounts creeping in along the way.

14 MR. VAUGHAN: That is right. They cannot because, unless you take yourself out of the  
15 system, you cannot give a back-hander or anything along the system.

16 THE PRESIDENT: What I have not understood yet - and I am not saying you are wrong - I  
17 simply had not understood it - is that zero discount drug equals direct delivery from the  
18 manufacturer drug. I am not sure that that is right. I do not think it matters much for  
19 the purposes of your argument.

20 MR. VAUGHAN: There will clearly be a tendency towards that because otherwise ----

21 THE PRESIDENT: I am sure we can sort it out.

22 MR. VAUGHAN: I cannot imagine many people driving around the countryside for free.

23 THE PRESIDENT: No, but what I am not sure of - I just need to have somebody check it  
24 for me - is whether zero discount drug means zero discount to the pharmacist or zero  
25 discount ex-manufacturer. I think it is the latter not the former, but I may be wrong.  
26 No doubt the Office can help me.

27 MR. VAUGHAN: It is the former, I think.

28 THE PRESIDENT: Mr. Doradra's evidence is that it is the former, but I am not quite sure  
29 that he is completely right on the second sentence of paragraph 21.

30 MR. VAUGHAN: It has been accepted as being right since nobody has put in any evidence  
31 in, but let us try and get it right and see where we get to.

32 THE PRESIDENT: Yes.

33 MR. VAUGHAN: That is the basis upon which the decision is taken on zero discounts.  
34 If we were to introduce an ex-manufacturer's price or a wholesaler's price or  
35 whatever, it would have to take us out of the zero discount system in a system where -  
36 because we would be having to give discounts to people to whom we do not give  
37 discounts. That is a system where everyone is quite happy, the Health Service is quite  
38 happy that we are in this situation and it would place us at a disadvantage over all the

1 other people who, because of their economic position, can retain zero discounting  
2 advantages. Presumably there are advantages in zero discounting and the cost of their  
3 own delivery is, in those cases, less than the amount they would have to pay the  
4 wholesaler to do the same task.

5 MR. GRINYER: Initially, as I understand it, you did give a discount of a kind to - was it  
6 Caremark?

7 MR. VAUGHAN: Yes.

8 MR. GRINYER: How does this affect your argument? You still had a zero rated charge.

9 MR. VAUGHAN: I am not sure what the position was. This is the early 1990s when they  
10 first came on. That was the way we remunerated them to be our exclusive distributor.  
11 Then we had a different system to remunerate Healthcare at Home.

12 MR. GRINYER: That was before you joined the PPRS. You still had a list price when it  
13 was zero rated at that point?

14 MR. VAUGHAN: I just do not know, but those were the days when we were not doing it  
15 ourselves and we had exclusive distribution agreements.

16 MR. VAUGHAN: I am told they gave discounts when it was on a named patient basis.  
17 That is when the goods came in from America for Mr. So-and-So and they got a  
18 discount then off the dollar price.

19 THE PRESIDENT: They got a discount because it was on a named patient basis. It was a  
20 zero discount drug, so they were reimbursed at the full list price, i.e. the concept of a  
21 zero discount drug is related to the pharmacy stage, it is not related to the ex-  
22 manufacturer stage.

23 MR. VAUGHAN: No, but it is relating to the delivery to patient stage, because the patient  
24 then takes delivery from the pharmacy in the ordinary event.

25 THE PRESIDENT: The whole concept of a zero discount drug is linked to the arrangements  
26 for reimbursing pharmacists.

27 MR. VAUGHAN: Absolutely, yes.

28 THE PRESIDENT: It is not linked to the arrangements made by the manufacturer for selling  
29 to wholesalers or to the pharmacy: it is related to what the pharmacist can get back.

30 MR. VAUGHAN: Certainly, but what it does do is, economically, it shows that there are a  
31 number of drugs where the producer is able to be in the market in such a situation and  
32 he does not have to give away a discount; but, obviously, he has to arrange somehow  
33 for delivery to take place.

34 THE PRESIDENT: Yes. Which he presumably does either by doing it himself or paying a  
35 fee to somebody else for doing it.

36 MR. VAUGHAN: That is right.

37 THE PRESIDENT: Or giving somebody else a wholesale margin on a wholesale activity.  
38 Let us not stop on the detail. We must be able to establish it without too much

1 difficulty. I think Professor Yarrow has some evidence about this.

2 MR. VAUGHAN: Yes.

3 THE PRESIDENT: But I am not sure whether he actually deals with this point. Perhaps he  
4 can be asked what the situation is, if he is coming tomorrow.

5 MR. VAUGHAN: I do not want to open it up now, but if you look at Mr. Gottfried's  
6 witness statement at CB2. I do not really want to turn that up, unless you wish me to.

7 THE PRESIDENT: No, I do not think I particularly want to try to get to the bottom of it.

8 MR. VAUGHAN: It is CB40, page 571, Mr. Gottfried. He deals with the early days and  
9 how Caremark were paid in the early days. That is the first objection: that it would  
10 open up the whole question of zero discounting and the benefits which we have from  
11 that.

12 Secondly, it would force us into dealing with people we do not trust or deal with  
13 who would be supplying services downstream. Any Tom, Dick or Harry or the  
14 equivalent would be entitled to come to our front door and take these products and  
15 provide these services, providing, obviously, he had a prescription, so it is a certain  
16 type of Tom, Dick or Harry, but we have no control over the people who take the  
17 product.

18 THE PRESIDENT: Why do you need that control; why are you different from any other  
19 manufacturer?

20 MR. VAUGHAN: Because our product is a product which in some cases needs nursing  
21 treatment, in some cases does not need nursing treatment. We see it as a real need to  
22 ensure that the quality is maintained of the nursing treatment. You will see that we  
23 gave up Caremark because their quality dropped down. We had problems with  
24 Healthcare at Home, though that was not the reason for terminating them.

25 THE PRESIDENT: But you have spent a long time telling us that it is only a minority of  
26 patients who need nursing treatment and most of those are looked after by the NHS.

27 MR. VAUGHAN: Not most of them. A proportion of them are dealt with by them.  
28 Obviously, we have no problems about them. We have no real problems about  
29 Healthcare at Home for doing it. The problem is if a third person comes in or a fourth  
30 person and we have no control at all over the quality of the nursing that is given. If  
31 Caremark fell down below the requisite standards, for example, we would not want that  
32 to happen to our product, because inevitably in a market with such a tiny population we  
33 are cast with the same brush as the person who provides the services.

34 MR. MATHER: You regard yourselves as specially responsible for the use of this drug.

35 MR. VAUGHAN: Absolutely, because we know each person individually. Miss Kelly  
36 knows all our patients personally: she has been to their homes and that sort of thing.  
37 The population is tiny that one is talking about. Also, there is the Gaucher Association,  
38 with which we have continued dealings. It is very much a personal basis. Indeed, it is

1 a point Dr. Cox makes about the personal relationships that exist.

2 MR. MATHER: Going back to your reasons for changing Homecare Services at various  
3 stages, does this mean that it is the quality of care which is the highest priority in those  
4 reasons for change? How would you rate that vis-a-vis the feedback to your client, the  
5 cost, the efficiency argument? Could you give me a sense of what is most important?

6 MR. VAUGHAN: At the time it actually happened, it probably is fair to say, if one looks at  
7 the documents that were produced, there was a commercial reason and there was a  
8 healthcare reason, because we were supplying healthcare at home at a price we  
9 regarded as excessive. If that price had come down to a reasonable price (whatever that  
10 might mean) then that issue would disappear. But then the other issues would still be  
11 there.

12 The problem in this case is, we cannot deal only with Healthcare at Home: we  
13 have got to deal with all-comers. Therefore, one person we may be able to control, but  
14 all-comers we just cannot control in that sense.

15 MR. MATHER: But if we take Mr. Farrell's evidence, he says, "I would like to be able to  
16 deal with homecare suppliers on the basis that I can get a package from them and I,  
17 Mr. Farrell, am extremely choosy about who I deal with and I go and visit their  
18 premises and I check their staff and we verify what they are saying and all the rest of  
19 it", why should not Mr. Farrell have the chance to say, "I've got three tenders from  
20 Genzyme, from Healthcare at Home and from Clinovia to cover several diseases and I  
21 am going to choose the most efficient one, I am going to have my own quality control, I  
22 am going to verify it all and, in this particular case, company X is the most efficient.  
23 That is the one I am going to go to." The result is that company X, the homecare  
24 services provider, will provide the services on a contract in an open tender and that  
25 company will obtain the drugs in question from each of the suppliers at some margin  
26 that allows it to do the homecare services role. Why should not that take care of your  
27 worries about the quality of the people to whom you are selling the drug?

28 MR. VAUGHAN: To some extent it could, because, obviously, if he was able to do it  
29 entirely and satisfy us that that was perfectly well done that may be so, but we are  
30 certainly not satisfied that that would remain the existing system. We want to maintain  
31 ----

32 MR. MATHER: You want to do it.

33 MR. VAUGHAN: We want to do it. By wanting to do it, one comes on almost to the next  
34 point: we are not excluding Healthcare at Home from anything other than its 37  
35 patients for whom it provides nursing, because these are the only people that it would  
36 be excluded from.

37 Healthcare at Home has got a very wide business covering all these other  
38 activities which we say - and the OFT agree, subject to our conduct point - that it is

1 able to do that and has got a very good business in many other things.  
2 If he wants, he can always buy in and get people to do the contracting service  
3 and pay for the nurses if he wants to do that, but he has got to buy at the list price and  
4 do that. He can always invite tenders from people to do it: it is not excluding them  
5 from the market at all; it is excluding them from the particular source of the market,  
6 that is, buying the goods themselves and then using them themselves and performing  
7 the nursing services themselves. If we were exceeding the PPRS target, then our price  
8 would be cut down.  
9 If it was thought by the Department of Health to be a better system, that would  
10 be - I am sorry, I am getting too many notes. If we were being excluded from the  
11 whole system at the time - I am sorry, I have forgotten where I was. My friend cannot  
12 remember either. I may well remember in a moment.  
13 THE PRESIDENT: I think you were saying that it is not really exclusionary.  
14 MR. VAUGHAN: It is not exclusionary in this sense. They can perfectly well carry on  
15 these services, it is just that they cannot carry on these services by buying the good  
16 from us without further financing to provide the same work.  
17 When one is talking about quality of service, in the Fabry product, in  
18 Fabrazyme - there is evidence about this - the nursing quality becomes much more  
19 important. It is a much more intrusive product and has a much greater effect on  
20 individuals and also we are at a very early stage in the development and we need to get  
21 back for reporting systems, for pharmaco-vigilance reasons, any problem that we might  
22 encounter in that system. Particularly for that product, it raises different points.  
23 THE PRESIDENT: So you would say even if the OFT was right on Cerezyme there is no  
24 read across to Fabrazyme because that is a different situation.  
25 MR. VAUGHAN: That is right, yes.  
26 MR. GRINYER: Fabrazyme actually has a competitor anyway.  
27 MR. VAUGHAN: Fabrazyme have a competitor where somebody is bigger. TKT is bigger.  
28 MR. GRINYER: Referring to your point about Fabrazyme, are you saying that it is more  
29 important to have a tied exclusive distributor with very strong feedback of information  
30 relating to patients at an early stage of the entry of the drug to market and you need to  
31 be monitoring symptoms and developments of that kind much more than the later one?  
32 MR. VAUGHAN: For a different reason. There are two reasons in the earlier stages. One  
33 is pharmaco-vigilance and healthcare. The other one is probably only healthcare and  
34 quality of service. We do not want just anyone who happens to win a tender to treat  
35 our patients, basically. The patients are receiving our things.  
36 THE PRESIDENT: You regard them as **your** patients?  
37 MR. VAUGHAN: Yes, because all the people, Mr Termeer and all the people working in  
38 Boston have done this thing for Brian Burman, the boy in New York who was the very

1 first patient, the boy who suddenly recovered in three days, or whatever it was, from  
2 being treated in this way.

3 THE PRESIDENT: We have, perhaps incorrectly, understood that this particular kind of  
4 distribution system we are talking about today is not the one that Genzyme uses in the  
5 United States or in other States of the European Union.

6 MR VAUGHAN: That is right, because there it is down to the hospital. I think this is right,  
7 homecare is something that is---

8 THE PRESIDENT: Under the hospital, so broadly speaking, in other developed countries,  
9 the system is you deliver to the hospital and the hospital is responsible for the  
10 homecare.

11 MR VAUGHAN: They do it all. In France, I think I am right in saying, the French are  
12 looking at the English system and thinking it might be a way forward. It is a surprise to  
13 find the French looking here. It is hospital treatment in France, it is not that they do the  
14 homecare themselves.

15 THE PRESIDENT: What about the United States?

16 MR VAUGHAN: The Cincinnati Centre, we have put in evidence about that and the  
17 people go to Cincinnati and have this in the system, and it is all done in hospital.

18 THE PRESIDENT: So there is no equivalent, you are saying, of the situation in the United  
19 Kingdom where people can stay at home and get it done?

20 MR VAUGHAN: Not really no, not at all I think. It is one of the things we are very proud  
21 of because it is us that developed that, if you look through the evidence.

22 THE PRESIDENT: I am a bit surprised to hear that it does not exist in the United States,  
23 you would have thought that they would be at the forefront of it, homecare.

24 MR VAUGHAN: Maybe it is such a big place that it is easier to get the Centres of  
25 Excellence, and everyone going for their treatment.

26 THE PRESIDENT: People cannot go to Cincinnati every two weeks for treatment, can  
27 they?

28 MR VAUGHAN: I think a lot of them are in hospital, and they are not in that way.

29 THE PRESIDENT: I see. Yes?

30 MR VAUGHAN: But I think it is one of the things we are particularly proud of, the  
31 development of this and the fact that it is the norm now, doing it at home, rather than  
32 abnormal in that situation. They go to their local hospital, sorry, they do not all go to  
33 Cincinnati, they go to their local hospital, but Cincinnati is the great centre.

34 THE PRESIDENT: They go to the local hospital for an infusion.

35 MR VAUGHAN: For infusion, yes, and sit there for two hours or whatever, and have the  
36 infusion there, and the pride is that we have broken away from that and indeed, I think  
37 the intention always was we should get to this situation, but when we first arrived there  
38 were six patients only. The tendency is, I am told, that people tend not to diagnose

1 illnesses for which there is no treatment, and apparently in Japan it is unlawful to  
2 diagnose something if you have not got a treatment for it and one can well see the  
3 reason. Try telling somebody "it is terminal, and we can do nothing", is not much help  
4 to most people, unless it is really true.

5 So basically there are those factors in this, and we do regard these as personal  
6 friends, personal patients, in that way and they are treated accordingly.

7 The next point is really if one is to go down that line, the X manufacturing  
8 price, one is really going back again into this refusal to supply point, which the OFT  
9 have repeatedly denied since the Rule 14, that this is a refusal to supply case. In their  
10 skeleton in defence they make a big point right at the beginning, this is not a refusal to  
11 supply case, but it is if one analyses in this way, because we are refusing to supply at  
12 anything other than the Drug Tariff price.

13 If one looks at the decision itself at paragraph 381. It starts at paragraph 380. It  
14 is in file 1, page 100.

15 THE PRESIDENT: Yes.

16 MR VAUGHAN: "Genzyme also contend the Director's case on margin squeeze is a  
17 blatant attempt to avoid confronting the reality of HH's complaint which is of a refusal  
18 to supply", and then 446 they refer to passages. "Genzyme has argued throughout its  
19 response that the Director's case about Genzyme's initial decision to stop supplying HH  
20 with Cerezyme. This view is misconceived. The case is clearly set out in the Rule 14  
21 Notice, and none of the abuses alleged refer to Genzyme's refusal to supply HH with  
22 Cerezyme. The Director put this to Genzyme during the oral hearings...etc." and they  
23 quote me and my response. "This is mistaken. The case set out is not one of refusal to  
24 supply. There is no need for the Director to address Genzyme's representations with  
25 disrespect."

26 So we are back into this pretty fundamental point, that the Director has to put  
27 his case clearly, and it is not the role of this Tribunal to mop it up and to try and  
28 reconfigure the case in order to make a different case, because that is the case we have  
29 met and that is the case we are meeting now.

30 THE PRESIDENT: We may at some stage have to hear submissions on what the powers of  
31 the Tribunal are, with respect. It is not as simple as it is with the Court of First Instance,  
32 you either annul or you do not.

33 MR VAUGHAN: But that is the basic thing one has to look at.

34 THE PRESIDENT: The basic point you make is it has never been put like that.

35 MR VAUGHAN: Yes.

36 THE PRESIDENT: And "we have never had to meet that case"?

37 MR VAUGHAN: That is right. And it is not, we would submit, it is not a question of  
38 sending it back for them to try and buff up their case, to put it in a completely different

1 way when we have spent three years fighting this case. It would be intolerable if that  
2 were the situation.

3 So basically one has to analyse what is the case? We say it is a refusal to supply  
4 case. In that situation that issue would only be relevant if there is a question of essential  
5 facilities, that is to say, that you absolutely had to have that product in order to remain  
6 in business - it is not necessarily "in the market" or whatever it might be, it is to remain  
7 in business, and the business that you are in. The business Healthcare at Home is in is  
8 the wide range, with this being a tiny subsegment of its business which, at one stage,  
9 was particularly lucrative. So we say there is no question of a refusal to supply having  
10 any legal consequences in that situation.

11 If one looks at their current website one sees there is something like 5000  
12 people they are treating, for example. When the contract came to an end in 2001 they  
13 had 2000 patients.

14 THE PRESIDENT: When you say "to remain in business", is it really business in the wide  
15 range, or is it business in the supply of the drug in question?

16 MR VAUGHAN: Well, absolutely.

17 THE PRESIDENT: Because we know that, well you submit at least, that this legislation is  
18 not there to protect HH, it is there to protect the competitive structure?

19 MR VAUGHAN: Yes.

20 THE PRESIDENT: The competitive structure does not depend on whether HH has other  
21 businesses that it, HH, will continue to supply. It depends on HH's ability to get this  
22 particular product for these particular patients.

23 MR VAUGHAN: Well, no, with respect that is not right. The question is: are they entitled  
24 to remain in the market, as it were? Not are they entitled to keep doing exactly what  
25 they were doing before?

26 THE PRESIDENT: I do not think it is a question of what they are entitled to do, it is a  
27 question of what the Chapter II prohibition obliges Genzyme to do in order to maintain  
28 conditions for effective competition in this particular factual circumstance. We are not  
29 looking at HH interest as HH.

30 MR VAUGHAN: Not as HH, but HH as a competitor in the downstream market, which it  
31 accepts, it is evidenced in Fresenius, could not be one product by itself.

32 THE PRESIDENT: So you say the exclusion of HH, if it were to follow, from the "market  
33 for Gaucher patients" is neither here nor there, so long as HH can carry on in general  
34 supplying other homecare services?

35 MR VAUGHAN: Yes, because they accepted at Fresenius that one product was not enough  
36 to keep a business, you needed more. So if one product is not enough to keep a  
37 business, then there is nothing upon us to keep a business going with one product. That  
38 effectively is the position. Also, the other thing is that whatever the duties of a

1 dominant undertaking are, is not to create or resurrect competition where there is no  
2 need for competition in any particular field.

3 The mere fact there is no competition in a particular field is just a fact of life  
4 sometimes. There are monopolies all over the place in that situation. Otherwise, if it  
5 were that, then no dominant undertaking could vertically integrate at all. But it takes  
6 one basically back to Oscar Bronner, what are in the refusal to supply situation, which  
7 our case is that this is that, what are the duties?

8 I think it might be quite helpful if I take you to the relevant passages of Oscar  
9 Bronner in that. This is in our authorities, I do not know how you number them - 40.

10 THE PRESIDENT: Yes.

11 MR VAUGHAN: The facts of that case I entirely accept to some extent are different to  
12 this. The question was did the dominant undertaking owe it to another undertaking to  
13 make use of its distribution agreements in that situation?

14 The passages which are of particular relevance, the Advocate General dealt with  
15 all the sort of cases which one would expect to see in that case, like Telemarketing,  
16 GB&O and those sort of cases, United Brands, and McGill. The passages of particular  
17 relevance are at paragraph 49. This is really dealing with the Commission's pleadings,  
18 and refers to the American rulings on essential facilities and bottleneck monopolies in  
19 paragraph 46, 47, 48, and they set out the proposition in 48, bottom right hand corner,  
20 this is the Commission's written submissions: "An undertaking which occupies a  
21 dominant position in the provision of an essential facility and itself uses that facility,  
22 i.e. a facility or infrastructure without access to which competitors cannot provide  
23 services to their customers, an which refuses other companies access to the facility  
24 without objective justification or groundset ...competitors only on terms less favourable  
25 than those which it gives to its own services, infringes Article 86 if the other conditions  
26 of the Article are met. An undertaking in a dominant position may not discriminate in  
27 favour of its own activities in a related market. The owner of an essential facility which  
28 uses power in one market in order to protect its strength and its position in another  
29 related market, in particular by refusing to grant access to a competitor, or by granting  
30 access on less favourable terms than those of its own services, and thus imposing a  
31 competitive disadvantage infringes Article 86.

32 THE PRESIDENT: That is from Holyhead Harbour is it not?

33 MR VAUGHAN: That is from Holyhead Harbour. 49 sets out the basis of the other legal  
34 basis of that. Then it goes on to say: "It is clear that the Commission considers a refusal  
35 of access to an essential facility to a competitor can of itself be an abuse, even in the  
36 absence of other factors, such as tying of sales, discrimination vis a vis other  
37 independent competitors, discontinuation of supplies to existing customers, or  
38 deliberate action to damage a competitor". They related that in many of the cases it

1 dealt, "such additional factors are to a greater or lesser extent present."

2 "An essential facility can be a product, such as a raw material or a service,  
3 including provision of access to a place such as a harbour or airport, or distribution  
4 system, such as a telecommunications network." Indeed, the decision in this case relies  
5 up on telecommunications' cases.

6 "In many cases the relationship is vertical in the sense the dominant undertaking  
7 reserves the product or service ..discriminated in favour of its own downstream  
8 operation at the expense of competitors on the downstream market. It may also be  
9 horizontal in the sense of tying services related to distinct products or services."

10 Then it goes on, as it were, to deal with how the Commission deals with what is  
11 a essential authority. I am pleased to see the author of the footnote, 58, present in court.

12 THE PRESIDENT: Yes, he cites Mr Temple Lang, yes.

13 MR VAUGHAN: Then, 53 is important. "The laws of the Member States generally regard  
14 freedom of contract as an essential element of free trade. Nevertheless, the Competition  
15 Rules of some member states explicitly provide that unjustifiable refusal to enter a  
16 binding contract may constitute an abuse of a binding or a dominant position". Then he  
17 gives examples of that in each of the cases. But they are pretty limited when they  
18 really are essential facilities in that sense. In any of the cases one has seen, they do not  
19 become essential merely because somebody individually requires them as necessary to  
20 do their job.

21 "Against that background, I turn to the issue raised by the National Court's first  
22 question...although one of Bronner's complaints in refusing access to the home-  
23 delivery and network Mediaprint has discriminated between it and another publisher,  
24 the referring court has not put the question on that issue. The purpose of the National  
25 Court's first question is to discover whether an undertaking in Mediaprint's position  
26 commits an abuse, in the absence of any other factors, to cut off supplies, tying of sales,  
27 etc. if it refuses to allow another newspaper publisher to have access to a distribution  
28 system which it has developed for the purposes of its own newspaper business.

29 "It is clear from the above discussion, that question raises a general issue which  
30 can arise in a variety of different contexts. So he is not dealing specifically with the  
31 facts of the case, but saying it raises important general issues.

32 "Whilst it would not be appropriate, on the facts of the present case, to attempt  
33 to provide a comprehensive guidance, a number of general points should be made  
34 before I turn more specifically to the present case.

35 "First, it is apparent that the right to choose one's trading partners and freely to  
36 dispose of one's property are generally regarded as principles in the laws of the  
37 Member States, in some cases with constitutional status. Incursions on those rights  
38 require careful justification."

1                   That is obviously fair, obvious and correct.

2                   "Secondly, the justification in terms of competition policy for interfering with a  
3 dominant undertaking's freedom to contract, often requires a careful balancing of  
4 conflicting considerations. In the long term it is generally pro-competitive and in the  
5 interest of consumers to allow a company to retain for its own use, facilities which it  
6 has developed for the purposes of its business. For example, if access to the production,  
7 purchasing or distribution facility were allowed too easily there would be no incentive  
8 for a competitor to develop competing facilities. Thus while competition was increased  
9 in the short term it would be reduced in the long term. Moreover, the incentive for a  
10 dominant undertaking to invest in efficient facilities would be reduced if its competitors  
11 were, upon request, able to share the benefits. Thus the mere fact that by retaining a  
12 facility for its own use a dominant undertaking retains an advantage over a competitor  
13 cannot justify requiring access to it.

14                   "Thirdly, in assessing this issue it is important not to lose sight of the fact that  
15 the primary purpose of Article 86 is to prevent distortion of competition - and in  
16 particular to safeguard the interests of consumers - rather than to protect the position of  
17 particular competitors" and that is not insignificant when one is talking about the  
18 position of Healthcare at Home. "It may therefore, for example, be unsatisfactory in a  
19 case in which a competitor demands access to a raw material..." and so it shows it is in  
20 general terms and not fact related, "...in order to be able to compete with the dominant  
21 undertaking on a downstream market in a final product, to focus solely on the latter's  
22 market power on the upstream market and conclude that its conduct in reserving to  
23 itself the downstream market, is automatically an abuse. Such conduct will not have an  
24 adverse impact on consumers unless the dominant undertaking's final product is  
25 sufficiently insulated from competition to give it market power". That clearly cannot  
26 apply in our case.

27                   Then in Commercial Solvents: "Advocate General Warner, in coming to the  
28 same result as the Court, also considered the position on the downstream market:" I do  
29 not think that the question whether the market for the raw materials for the production  
30 of a particular compound is a relevant market can, logically, be divorced from the  
31 question whether the market for that compound is a relevant one." So he goes back to  
32 seeing what is the relevant market, not what is the particular interest of the potential  
33 customer ----"

34 THE PRESIDENT: How much of this do you want to read,  
35 Mr. Vaughan?

36 MR. VAUGHAN: Then he says at 60 - he deals with McGill, which can be explained on its  
37 own special facts. That is 63. Then 65: "It seems to me that intervention of that kind,  
38 whether understood as an application of the essential facilities doctrine or, more

1 traditionally, as a response to a refusal to supply goods or services, can be justified in  
2 terms of competition policy only in cases in which the dominant undertaking has a  
3 genuine stranglehold on the related market. That might be the case, for example, where  
4 duplication of the facility is impossible or extremely difficult owing to physical,  
5 geographical or legal constraints or is highly undesirable for reasons of public policy.  
6 It is not sufficient that the undertaking's control over a facility should give it a  
7 competitive advantage."

8 Then 69: "To accept Bronner's contention would be to lead the Community and  
9 national authorities and courts into detailed regulation of the Community markets,  
10 entailing the fixing of prices and conditions for supply in large sectors of the economy"  
11 - or, indeed, in small sectors of the economy. "Intervention on that scale would not  
12 only be unworkable but would also be anti-competitive in the longer term and indeed  
13 would scarcely be compatible with a free market economy."

14 So all that sets out and seems to be accepted as a correct statement of the basic  
15 principles and is of very considerable significance. Genzyme has invested massive  
16 sums in these particular types of product and, of course, one is not just concerned with  
17 Cerezyme, it is all the succeeding products as and when we succeed in getting them to  
18 the market, so it is a matter of very great importance to us, not just for Cerezyme but  
19 for the future. It is also, as one sees from Mr. Alisky's reaction that it is extremely  
20 important for him with TKT and Hurler that if we can come in and ruin his market on  
21 the downstream and he has to supply at less than market price then his commercial  
22 investment will be dramatically undermined in that way and we could engage in  
23 spoiling tactics in order to do that.

24 Here one has a market - and that is the reason why this case is so important -  
25 which departs from the Commission's rather simplistic view before and where it is the  
26 OFT's alternative view that once you are dominant therefore you have got to supply all-  
27 comers if they want it and if they want to get into the market they want to get into, then  
28 it completely destroys that sort of case.

29 It is also extremely important because it makes clear that the market you are  
30 looking at is not just the market the potential customer wants to get into, it is what is  
31 the relevant market, which actually exists in that case. We say clearly the relevant  
32 market here is homecare generally. It is certainly not Cerezyme and Gaucher  
33 treatment. Whether you divide that into one or two, into delivery and nursing is a  
34 different matter, but it is a broad market and nothing we do takes them out from that.

35 The court in general terms - although obviously they do not go down the same  
36 line - accepted the whole thesis of that. Paragraph 41. Basically, it was saying that you  
37 cannot rely on these sorts of principles in order to get access to their distribution  
38 system. Indeed, when one gets to Du Pont ----

1 THE PRESIDENT: Before we leave Bronner, if we look at the judgment of the court itself,  
2 particularly at 43, 44 and 45, can we reason along these lines? If you are right and you  
3 win this appeal, the effective result is that Healthcare at Home will cease probably  
4 supplying the existing Gaucher payments because there is no margin for them to do so  
5 between the list price and ----

6 MR. VAUGHAN: Unless they are funded by Mr. Farrell.

7 THE PRESIDENT: Unless they are publicly funded by Mr. Farrell by some means or other.  
8 If one then asks oneself, "How then can homecare services for Gaucher payments be  
9 supplied by anyone other than Genzyme?", the answer is, "Probably they cannot in  
10 practical terms be supplied by anyone other than Genzyme."

11 MR. VAUGHAN: They can buy from a hospital; they can get it from a pharmacy.

12 THE PRESIDENT: At the expense of paying, as the OFT puts it, twice over.

13 MR. VAUGHAN: Either themselves paying or getting somebody else to pay for it.  
14 Whatever is going to happen, somebody else is going to have to pay for this treatment.  
15 The Health Service is going to have to pay for this treatment. This is inevitable.

16 THE PRESIDENT: At the moment, according to you, the treatment is included in the cost of  
17 the drug and as long as it is included in the cost of the drug the Health Service either  
18 has the choice of buying the drug and getting the service from you or buying the drug  
19 from you and getting the service from someone else at an additional cost.

20 MR. VAUGHAN: I would not put the first bit in the way that you do. I would say that  
21 there is no payment for the treatment. The treatment is provided free by us. The  
22 question is, are we allowed to provide it free? The second part is completely right: if  
23 they wanted to come in, they either have to buy at the list price, like everyone else, and  
24 find the funding to do it or else finance it themselves, which is pretty unrealistic, and  
25 drop out of their segment of the market.

26 THE PRESIDENT: If we asked ourselves the question - I am not saying at all it is the right  
27 question to ask even, I am just asking it - if we looked at 43, 44, 45 and 46 of Bronner,  
28 if we said, "What other methods of distributing homecare services for Gaucher  
29 payments would exist?" - 43 - 44, "Are there any other technical, legal or economic  
30 obstacles making it impossible, even unreasonably difficult, for any other supplier of  
31 homecare services to supply homecare services to Gaucher patients?" - 45, "Is it  
32 effectively indispensable to have supplies of this product at a price lower than the list  
33 price in order for anyone to compete with Genzyme Homecare?", what is the answer is  
34 one asked oneself those questions?

35 MR. VAUGHAN: If you ask those questions, you get the answer that the OFT gets.

36 THE PRESIDENT: What are the questions we should ask, according to you?

37 MR. VAUGHAN: The questions are, "Is it essential for Healthcare at Home to remain in  
38 the healthcare to obtain Cerezyme" - first of all that - "and to do so at a price that

1 allows it on that product a sufficient margin?", when, in fact, a lot of its other products  
2 are not on a sufficient margin, because otherwise they would not have been so  
3 desperate to keep Cerezyme. So if one asks, with respect, the wrong question one gets  
4 the wrong answer.

5 THE PRESIDENT: I am not saying it is the right question.

6 MR. VAUGHAN: No, I am sorry, but I have almost got to engage you on the alternative, as  
7 it were, with respect. If one asks the OFT's question, then the answer is very simple,  
8 but the OFT accept that absent our conduct the market is much wider than the one they  
9 have done. What they say is, because of our conduct, we have narrowed the market  
10 and we just do not see that.

11 THE PRESIDENT: Would the legal analysis be different if Cerezyme had been Healthcare  
12 at Home's only product?

13 MR. VAUGHAN: If they could not get into anything else; if all their skills were such that  
14 they only could be in that situation and all their nurses were dedicated Cerezyme  
15 people; and all their vans were Cerezyme vans it might well be so. I do not want to  
16 concede it, but it could well be so, but here we have got multi-purpose vans and multi-  
17 purpose nurses. Obviously, the court answered the question that it had to deal with.  
18 But the whole principle seemed to be accepted that what General Jacob said is basically  
19 a good starting point, if not the concluding point, of any analysis of this sort of  
20 exercise. Indeed, since then the essential facility cases seem to have rather withered  
21 away from that.

22 It is important and not to be despised, the fact that Mr. Justice Laddie in the  
23 cases we have referred to - I do not want to open up those now because otherwise we  
24 will be here until supper time - proceeded on the basis that that was right: that people  
25 even in a dominant position are entitled to certain rights and are not bound to trade with  
26 everyone simply because everyone would like to trade with them, however important it  
27 is to their business.

28 If we can look very briefly at the facts of those other cases, Getmapping in the  
29 bundle of authorities at tab 5, it was unarguable that the Ordnance Survey was  
30 dominant in that situation and it was unarguable that Getmapping needed to get to the  
31 Ordnance Survey in order to carry out part of its business, but the question really was -  
32 in the holding, Mr. Justice Laddie entirely accepts it is an interim relief case, but he  
33 went into this in considerable detail in order to be able to resolve the issue of whether it  
34 was arguable - or whatever the appropriate test is on interim relief - that they had a  
35 good case to justify interim relief. "It was uncontested that the defendant occupied a  
36 dominant position in the market for the maps of the UK. A dominant company could  
37 be forced to contract with a third party in situations in which it 'unfairly leverages its  
38 market power in the dominant market to gain a competitive advantage in the non-

1 dominant market'. The vice here would consist in 'achieving dominance of the new  
2 market by anti-competitive means (emphasis in the original) and it is not a per se abuse  
3 for an undertaking to use its financial and economic strength to move from a market in  
4 which it is dominant into a new market. The fact that the funds which would support  
5 the move came from a public source would not, in the absence of any authority to the  
6 contrary, be relevant to the issue of abuse. The essential facilities doctrine was not  
7 relevant in the case as it was not argued that, without the relief sought, the claimant  
8 would be unable to compete with the defendant. In order to succeed, the claimant  
9 would have 'to demonstrate that OS' choice of ortho-rectification is incapable of being  
10 objectively justified' and this 'demands more than showing that a rational trader in OS'  
11 position could have made a different choice. In substance, it means that that OS' choice  
12 has to be clearly unjustified'. In light of this, the judge came to the conclusion that  
13 'there is no credible case' and the application was refused."

14 Then at paragraph 32 - it is a very similar type of case - "At first blush, one  
15 might have expected GM to have advanced an essential facilities case. However,  
16 Mr. Brealey expressly disavows this. He accepts the OS website through which the  
17 imagery will be made available to the public is not a bottleneck monopoly. GM will  
18 not be obliterated if it is not on the site (or the link to it is not made more prominent or  
19 moved closer to the 'front' of the shop). It is still open to it to sell its imagery to all and  
20 sundry. It can make available on the internet and it can supply it to others to do so."  
21 These are alternative ways of carrying out its business.

22 Obviously, each of these cases is very much fact dependent, but the significance  
23 of that is effectively, as one will see - from a further reading he goes on to deal with  
24 Oscar Bronner etc. He distinguishes McGill and so on. He deals in considerable detail  
25 with the law.

26 The dominant undertaking did not have to trade with Getmapping to get  
27 Getmapping into a particular sort of business and Getmapping was perfectly able to  
28 compete and carry on business, as it does.

29 Then Suretrack, which is the next tab. "JPN [the defendant] is one of three  
30 subsidiaries of London Underground with responsibility for maintenance and  
31 improvement of rolling stock and belowstructure for the Underground network.  
32 Suretrack provides safety staff ... who are self-employed subcontractors, on an agency  
33 basis to the defendant. A tendering process agreed between JPN and two other  
34 subsidiaries resulted in three companies being chose to supply protection masters, and  
35 track contractors were required to either employ the protection masters they used, or to  
36 use one of the three agencies. Suretrack was not in existence at the time of the  
37 tendering process, so was not one of the three selected agencies, but when the policy  
38 was put in place, in June 2002, it faced the prospect of being cut out of its core

1 business. The complainant complained on the basis of the Competition Act." It  
2 followed Getmapping. It deals with the economic group point and it was found that it  
3 was capable of objective justification and found that the claimant's case was weak. Mr.  
4 Turner was for one side and he relied on general principles and Mr. Flynn on the other  
5 side relied on Oscar Bronner. He came down in favour of Oscar Bronner.

6 Obviously, each of these cases is different, but each of them gives the flavour of  
7 the dominant undertaking, even though it is very important and indeed even if in some  
8 terms it is essential for the purchaser to remain in a particular sort of business, it does  
9 not commit an abuse of the dominant position by refusing to supply.

10 Then there is the recent Du Pont case - Monday's case - if I can take you briefly  
11 to that, which is in our reply file, our skeleton file. It is file 46, it is our supplemental  
12 skeleton. We annex the decision itself. It is probably easier to take you to our skeleton  
13 because we pick out what we think are the real points there.

14 46, I am not sure what tab it is.

15 THE PRESIDENT: It is labelled "supplemental", it is a blue tab in our file.

16 MR VAUGHAN: I am not going to take you to the decision itself, but obviously you will  
17 need to read it, and my friend, no doubt, will deal with it. Paragraph 3 in that decision  
18 the OFT rejected a complaint of refusal to supply. Du Pont developed and  
19 manufactured a film for making holograms. Du Pont was found to be dominant in the  
20 upstream market.

21 "Du Pont uses film to manufacture a number of holographic anti-counterfeiting  
22 products. OPG" which is the complainant, "..manufacture holographic... had been  
23 supplied with a film by Du Pont between 1998 and 2001 under a supply agreement. Du  
24 Pont terminated the supply agreement in accordance with its terms.." Exactly the same  
25 sort of thing as here. "OPG complained to the OFT. The OFT based its decision to  
26 reject OPG's complaint on an application of product."

27 As the OFT's case against Genzyme - this is our submission, skeleton - is in  
28 reality an application of abuse or refusal to supply, it is relevant to see how the OFT  
29 applied Bronner and Du Pont. The OFT cited Advocate General Jacobs, at paragraph  
30 28 of his decision, the only exceptional circumstances point, and then we compare that  
31 with our Notice of Appeal, 483(i), any incursion on rights to choose trading partners  
32 and freedom to dispose of one's property would require careful justification....before  
33 coming here.

34 "The OFT rejected OPG's contention that the film manufactured by Du Pont  
35 was an essential facility to which it was entitled to have access. The OFT observed that  
36 the holographic film is the product of research and development by Du Pont. The effect  
37 of treating every new product which, at the time of discovery, had unique properties, as  
38 an essential facility this product was a necessary input into a downstream market would

1 be to admit an excessive degree of interference in the freedom of undertakings to  
2 choose their own trading partners, as stated above Competition Law would have this  
3 effect only in exceptional circumstances".

4 You can almost see Mr Robertson having written that, because basically it is  
5 exactly what we say. If you would transpose that and put "Cerezyme" in each case -  
6 Cerezyme is the product of research and development by Genzyme. The effect of  
7 treating every new product which at the time of its discovery had unique properties, as  
8 an essential facility, this product was a necessary input into downstream market  
9 (Cerezyme) would be to admit an excessive degree of interference in the freedom of  
10 undertakings to choose their own trading partners. As stated above, Competition Law  
11 should have this effect only in exceptional circumstances". Then we make the point  
12 that is exactly what we said in our Notice of Appeal about substantial investment.

13 "Du Pont's justification for refusing to supply was that as it was producing an  
14 anti-counterfeiting product, Du Pont needed to guarantee complete supply chain  
15 security, and that ruled out supplying to customers for use in graphic art applications."  
16 That is very similar to the point of security of supply made by Mr Termeer in his  
17 affidavit. It guarantees a quality as in our case guarantees security.

18 "No objection was taken by the OFT to Du Pont's justification. It is implicit the  
19 OFT accepted Du Pont's distribution policy was not one which no rational and fair  
20 minded person could justify", which is our submissions based upon Laddie J.

21 Basically, we say this is exactly what they should have done at the beginning of  
22 this case - treated it as a refusal to supply, applied these general principles which they  
23 have done in Du Pont, and rejected the complaint, because OPG was perfectly able to  
24 carry on this graphic art business. It is clearly in that situation. If it had wanted to get  
25 into the security market even more so would Du Pont have been entitled to say "no" in  
26 that situation. It cannot be simply because you want to reproduce the same market you  
27 are entitled to come into that market.

28 Basically our contention is that Oscar Bronner rejects Du Pont and these other  
29 cases, rejects this second alternative in that way. Basically the X manufacturing  
30 discount would be just doing what Oscar Bronner tells you not to do, but particularly  
31 difficult is it would be intervening in an area which is highly regulated already by the  
32 DHS system, by the PPRS system, by all these other systems, and it would be doing  
33 exactly what Mr Advocate General Jacobs said would be imposing excessive regulation  
34 and a new form of regulation, a different form of regulation into this whole area - and a  
35 form of regulation which is impossible under the Competition Act to resolve, because  
36 as everyone accepts there is no such thing as a price which can be said to be the price,  
37 in any sort of meaningful sense of the word. The Competition Law Act is not designed,  
38 as it were, to resolve these things. What is the discount that has to be given? Is it cost?

1 Is it profit in these things? What is a reasonable margin in this sense? Is it a margin for  
2 delivery only, or is it a margin for nursing or both? Or is it an average of the two in that  
3 sense? Equally, what price does one take? What is the ex-factory price? There is no  
4 such thing as an ex-factory price, and how much delivery are we entitled to include in  
5 the ex-factory price? What overheads are we entitled to include in the ex-factory price  
6 over and above the transfer price in that situation?

7 Then the question is for what benefit is one to do that? Here we have 42 patients  
8 dotted around the country in a large number of different ECTs. On average there are 42  
9 hours of nursing, that is 42 people who in fact get it once every two weeks, and it  
10 therefore comes down to, on average, 42 hours a week nursing dotted around the  
11 United Kingdom.

12 So there are enormous problems, and it was exactly the sort of problems that Mr  
13 Advocate General Jacobs warned against, and done in a system where the Health  
14 Service have these powers, or the DoH has these powers and the Secretary of State has  
15 these powers to intervene if he thinks it is appropriate and if he wants to intervene as  
16 he did in the ER95 situation. He can intervene on price. He can intervene through the  
17 PPRS. He can intervene on service, on what is to be covered by the prescription, and he  
18 can intervene generally. But he has not, and nobody in the DoH has ever made any  
19 suggestion that they want to intervene in this particular situation.

20 Obviously some consultants do not like the system, and you can see from the  
21 evidence they do not like it, others do like the system. If there is a new system, it has to  
22 be based on a tendering system if that is the situation. To get to the hospitals it would  
23 have to be based on tendering. Mr Cox refers to tendering every two years, and so if  
24 that was the system, you do not know who is going to be carrying out the nursing  
25 services - from anywhere within the community there may well be people who win the  
26 tender. So we would have no control whatsoever, we cannot guarantee it would be  
27 Healthcare at Home who wins the tender under the current procurement rules.

28 PROF GRINYER: Is your suggestion, Mr Vaughan, that you will have a better ability to  
29 control the quality of the homecare provision than, say, Mr Farrell or other provider  
30 who is dealing with tenders?

31 MR VAUGHAN: Yes, because we are just dealing with us, he wants to deal with all these  
32 on an equal basis.

33 PROF GRINYER: He wants multiple disease delivery.

34 MR VAUGHAN: Yes, and so in that way we would be treated like a number of other IV  
35 infusion systems, and we would be extremely concerned about that, and the fact that he  
36 may specify particular rules in his tender documents in that situation. We have no  
37 control over what he puts in, no control over equality in any of that sort of system. We  
38 would be extremely unhappy to find ourselves lumped in with everyone else in that sort

1 of situation, because he does not suggest that he is going to do a one product tender. It  
2 is a general tender is what he wanted to do.

3 Of course, he can do that if he wants, but he has to pay for it. There is nothing  
4 to stop him, having bought it from us, putting this service out to tender, but he has to  
5 pay for it and he has to be responsible for that, under that situation.

6 Then all sorts of other problems arise, how do we tender for that? Can we  
7 tender at £1, £1000, £10,000 in order to secure our position in the market? What is the  
8 power of a dominant undertaking, having to tender in a public tender for these sort of  
9 services. Assuming we are all equal - treatment - can we tender for £1, £50, £500,  
10 whatever might be the thing, and we may well find ourselves getting the whole lot  
11 under public procurement rules in that situation. But we are unhappy at the idea that  
12 other people might buy from us and then provide service directly for us without control  
13 by us. At least under the old system we had control under the exclusive distribution  
14 agreement, so we were able to control what they did. Under the new system the OFT  
15 proposes we have no control whatsoever, and no say whatsoever, and they can produce  
16 what nurses they like, or anything like that. I am not suggesting they would, but they  
17 could, and we have to legislate really for the possibility in the future, not for anything  
18 else.

19 Basically, the final point, really, is to make Professor Yarrow's point, which has  
20 never really been answered at all. If one looks at the decision, 330, bundle 1, paragraph  
21 330, this is the point I had got to just before the short adjournment, it is another  
22 example of them, as it were, rejecting, like 380 I think it was, rejecting our case.

23 "Genzyme also argued that it is not an abuse for a supplier of a product to  
24 choose to supply it to the market directly rather than through wholesalers, distributors  
25 or other third parties. That is an argument that Genzyme has made throughout its  
26 response." It still does. "However, this argument has no bearing on the abuse as set out  
27 in the Rule 14 notice and in its decision. The abuse, as set out in those two documents,  
28 is making the NHS pay" - and obviously we have a lot to say about that - "a price  
29 which includes Homecare's services if it wishes to purchase Cerezyme, thereby  
30 reserving to itself ...undertaking acting under contract to Cerezyme ...the ancillary but  
31 separate activity of providing Homecare services", which it defines earlier on as being  
32 for Cerezyme.

33 "The abuse is not Genzyme's decision to supply Cerezyme directly, and not  
34 through HH or any other third party. In view of this there is no need for the Director to  
35 address Genzyme's representations." But this is exactly the abuse which they would  
36 have to succeed on in order to succeed on this sort of basis, that is that we had to  
37 supply them on that basis, at some ex-manufacturer's price.

38 Professor Yarrow, in bundle 37, CB22, page 192, is dealing with a point about

1 the location of the pharmacy in the vertical chain, because of the funny situation that  
2 one has the pharmacy in-house, as it were, in both cases.

3 Then at the bottom of 192: "One possible interpretation of the OFT decision is  
4 that it is seeking to create a new price in the vertical chain for just an embedded  
5 location. If that is the case, all I would say is (1) it is not what the direction says. Both  
6 the direction and the preceding analysis are notably silent concerning a locational  
7 definition of the various prices referred to", and that is a problem which any  
8 manufacturer is going to have to confront with. "The new price would be a wholesale  
9 price if that would relate to a transaction or depot level, prior to secondary distribution  
10 or delivery. There could then be a difference between an NHS list price ...supply  
11 locations ...and the wholesale price ...secondary distribution agreement, ancillary costs  
12 considered appropriate by the DSS.." that is the ex-manufacturer's point.

13 "Whilst it would at least be logical to seek the mandate to supply ... wholesaling  
14 price, the decision is quite explicit that this is not the intention", and then he quotes that  
15 paragraph. "Thus Genzyme's attempts to make sense of the rule set at nought".

16 So he is basically saying you could have looked at it this way, but they  
17 expressly and deliberately said that is not their case. Their case is "We are making the  
18 NHS pay" and neither the directions nor the abuse go to anything like these sort of  
19 directions.

20 So that is basically our answer, as it were, to the second point.

21 What I would like to do is rather skim through the other matters, and I do not  
22 intend to spend over long on these because it seems to me the matters we have dealt  
23 with are the important issues and that the other matters are very satisfactorily dealt with  
24 in our submissions.

25 THE PRESIDENT: Yes.

26 MR VAUGHAN: But you will see there are quite a lot of them, 11 I think, but I would just  
27 like to headline them.

28 One of our main complaints is about the flawed investigation and Mr Brownlee  
29 now has become a new target of our criticism in this - not him personally, but the way  
30 in which what he has said has been dealt with and the attempt not to produce his email  
31 on the basis of it is exactly the same, but it is not certainly not exactly the same at all,  
32 and very different.

33 The 2.40 is a perpetual course of our complaint, because that shows the width of  
34 the downstream market in particular, and those are the passages which we would ask  
35 you to read on that matter.

36 The flawed investigation is not just a technical flaw, it is something that goes to  
37 the very heart of these things: it is a "but for" situation. That is to say, if they had done  
38 it differently they could well have come to a different answer. That is not necessarily

1 to say they would have come, but they could well have come to a different answer. We  
2 say they are bound to have come to a different answer, as they have really begun to  
3 accept on the downstream market, even without investigating things properly.

4 On orphan drugs, we obviously place great reliance upon them. They say they  
5 are only relevant to market definition. We see the orphan drug issue as being relevant  
6 right throughout the case. We place great stress on it from Mr. Termeer to Mr.  
7 Tamboyzer right through the whole case. It is just not right to say it is only relevant to  
8 market definition. If they had looked at it properly, they would have seen that. There  
9 is virtually no reference at all in the decision to the orphan drug point.

10 It affects not only the market, which obviously we say it does or has relevance  
11 to the market: it affects the abuse, it affects the dominance and it affects the objective  
12 justification, the directions and any penalty that might be imposed.

13 So we say that orphan drugs permeates this whole case and is a fundamental  
14 defect of the whole case, but they have not appreciated this at any stage.

15 Orphan drugs also is important because, although Cerezyme is a quasi-orphan  
16 drug the others are and will be genuine orphan drugs for which we will get a total ten  
17 year monopoly and it is a matter of the gravest concern to us, as Mr. Tamboyzer  
18 expressed as the chairman of, basically, the orphan drug organisation in Europe, real  
19 concerns about European development in this matter. Nobody has suggested that he  
20 was wrong about these matters.

21 If competition law is going to take away or shackle or inhibit the orphan drug  
22 producer on price or on distribution, then it is going to create a real problem. Each  
23 individual orphan drug in the first period under pharmaco-vigilance will have a higher  
24 duty to ensure that - there is clearly going to come a time when it gets out of that  
25 situation when there is still a reporting situation but still not quite so important. But it  
26 is an area and therefore, because it creates an intellectual property right or a stronger  
27 than intellectual property right because it is more than a patent, it is a total monopoly  
28 and once TKT produced the Hurler system in Europe, the treatment - the Hunter one -  
29 then nobody else can produce a Hunter treatment however they do it, unless it is a  
30 completely different make-up or it is a significantly better product. So it is miles better  
31 than the patent, it is a total monopoly: it is like Queen Elizabeth's Statute of  
32 Monopolies in the old days.

33 If as soon as you have got an orphan drug and got permission and got that  
34 protection you were immediately shackled with the obligations of a dominant  
35 undertaking, then we would consider that there are grave dangers which anyone has got  
36 to think about. Applying the Oscar Brunner tests, this becomes an added factor in  
37 suggesting reticence and exceptional circumstances rather than just applying it as yet  
38 another drug, which is what they approach this case as being. They did not accept we

1 had any special significance as an orphan drug.

2 There is a lot of our evidence concerning the upstream market and how progress  
3 in one is progress in another. So looking supply side these products are all very closely  
4 inter-related. Genzyme made the breakthrough in Gaucher, but one will see from the  
5 documents the reason why Gaucher was targeted was there were more people than  
6 others. But, equally, it was because the breakthrough happened there. We were  
7 working in many of the other products at the same time and that was where the  
8 breakthrough happened. Brian Burkeman happened to be suffering from that disease,  
9 but he could well have been suffering from any other the others.

10 Without wishing to be too dramatic, some of these are left-threatening diseases,  
11 and certainly life quality threatening diseases; a lot of them kill children at a very early  
12 age and we are effectively providing treatment for something for which there is no cure  
13 at all. It enables a lot of people to live a reasonable live who otherwise would not be  
14 able to lead a reasonable life. It means that a lot of people live who might otherwise  
15 die, but a lot of people have a much better life.

16 So from the supply side these require very special treatment and one is looking  
17 at markets and then on through abuse and through the other things in that way.

18 The R&D, obviously, is massive in these cases. We built the factory before we  
19 had even got permission to produce the drug in Boston and the whole thing is a massive  
20 exercise in entrepreneurial ability and confidence in the skills of the scientists and the  
21 ability to translate what were 15 years of failure into a very successful product and  
22 other people are desperately keen to get into these market. If it had not been for us,  
23 nobody else would be wanting to get into these markets, so the supply side here is an  
24 extremely important thing. Obviously, Genzyme has made a lot of money out of  
25 Cerezyme, but on the other side it has lost a lot of money in other things and the idea  
26 that the first mover has this great advantage, which the OFT make without any  
27 explanation at all - there is no basis for that. What happens is the first mover is  
28 Christopher Columbus, who finds America, and that became a target for everyone else.

29 Christopher Columbus did not have any great advantage of that: it is all the successors  
30 who went and took advantage of his discovery. It is very similar. We have done very  
31 well out of this product, but it does not mean that we have any inherent advantage,  
32 expect for the advantage of it being an orphan drug.

33 Item 60, markets generally, upstream market. Those are the references; we  
34 have dealt with that to a great extent. The downstream market - those are the  
35 references from where we have dealt with those.

36 The expert economic evidence, if I can take that first. You have got - and I ask  
37 you to accept - Professor Yarrow's evidence. It is a very distinguished piece of work.  
38 It is the only economic evidence before you and we say it is entirely convincing.

1           On the pharmaceutical evidence, the same, we say, for Mr. Williams. Again, a  
2 very considerable expert on the financial side of the pharmaceutical world and nobody  
3 has gainsaid him. Indeed, Professor Yarrow is also very distinguished in the  
4 pharmaceutical world. Both those witnesses are very substantially supported now by  
5 what we see from what Mr. Brownlee was saying. Previously they were saying, "He is  
6 not wrong, but he doesn't go further, which he should have done". In fact, we see that  
7 he did go further, but we were not allowed to see that.

8           The drug tariff price and the PPRS. I think I have dealt with that sufficiently. It  
9 ties in with

10 Mr. Brownlee on that matter.

11           The meetings on 13th February 2001. You have seen all the documents and we  
12 are extremely unhappy about the letter of Mr. Carroll and if possible we would like to  
13 know before the close what my friend intends to do about Mr. Carroll, whether he  
14 wants to put in that letter and, if so, how we are going to be able to question him, which  
15 certainly we would want to do if he wants to pursue that letter.

16           One of the interesting things we know is that  
17 Mr. Johnson says there was a Dr. Doyle at the NESACAG who knew all about the  
18 position of Genzyme and who was not at the meeting of 13th February. It is interesting  
19 to see that Miss Stallibrass refers to this annex 7 item, file  
20 47 ----

21 MR. ROBERTSON: It is file 47, tab 2, and there are exhibits at tab 3.

22 MR. VAUGHAN: Thank you. In tab 7, which is page 5 of tab 3 - the page is at the bottom  
23 right-hand corner, handwritten.

24 THE PRESIDENT: Yes.

25 MR. VAUGHAN: "NESACAG, restricted policy and not for distribution." It is interesting  
26 because it does show that NESACAG was very interested in Cerezyme and not that it  
27 was a matter outside their control at all - and the system of distribution about it,  
28 because Mr. Carroll says that it was of no particular interest to them at all. But the  
29 significant thing is, we have been told now - we asked who was at that meeting - Dr.  
30 Doyle was at the meeting. Mr. Johnson knows all about it and has been told all about it.

31           If one looks in that same tab, there are  
32 Mr. Carroll's notes.

33 THE PRESIDENT: The manuscript notes.

34 MR. VAUGHAN: The manuscript notes. It is suggested there are only a couple of points  
35 made about that. It is page JS2, page 2. It is suggested that there is almost nothing  
36 about Ceredase/Cerezyme in that, but if we look through that that is far from correct. If  
37 Mr. Carroll was here, we would be putting points to him because virtually the whole of  
38 the first page relates to Cerezyme and then it went on to deal with - and a bit over the

1 top - with Fabry and Fabrazyme. The idea that this meeting was just to discuss  
2 Fabrazyme is just not right and it may be sensible if we put in a witness statement  
3 telling you what we say - a marked up one.

4 I think probably you would rather have a witness statement, rather than me  
5 trying to tell you whether that is square with (iv) to the bottom - as to what that relates I  
6 do not know.

7 THE PRESIDENT: It is a bit difficult to read this document.

8 MR. VAUGHAN: That is right and what we might try and do - if Mr. Carroll was here I  
9 could question him. If not, we will put in a witness statements which tries to  
10 transliterate ----

11 THE PRESIDENT: I think it is clear from the evidence that we have got that Gaucher's  
12 disease and the position of Genzyme was one important subject discussed at this  
13 meeting.

14 MR. VAUGHAN: That is right, yes.

15 THE PRESIDENT: It emerges clearly from agenda item 7 that the committee had quite a bit  
16 of information about what was going on and it is clear from Dr. Carroll's note that there  
17 was discussion of Genzyme because it does appear, as far as we can work out, that  
18 most of the first page is actually related to Genzyme.

19 MR. VAUGHAN: That is exactly what we would have been saying.

20 THE PRESIDENT: Whether we actually need any evidence going any further than that I  
21 rather doubt.

22 MR. VAUGHAN: We are perfectly content with that.

23 THE PRESIDENT: If that is the right inference to draw and no doubt we will be told if it is  
24 not the right inference to draw.

25 MR. VAUGHAN: We entirely accept they did not have power to forbid us to do things, but,  
26 equally, they had power to raise they eyebrows and to express concern, as Mr. Malcolm  
27 Johnson says - if they had said, "You can't do that", as we were still in a contractual  
28 relationship with Healthcare at Home, we would have thought again about what to do  
29 about the situation, and nobody suggests that  
30 Mr. Johnson is wrong about that.

31 If we go back to the skeleton at 65 - I am nearly finished - the powers of the  
32 DoH. You have seen an abundant amount of that in the EL(95) documents; you have  
33 seen it in the MMC report; you have seen it both sides. Basically our contention is that  
34 they have got much more power than the OFT seem to suggest. They have got power  
35 to deal with these things and, indeed, in EL(95) there was not an invitation which could  
36 be accepted or rejected by anyone. Then, obviously, Mr. Brownlee's e-mail adds great  
37 confidence to us about this matter, because clear the DoH, if they thought something  
38 was wrong, Mr. Brownlee or somebody in his team would have intimated that to us at

1 some stage, and nobody ever has done that from the health side at all.  
2 Abuse and objective justification. You would not be surprised to know that  
3 there is a lot about that.  
4 The last thing is penalty. Obviously, I do not want to spend time on that  
5 because we say there is no basis for the case at all, but, with great respect, one must not  
6 forget that there is that issue in this case and basically our contention is, even if one got  
7 down to that area the penalty is ludicrous. They admit they did not take into account  
8 any of the orphan drug things; they seem to accept now that they got the markets  
9 wrong; they did not produce various matters; they have taken wholly inconsistent  
10 positions throughout the last two years and wholly irreconcilable positions in that time  
11 and it is very difficult to see at what stage, if we should have changed, we should have  
12 done so. Given the previous inconsistent position, we would say that even if we got to  
13 that situation it is clearly not a case for any penalty at all. But we have dealt with our  
14 stage one, stage two, stage three and stage four points in our notice of appeal and I do  
15 not want to spend time on that now.  
16 Unless you have got any points, you, the Tribunal, it is three minutes past four  
17 and I have got through what I was planning to get through.  
18 THE PRESIDENT: Thank you, Mr. Vaughan. No, thank you very much, Mr. Vaughan.  
19 THE PRESIDENT: Yes, Mr. Thompson? I think we need an explanation for these e-mails, if  
20 we may, please.  
21 MR. THOMPSON: What the position is in relation to the e-mails? Yes, certainly, I am very  
22 happy to deal with that. I have given you already this morning the position in relation to  
23 the historical ----  
24 THE PRESIDENT: I think it is probably useful to take us through the chronology again.  
25 MR. THOMPSON: Go to the core bundle number 1, which is now bundle 37. It is CB31.  
26 You will see at page 321 there is an e-mail from Anne Pope, who is the primary case  
27 officer in this case along with Mitani Arikistan, who is copied in at the bottom here.  
28 You will see an e-mail to Mr. Kullman dated 27th November 2002. If we then take the  
29 bundle of documents that were handed up by Mr. Vaughan this morning, you will see on  
30 the fourth, fifth and sixth pages the exchange of e-mails that Mr. Vaughan has raised  
31 with the Tribunal this morning.  
32 THE PRESIDENT: Yes.  
33 MR. THOMPSON: If you turn to the back of them, you will find it starts with an e-mail from  
34 Mr. Kullman dated 11th December 2002. I may be wrong, but I think the timing - it says  
35 at the top of the e-mail - 12.29.  
36 THE PRESIDENT: That is back to Mrs. Pope.  
37 MR. THOMPSON: If you take that in juxtaposition with the e-mail dated 27th November  
38 2002, you will see that point 1 is the same question.

1 THE PRESIDENT: That is the reply to Mrs. Pope's question.  
2 MR. THOMPSON: So she had asked a question at the end of November, to which she  
3 received an answer under point 1 and then at point 2 you will see again the question and  
4 you will see that in Mrs. Pope's version there is underlining.  
5 THE PRESIDENT: When you say "Mrs. Pope's version" --?  
6 MR. THOMPSON: The original e-mail at page 321 says, "The NHS list price also covers de  
7 facto the costs of delivering the medicine to the patient" - underlined.  
8 THE PRESIDENT: Yes.  
9 MR. THOMPSON: And then you will see that in the e-mail from Mr. Kullman the same  
10 sentence appears but the underlining has disappeared, presumably just for technical  
11 reasons. Then the answer comes, "I am not aware that the NHS list price is defined, but  
12 would not disagree with the above statement", then, "I am out of the office for the next  
13 few days, but can you contact Mike Brownlee in my absence." So that is how Mr.  
14 Brownlee became involved in this exchange, which was originally between Mrs. Pope  
15 and  
16 Mr. Kullman.  
17 MR. VAUGHAN: So he agrees with us.  
18 THE PRESIDENT: Let us establish the chronology at the moment. Then what happens?  
19 MR. THOMPSON: Then there is a further e-mail of the same date and - it is difficult, but it  
20 looks like the timing was one minute to four.  
21 THE PRESIDENT: At 15:59.  
22 MR. THOMPSON: On the same date.  
23 THE PRESIDENT: This is now Mrs. Pope to Mrs. Brownlee, still 11th December,  
24 apparently.  
25 MR. THOMPSON: Seeking clarification of a point raised in  
26 Mr. Kullman's e-mail and then it is obviously being discussed on the telephone between  
27 Mrs. Pope and  
28 Mr. Brownlee.  
29 THE PRESIDENT: Yes.  
30 MR. THOMPSON: To which the response is then given by e-mail by Mr. Brownlee at 4.28  
31 on 11th December.  
32 THE PRESIDENT: Then it is Brownlee-Pope and that is still 11th December, but now this  
33 time the date has got reversed, US style; is that right?  
34 MR. THOMPSON: Yes. That seems to be an anomaly of  
35 Mr. Brownlee's e-mail system. It does not seem to be the same on Mr. Kullman's or  
36 indeed on Mr. Brownlee's ----  
37 THE PRESIDENT: Maybe it is just a typo or something.  
38 MR. THOMPSON: It is an anomaly.

1 THE PRESIDENT: At any rate, she asks the question at 15:59 and he seems to reply at 4.28.

2 MR. THOMPSON: Yes.

3 THE PRESIDENT: He is not on a 24 hour clock for some reason.

4 MR. THOMPSON: I do not know why that is, but one possibility would be at least for those  
5 people are entitled to see this these documents could be put together with the documents  
6 at tab CB21 in that they are effectively the intermediary e-mails between the first e-mail  
7 from

8 Mrs. Pope and the final e-mail that appears at page 322.

9 THE PRESIDENT: That is the following day.

10 MR. THOMPSON: It is, I think, two days later, on 13th December at 2.57.

11 THE PRESIDENT: I am not quite clear how this last e-mail comes into existence at the  
12 moment; what is this in answer to?

13 MR. THOMPSON: I cannot help you on that question. So far as I can see and so far as I am  
14 aware, that is a free-standing e-mail. The reason, as I understand it, was that, given the  
15 significance of the issue, the OFT wanted a formal statement of the Department's  
16 position that could be used publicly rather than simply internal exchanges and this was  
17 the formal answer that was produced by the Department of Health.

18 THE PRESIDENT: So at some point between 4.28 on 11th December and 14:57 on 13th  
19 December somebody prepared a statement in this form with these words.

20 MR. THOMPSON: Yes, and obviously it would be pure speculation on my part but I would  
21 assume that it was Mr. Kullman and Mr. Brownlee, but how it apportioned the  
22 responsibility and whether anyone else at DoH was involved I do not know.

23 THE PRESIDENT: Very well.

24 MR. THOMPSON: Given the position whether or not a compromise or temporary position  
25 on confidentiality, I would not propose to go into the details of the contents of the two e-  
26 mails. I think it is the last one from Mr. Brownlee that Mr. Vaughan refers the Tribunal  
27 to and he draws certain inferences. The only thing I would say is that the contents of the  
28 e-mail are, in our submission, not materially different from the contents of the final  
29 answer and I would draw the Tribunal's attention in particular to the penultimate  
30 paragraph on page 323 and, in particular, the last sentence of that paragraph, which  
31 states: "If a company's distribution costs are high, for example as a result of including  
32 the cost of delivery to the patient, the level allowed might be restricted and might result  
33 in excess profits being repaid."

34 As I understand it, the relatively qualified form used there reflects caution on  
35 the part of the Department of Health in an area where issues of sensitivity clearly arise in  
36 relation to the public purse and where the Department of Health is reluctant to make its  
37 policies public in advance in areas which have not arisen and where the policy would be  
38 made up, as it were, on the hoof and on a theoretical basis. I have seen many judges take

1 exactly the same position where difficult points of law arise that do not require to be  
2 resolved in a case. As I understand it, Mr. Brownlee was taking a similar stance.

3 In terms of what should be done with these documents now, the OFT's position  
4 is that they are well within the scope of its discretionary policy under its own guidelines  
5 as internal documents in the sense understood by the OFT of exchanges between the  
6 Office of Fair Trading and Government departments undertaken for the purposes of  
7 informing itself properly on the matters under investigation.

8 THE PRESIDENT: Where are those guidelines?

9 MR. THOMPSON: They are in the Director's rules. It is Rule 30(1)(f) and 14(6). I should  
10 explain that the reason why the Office of Fair Trading has not taken its stand on this  
11 point here is because the matter has arisen in quite exceptional circumstances where the  
12 Office of Fair Trading, through its legal officers, had given an answer back in April or  
13 May which turned out to be materially incorrect in that we had assured Genzyme that  
14 there were no other documentary records from Mr. Brownlee, whereas on an  
15 investigation made - I cannot remember if it was at the end of last week or the beginning  
16 of this week - it turned out that that was not in fact true and these e-mails in fact existed.

17 In those circumstances and also in the circumstances that Mr. Brownlee was in fact,  
18 perhaps coincidentally, going to give evidence on Friday, it appeared to us, in all the  
19 circumstances, both that we should make the thing public to Genzyme and if the  
20 Tribunal thought it appropriate and Genzyme sought to pursue it, we on behalf of the  
21 OFT do not actively resist the making available of the documents. In fact, we do not  
22 resist it at all.

23 The only reason why we are so tentative, as we are, is that this is a matter of  
24 considerable sensitivity to the Department of Health that it should not be prejudiced in  
25 its relationships with the industry by any perception, whether or not accurate - and we  
26 would say clearly inaccurate - that it has an inappropriately close relationship with the  
27 Office of Fair Trading. That is also a matter of sensitivity for the Office of Fair Trading  
28 in that it seeks to investigate across the board, including in sensitive areas of public  
29 policy, and it wishes to be able to inform itself properly with other Government  
30 departments of the policy and factual issues that arise; and, clearly, it is a matter of  
31 concern if its ability to do so is compromised by the fact that other departments may be  
32 reluctant to co-operate on the basis that their policies will become public in this way.

33 So that is our policy stance and if the Tribunal was to make any general  
34 findings about what the OFT's policy should be in this area on the basis of this rather  
35 exceptional set of circumstances that would be a matter of considerable concern to the  
36 OFT and we would wish to make further representations. However, that is the position  
37 as it stands in relation to this matter as of now. I hope that is helpful.

38 THE PRESIDENT: Thank you, Mr. Thompson. I think, first of all, it was extremely proper

1 for these documents to be disclosed, albeit at this stage, and the Tribunal is grateful for  
2 it.

3 I think what is of concern at the moment - I just make the point now and we can  
4 deal with it in the morning if we need to - is that in this particular decision the Director  
5 has relied very heavily on Mr. Brownlee's evidence. I am looking particularly at  
6 paragraph 82 of the decision: "The Director considers the head of the PPRS a very  
7 reliable expert on matters related to the NHS list price and the PPRS" and later in that  
8 paragraph: "The Director considers the evidence given by the head of the PPRS -  
9 through his work, he is intimately familiar with the workings of the NHS list price -  
10 more reliable than any other evidence put to him on this matter."

11 So we are in a rather special situation where the Office of Fair Trading is not  
12 just getting information from the Department of Health but is actually relying very  
13 heavily on what it is being told by the head of the PPRS.

14 At paragraph 83, on the basis of Mr. Brownlee's evidence, the Director arrives  
15 at a conclusion: "The Director therefore concludes that the NHS list price intended to  
16 cover the cost to the manufacturer of producing the drug and the cost of the wholesale  
17 delivery of the drug to the pharmacy plus a reasonable profit on these activities.  
18 However, it is not intended to cover the cost of delivering the drug from the pharmacy to  
19 the patient's home."

20 What is at the moment of some concern to the Tribunal is that that statement  
21 appears to be a somewhat definitive statement, but in the e-mails now disclosed, one of  
22 which is from Mr. Brownlee - that of the 11th December at 428 - he does say, "We have  
23 not had to consider a case where medicine is delivered to a patient's home and I am not  
24 prepared to say that in no case would we accept this." Later on, at the end, he says: "In  
25 the absence of a specific example, therefore, I am not prepared to say there are no  
26 circumstances in which we would allow some at least of home delivery costs."

27 Mr. Kullman in the earlier e-mail in reply to  
28 Mrs. Pope's original questions says he does not disagree with the statement that the NHS  
29 list price covers de facto the cost of delivering the medicine to the patient, from which  
30 one might have been able to draw the conclusion that the situation as regards home  
31 delivery is a little less clear cut than paragraph 83 of the decision might suggest.

32 MR. THOMPSON: I was only standing up to gently remind the Tribunal of the position in  
33 terms of confidentiality, because I have been prompted to do so, but that is a matter for  
34 you and obviously what has been said has been said.

35 THE PRESIDENT: Yes. I am sorry if it has been said, but that is the situation we are in. It is  
36 very difficult to discuss the situation without going into it at least to some extent, but we  
37 are fairly clear that it is going to be very difficult to maintain confidentiality for this sort  
38 of evidence bearing directly on a conclusion that the Director has reached in the case.

1 MR. THOMPSON: The only thing that I would add - and it is a point that occurred to Mr.  
2 Turner as well - is that  
3 Mr. Vaughan is, if I may say so, placing a very large amount of egg into the pudding in  
4 that you will recall that Mr. Brownlee has given not only one statement but two  
5 statements.

6 THE PRESIDENT: Yes, but what we are considering at the moment is not what Mr.  
7 Brownlee has now said but what could or should have been done during the  
8 administrative procedure and the question is, what sort of disclosure is necessary during  
9 the administrative procedure to enable the company to defend itself? That is what I  
10 would have thought.

11 MR. THOMPSON: There is an issue as to procedure, but there is also, in my submission, at  
12 this stage the more substantive question as to whether or not the finding of the Office of  
13 Fair Trading on the basis of Mr. Brownlee's evidence was soundly based.

14 THE PRESIDENT: Yes.

15 MR. THOMPSON: That is a matter that was obviously roundly criticised by Professor  
16 Yarrow in the evidence accompanying the notice of appeal and the notice of appeal  
17 itself. It was dealt with directly by Mr. Brownlee in his statement, in particular at  
18 paragraph 22, and then when the issue was raised both by Professor Yarrow in his  
19 second statement and in the reply on this very issue it was then addressed again by Mr.  
20 Brownlee.

21 THE PRESIDENT: Yes.

22 MR. THOMPSON: The Office of Fair Trading recognised that it had placed considerable  
23 reliance on Mr. Brownlee's evidence and therefore asked him - and he readily agreed - to  
24 give witness evidence, subject to cross-examination, in this case and, indeed, gave  
25 evidence on this very question and then it has been a matter pursued by Mr Vaughan,  
26 both in his pleadings and to date. So it is not as if he has discovered anything that he did  
27 not know already. He could have made comments, indeed has made comments, on this  
28 very issue in all his pleadings to date - first of all on the basis of Professor Yarrow's  
29 evidence, and now on the basis of two statements from Mr Brownlee. So it is not clear to  
30 me now why he is saying that this is such a key point. It is no more of a key point than it  
31 was when he served his pleadings and his evidence before. He was saying that we  
32 misunderstood what Mr Brownlee was saying and he has relied on Mr Brownlee's  
33 witness evidence to say that.

34 I accept there is the procedural point that you are putting to me, but I am not  
35 sure where it goes to given that we now have detailed evidence from Mr Brownlee and  
36 he will be here tomorrow to speak for himself.

37 THE PRESIDENT: Well I think we had probably better wait until we have heard from Mr  
38 Brownlee and then see where we are on all this. Mr Mather has a question.

1 MR MATHER: Mr Thompson, you said that an investigation at the end of last week, or the  
2 beginning of this week had led to the discovery of the email, and that this was perhaps  
3 coincidental with Mr Brownlee's appearance before us. Could you expand a little on that,  
4 what sort of investigation?

5 MR THOMPSON: What it was, it was an entirely coincidental issue. In relation to the  
6 NSCAG issue, there was a minute disclosed of a meeting with Mr Brownlee in, I think,  
7 June, 2001 and Taylor Vinters said that is strange, you said there was no documentary  
8 evidence from Mr Brownlee, and perhaps the then rather pedantic dispute broke out as to  
9 whether or not the minutes of a meeting with Mr Brownlee was documentary evidence  
10 from Mr Brownlee, but in order to satisfy ourselves of the situation we then asked for a  
11 double check on whether or not there were any documents from Mr Brownlee, at which  
12 point these documents emerged. It had nothing to do with the fact that Mr Brownlee was  
13 going to give evidence, it simply happened to arise at the same time.

14 MR MATHER: With respect to what you have just said a moment ago before my question,  
15 do you not feel that the email which has emerged is quite different in nature from the  
16 earlier evidence and places a number of matters in a different light, matters which had  
17 been perplexing the Tribunal?

18 MR THOMPSON: I do not think I would accept that. I accept that the tone is different,  
19 because it is much more of the tone of an informal exchange, but that reflects the nature  
20 of the exchange, and that is obviously a matter which is of concern to the Office of Fair  
21 Trading as to whether or not all its relationships with all other Government departments  
22 must be exclusively on a sort of arms' length formal basis, which is in my submission not  
23 very realistic in a modern and email world.

24 MR MATHER: Another way of putting my question is that your explanation of the  
25 sequence of events led me to the feeling that there had been an attempt to obscure or  
26 conceal the exact policy of the Department, perhaps for reasons of commercial  
27 negotiation.

28 MR THOMPSON: I do not think it was intended to obscure it. It was simply a matter, as I  
29 gave the analogy of a Judge not expressing a view on a matter which was not actually  
30 necessary for his decision. Mr Brownlee, in my submission quite properly, does not want  
31 to give public evidence about matters which have never actually crossed his desk.

32 MR MATHER: But there is not a problem in making the Departments policy public?

33 MR THOMPSON: In so far as there is one. You appreciate, like any other legal or  
34 administrative process, however detailed the rules are the event that happens tomorrow  
35 will be the very event which the rules say nothing about. Mr Brownlee was reluctant to  
36 speculate on a case of that kind.

37 THE PRESIDENT: I think the situation we have here, Mr Thompson, is not the situation of  
38 the OFT in regular contact with other Government Departments trying to rootle round

1 and find out what is going on.

2 The situation here is where, in a decision involving a massive penalty the OFT  
3 has relied directly on evidence from another department on the evidence of a particular  
4 individual, and the conclusions drawn by the Director from that evidence are quite  
5 material to the case and in terms of disclosure there appears to be at first sight, and  
6 maybe we will be reassured on this point tomorrow, at least some suggestion that the  
7 material that was actually in the Director's possession at the time he took the decision  
8 was much more equivocal on the point on which the evidence is relied on, than the  
9 decision might be thought to suggest. That is the point that we need to explore at some  
10 stage.

11 MR THOMPSON: I understand how it is put to me. The way I put it back to you is that  
12 frequently there will be drafts exchanged, it may be that when the Tribunal comes to  
13 write its Judgment drafts will be exchanged and then at the end a formal text will be  
14 approved, and that is the formal text.

15 MR MATHER: This was not a draft, Mr Thompson. The email we are talking about was not  
16 a draft, it was an actual email. It was a substantive answer to a question.

17 MR THOMPSON: All I am putting to the Tribunal is that the final version, which appears at  
18 pages 323-4 was a formal statement, and it was appropriate to refer to that rather than  
19 any - whether "draft" is the right word - any provisional views that led to that final  
20 statement.

21 MR MATHER: With respect it was not a provisional view either, was it, on the face of it, it  
22 was an answer to the question and that was changed later, and we have seen the changed  
23 version earlier, and we have not seen the original version.

24 MR THOMPSON: It may be that it is a matter that has to be pursued with Mr Brownlee, but  
25 as I understand it the reason why the OFT did not wish to refer to what I call the  
26 informal exchanges was because the DoH was co-operating on the basis that its views  
27 would be treated with a degree of confidentiality.

28 THE PRESIDENT: But how can a subject like what the list price of a drug in the Drug Tariff  
29 does or does not cover be a matter of confidentiality, it is an objective matter, is it not?  
30 Either it is clear what it does cover, or it is not clear, and if it is a question of crossing the  
31 bridge when we get to it and working out what we would do in a particular situation  
32 when that situation arose, which is perhaps one of the inferences to be drawn from some  
33 of these documents, the resulting inference is that we do not quite know what the NHS  
34 list price covers, because we have not thought about it yet.

35 MR THOMPSON: What I am resisting is the suggestion that it was improper in any way for  
36 the OFT to base its decision on the statement that was included after reflection, as it  
37 were, by Mr Brownlee, possibly with Mr Kullman, I don't know.

38 THE PRESIDENT: I do not think anyone is making any suggestions at the moment, Mr

1 Thompson, about whether anything is improper or not. At the moment the Tribunal is  
2 just trying to get to the bottom of what has transpired and in particular whether there is  
3 any validity in Mr Vaughan's suggestion that these internal views of Mr Brownlee ought  
4 to have been disclosed earlier in some way or another on the grounds that they do not  
5 entirely conform with what the decision actually says. That is the point. The analogy, I  
6 think, would be the duty of the prosecution to allow the defence to see statements that do  
7 not support the prosecution's case. But you might like to think about it overnight.

8 MR THOMPSON: Certainly, I am not sure I can take it much further, but I see exactly what  
9 the Tribunal is saying to me. There is obviously Mr Brownlee's position to be taken into  
10 account.

11 THE PRESIDENT: Yes.

12 MR THOMPSON: Could I just raise formally, on behalf of the Office of Fair Trading, in so  
13 far as you referred to these documents which are technically still under your order, that  
14 part of the transcript should be redacted, at least until this matter has been finally  
15 resolved.

16 THE PRESIDENT: Well I do not think there will be a transcript available tonight anyway,  
17 and that order only runs until tomorrow morning. What is apparent, I think to me from  
18 this discussion is that we are going to be quite unable to pursue this effectively with Mr  
19 Brownlee tomorrow unless these documents are available openly. I do not see any real  
20 way of maintaining confidentiality of these documents at the moment.

21 MR THOMPSON: I think it is a matter of the way in which the hearing, which is a matter I  
22 raised with the Tribunal on Monday, the issue with Mr Brownlee is dealt with anyway,  
23 and of course this now raises it in a novel and acute form.

24 THE PRESIDENT: You are welcome to think about it overnight but I think at least at first  
25 sight, the Tribunal would not be particularly sympathetic to an application to clear the  
26 court in order to hear this evidence in camera.

27 MR THOMPSON: I have not spoken to Mr Brownlee, and I will obviously speak to him as  
28 soon as I can.

29 THE PRESIDENT: I would like you to say to Mr Brownlee, if you would, that as far as the  
30 Tribunal is concerned, we are investigating matters under the Competition Act, 1998.  
31 We are only in a very subsidiary way investigating the workings of the PPRS. We are  
32 not investigating how the PPRS might work in particular hypothetical circumstances,  
33 nor are we trying to arrive at any view as to how the DoH thinks the PPRS works in a  
34 way that might bind the DoH in other cases that have not yet arisen or have not yet  
35 crystallised. Moreover, we are only looking at the events of 1999 so far as they are  
36 relevant to this case, and not in so far as the correctness or otherwise of the steps then  
37 taken vis a vis the PPRS were correct. I think there could be a certain degree of over  
38 sensitivity in this matter from the DoH point of view, for the reasons I have just given.

1 MR THOMPSON: I think the only point is that the DoH is plainly reluctant to speculate on  
2 matters which are not concrete, and therefore I anticipate that Mr Brownlee will have the  
3 same reluctance to do that tomorrow, as he has shown hitherto.

4 THE PRESIDENT: Well I think there are two stages in Mr Brownlee's evidence, as I  
5 indicated earlier this week. We first need to reassure ourselves that we have a basic  
6 understanding of how the system works, and the relationship between all its various bits  
7 are - it will probably turn out not to be controversial but we can see for ourselves what  
8 the situation is. Secondly, to understand the strength, from Mr Brownlee's point of view,  
9 of the conclusion that the Director draws in the decision and if Mr Brownlee says "I  
10 would rather not speculate on that hypothesis" well he would rather not speculate, that is  
11 his answer. I am not going to force him to take a position on something he does not want  
12 to take a position on. Does that help you at all?

13 MR THOMPSON: Well, I hope it will help Mr Brownlee.

14 THE PRESIDENT: Yes, I will explain that all to him tomorrow when we get him here,  
15 obviously. It is probably better now to leave it where it is and see how we get on  
16 tomorrow.

17 MR VAUGHAN: I do not want to reopen this, my friend said that I was only concerned  
18 about Mr Brownlee's latest email, I am certainly very concerned by the fact that Mr  
19 Kullman, the point you pointed out, is the only person who ---

20 THE PRESIDENT: Just say it in code for the moment, I know I said it a moment ago, but it  
21 happened.

22 MR VAUGHAN: The only person who definitively deals with the list price point is Mr  
23 Kullman, who unequivocally supports us. So my friend must not think he has only to  
24 deal with Mr Brownlee's one, and nobody gainsays Mr Kullman, if one looks through in  
25 detail. Mr Brownlee carefully avoids coming down on that issue, probably sensibly,  
26 because it is not his view.

27 THE PRESIDENT: How do you see things unfolding tomorrow, Mr Vaughan.

28 MR VAUGHAN: I have unfolded!

29 THE PRESIDENT: Unfolded or folded as the case may be. Mr Brownlee is very kindly  
30 coming tomorrow, for which we are very grateful. Do the parties feel that they wish to  
31 ask him some questions first, or do you wish the Tribunal to ask him the questions the  
32 Tribunal wants to ask, or how would you like to proceed.

33 MR VAUGHAN: I think if you ask your questions and then we would ask supplementaries,  
34 as it were, not by way of cross-examination but sort of elucidation. I think it is merely  
35 clarification that one is looking for. Then there is obviously Mr Farrell and then there is  
36 the question of Dr Carroll, whether my friend is going to put forward that letter as being  
37 part of the case.

38 THE PRESIDENT: Well, I have given you an indication at the moment what we think the

1 situation is regarding that meeting, and I venture to suggest that it is unlikely we shall  
2 want to go into much more detail about it.

3 MR VAUGHAN: Thank you.

4 THE PRESIDENT: Very well, 10.30 tomorrow.

5 MR VAUGHAN: Thank you very much indeed.

6 (Adjourned until 10.30 am the following day)

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