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IN THE COMPETITION APPEAL TRIBUNAL Case No. 1013/1/1/03 (IR)

New Court
48 Carey Street
London WC2A 2JT

Wednesday 16 April 2003

The President
SIR CHRISTOPHER BELLAMY QC
(Chairman)

B E T W E E N:

GENZYME LIMITED

Applicant

- and -

THE DIRECTOR GENERAL OF FAIR TRADING Respondent

MR DAVID VAUGHAN QC and MR AIDAN ROBERTSON appeared on behalf of the Applicant.

MR JON TURNER (instructed by the Director of Legal Services, Office of Fair Trading) appeared for the Respondent.

MR BEN TIDSWELL (instructed by Messrs Ashursts) appeared on behalf of the Intervener.

P R O C E E D I N G S
(in open court)

Transcribed from the shorthand notes of
Harry Counsell & Co.
Cliffords Inn, Fetter Lane, London EC4A 1LD
Telephone 020 7269 0370

1 THE CHAIRMAN: Good afternoon, ladies and gentlemen.

2 Mr Vaughan, I think before I give you the floor, if
3 I may, I think it might be useful if I just explain how
4 far I have got in getting into this case, make one or
5 two preliminary observations and then ask one or two
6 questions of clarification just to set the scene for
7 the submissions you are about to make.

8 First of all, could I say that I am very grateful
9 for the cooperation the parties have so far shown, in
10 particular on the issue of confidentiality. I know
11 that to some extent it is quite a difficult issue. We
12 just have to do the best we can in the situation that
13 we are in.

14 Could I remind everybody that we are sitting in
15 Open Court at the moment and that if we do need to go
16 into camera for any reason then an application will
17 need to be made.

18 It is also clear that everyone has been working
19 under very great pressure and if people need more time
20 then please let me know.

21 I think I can usefully tell you so far where I have
22 got to in the papers before we discuss matters of
23 clarification and indeed the timetable for the main
24 appeal, which I think is going to be quite relevant to
25 this afternoon.

26 What I have so far read in outline only is the
27 Decision, Genzyme's application for interim relief of 3
28 April 2003 but not necessarily all the supporting
29 documents, the OFT's opposition to that application
30 dated 11 April 2003, HH's request to intervene dated 11
31 April 2003 and Ashursts' letter of the same date,
32 Genzyme's observations on HH's request to intervene of
33 14 April and the OFT's observations on HH's request of
34 the same date, and Genzyme's response dated 15 April
35 2003. I have also skim-read the MMC report on the
36 Fresenius/Caremark merger, which seemed to me to be
37 quite an interesting background point of reference as a
38 way of getting into this case, but I would be very

1 grateful, if it becomes apparent that my understanding
2 is still incomplete, if people will signal to me
3 matters that I have omitted.

4 As a matter of general approach to applications of
5 this kind it seemed to me provisionally that there were
6 three things that the Tribunal would be likely to be
7 bearing in mind, subject to what the parties say.

8 The first is that, so far as possible, an applicant
9 should not be deprived of the fruits of a potentially
10 successful appeal by reason of a mandatory order that
11 takes effect before that appeal can be heard, so long
12 as there is a prospect of that appeal being successful.

13 That is the first point.

14 Secondly, the bringing of the appeal, and in that I
15 include the possibility of further appeals and/or a
16 reference to the ECJ, which was mentioned at one point
17 in the papers, should not automatically prevent the
18 decision taking effect from its original date if
19 ultimately the appeal is unsuccessful, ie whereas the
20 Act automatically postpones the payment of the penalty
21 until the appeal is determined, it is not necessarily
22 the same for a direction. It may well be appropriate
23 that the direction should take effect from its original
24 date in the event that the appeal is unsuccessful.

25 Thirdly, and perhaps in particular, in granting any
26 interim relief that may be appropriate, the Tribunal
27 should be concerned to safeguard in the interim the
28 competitive outcome which the decision envisages. By
29 that I mean more specifically, if HH were to go out of
30 business in the course of the appeal but the appeal
31 were to turn out to be unsuccessful, that could be
32 regarded as an unsatisfactory outcome from the point of
33 view of the competitive structure in the market and
34 competition in general.

35 I think it also right to add, in relation to each
36 of those three points, that the Tribunal is looking at
37 the matter from the objective point of view of the
38 preservation, or otherwise, of competition. The
39 private interests of the parties and any dispute there

1 may be between the parties is, at least at this stage,
2 a matter of subsidiary concern. The principal concern
3 is to protect, first of all, the integrity of the
4 appeal process and, secondly, the final outcome from
5 the point of view of competition.

6 Those are some preliminary indications, probably
7 more or less self-evident, that I have in mind at the
8 moment.

9 What I would like to do now, if you will permit me,
10 is to turn in particular to the OFT and Mr Turner to
11 ask one or two points of clarification as to how the
12 proposed directions are supposed to work.

13 I am sorry, Mr Turner, you may have had very little
14 time to change gear, as it were, and switch to this
15 matter, so please, if you need more time, do not
16 hesitate to ask for it.

17 MR TURNER: I have able assistance, Sir.

18 THE CHAIRMAN: I think for present purposes it does not
19 matter whether I work on the redacted version or the
20 unredacted version. I am on paragraph 396 of the
21 Decision, which is effectively the directions, and I am
22 on paragraph 2, which says in particular "In 15 working
23 days from the date of the Decision the price at which
24 Genzyme supplies Cerezyme and Ceredase to the National
25 Health Service shall be in respect of each drug a
26 standalone price for the drug only that is exclusive of
27 any homecare services that may be provided". And, (2)
28 "The price at which Genzyme supplies Cerezyme and
29 Ceredase to third parties shall be in respect of each
30 drug no higher than the standalone price for the drug
31 only, as agreed between Genzyme and the Department of
32 Health." Then there is a definition of homecare
33 services.

34 What I am not clear about at the moment is how the
35 OFT envisages this direction working. The wording of
36 paragraph 2.2 would seem to imply that a standalone
37 price for the drug is to be agreed between Genzyme and
38 the Department of Health.

39 The first question is, does the operation of this

1 direction imply some agreement being reached between
2 Genzyme and the Department of Health, and in this
3 respect what does one mean exactly by the Department of
4 Health? Is one considering the Central Purchasing
5 Authority? Is one considering the Local Health
6 Authorities who have to pay for it? Is one considering
7 various hospital trusts and, if so, which and different
8 ones, or what? That is the first question.

9 The second question is, under the system as it is
10 now, if these directions were to be implemented, what
11 is the precise machinery under which either Genzyme
12 Homecare or HH would be remunerated for any homecare
13 services? How do you see it working? Will the
14 consultant still write a prescription and, if so, on
15 what basis would the NHS or any bit of it reimburse
16 that subscription; on the basis of a contract or the
17 supply of services; and, if so, a contract that was
18 entered into after some tendering procedure, or on some
19 other basis? Or is somebody just going to present them
20 with a bill and hope that it is going to be paid, or
21 what? I want to try to understand what the machinery
22 of it all is.

23 What lies behind that question is my preliminary
24 reading of the Fresenius/Caremark case, which suggested
25 that there are in the pharmaceutical industry a number
26 of treatments, at the date of this report five, that
27 were provided in response to prescriptions, it being,
28 according to 1.4 and other references in the report,
29 understood by custom and practice that the prescription
30 included the cost of the equipment and other services,
31 whereas for some other drugs, following, I think,
32 EL95(5), the NHS refused to continue with that system
33 but insisted that there should be contracts between
34 Health Authorities for the provisions of the services
35 with relevant private sector providers or other
36 hospital trusts.

37 In the light of that background, how is a direction
38 of this kind intended to work?

39 MR TURNER: Sir, if I may begin by addressing the points

1 to the limits of my current knowledge and then I will
2 be assisted where I fall short and certainly prompted
3 where I go wrong.

4 THE CHAIRMAN: Yes.

5 MR TURNER: Taking your first question first in relation
6 to the standalone price.

7 The first place to look is paragraphs 393-394
8 directly above. I do not know if you have the
9 unredacted version of this?

10 THE CHAIRMAN: Yes.

11 MR TURNER: That makes clear that what is envisaged is an
12 unbundling of the inclusive price that was agreed
13 between Genzyme and the Department of Health, centrally
14 the PPRS branch in 1999 in relation to the PPRS period
15 1999 - 2004.

16 If you turn then to paragraphs 95 to 103. I do not
17 know, Sir, if you have had the opportunity to read
18 these paragraphs yet in detail?

19 THE CHAIRMAN: 95 - 103.

20 MR TURNER: What you will find there is a blow by blow
21 description of the process by which the existing
22 inclusive price of £2.975 per unit plus VAT was agreed
23 between Genzyme, on the one hand, and the PPRS branch
24 within the DoH, on the other hand.

25 What is envisaged by the direction is that, subject
26 to a renegotiation within the constraints of the PPRS
27 scheme (I am told that the prices are confidential) the
28 existing position should prevail but that there should
29 be the possibility of a similar renegotiation of the
30 standalone price as took place in 1999 and early 2000.

31 THE CHAIRMAN: How would such a renegotiation operate?

32 What meaning should one attach to the word "agreed" in
33 paragraph 396.22?

34 MR TURNER: I will certainly be corrected if I am wrong,
35 but as I understand it and recall from previous cases,
36 in particular Napp, there is the possibility for a
37 party in the position of Genzyme to propose that it
38 should be able to charge a different price for a
39 particular drug, such as, in this case, Cerezyme, but

1 that the effect of that upon the overall profit made by
2 the company, so far as relevant, needs to be considered
3 within the context of the PPRS which addresses that
4 overall position and that before a company which has
5 joined the PPRS, which is a voluntary scheme, may
6 change a price under the PPRS, it needs to have that
7 approved to ensure that it still falls within the rules
8 of the scheme overall.

9 THE CHAIRMAN: So your position is that under the direction
10 Genzyme should forthwith supply the Department of
11 Health with Cerezyme and possibly Ceredase at the
12 confidential price per unit that is set out in
13 paragraph 394 of the Decision which, according to you,
14 is the price which has already been agreed between the
15 DoH and Genzyme?

16 MR TURNER: Yes, and the detailed extracts from the
17 letters support that proposition.

18 THE CHAIRMAN: If that is so, from whom and by what
19 mechanism does Genzyme or HH effectively obtain
20 remuneration for the homecare services?

21 MR TURNER: As I understand it, Genzyme would be
22 remunerated separately for the homecare services by the
23 hospitals concerned.

24 THE CHAIRMAN: That is supplies to the hospitals, is it?

25 MR TURNER: The supplies would be made to the hospitals.
26 Were HH (Healthcare at Home) to obtain supplies of the
27 drug itself, those could either be dispensed, in which
28 case it would receive remuneration as a pharmacy, or
29 alternatively it could purchase those supplies of the
30 drug from the hospitals concerned, in which case it
31 would not be remunerated as though it had dispensed
32 them. A precursor for that is indicated, for example,
33 at paragraph 118 of the Decision.

34 THE CHAIRMAN: It could purchase them, but who is going to
35 reimburse Genzyme for its expenses? On the basis of
36 what set-up, if I may use a neutral word? The gap in
37 my knowledge is this, that at the moment, for whatever
38 reason, it does look at first sight as if the NHS list
39 price is the mechanism for reimbursing both the cost of

1 the drug and the cost of the services and if you take
2 away the cost of the services what is the substitute
3 mechanism you could put in its place for remunerating
4 HH? Is it a contract?

5 MR TURNER: Yes.

6 THE CHAIRMAN: And, if so, with whom and at what price?

7 MR TURNER: It would be a contract with the hospitals
8 concerned, who have the care of the relevant Gaucher
9 patients.

10 THE CHAIRMAN: Well the Decision says that the cost is
11 borne by the relevant health authorities. I do not know
12 whether that is the same as the hospitals or whether it
13 is something different. If the patient is living in an
14 area that is not within the immediate vicinity of the
15 hospital, whether it is a local health authority that
16 picks up the tab or somebody else, and whoever it is,
17 whether it is a matter of agreeing with the hospital or
18 the authority what they are going to pay and, if it is,
19 what procedures have to be followed by the hospital or
20 the authority in order to agree that price. Is there a
21 tendering procedure that has to be followed, is it a
22 price that depends on the service that is being
23 provided in the particular case, which may be full
24 nursing or hardly any nursing, or what is it?

25 MR TURNER: Sir, if I may, I will take instructions on
26 those detailed points. At the moment my understanding
27 is simply that there is undisputedly the possibility
28 for service agreed to be remunerated directly with some
29 entity, whether it be the hospital or the local trust.
30 I will take instructions. Sir, would you excuse me
31 for a moment. I will just confirm.

32 THE CHAIRMAN: Yes, of course, Mr Turner. Take your time.
33 If you want me to rise for a minute or two I am very
34 happy to do so.

35 MR TURNER: Well, Sir, it may be convenient. If I could
36 have five minutes perhaps to establish these points
37 with the client?

38 THE CHAIRMAN: Yes, of course. Let me know when you are
39 ready. While you are taking instructions, Mr Vaughan,

1 I am sure you are going to be able to tell me a bit
2 more about the timetable for the appeal.

3 MR VAUGHAN: Can I just tell you?

4 THE CHAIRMAN: Yes.

5 MR VAUGHAN: Obviously a lot of the last week has been
6 spent doing this.

7 THE CHAIRMAN: Yes. There has been heavy cannonading going
8 on in all directions.

9 MR VAUGHAN: Yes. We are confident that we can serve the
10 notice of appeal on 16 May. We have looked at that
11 very carefully. It involves abandoning all the Easter
12 holiday in order to achieve that, apart from Good
13 Friday, I suppose, effectively to do that. The plan is
14 that we have got various experts who will be giving
15 expert evidence on the PPRS and the Drug Tariff prices,
16 because a lot of our complaint, as you have seen, is
17 that the OFT do not really understand the system that
18 we are talking about.

19 THE CHAIRMAN: So there will be expert statements?

20 MR VAUGHAN: Yes, from various people who are experts in
21 this and from an economist who is a particular expert
22 on the PPRS and the Drug Tariff price and advises the
23 DoH on all of these matters.

24 We hope to get our first internal draft on Monday
25 28 April. We are spending that week talking about that
26 with our experts. Then our second draft on 6 May; all
27 of that week talking in terms of that and then what we
28 call the 'semi-final' draft on 12 May leading up to the
29 serving on either the Thursday or the Friday, 15 or 16
30 May. We cannot shorten that and also our clients are
31 in America so we need to consult. Indeed at the
32 hearing we had various experts coming from America to
33 deal with the particular problems of orphan drugs and
34 this high technology area that one is concerned with.
35 They will need to be consulted to see if the appeal
36 fits in with what they say. So basically we would
37 achieve that.

38 What we have indicated is that we hope that there
39 will be a hearing at the end of July. That is going to

1 | be a tight timetable, we appreciate that, but we are
2 | obviously keen to get on with it so that the matter is
3 | resolved.

4 | THE CHAIRMAN: If we might pursue this while we are on it.
5 | Have you any provisional view about the shape that
6 | that hearing could take? What I mean is, is the
7 | Tribunal to expect, first of all, interlocutory
8 | applications for discovery and matters of that kind?

9 | MR VAUGHAN: I do not think so, unless it is against
10 | Healthcare at Home.

11 | THE CHAIRMAN: Well, for example?

12 | MR VAUGHAN: Well against them there will be, but we have
13 | indicated to them what we expect to see already.

14 | THE CHAIRMAN: Because that is a further stage to build
15 | into the mental timetables one is constructing so far.

16 | MR VAUGHAN: They are already in and so their timetable
17 | would work from the date --

18 | THE CHAIRMAN: Yes, but if there is an application for
19 | disclosure and if that application is resisted, there
20 | would have to be a hearing on that at some point and
21 | that could lengthen the proceedings, depending on how
22 | complicated it was.

23 | MR VAUGHAN: I think what we would do is indicate to the
24 | existing intervener anyhow what documents we expect to
25 | see in their pleaded case, as it were, and indicate to
26 | them what we would expect to receive by way of
27 | documentation on that matter. Obviously if there is a
28 | dispute I think that could then be dealt with at a case
29 | management conference after the lodging of the
30 | application, so that there would not be a standalone
31 | application for discovery.

32 | THE CHAIRMAN: It just needs to be, as it were, built into
33 | one's mental framework?

34 | MR VAUGHAN: Absolutely. Obviously we are as keen as
35 | anyone to get it on.

36 | THE CHAIRMAN: If I may then ask you as far as the hearing
37 | itself is concerned (and I will come back to Mr Turner
38 | later) but do you at least envisage cross-examination
39 | taking place?

1 MR VAUGHAN: I think there would have to be, because our
2 experts, as far as I can see from initial discussions,
3 are saying that the OFT have just got completely wrong
4 the PPRS and particularly the Drug Tariff, and the
5 PPRS, in our case, is not really the heart of the
6 matter, it is the Drug Tariff that is the important
7 thing.

8 THE CHAIRMAN: When you say the Drug Tariff, do you mean
9 the NHS list price? Are those two terms
10 interchangeable?

11 MR VAUGHAN: Yes, the £2.97 price, which is a non-
12 confidential. It is in the published thing.

13 THE CHAIRMAN: The £2.97 price, yes.

14 MR VAUGHAN: Which is the price which the pharmacy is
15 reimbursed.

16 THE CHAIRMAN: The list price?

17 MR VAUGHAN: The list price which the pharmacy is
18 reimbursed by the State, putting it generally, without
19 going into detail about who it is. It is for that and
20 upon which the 2 per cent dispensing is calculated.

21 THE CHAIRMAN: Quite, I understand that. If there is, or
22 might be, cross-examination, though I think the
23 Tribunal would have to think about that at one of the
24 Case Management Conferences, what sort of length of
25 hearing does that mean we are looking at?

26 MR VAUGHAN: I think we would be looking at a two day
27 hearing realistically.

28 THE CHAIRMAN: A two day hearing. That is quite ambitious,
29 if there is going to be any cross-examination of any
30 sort of depth.

31 MR VAUGHAN: Basically the OFT would have to work out
32 whether they want to challenge.

33 THE CHAIRMAN: They would have to work out whether they
34 want to challenge, but is there anybody that you are
35 likely to want to cross-examine - or perhaps you have
36 not got as far as thinking about that?

37 MR VAUGHAN: We have thought about it, but we have not got
38 a position. Potentially there are one or two people
39 but I am not sure. We would make an application when

1 appropriate. But there would not be extensive cross-
2 examination. It is not, as it were, you say black but
3 it is white. If there was cross-examination it would
4 be on shades rather than anything else. But I think
5 there might be some on HH, on Mr Walsh. There may be
6 cross-examination of him, because basically all their
7 written documents support us on downstream market
8 definition. We may not have to cross-examine.

9 THE CHAIRMAN: Well if you can get what you need from the
10 documents, you may not need to ask Mr Walsh "Isn't that
11 what you wrote on" whatever it is?

12 MR VAUGHAN: Yes.

13 THE CHAIRMAN: We will just see how it goes.

14 MR VAUGHAN: Obviously we are well aware of the Tribunal's
15 attitude and the need for resonance in what we ask.

16 THE CHAIRMAN: Yes, but on the other hand if it is
17 essential we will permit it, obviously.

18 MR VAUGHAN: The hearing before the OFT took one day with
19 about five witnesses, presentations, as it were, but
20 the presentations won't be necessary from your point of
21 view because you will have the presentations as read.
22 We will put forward the presentations as witness
23 statements and then the OFT can decide whether to
24 cross-examine. They were not questioned at all at the
25 hearing.

26 THE CHAIRMAN: On that timetable, if we manage to get to a
27 hearing at the end of July, it is unlikely that there
28 would be a judgment before the end of September.

29 MR VAUGHAN: Absolutely.

30 THE CHAIRMAN: So we are probably looking at a five or six
31 months time span from today. The question I think is,
32 what is the best way of dealing with the three points
33 that I made at the outset in the context of a possible
34 six month timetable at this stage of the appeal,
35 leaving aside any further stages there may be after
36 that.

37 MR VAUGHAN: My impression is that on the first point the
38 difference is not as great as it would seem to suggest
39 from the skeleton.

1 THE CHAIRMAN: We are going to get on to this shortly. I
2 will now give Mr Turner a chance to deal with the
3 questions I have asked. I will now rise for, let us
4 say, ten minutes or so. Let me know when you are ready
5 and I think we can then focus on what we should do
6 next, if we may.

7 MR VAUGHAN: Yes.

8 **(Adjourned from 3.05 pm until 3.20 pm)**

9 THE CHAIRMAN: Yes, Mr Turner.

10 MR TURNER: Sir, I am obliged for that indulgence.

11 The position in relation to your second question,
12 so far as I have been able to gather is, as paragraph
13 86 of the Decision makes clear, the delivery homecare
14 service providers receive payment for dispensing
15 prescriptions so far as the cost of the drug is
16 concerned, in the same way as a community pharmacy, and
17 it then goes on to point out that payment for home
18 delivery and homecare services is often under a
19 contract between the provider and a local trust. That
20 contract may involve a number of patients receiving a
21 range of treatments. What is envisaged is that the
22 homecare services will be provided under contracts
23 between the providers and the local NHS trusts.

24 Sir, you referred to the MMC Report. The MMC
25 Report, in particular at paragraph 2.53, refers to how
26 contracts in respect of homecare services may be
27 awarded by one of three routes, one of those being
28 direct negotiation with only one supplier and,
29 particularly in relation to that latter category,
30 towards the end of that paragraph, one may have an
31 existing contract with the supplier concerned and a
32 purchasing body may be minded to extend that contract,
33 provided that satisfactory terms can be agreed, so that
34 there is the facility for that to be done relatively
35 informally.

36 So far as these directions are concerned, the
37 position at present, and subject to the directions, is
38 that Healthcare at Home is not remunerated at all for
39 the provision of homecare services. As, Sir, you are

1 aware from the Decision, the position is that it is
2 providing those services essentially for free.

3 What is envisaged is that there will be no hiatus
4 of any kind if the directions are implemented, that
5 those patients who are currently under the care of
6 Healthcare at Home will continue under the care of
7 Healthcare at Home, and that contractual terms can
8 subsequently be agreed, whichever of the three routes
9 indicated in paragraph 2.53 of the MMC Report is
10 appropriate.

11 The principles of this have been discussed with Mr
12 Brownlee, who is the head of the PPRS branch of the
13 Department of Health, who has seen no problem with its
14 practicability.

15 THE CHAIRMAN: What about the patients who are at present
16 being cared for by Genzyme Homecare?

17 MR TURNER: Again those patients will continue to be
18 provided with services by Genzyme Homecare and the same
19 position will obtain.

20 THE CHAIRMAN: What I am driving at is this - and I am
21 trying to clarify facts at this stage. I am not taking
22 any sort of position. These directions are supposed to
23 take effect within 15 working days, of which today is
24 the last one. They seem to envisage at some stage,
25 sooner rather than later, a network of contracts of
26 some sort being put into place and that network, in a
27 sense, becomes the substitute for the existing
28 arrangements, however imperfect they may be. What I am
29 wondering to myself is whether one should at an interim
30 stage be going down the road of putting in place new
31 contractual arrangements on the part of both Genzyme
32 Homecare and HH before we know what the outcome of the
33 appeal is going to be, because if the appeal were to be
34 successful presumably all those arrangements would have
35 to be unscrambled again. In other words, can you really
36 expect a change in the existing principles of the
37 distribution system before the appeal has been decided?

38 MR TURNER: In my submission, certainly, Sir.

39 THE CHAIRMAN: It may be that my understanding is

1 completely wrong and you will be able to tell me that
2 it does not involve that sort of change at all, but if
3 it does involved that sort of change then that is, I
4 think, a possible element for the Tribunal in deciding
5 what to do.

6 MR TURNER: I fully understand that, Sir. You are correct
7 to raise that. The position must be that contractual
8 arrangements will need eventually to be put in place.
9 The issue is whether it necessarily follows that,
10 should the appeal be successful, the unscrambling of
11 those contractual arrangements would provide a bar or
12 difficulty which would in some sense come up against
13 the first principle that you mentioned, namely negating
14 the fruits of a successful appeal.

15 In my submission, there is no reason at all why
16 that should be thought to be the case. It could easily
17 be achieved that the terms of any such contracts should
18 reflect the fact that, were the appeal to be successful
19 or the arrangements need to be unscrambled, that that
20 could be done. It is therefore a legitimate
21 consideration. It is not a bar or a factor that should
22 weigh against the Director in this balance.

23 THE CHAIRMAN: Thank you for that.

24 MR TURNER: Finally, Sir, just to round this off, my
25 attention was drawn to paragraph 308(iii) of the
26 Decision. You will be aware, Sir, that there are only
27 five hospitals which are concerned with the care of
28 Gaucher patients. They are listed at paragraph 38 of
29 the Decision and that in itself perhaps tells in favour
30 of my point because it means that if there are
31 contractual arrangements one is talking about a
32 relatively limited number. 308(iii) refers to the
33 fact that the Royal Free Hospital has indicated that it
34 would like to combine Gaucher disease treatment
35 homecare services with a range of treatment of other
36 complex conditions.

37 Sir, those are, as far as I have been able to
38 gather, the points in response to your question.

39 THE CHAIRMAN: Thank you very much, Mr Turner.

1 I think, Mr Vaughan, it is now for you.

2 MR VAUGHAN: Basically the position we have set out in our
3 application at paragraphs 75 through to 89. That is
4 our position.

5 One of our great concerns about this whole thing is
6 that the OFT has mainly understood the whole system of
7 the inter-relationship of the PPRS and the Drug Tariff.

8 We are not talking about the PPRS, which is a cap on
9 pricing for drugs generally and not drug by drug, we
10 are talking about the Drug Tariff. The Drug Tariff
11 price for these products is the published price of
12 £2.975 per unit. That is the price which the pharmacy
13 gets. It goes to the pharmacy at that price and that
14 is the price the pharmacy gets and then, because these
15 are very expensive drugs - because the unit is fairly
16 misrepresentative of what the price would be - he gets
17 his 2 per cent on top of that. That is the price which
18 we get paid - the Genzyme Pharmacy, because we have our
19 own pharmacy. That is the price that Genzyme sells to
20 the pharmacy and the pharmacy receives from the
21 National Health Service, or from the State.

22 As **Fresenius** makes clear, these are prescribed
23 services and that means that you do not get anything
24 more unless you can persuade the NHS Executive, or
25 whatever it is called nowadays, to alter its document
26 attached to the **Fresenius** Report, the EL95. That is
27 something that would have to be done if there is to be
28 a change in the situation. One of the points we make
29 in our letter is that if somebody can persuade the
30 Government to treat these as being contracted services,
31 then everyone would be very happy because they would be
32 paid for doing this, which at the moment we do not get
33 paid for.

34 THE CHAIRMAN: Are you saying that there is potentially a
35 void that is not really addressed in the Directions,
36 which is that, if the Direction were to take effect,
37 there is no certainty on what basis you would be
38 remunerated for that homecare service in question?

39 MR VAUGHAN: Either that or for the drug itself, because

1 | if we are forced to change the price of the drug, then
2 | that will become the Drug Tariff price and that is the
3 | price the pharmacy will get. Instead of £2.975 it will
4 | become a lower figure and that will become the Drug
5 | Tariff price. The pharmacy and Healthcare at Home
6 | would be reimbursed by the State at that lower price
7 | and it still would not have solved this problem. It
8 | would be worse off, because the 2 per cent would be
9 | based on a lower value and it would still have to bear
10 | its home services for free. The whole thing is
11 | circular.

12 | We have not been charged with over-pricing, or
13 | anything like that. We have been charged with
14 | bundling. Nobody has suggested that we are over-
15 | pricing. But there is no system for paying us for
16 | this. If we are bundling it is under compulsion,
17 | because people need to have treatment. We have
18 | accepted that and we have always accepted that.
19 | Treatment is provided either in hospital, which is
20 | under a cost to the hospital, or at home which is, in
21 | the majority of cases, by NHS community nurses, in some
22 | cases by Healthcare at Home and in other cases by
23 | ourselves. If the National Health Service decides to
24 | pay people for providing these services, they would
25 | have to pay everyone, including their community nurses,
26 | because otherwise they would be undercutting everyone
27 | in that way, or else they would only use them because
28 | they would not have to pay them, one way or the other.

29 | The whole thing is nonsensical in our position, and
30 | that is one of the points we have made.

31 | We entirely accept, and have given undertakings,
32 | that we are not going to change our contractual
33 | relationships with Healthcare at Home. We will go on
34 | providing them with these things. They will continue
35 | to pay us and they will continue to be reimbursed by
36 | the State at the Drug Tariff price, whatever it happens
37 | to be, plus 2 per cent for the high cost prescription
38 | rates. If they want to be in this market, they have
39 | either got to bear the cost themselves or they have got

1 to persuade somebody to change their system, and that
2 person would be the NHS Health Trusts or the NHS
3 Executive in that way. Anyhow, as we say in our
4 application, this is a standalone price. They talk
5 about a standalone price. We have developed that and I
6 am not going to repeat that point here.

7 Also we say the Direction - and we develop that -
8 is unclear because you cannot work out the price at
9 which you actually have to supply without an agreement
10 and the agreement with the PPRS, if there were an
11 agreement in 1999, is not the agreement with the Drug
12 Tariff price people. That is a different thing.

13 THE CHAIRMAN: Just tell me where that is.

14 MR VAUGHAN: That may be an additional point, but what we
15 have discussed with them for the purpose of the PPRS,
16 at a time when we were paying HH for providing services
17 under our agreement with them, is not the same as what
18 price would be agreed now, when we are providing the
19 service, and anyhow could certainly be a different
20 body, as to how the Drug Tariff is worked out.

21 The Drug Tariff is worked out on a completely
22 different system and not on a capping system. It is
23 based upon effectively taking the price which the
24 pharmaceutical company puts forward in that case as
25 being the appropriate price. It may be subject to some
26 negotiation if it was excessive, but if it was
27 excessive they would be cut down by the PPRS, because
28 they would be making excessive profits and that would
29 cut them out in that way. The price they put in has
30 got to take into account the fact that the company
31 would not want to get too much out of the Drug Tariff
32 and immediately be cut down by the PPRS system.

33 THE CHAIRMAN: Where I have got to so far is that you say,
34 on the overall merits of the case, putting it at its
35 lowest, that the appeal is not manifestly unfounded and
36 that, on any view, there are significant practical
37 difficulties in implementing these directions,
38 certainly on an interim basis.

39 MR VAUGHAN: Yes.

1 THE CHAIRMAN: Just taking that as sufficient on those
2 points for the time being, we then come to the other
3 two points that I ventured to raise in my introductory
4 comments, namely, what is the position regarding the
5 Directions in the event that the appeal is ultimately
6 unsuccessful and what, if any, suggestions can be made
7 for protecting the proposed competitive structure, also
8 in the event the appeal is unsuccessful?

9 MR VAUGHAN: For the last three years Healthcare at Home
10 has put forward a case that it is in imminent danger of
11 going out of business. We had that at the interim
12 measure stage and we produced a lot of evidence that
13 that was completely untrue. Indeed, at that stage they
14 were winning prizes for being the best independent
15 company, or the second best independent company, in the
16 country. They were busy recruiting at that stage and
17 we put a lot of evidence in about that.

18 Cerezyme and Gaucher disease is a very small part
19 of their business. We do not know how big a part it is
20 but certainly it is a small part. I think there were
21 eight nurses out of 108 at one stage that were involved
22 in this. (Mr Robertson nods in approval). At the
23 present stage they are busy telling their shareholders.

24 Have you seen the recent letter that we wrote?

25 THE CHAIRMAN: I think it is mentioned in your latest
26 observations on 10 April.

27 MR VAUGHAN: It is the latest letter, the letter that we
28 wrote sent to you on --

29 THE CHAIRMAN: I think this came in either this morning or
30 --

31 MR VAUGHAN: It came in this morning, yes.

32 THE CHAIRMAN: I think it is the latest report and
33 accounts.

34 MR VAUGHAN: First of all, there is our response to the
35 OFT's written observations, which are at annex 2, which
36 exhibits Healthcare at Home's accounts. Paragraph 38
37 of that sets it out in full on page 1 from their
38 report. If you read paragraph 38 of that document at
39 page 9, reading at the bottom, it says: "The Directors

1 remain confident in the outlook of the business" - and
2 this is a document dated 22 August 2002, being their
3 report for the year ended 2001 --

4 THE CHAIRMAN: I am sorry, Mr Vaughan. Tell me where you
5 are again.

6 MR VAUGHAN: Sorry. It is Genzyme's response to the OFT's
7 written observations at paragraph 38.

8 THE CHAIRMAN: I have it.

9 MR VAUGHAN: It is probably best to look at the original
10 document rather than our quote so that you will see it
11 in context. This is Healthcare at Home's annual report
12 for the year to the end of 31 October. Then if you
13 look at printed page 2 you will see that this is signed
14 by the secretary on 22 August 2002. Then if you look
15 at the business review, the loss for the year is
16 £637,000.

17 THE CHAIRMAN: Which page is the business review?

18 MR VAUGHAN: Printed page 1. "Sales continue to grow at a
19 satisfactory rate as a result of the continuing
20 acquisition of new businesses. The company's profits
21 were adversely affected by a reduction in margins from
22 one contract [presumably that is us] to raise from
23 pricing ..." -

24 THE CHAIRMAN: Yes, I have read that.

25 MR VAUGHAN: "The directors remain confident in the
26 outlook of the business. Continuing new growth in new
27 contracts will over time offset the loss of margin in
28 respect of the ultimate outcome of the OFT
29 investigations."

30 To our mind, that fairly clearly shows that there
31 is no immediate risk.

32 THE CHAIRMAN: So your first submission is that there is no
33 risk to HH?

34 MR VAUGHAN: In the intervening period. Insofar as they
35 suffer a loss - and this is contained in a letter from
36 us to the OFT dated 16 April 2003 - we set out
37 basically why we say Healthcare at Home should not be
38 specially protected by an undertaking. In paragraph 1:
39 "It is clear that no obligation is placed on Genzyme

1 to supply any particular third party with Cerezyme",
2 and we refer to paragraphs 380 - 381 of the Decision.
3 "We have agreed to and supplied Healthcare at Home with
4 Cerezyme and continue to offer homecare pending the
5 outcome", in the spirit of holding the ring. If we
6 have to compensate both by the same amount, then we
7 would be reimbursing twice, because insofar as we have
8 agreed to pay the NHS the difference between the lower
9 price and the higher price, if we are found to have
10 been in breach to that extent, we go on to say that if
11 we undertake to do the same to Healthcare at Home we
12 would have to pay twice because they would be taking at
13 the lower price and also the NHS would be taking at the
14 lower price.

15 Paragraph 6 is the point we have already made:
16 "The only loss that Healthcare at Home could
17 conceivably incur between now and the ultimate
18 resolution would be in relation to its failure to
19 persuade the NHS to pay for use of its services as a
20 homecare provider rather than to use NHS resources,
21 such as community nurses. The OFT's case appears to be
22 that the NHS ought to use the difference or margin
23 between the lower amount to pay for Cerezyme to fund
24 the purchase of homecare supplies as Healthcare at
25 Home. Healthcare at Home's alleged loss would thus
26 arise out of its failure to earn a part of this
27 margin." Basically this is going back to the point
28 that any loss they suffer is a result of failing to
29 persuade the NHS to treat this as being a contracted
30 service.

31 THE CHAIRMAN: Hang on a minute. I have not had a chance
32 to absorb this. This letter came in this morning, I
33 think, while the Tribunal was doing other things.

34 MR VAUGHAN: Mid-morning, I think.

35 MR TIDSWELL: Excuse me, Sir. I hesitate to interrupt,
36 but may I say that I do not think we have seen that
37 letter, Sir. It may be that it is confidential and we
38 should not, but I am not sure that it was copied to us.

39 MR VAUGHAN: I do not think it was.

1 THE CHAIRMAN: I do not think it was, Mr Tidswell. But on
2 a quick look, it does not look as if there is anything
3 confidential in it, but that needs to be checked.

4 MR VAUGHAN: I do not think there is any figure there.

5 THE CHAIRMAN: Perhaps the potential intervener could be
6 shown a copy of this letter?

7 MR VAUGHAN: Then point 8, as regards the period between
8 the start of this dispute and now, or the Decision, if
9 they want to recover damages then they have got to go
10 to the High Court in order to recover them. Then all
11 rights, obligations and defences can be properly
12 evaluated in the light of a proper understanding of the
13 Drug Tariff and the PPRS system.

14 We say that exactly the same should happen to this
15 period if they succeed, or if we fail, in the appeal,
16 because they would have to go to court anyhow for the
17 other period and it would be wrong in principle, in our
18 submission, if we have to give an undertaking which may
19 well be to the contrary effect to what the High Court
20 decided in any litigation as regards the previous
21 period.

22 I think the other point to bear in mind is the fact
23 that this existing system has now gone on for at least
24 two years. With the existing system arising, interim
25 measures were not granted by the OFT in this case, so
26 the interim position still remained in that position.
27 The interim measures were rejected on the grounds that
28 they could not require us to supply them with any
29 particular drugs in that situation. They now say that
30 any exclusivity granted by us to anyone else would be
31 unlawful.

32 The other thing to bear in mind is that, if that is
33 brought into force, we would probably be under an
34 obligation to supply anyone who came to us at that
35 price. It would not just be Healthcare at Home, and
36 there are others knocking at the door in that
37 situation. We have undertaken at the moment to
38 maintain the position. We have told the Director that
39 if we want to change or have to change we would go back

1 to him before we did change, but it may be that others
2 would force us to reconsider our position on that. The
3 Director's position is that we are not entitled to deal
4 with anyone exclusively in that way. Again there is an
5 extra problem created in that respect.

6 I think the last point, which we have not put down
7 in writing, is that another major problem is that the
8 NHS services are now contracting only with one provider
9 across the board for all their requirements of drugs.

10 THE CHAIRMAN: When you say "NHS", who are we talking
11 about?

12 MR VAUGHAN: The Hospital Trusts are now embarking on a
13 system where they will only deal with one person for
14 all their drugs and that is going to create for us and
15 everyone a major problem. Certainly it will be
16 extremely difficult to work out how these directions
17 are going to apply if we have to supply one person
18 only, who may not be Healthcare at Home.

19 THE CHAIRMAN: When you say all their drugs, do you mean
20 all their drugs that require home treatment?

21 MR VAUGHAN: No, all of them. Every single drug. This is
22 a new system.

23 THE CHAIRMAN: I do not think I am on top of it.

24 MR VAUGHAN: No. This is, as it were, a new point that we
25 have not put forward, but it is a point of some
26 significance in that we are now being informed that the
27 NHS Trusts want to deal with only one drug provider,
28 not just for these specialist drugs but for all drugs.

29 THE CHAIRMAN: Do you mean, normally speaking, that would
30 be one wholesaler?

31 MR VAUGHAN: One wholesaler probably, yes, and that is
32 going to create a major problem for these directions.

33 THE CHAIRMAN: That is another issue that the Director
34 might want to have a look at!

35 MR VAUGHAN: Absolutely. We are nearly a complainant!
36 Anyhow after Bettercare.

37 Basically our contentions are --

38 THE CHAIRMAN: Well what you are saying is that on such
39 evidence as the Tribunal has, there is no reason to

1 suppose that HH is in any jeopardy of the kind that
2 requires some protection?

3 MR VAUGHAN: Yes.

4 THE CHAIRMAN: Let me explore for a moment analytically,
5 and it is perhaps a bit difficult to get one's mind
6 round it. If you were at the end of the day to lose the
7 appeal and if the directions were to stand and the
8 Tribunal were to say that they were to stand with
9 effect from the date of the decision, what then is the
10 position of HH, according to you, that they should go
11 to the High Court to get whatever the High court thinks
12 they should?

13 MR VAUGHAN: Well they have to do anyhow for the period of
14 the last two years.

15 THE CHAIRMAN: For the earlier period, yes.

16 MR VAUGHAN: We would obviously have various points we
17 would want to make and they would have points they
18 would want to make. We would call evidence from
19 experts in these various things, who would appear and
20 be cross-examined properly as a private law suit
21 between people rather than as a public law issue. They
22 have got to go there anyhow for that period. We say
23 they should go to the court for this period.

24 THE CHAIRMAN: So they should be left to their remedy in
25 the High Court?

26 MR VAUGHAN: Yes, the private law remedies. I do not
27 think the Enterprise Act would make this decision
28 automatically binding, but it would be pretty difficult
29 - I think I am right - because I do not think that part
30 is enforced yet. But in any event, after Iberian it
31 would be a pretty difficult thing to persuade a High
32 Court Judge to revisit the question of liability.

33 THE CHAIRMAN: Yes.

34 MR VAUGHAN: Whether it is technically enforced or not
35 does not really matter for this purpose. The matter
36 would then be resolved in the proper private law way
37 between parties. That has been one of our main
38 complaints in this case from the beginning. If this
39 had been dealt with in the High Court, if they have got

1 a good case they would have got an injunction two years
2 ago, and if they had not that would have been an end of
3 the matter.

4 We would ask you to impose a stay on our
5 undertaking to pursue the appeal with expedition and to
6 reimburse the NHS to the extent that we have done so,
7 and I do not think there is any dispute that that is an
8 appropriate undertaking to give and does not require
9 any clarification. We undertake to continue to supply
10 Healthcare at Home with Cerezyme in this period at the
11 Drug Tariff price and we will not change it without
12 going back to the Director for approval at that time.
13 We have no doubt at all that Healthcare at Home can
14 continue in business in that time. Indeed they have
15 not produced any real evidence today of imminent
16 demise.

17 THE CHAIRMAN: The Registrar points out that the provision
18 of the Enterprise Act allowing parties in whose favour
19 there has already been a finding of infringement to
20 bring an action in front of the Tribunal comes into
21 force on 20 June of this year. I think from memory
22 such cases can be brought within a limitation period of
23 two years.

24 MR VAUGHAN: But whether 24 June is the date of the
25 decision or not? I suspect it probably is the date of
26 the decision, is it?

27 THE CHAIRMAN: It is retrospective for two years, I think
28 from memory. Anyway, in addition to the High Court
29 there is the possibility of a follow-on claim of some
30 kind in front of the Tribunal.

31 MR VAUGHAN: Well that rather improves my submissions.

32 THE CHAIRMAN: Mr Robertson will correct us if I am wrong
33 on that.

34 MR VAUGHAN: My Lord, those are my submissions.

35 THE CHAIRMAN: Thank you, Mr Vaughan.

36 Yes, Mr Turner.

37 The stage that I think I have provisionally reached
38 at the moment, and subject to anything you say, is that
39 it is going to be somewhat difficult, without going

1 into the merits in detail, for the Tribunal to say at
2 this stage that this appeal is manifestly unfounded, if
3 that is the right test. At the moment, I am operating
4 under the assumption that there are at least some
5 practical difficulties possibly in implementing these
6 directions before the Tribunal gives judgment.

7 I am, however, concerned about what kind of
8 protections, if any, should be put in place in the
9 interim to ensure that in six months' time the outcome
10 for which the Director argues is still feasible, if the
11 Director wins the appeal.

12 MR TURNER: Yes. Sir, I will attempt to deal with things
13 in a slightly unusual order by addressing the points
14 that have been canvassed between yourself and Mr
15 Vaughan and perhaps then return to some of the other
16 points, but I bear in mind, Sir, your indication.

17 Starting with the canvassing of the issues on the
18 merits, I shall not elaborate now. You have had the
19 opportunity to go through the written materials, but my
20 submission is that even if the case is not to be
21 regarded as manifestly unfounded on the basis of the
22 material that you have seen, it is appropriate for the
23 Tribunal to take into account the lack of cogency of
24 that material when balanced against the extremely
25 painstaking and high quality nature of the reasoning in
26 the Decision as a factor in the Tribunal's discretion.

27 So far as the difficulties with directions are
28 concerned, Mr Vaughan I think touched in particular
29 upon two matters. The first was a lack of clarity
30 about what system would apply for the payment
31 separately for providers of homecare services.

32 That, as I understood the point, has not been
33 trailed particularly in the written submissions, but it
34 has been opened up this afternoon. In relation to
35 that, for the reasons that I gave earlier, there are
36 not in the OFT's view significant difficulties, or
37 indeed any difficulties with the operation of these
38 directions. We are obviously concerned that there
39 should be a full understanding on the OFT's part of any

1 concerns that the Tribunal may have and we will attempt
2 to address those. But at the moment it seems to the
3 OFT that there is no difficulty with implementing the
4 system described in the Directions under which the drug
5 price becomes the lower price indicated at paragraphs
6 393 and 394 of the Decision which, for the reasons
7 given earlier in the Decision, is the implied
8 standalone NHS list price for the drug and separated
9 from the homecare services element of the current
10 bundle price. I say that with some force because, in
11 my submission, it is apparent from the terms of those
12 letters, which are cited at paragraphs 95 to 103 of the
13 Decision, that Genzyme itself has described the price
14 as representing two elements, one of which is the drug
15 price and the other of which is the homecare services
16 element.

17 THE CHAIRMAN: But the factual assumption upon which I am
18 operating at the moment, and I am very ready to be
19 corrected if I am wrong, is that if this price was
20 reduced in the way that is suggested, in order to
21 obtain remuneration for the services, any service
22 provider, which is, as I say, Genzyme Homecare or HH,
23 would have to negotiate some kind of contract either
24 with a trust or with the NHS essentially, under which
25 some price would be agreed for those homecare services.

26 MR TURNER: Yes.

27 THE CHAIRMAN: I need to know if that is an incorrect
28 factual assumption or not.

29 MR TURNER: Sir, I believe having discussed it with the
30 client - and the client is nodding - that is common
31 ground. As I say, the principles have been discussed
32 with at least the head of the PPRS branch in the
33 Department of Health, who has seen no problem with
34 that.

35 MR VAUGHAN: Can we see the document? We have not seen
36 the document.

37 MR TURNER: Well. The next point to address is apparently
38 a lack of clarity about what the standalone price
39 should be, because it is said that in reality the PPRS

1 is something completely different from the NHS list
2 price. In addition to the paragraphs to which I have
3 already drawn your attention, Sir, that was
4 specifically addressed, because it was an issue that
5 arose in the administrative procedure at paragraph 68
6 and following of the Decision and it does touch on the
7 points that I was making to you earlier. Paragraph 68
8 is just under a heading in the NHS list price and the
9 PPRS. It refers to a report which had been
10 commissioned by Genzyme. The last sentence of that
11 paragraph in particular points out that "The report
12 explained that the prices permitted under the PPRS
13 become the NHS list or basic price, as appropriate,
14 listed in the Drug Tariff. A company cannot then
15 increase its price ..."

16 THE CHAIRMAN: I am sorry, which paragraph are we on?

17 MR TURNER: I am sorry, 68. In relation to the point that
18 the PPRS is unconcerned with individual prices,
19 Genzyme's own evidence was that the company cannot then
20 increase its price, for a specific product, that is,
21 without negotiations with the DoH.

22 Sir, the final point to make in relation to the
23 practicability of the system is that there is no reason
24 to think, in my submission, that any contracts which
25 would need to be struck in relation to the provision of
26 homecare services would be difficult to unscramble,
27 that they would need to run for lengthy periods or
28 anything of that kind, or that they could not be made
29 subject to the outcome of this appeal.

30 Sir, the next point, or area, that Mr Vaughan
31 addressed in relation to your three principles, was the
32 issue of Healthcare at Home and their financial
33 difficulties.

34 THE CHAIRMAN: Before we go on to that, Mr Turner, just on
35 these passages of the Decision from 68 to 83 and one or
36 two subsequent references where the Director concludes
37 that the NHS list price is not intended to cover the
38 cost of delivering the drug from the pharmacy to the
39 patient's home, and I think it is later said not

1 intended to cover the cost of homecare services, I was
2 left wondering about that conclusion in the light of
3 notably paragraph 1.4 of **Fresenius/Caremark**.

4 MR TURNER: And paragraph 2.43 of that Report.

5 THE CHAIRMAN: And there are a number of other paragraphs.
6 For present purposes I think we can just leave that
7 point hanging there, because it is not a point that I
8 have got to the bottom of yet or would wish to be
9 thought to be expressing a view at this stage.

10 MR TURNER: Sir, interestingly that is a point which I
11 myself have also raised with the client. As I
12 understand it, the general position is that that is the
13 case with the NHS list price. In the case of certain
14 circumstances, of which Cerezyme is one, the list price
15 does include the price for associated homecare
16 services.

17 THE CHAIRMAN: The impression that I have received is that
18 this product is one of a relatively small number of
19 products that does not quite fit the standard NHS
20 structure in that it is not quite the normal situation
21 of a supplier, then a wholesaler and then a retail high
22 street pharmacy that dispenses the drug, which is the
23 basis of the main NHS system. It is a somewhat
24 specialised system of delivery in which the
25 manufacturers undertake the wholesaling side of it in
26 which drugs, as I understand it, are not delivered to
27 high street retail pharmacies but are delivered to
28 specialist companies, like specialist homecare
29 providers who happen to be licensed as pharmacies and
30 are then supplied to patients in a home setting, all of
31 which operations seem on the whole to be wrapped up in
32 the price of the drug, for whatever reason.

33 MR TURNER: Yes.

34 THE CHAIRMAN: Unless it is a drug to which EL95(5) has
35 been applied.

36 MR TURNER: Yes.

37 THE CHAIRMAN: That is the impression I have at the moment,
38 but I am open to correction if I am wrong, of course.

39 MR TURNER: No, subject to correction, I submit that that

1 is correct. But the position here is not perhaps one
2 of nomenclature. The issue is whether, as the Director
3 General submits, which is crucial to the case, the
4 existing NHS list price is a bundled price and on top
5 of that a provider, such as Healthcare at Home,
6 receives nothing for the provision of services, it
7 makes no margin, no profit on that activity at all, or
8 whether, as Genzyme submits in its written
9 representations in the clearest terms at paragraph 56,
10 the price is not a bundled price, a position which it
11 has maintained throughout the proceedings.

12 THE CHAIRMAN: They have submitted, at least at some stage,
13 as I understand it, that the price is the drug price,
14 the services are free, the number of patients involved
15 in being supplied with the services is rather small,
16 certainly smaller than the Director thinks, and that we
17 are therefore not talking about a bundle price, if I
18 have understood the argument.

19 MR TURNER: Yes.

20 THE CHAIRMAN: To which you reply, I think, that that is at
21 first sight not quite consistent with the
22 correspondence with the Department of Health in
23 1999/2000.

24 MR TURNER: And indeed with the previous course of
25 history.

26 THE CHAIRMAN: And with the previous course of history,
27 yes. So that issue is there. It is not an issue that
28 I can conceivably take a view on at this stage, but
29 that is the issue.

30 MR TURNER: No. However, that is central to the
31 directions and indeed to the case as a whole.

32 When one comes to the position of Healthcare at
33 Home, I should begin by making it clear the Director's
34 interest in this, because the Director - the OFT now -
35 does not regard this as an aspect of a private dispute.

36 As a number of European authorities made clear, and
37 in particular the IMS case at paragraph 84, there are
38 circumstances, of which we say this is one, where the
39 interests of competing undertakings may not be

1 separable from the interests of an effective
2 competitive structure. That is why the Director is
3 concerned in relation to Healthcare at Home.

4 In relation to Mr Vaughan's points, I would make a
5 number of comments. First, in relation to the
6 accounts, to which you rightly drew attention, it is
7 very important not to confuse the overall business of
8 Healthcare at Home with its position on this market.
9 Whether or not Healthcare at Home may survive as a
10 company is not the issue. The issue is whether it will
11 be forced to exit, or will exit from this market. That
12 is not a question which is addressed in the extract to
13 which Mr Vaughan drew attention.

14 Secondly, on that issue, which we say is the
15 relevant one, Healthcare at Home is bleeding freely
16 under the current arrangements. It receives no
17 remuneration for the provision of homecare services and
18 is therefore making ongoing losses. That is
19 necessarily the case. Sir, I have given you all the
20 references in the submissions.

21 THE CHAIRMAN: It gets its 2 per cent dispensing fee, but
22 that is all.

23 MR TURNER: But that is all. One does observe the
24 position of increasingly mounting losses.

25 THE CHAIRMAN: When you say you have given me all the
26 references?

27 MR TURNER: I am sorry. They are in the observations.
28 Paragraphs 120, footnotes 200 and 303 I think in
29 particular, but they are listed in the written
30 observations. I can come back to those.

31 Third, and this is the important point from the
32 OFT's perspective, are the consequences. What happens
33 if these directions do not take effect as envisaged and
34 Healthcare at Home does exit the market, which, after
35 all, is its evidence now as well.

36 The important point from the Director's perspective
37 is that that seriously affects the market structure.
38 In the homecare services segment of the downstream
39 market there are currently two actual providers, namely

1 Healthcare at Home and Genzyme Homecare. Healthcare at
2 Home is a major competitor in the downstream market.
3 If it exits, the result will be that Genzyme Homecare
4 will be left in a monopoly position.

5 In the particular circumstances of this industry,
6 that has serious consequences. The Decision makes
7 clear that the providers of such services and the
8 patients form close relationships and such
9 relationships are, firstly, distressing to break and
10 then renew and, secondly, to restore in the event that
11 it turns out at the end of the day that Genzyme
12 Homecare is not the preferred provider.

13 Fourthly, as indicated in the written submissions,
14 you will have seen that the specialists themselves have
15 expressed preference to be able to choose effectively
16 the homecare service provider for their Gaucher disease
17 patients. That is in particular at paragraph 308 of
18 the Decision. The references to the close relationship
19 that is formed is at paragraphs 333 to 334 and 336 in
20 particular.

21 For all those reasons we say that there is a
22 serious matter to be borne in mind, a very weighty
23 matter, if these Directions do not come into effect and
24 Healthcare at Home is thereby forced to exit the
25 market.

26 I am not able to address the additional point that
27 Mr Vaughan made about how NHS trusts now wish to deal
28 with only one wholesaler for all their drug
29 requirements. We have no information on that and I am
30 not able to assist the Tribunal on that.

31 Sir, the next matter was your second point: what
32 happens if the appeal is unsuccessful and the
33 directions are then deemed to stand as from the date of
34 the Decision? Can the consequences of the absence of
35 the Directions be undone?

36 In my submission they cannot. The consequences of
37 foreclosure of the downstream segment of the homecare
38 services segment of the downstream market cannot be
39 repaired. There are two dimensions to that. The first

1 is the exit of Healthcare at Home, which is a
2 substantial risk. The second is the continued
3 inability of other potential providers to enter the
4 market. Sir, I drew your attention to the express
5 preference of the Royal Free Hospital at paragraph
6 308(iii).

7 In the event that the appeal takes place and
8 Genzyme loses the appeal and we then find that Genzyme
9 Homecare is sitting in a monopoly position in the
10 downstream services market, from the point of view of
11 the competitive structure the consequences will not be
12 possible to repair. It is not a question of private
13 financial remuneration of particular individuals, but
14 to the market structure.

15 Finally, Sir, in relation to the undertakings,
16 there are two. The first is the reimbursement of the
17 NHS retrospectively. Attention was drawn to what
18 happened in the **Napp** case, where an undertaking along
19 those lines was accepted. I would make the following
20 comments.

21 First, **Napp** was of course, or at least in part, an
22 excessive pricing case and it was to that mischief that
23 the reimbursement undertaking was directed. Moreover,
24 Sir, you may recall that at the end of the day in the
25 substantive hearing on that, it was realised on the
26 Director's part that we had omitted to recall the
27 volume effects of the directions, not the proceeding in
28 the interim, and the changes in the market structure
29 that may have occurred in the mean time and the need to
30 compensate for those at all. That had simply been
31 lost.

32 In this case, the only point really for present
33 purposes is foreclosure and the reimbursement of the
34 NHS at a later stage does not address that mischief.

35 Sir, in relation to other points, because I have
36 just been tracking in order Mr Vaughan's submissions,
37 the factors which the Tribunal may weigh in the balance
38 include also the issue of serious and irreparable
39 damage in relation to the applicant itself, here

1 Genzyme.

2 Our submissions on that are really quite simple,
3 namely that although Healthcare at Home refers to the
4 fact that it stands to lose money, which undoubtedly it
5 does, although the amount may be uncertain, it has not
6 shown that it will sustain serious and irreparable
7 damage, at least as that term now appears to be being
8 treated at the European level. I have referred in
9 particular to the IMS case. I perhaps do not need to
10 turn it up in view of the hour?

11 THE CHAIRMAN: No, I think I have got the point.

12 MR TURNER: There are two aspects to it. It must threaten
13 the survival of the firm and one may take into account
14 the position of the group.

15 Sir, unless I can assist you further, that is my
16 submission.

17 THE CHAIRMAN: That is very helpful, Mr Turner, thank you.

18 MR TIDSWELL: Thank you, Sir, quite so.

19 Sir, I am somewhat in your hands as to status and
20 indeed where I can assist you. I am not sure whether
21 you want to deal with intervention?

22 THE CHAIRMAN: I have not formally made an order admitting
23 Healthcare at Home as an intervener, but it seems to me
24 that I should make such an order. I have taken into
25 account all the observations that have been made so I
26 must now treat you as an intervener for present
27 purposes.

28 MR TIDSWELL: In the proceedings. Thank you, Sir.

29 Sir, all I really wanted to address was, firstly,
30 to say that obviously we support the Director's case
31 and the comments made by them so far.

32 THE CHAIRMAN: What I want to know primarily from you, so
33 far as you can tell me - and it may be a question that
34 I need some evidence about at some point - is the
35 position of HH from now until the end of September.
36 That is really what I want to know about.

37 MR TIDSWELL: Sir, what I cannot do is tell you what their
38 plans are financially.

39 THE CHAIRMAN: Do you have any clients present in the room?

1 MR TIDSWELL: No, I do not, Sir.

2 THE CHAIRMAN: You are on your own?

3 MR TIDSWELL: We are on our own, I am afraid. Sir, what I
4 can do is perhaps make some points about the position
5 as recorded in documents to date.

6 THE CHAIRMAN: Yes. You have not been able to take
7 instructions from your clients as to what their
8 position is?

9 MR TIDSWELL: I think there are two points about that.
10 First of all, Sir, I suspect that they would be very
11 reluctant to have that sort of information, which they
12 regard as being very sensitive, discussed in open
13 court. Although I think they would want to help, if
14 that was of assistance, they would want to do that in a
15 way that did not result in that information becoming
16 widely known.

17 THE CHAIRMAN: We can go into camera for very sensitive
18 matters if it is absolutely necessary.

19 MR TIDSWELL: Indeed. The second point is that I am
20 certainly not in a position. I have no information or
21 instructions on that point and I am not even sure that
22 they necessarily are in a position to instruct me on at
23 what point they would say enough is enough and it may
24 not necessarily be in their hands. There are issues as
25 to the positions of third parties, such as bankers and
26 the hospitals themselves.

27 What might be helpful is for me to try and draw out
28 some of the points about the position as it is at the
29 moment.

30 THE CHAIRMAN: I think it is your letter of 11 April, isn't
31 it?

32 MR TIDSWELL: Yes, sir.

33 THE CHAIRMAN: Is that what you are going to take me to?

34 MR TIDSWELL: Well there are actually two points referred
35 to from that and I wondered whether I could take you to
36 those two places. One is the accounts for 2001.

37 THE CHAIRMAN: Where do I find those?

38 MR TIDSWELL: They are attached to the observations on
39 intervention. I think I have seen them to your right

1 in that folder there, Sir. The relevant page is page
2 6. Indeed can I start at page 5, which is the profit
3 and loss for the year ended 31 October 2001. There is,
4 and I am unable, I am afraid, to reconcile this, a
5 slight different between the number in our 11 April
6 letter and the number here but the Tribunal will see at
7 the middle of the page the loss of ordinary activities
8 before taxation.

9 THE CHAIRMAN: Yes. There is a 533 as a published figure.

10 MR TIDSWELL: Precisely, compared with the figure for the
11 year before, which is a profit of 312. Then over the
12 page the consequence of that movement in the balance
13 sheet and net assets at 1506 in 2000 down to 973 in
14 2001, reflecting the consequence of that loss.

15 THE CHAIRMAN: Yes.

16 MR TIDSWELL: Then, as the Tribunal knows, there are no
17 filed accounts for the next year, 2002, but the letter
18 of 11 April puts the position as being worse than the
19 year ended 2001.

20 THE CHAIRMAN: I think I had better look at the letter of
21 11 April, if I may.

22 MR TIDSWELL: It is at the top of page 3, sub-paragraph
23 (i). The letter records the loss for the year 2001 and
24 then goes on to say - and there is a discrepancy, and
25 you have seen the figure 560 instead of 533, and I am
26 sorry but I do not know how that came about. Then in
27 the financial year ending October 2002, during which
28 time Genzyme has continued to refuse to supply, HH
29 suffered losses of even greater magnitude.

30 THE CHAIRMAN: What is this letter based on? From whom is
31 this information gleaned?

32 MR TIDSWELL: These are instructions from our client.
33 Certainly, Sir, if it would help it would be very easy
34 to obtain a witness statement to verify the contents of
35 it.

36 THE CHAIRMAN: You would be able to obtain a witness
37 statement to support it?

38 MR TIDSWELL: Yes. The point from that, Sir, is taking
39 account of the net asset position at the end of 2001,

1 one can see that there is a further erosion of that in
2 relation to the loss which is suggested in that
3 paragraph in 2002.

4 I think that is as far as I am able to go on the
5 present information in relation to the published
6 accounts and the accounting information.

7 The other source of information on which I rely is
8 the Director's findings. Probably the easiest way to
9 access that, I do not know, Sir, if you have seen our
10 letter of 15 April? It was not one of the ones you
11 mentioned that you had read, but it is a response to
12 Genzyme's written observations.

13 THE CHAIRMAN: I am not sure that I have, Mr Tidswell. You
14 had better let me see a copy of it to make sure I know
15 what we are talking about. (Copy handed to the
16 Tribunal)

17 I do not think I have had a chance to read this
18 yet, Mr Tidswell. What bits of it do you want me to
19 read?

20 MR TIDSWELL: Particularly, Sir, on page 2 under the
21 heading "Paragraph 7". There is a reference in the
22 second paragraph under the heading "Paragraph 7" to a
23 number of places in the Director's decision where the
24 Director makes findings - we say findings of fact upon
25 which we rely - as to the viability of any party, let
26 alone Healthcare at Home, in continuing to supply at
27 low margin. Of those there was one that I would
28 particularly like to take you to, which is paragraph
29 376. I am looking particularly at the last two
30 sentences of 376 where the Director finds that the
31 price charged by Genzyme to HH for drugs is the same
32 price charged to the NHS. Then particularly the last
33 sentence: "It allows HH no profit. It causes it to
34 sustain a loss in the provision of homecare services.
35 There is no undertaking as regards how efficiently it
36 could trade profitably in the downstream market under
37 these terms". Then paragraph 377, and particularly the
38 second sentence: "HH will eventually be forced to
39 leave this segment of the market as it cannot continue

1 to sustain losses indefinitely. The effects of this
2 will be particularly serious ..." and so on.

3 THE CHAIRMAN: Where is that?

4 MR TIDSWELL: I am sorry. It is 377, the second sentence.
5 We say finding by the Director that it will eventually
6 be forced to leave the market. That seems to accord
7 with logic.

8 Then in 378, a point perhaps picking up on the
9 sensitivity of this point: "Genzyme is aware of the
10 current conditions under which it is supplying Cerezyme
11 to HH will have the effect of pushing HH out of the
12 homecare services segment. Genzyme sent letters to a
13 number of doctors responsible for Gaucher patients
14 advising them to switch their patients as HH will not
15 be able to provide homecare services at competitive
16 prices in the long term."

17 I think that perhaps illustrates the concerns we
18 have about some of the sensitivity of the information
19 not going to the parties but going beyond the purposes
20 of these proceedings.

21 Sir, the point about those passages in particular,
22 and the other ones in the 15 April letter, is that we
23 say they are findings of the Director which, at least
24 for the mean time, stand as findings of fact that it is
25 not economic to continue and we will be forced out at
26 some stage. What I cannot say to you, Sir, is when
27 that will take place. In our submission it is,
28 firstly, relevant that timing ought to include
29 considerations, such as appeals and, secondly, we
30 submit that the question for the Tribunal in this
31 respect is whether, on the evidence before you, you can
32 reasonably expect us to carry on what we are doing in
33 the market place, whether it is fair to expect that
34 where there is clearly a loss - and clearly not all
35 damage would be unrecoverable, such as the loss of
36 reputation and the loss of relationships - we should
37 continue to do that, and also, particularly in relation
38 to third parties, whether it is reasonable to assume
39 that banks, hospitals and other parties will take the

1 same view, given the history of this matter and given
2 that they were told some time ago, as I think the
3 Director's Report notes, that the end might be in
4 sight. That is the Director's decision.

5 THE CHAIRMAN: You have not asked for an adjournment in
6 order to file any further information, even on a
7 protected basis, as far as confidentiality is
8 concerned. Do I take it that for present purposes you
9 are content to rely on the information that is already
10 before the Tribunal and in the Decision, or is there a
11 suggestion that the Tribunal might adjourn for further
12 information to be supplied?

13 MR TIDSWELL: I am certainly not making an application or
14 a submission that you should adjourn at the moment.

15 Sir, there are two further points to make, one in
16 relation to the perception of Genzyme, and may I ask
17 you to note it rather than taking you to it. In the
18 *Dixon Report* (I am not quite sure how it is in the
19 Tribunal's bundle but I think it follows on from the
20 accounts that we looked at) there is a reference at
21 paragraph 11.27 to the perception that external parties
22 might have to Healthcare at Home's business and
23 particularly commenting on why third party creditors
24 might be concerned about the position of Healthcare at
25 Home. In my submission, that is relevant to the
26 question of the likelihood of Healthcare at Home
27 continuing in this business to make these losses. That
28 is the second paragraph at 11.27 in the *Dixon Report*.

29 The last point, Sir, is this. If I can assist in
30 relation to the question of the form of the directions,
31 I think we are able to say that our client considers it
32 would be able to enter into contracts with the relevant
33 health authorities, of which there are only five, I
34 understand, and indeed, as far as price went, in effect
35 it would only be the difference of now getting nothing
36 for that service as opposed to contracting to get
37 something for it. But we would not envisage that there
38 would be any significant practical disruption as a
39 result of the Director's directions coming into force.

1 Unless I can help you further, Sir, that is all I
2 have by way of submissions.

3 THE CHAIRMAN: That is very helpful, Mr Tidswell.

4 Mr Vaughan, I think provisionally where I am at the
5 moment is not very far from where I was a few minutes
6 ago, that is to say, that if you assume, for argument's
7 sake, that you have surmounted the hurdle of 'not
8 manifestly unfounded' and that you have surmounted the
9 hurdle of 'practical difficulty and/or
10 inappropriateness of the directions taking effect in
11 their present form prior to the hearing of the full
12 appeal', the Tribunal is still very anxious to make
13 sure that at the end of this appeal there are still
14 potentially at least two suppliers who could operate.

15 MR VAUGHAN: Absolutely.

16 THE CHAIRMAN: It is very difficult, on the evidence that I
17 have got, to say that there is no risk of that
18 happening. What I would, if I may, look to you for is
19 some kind of solution to deal with that third point, if
20 you want interim relief.

21 MR VAUGHAN: On that, the question is that it now seems to
22 be put on the basis that the company would continue but
23 that this part of its business might go.

24 THE CHAIRMAN: There is at least a risk.

25 MR VAUGHAN: At least a risk that the business might go
26 but the company would continue.

27 THE CHAIRMAN: That would be the relevant question for this
28 part of the business.

29 MR VAUGHAN: Yes, but this part of the business would go.
30 'This part of the business' is artificially defined as
31 to be only the treatment for Gaucher disease, because
32 the business which Healthcare at Home provides in its
33 homecare is a much wider thing. The same nurses are
34 doing the same job in many cases.

35 THE CHAIRMAN: What I think we must not lose sight of in
36 these proceedings is the ultimate interests of the
37 patients who are at present, whatever the number is.
38 Even if it is only one, this is still something that
39 the Tribunal must try to protect.

1 MR VAUGHAN: Yes, absolutely. That is why we have given
2 an undertaking to continue all contractual arrangements
3 so they will get them. Mr Tidswell says that they have
4 no problems about getting contracts to provide
5 healthcare at home from the NHS providers, from the
6 Health Trusts. Well, that is what we have always been
7 saying is their remedy. That has always been our case.
8 If they can get a contract from the provider who would
9 reimburse them for doing that, then everyone would be
10 happy, because whether they get it at £2.975 or at some
11 lower price, then they will be in exactly the same
12 position unless they obtain - and indeed a rather worse
13 position because of the loss of the 2 per cent
14 proportion - they will be in exactly the same position
15 as they are at the moment. They would be buying at the
16 lower price and receiving the lower price and they
17 would still be getting nothing for the healthcare at
18 home, unless they can sign a contract. We have always
19 been saying, and it has always been our case, that the
20 proper remedy for them was to persuade the NHS or
21 hospitals to change the EL95 and include this as being
22 a contract service in that way. It does not matter at
23 all to Healthcare at Home what is the Drug Tariff
24 price. The question is, who is going to pay for the
25 service it provides. They seem to think now that they
26 can get that arranged. Mr Turner - and we certainly
27 have not seen any documents from the gentleman at PPRS
28 to this effect - says there would be no problem. If
29 there is no problem about any of these things then that
30 could be done. They will get their reimbursement for
31 the service that they provide. We will get the price
32 for the drug and everyone will be happy.

33 That is the critical question and that is the thing
34 that everyone seems to overlook in this case. If they
35 can get that, then that is the happy position, because
36 they cannot sell on the drug for any more than they buy
37 it for. They cannot make a profit on that, because
38 they would have to change the whole of the Drug Tariff
39 price. They pay the price and that is the price for

1 which they are reimbursed. We do not see any way in
2 which one can get round that position. Mr Tidswell is
3 saying that they have no problems about getting
4 contracts. Well that is fine. Then our undertaking
5 would remain. We would provide them with the drugs.
6 They would be getting the reimbursement from the only
7 way they can get it, which is from the NHS service. If
8 there is no problem - Mr Turner says there is no
9 problem and Mr Tidswell says there is no problem - then
10 that is the way to do it. If there is no problem, it
11 can be done tomorrow. They will be getting their
12 provision from the NHS service for the provision of
13 this service.

14 THE CHAIRMAN: If some arrangement akin to an EL95
15 arrangement were to be adopted tomorrow to the effect
16 that a distinction is now formally introduced between
17 the price of the drug and the cost of the services, and
18 there is some separate arrangement for reimbursing the
19 cost of the services, that is a possible solution.

20 MR VAUGHAN: A complete solution.

21 THE CHAIRMAN: But that would involve, I think, you selling
22 the drug to them at the lower price.

23 MR VAUGHAN: It would not matter to them what price they
24 got it at.

25 THE CHAIRMAN: Well it might matter to the NHS because it
26 would not want to pay twice over for the service
27 element that the Director says is in the --

28 MR VAUGHAN: Well that may be a question for discussion in
29 that respect.

30 THE CHAIRMAN: Yes.

31 MR VAUGHAN: I wonder whether it might be possible at this
32 stage to take a little time out?

33 THE CHAIRMAN: I think it would be useful, because I do
34 need to be reassured on this point. If arrangements
35 can be made in one way or another to safeguard the
36 position, the Tribunal would be very grateful.

37 MR VAUGHAN: Yes. I wonder if it would be possible to
38 take instructions to see whether we can in some way
39 bridge a gap?

1 THE CHAIRMAN: Yes, take instructions. There is the
2 question of the patient who is at home and there is
3 also the question of the products that are sold to
4 hospitals. There are those two elements.

5 MR VAUGHAN: Well that, of course, does not affect it.

6 THE CHAIRMAN: HH is not in the hospital sector at the
7 moment, and maybe one does not want to over-complicate
8 it by introducing the hospital sector at this stage.
9 There are those two aspects, but I think it would be
10 sensible to see if some bridge can be built.

11 MR VAUGHAN: For the interim period?

12 THE CHAIRMAN: For the interim period, subject, of course,
13 throughout to liberty to apply and for any change of
14 circumstances to be dealt with as we go along.

15 MR VAUGHAN: Of course, one of the factors we have got to
16 bear in mind is that if we do that, then this is
17 irrecoverable loss to us.

18 THE CHAIRMAN: You may be able to devise or think about
19 possible solutions that might even get over that
20 hurdle.

21 MR VAUGHAN: Yes. Thank you very much indeed. If we can
22 have ten minutes or so.

23 THE CHAIRMAN: Yes, I will rise. I am sorry that we are
24 going on somewhat late. I hope that does not
25 inconvenience people unduly. I think it better to try
26 to crack this tonight, if we can.

27 MR VAUGHAN: Absolutely.

28 **(Adjourned from 4.45 pm to 5.05 pm)**

29 THE CHAIRMAN: Yes, Mr Vaughan.

30 MR VAUGHAN: Sir, I wonder if we can go into camera now?

31 THE CHAIRMAN: Yes. Can I remind myself as to when we do
32 that? On what basis are we going into camera?

33 MR VAUGHAN: There are things to be disclosed that we do
34 not want to be revealed to third parties, and
35 particularly to be reported publicly.

36 THE CHAIRMAN: Rule 23: "The hearing shall be in public,
37 except as to any part that the Tribunal is satisfied
38 that it will be considering information which is, in
39 its opinion, confidential information."

1 | MR VAUGHAN: This would be the prices at which we are
2 | prepared to supply to Healthcare at Home.

3 | THE CHAIRMAN: Yes. That, I think, is sufficiently
4 | confidential.

5 | I wonder if I could invite members of the public
6 | who are not associated with any of the parties to
7 | kindly withdraw. Is there any person in court who is
8 | not directly associated with any of the three main
9 | parties?

10 |

11 | (The remainder of the hearing was heard in camera.
12 | Please see separate transcript)

13 |