Neutral citation: [2004] CAT 4

IN THE COMPETITION
APPEAL TRIBUNAL

Case No: 1016/1/1/03

11 March 2004

Sir Christopher Bellamy (President)
Professor Peter Grinyer
Mr Graham Mather

BETWEEN

GENZYME LIMITED

Applicant

-and-

THE OFFICE OF FAIR TRADING

Respondent

Mr David Vaughan QC and Mr Aidan Robertson (instructed by Messrs Taylor Vinters) appeared for the Applicant

Mr Rhodri Thompson QC and Mr Jon Turner (instructed by the Director of Legal Services, Office of Fair Trading) appeared for the Respondent

Heard at New Court on 25, 26 and 29 September and 6 October 2003

Note: Excisions in this judgment relate to commercially confidential information: Schedule 4, paragraph 1 to the Enterprise Act 2002.

CONTENTS

I. INTRODUCTION

1. By a notice of appeal dated 20 May 2003 Genzyme Limited ("Genzyme") appeals to the Tribunal against decision no. CA 98/3/03 taken by the Director General of Fair Trading on 27 March 2003 ("the decision") under section 18 of the Competition Act 1998 ("the 1998 Act"). That section prohibits the abuse of a dominant position which may affect trade within the United Kingdom.

2. On 1 April 2003 the functions of the Director General of Fair Trading ("the Director") were transferred to the Office of Fair Trading ("the OFT") pursuant to section 2(1) of the Enterprise Act 2002 ("the 2002 Act"). Similarly, as from 1 April 2003 references to the Director in the 1998 Act are replaced by references to the OFT, pursuant to section 2(3) of the 2002 Act. By virtue of Schedule 24, paragraph 6 of that Act, the decision is to be treated as if taken by the OFT, who is the respondent to these proceedings[1]. References to the OFT in this judgment are to be taken as including the Director.

(1) *The Statutory Framework under the 1998 Act*

3. Section 18 of the 1998 Act provides, so far as material:

> "18.-(1) … [A] ny conduct on the part of one or more undertakings which amounts to the abuse of a dominant position in a market is prohibited if it may affect trade within the United Kingdom.
>
> (2) Conduct may, in particular, constitute such an abuse if it consists in -
>
> (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
>
> (b) limiting production, markets or technical development to the prejudice of consumers;
>
> (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
>
> (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or

[1] See generally S.I. 2003 no. 766

according to commercial usage, have no connection with the subject of the contracts.

(3) In this section-

"dominant position" means a dominant position within the United Kingdom; and
the "United Kingdom" means the United Kingdom or any part of it.

4. The prohibition imposed by section 18(1) is known as "the Chapter II prohibition": section 18(4). The Chapter II prohibition is closely modelled on Article 82 of the EC Treaty.

5. Following an investigation under section 25 of the 1998 Act, the OFT may, pursuant to section 31(1)(b), make a decision that the Chapter II prohibition has been infringed. Before doing so, the OFT must give the person likely to be affected by the decision the opportunity to make representations: see section 31(2) and Rule 14 of the Director's Rules set out in the Schedule to the Competiton Act 1998 (Director's Rules) Order 2000 (S.I. 2000 No. 293). This is customarily done by the service of what is known as "a Rule 14 Notice".

6. Section 33(1) of the 1998 Act provides that, if the OFT has made a decision that conduct infringes the Chapter II prohibition, it may give "such directions as it considers appropriate to bring the infringement to an end". Such directions may be enforced by the Director on an application to the Court: section 34.

7. Section 36(2) provides that, on making a decision that conduct has infringed the Chapter II prohibition, the OFT may require the undertaking concerned to pay a penalty in respect of the infringement. Under section 36(3), such a penalty may be imposed only if the OFT is satisfied that the infringement has been committed intentionally or negligently. By virtue of section 36(8), no penalty fixed by the OFT may exceed 10 per cent of turnover of the undertaking as determined in accordance with the Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000 No. 309). Any penalty so imposed is recoverable as a civil debt following the expiry of the period for appealing to this Tribunal, or the determination of any such appeal: section 37.

8. Section 38(1) of the 1998 Act requires the OFT to publish guidance as to the appropriate amount of any penalty. Under section 38(8) the OFT must have regard to that guidance when setting the amount of the penalty. The OFT has published such guidance entitled *Director General of Fair Trading's Guidance as to the Appropriate Amount of a Penalty* (OFT 423, March 2000).

9. A person in respect of whose conduct the OFT has made a decision may appeal to this Tribunal against, or with respect to, that decision: section 46(2).

10. The powers of this Tribunal to determine appeals under section 46 are set out in paragraph 3 of Schedule 8 of the 1998 Act, which provides:

> "3.-(1) The Tribunal must determine the appeal on the merits by reference to the grounds of appeal set out in the notice of appeal.
>
> (2) The Tribunal may confirm or set aside the decision which is the subject of the appeal, or any part of it, and may-
>
> (a) remit the matter to the OFT,
> (b) impose or revoke, or vary the amount of, a penalty,
> (c) grant or cancel an individual exemption or vary any conditions or obligations imposed in relation to the exemption by the OFT,
> (d) give such directions, or take such other steps, as the OFT could itself have given or taken, or
> (e) make any other decision which the OFT could itself have made.
>
> (3) Any decision of the Tribunal on an appeal has the same effect, and may be enforced in the same manner, as a decision of the OFT.
>
> (4) If the Tribunal confirms the decision which is the subject of the appeal it may nevertheless set aside any finding of fact on which the decision was based."

11. Section 60 of the 1998 Act provides:

> 60.- (1) The purpose of this section is to ensure that so far as is possible (having regard to any relevant differences between the provisions concerned), questions arising under this Part in relation to competition within the United Kingdom are dealt with in a manner which is consistent with the treatment of

corresponding questions arising in Community law in relation to competition within the Community.

(2) At any time when the court determines a question arising under this Part, it must act (so far as is compatible with the provisions of this Part and whether or not it would otherwise be required to do so) with a view to securing that there is no inconsistency between-

(a) the principles applied, and decision reached, by the court in determining that question; and
(b) the principles laid down by the Treaty and the European Court, and any relevant decision of that Court, as applicable at that time in determining any corresponding question arising in Community law.

(3) The court must, in addition, have regard to any relevant decision or statement of the Commission.

(4) Subsections (2) and (3) also apply to-

(a) the OFT; and
(b) any person acting on behalf of the OFT, in connection with any matter arising under this Part.

(5) In subsections (2) and (3), "court" means any court or tribunal

(6) In subsections (2)(b) and (3), "decision" includes a decision as to –

(a) the interpretation of any provision of Community law;
(b) the civil liability of an undertaking for harm caused by its infringement of Community law.

(2) ***The Decision in a nutshell***

12. Genzyme supplies a drug called Cerezyme for the treatment of Gaucher disease. Gaucher disease (pronounced "Go-shay") is a rare enzyme deficiency disorder. According to Genzyme, there are currently about 190 sufferers from Gaucher disease being treated with Cerezyme in the United Kingdom. Some of these patients are treated in hospital, but the majority (about 170) receive intravenous infusions at home. About 115 of these patients (or their parents) have been trained to self infuse, but others infuse with the help of a nurse.

13. The decision, which runs to 127 pages, concerns the arrangements for the delivery of Cerezyme to Gaucher patients' homes, and the provision of associated homecare services.

14. The OFT found, in the decision, that Genzyme has a dominant position in the "upstream" market for the supply of drugs for the treatment of Gaucher disease (paragraph 286 of the decision). The OFT further found that Genzyme has abused that dominant position by, in effect, pricing Cerezyme in a way which excludes other delivery/homecare services providers from the "downstream" market for the supply of home delivery and homecare services to Gaucher patients being treated with Cerezyme at home (paragraphs 290 to 386 of the decision).

15. Two separate abuses are found against Genzyme. The first abuse, which is conveniently referred to as the "bundling" abuse, is the practice of selling Cerezyme to the NHS at a list price which includes not only the supply of the drug, but also the provision of home delivery and homecare services: see paragraphs 294 to 363 of the decision. According to the OFT, the relevant services which are "bundled" into the price of the drug include dispensing, home delivery, an emergency help line, the supply of accessories (fridges, needles etc.), waste disposal, stock monitoring, training the patient to self infuse, and nursing support. Nursing support may range from respite care to taking full charge of the infusion. These services are collectively referred to in the decision as "Homecare Services"[2].

16. According to the OFT, the practice of "bundling" had the effect of excluding anyone other than Genzyme, or a person acting under contract with Genzyme, from supplying Homecare Services, as thus defined, in the period from 1 March 2000, the date when the 1998 Act came into force, until 27 March 2003, the date of the decision.

17. The second abuse, dealt with at paragraphs 364 to 385 of the decision, is conveniently referred to as "the margin squeeze abuse". In May 2001 Genzyme terminated its distribution agreement with a company called Healthcare at Home Limited ("Healthcare at Home" or "HH") which had been, since 1998, Genzyme's exclusive distributor for the delivery of Cerezyme and associated homecare services to Gaucher patients. As long as

[2] See paragraphs 34, 163 (ii) and 172 of the decision, and the more specific definition in paragraph 3 of the direction contained in paragraph 396.

that agreement was in force, Healthcare at Home was remunerated by Genzyme by service fees. As from May 2001, Genzyme decided to supply home delivery/homecare services itself, through a division named Genzyme Homecare ("Genzyme Homecare" or "GH"). As from that date, Genzyme has been prepared to supply Cerezyme to third party delivery/homecare services providers, including its former distributor Healthcare at Home, only at the NHS list price which, according to the OFT, is the price that Genzyme Homecare itself charges the NHS for a bundle which includes not only the drug, but also the supply of Homecare Services for Gaucher patients as well.

18. According to the OFT, this pricing practice has meant that any third party delivery/homecare services provider, wishing to compete with Genzyme Homecare in supplying Cerezyme and associated homecare services to Gaucher patients, has had no margin with which to do so, thus effectively securing a monopoly in respect of Homecare Services for Gaucher patients, as defined in the decision, in favour of Genzyme Homecare. The margin squeeze abuse is found by the OFT to have lasted from May 2001 to 27 March 2003.

19. The OFT also found in the decision that, in addition to foreclosing the market for Homecare Services as defined, the two abuses complained of have raised barriers to entry in the "upstream market" of drugs for the treatment of Gaucher disease, by making it more difficult for potential competitors of Genzyme to obtain access to Gaucher patients (see paragraphs 331 to 350, and 382, of the decision).

20. The OFT rejected Genzyme's arguments that its practices were objectively justified: paragraphs 351 to 363 and 383 to 385 of the decision.

21. The OFT's conclusion on the abuse of Genzyme's dominant position is set out in paragraph 386 of the decision in these terms:-

> "The OFT considers that Genzyme has abused its dominant position in the upstream market by, without objective justification
>
> (i) making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, thereby reserving to itself (or to an undertaking acting under contract for

Genzyme) the ancillary but separate activity of providing Homecare Services; and

(ii) adopting a pricing policy following the launch of Genzyme Homecare which results in a margin squeeze;

with the effect of

(i) foreclosing the Homecare Services segment of the downstream market; and

(ii) raising barriers to entry to the upstream market."

22. For these two abuses, the OFT has imposed a penalty on Genzyme of £6,809,598. The calculations are set out at paragraphs 397 to 444 of the decision.

23. The decision, at paragraphs 390 to 396, contains a direction to Genzyme intended to bring the abuses to an end. Paragraph 396 of the decision sets out the direction in these terms:

"1. Genzyme shall

1.1. within fifteen working days from the date of this Decision bring to an end the infringement referred to at paragraph 386 above;

1.2. thereafter, refrain from repeating the infringement referred to at paragraph 386 above; and

1.3. with effect from the date of this Decision, refrain from adopting any measures having an equivalent effect.

2. In particular, within fifteen working days from the date of this Decision

2.1. the price at which Genzyme supplies Cerezyme and Ceredase to the National Health Service shall be, in respect of each drug, a stand-alone price for the drug only that is exclusive of any Homecare Services that may be provided; and

2.2. the price at which Genzyme supplies Cerezyme and Ceredase to third parties shall be, in respect of each drug, no higher than the stand-alone price for the drug only as agreed between Genzyme and the Department of Health.

3. The term 'Homecare Services' in paragraph 2.1 means, in respect of each of Cerezyme and Ceredase, the delivery of the drug to a patient's home and the provision of homecare services (including,

but not limited to, basic stock check, supply of and monitoring of the need for accessories such as fridges and syringes, waste removal, dispensing the drug, training on how to infuse the drug, infusing the drug, providing an emergency helpline, respite care and full nursing support)."

24. In a judgment of 6 May 2003 [2003] CAT 12 the President of the Tribunal, acting under Rule 32 of the Tribunal's Rules[3] made an interim order suspending the Direction on certain terms pending the determination of this appeal or until further order (see paragraphs 126 to 128 below).

25. In a wide ranging appeal, in which the Tribunal has been invited to consider many documents and a large number of witness statements, Genzyme has contested every aspect of the decision.

II. FACTUAL BACKGROUND

(1) *Genzyme and the development of treatment for Gaucher disease*

Genzyme

26. Genzyme is a wholly owned subsidiary of Genzyme Corporation, located in Cambridge, Massachusetts, USA, which is a leading biotechnology company, founded in 1981, with a worldwide turnover of US$1.3 billion. Genzyme's annual United Kingdom turnover is some £65 million. Genzyme's turnover in Cerezyme is around £20 million. Genzyme also supplies Fabrazyme, which is a treatment for another rare enzyme deficiency disorder, Fabry disease, and other products. Genzyme Homecare, which distributes Cerezyme and Fabrazyme in the United Kingdom, is situated at Oxford.

Lysosomal Storage Disorders

27. Lysosomal storage disorders ("LSDs") are a group of about 40 metabolic disorders resulting from enzyme deficiency. LSDs give rise to relatively rare disorders such as Gaucher disease, Fabry disease, Pompe disease and other disorders.

[3] Since this appeal was lodged prior to 20 June 2003 it is governed by the Competition Commission Appeal Tribunal Rules 2000 (SI 2000 no. 261). Appeals lodged since that date are governed by the Competition Appeal Tribunal Rules 2003 (SI 2003 no. 1372): see paragraph 69 of these Rules.

Gaucher disease

28. In the case of Gaucher disease, the body lacks the enzyme glucocerebrosidase, which is used to degrade waste material. In the most common form of the disease (Type 1) this enzyme deficiency may lead to an enlarged spleen or liver, bleeding and bruising problems, fatigue, weakening of the skeleton and other difficulties. The symptoms may vary from mild to severe, may develop at any age, and may be potentially life threatening.

29. There is currently no cure for Gaucher disease. However, treatment is available for Type 1 Gaucher disease. According to the decision (paragraph 24), there are four potential methods of treatment, namely:

    (i) Enzyme Replacement Therapy ("ERT"). ERT involves a patient being administered replacement enzymes which degrade the stored waste material in white blood cells.

    (ii) Gene Therapy. This aims to introduce copies of normal genes into patients, which will lead to the production of the normal enzyme and therefore correct the enzyme deficiency. This therapy is probably many years away from being marketed.

    (iii) Substrate Balance Therapy ("SBT"). In contrast to ERT, this treatment partially inhibits the formation of waste material in the first place, resulting in less waste material being stored in white blood cells. Unlike ERT, however, it does not eliminate the waste material already stored. An SBT drug, Zavesca, was launched in the United Kingdom in March 2003.

    (iv) Other treatments. These include symptomatic treatments (such as splenectomy, hip replacement and/or pain medications) and bone marrow transplantation. Symptomatic treatments do not deal directly with the cause of the disease. Bone marrow transplantation treats the cause of the disease but is a highly complex and risky procedure associated with high mortality.

30. According to Genzyme, ERT is the most direct therapeutic approach to Gaucher disease as it supplements or replaces the enzyme missing in sufferers.

Ceredase and Cerezyme

31. The discovery that Gaucher disease was caused by a deficiency of the enzyme glucocerebrosidase was made in 1964 by Dr Roscoe Brady at the National Institute of Health in the USA. Genzyme Corporation took advantage of Dr Brady's research and used it to develop a drug called Ceredase to treat the disease.

32. Ceredase is derived from human placenta, and involves a massive gathering operation. According to Genzyme, in the early days of Ceredase it took 22,000 human placentas per patient per year to produce the drug. Ceredase was approved by the Food and Drug Administration ("FDA") in the USA in October 1991, and was apparently first imported into the United Kingdom in that year.

33. In 1993 it became possible for patients in the United Kingdom to receive infusions of Ceredase at home, thus obviating the need to go to hospital.

34. However, the reliance of Ceredase on human placentas gave rise to potential problems of adequate supply, and concern regarding the possibility of blood borne diseases carried by the placenta (e.g. HIV). To address these issues, Genzyme worked to establish a recombinant (i.e. artificial) equivalent to the enzyme glucocerebrosidase. Further research work led to the development of Cerezyme, a recombinant version of the same protein which comprised Ceredase.

35. The recombinant protein that comprises Cerezyme is produced from genetically engineered mammalian cells grown in bioreactors. Genzyme Corporation has built a bioreactor plant at Allston Landing, Boston, USA, which manufactures Cerezyme, and now also Fabrazyme. This pioneering plant necessitated a substantial investment, and is currently planned to expand to produce drugs for the treatment of other LSDs.

36. Cerezyme was first marketed in the United States in 1995. Cerezyme obtained the necessary European marketing authorisations in 1997, and first became available in the

United Kingdom in 1998. In 1998, production of Ceredase was largely discontinued and replaced with Cerezyme.

37. About 190 patients are currently receiving treatment in the United Kingdom with Cerezyme, although one patient continues to receive treatment with Ceredase at the Royal Free Hospital because of an intolerance to Cerezyme. Treatment for a Gaucher patient costs the NHS on average £100,000 per year, and must be continued throughout the patient's life.

38. According to Dr Alan Smith, Chief Scientific Officer of Genzyme Corporation, Cerezyme is "extraordinarily safe and spectacularly efficacious" and "works in essentially all patients". Cerezyme is marketed in 61 countries worldwide.

(2) ***Arrangements for treating Gaucher disease in the United Kingdom***

The specialist centres

39. In the United Kingdom all patients diagnosed with Gaucher disease are referred to one of four specialised centres. For adults these are the Royal Free Hospital, London (Dr Atul Mehta) and Addenbrooke's, Cambridge (Professor Timothy Cox). In the case of children, the centres are Great Ormond Street (Dr Ashok Vellodi) and Royal Manchester Children's Hospital (Dr Ed Wraith). These arrangements have been established under the auspices of the National Specialist Commissioning Advisory Group "NSCAG", which is part of the Department of Health "DoH".

Treatment at home

40. Patients infusing Cerezyme at home are usually prescribed the drug by hospital consultants or by GPs taking instructions from the specialist centre under "shared care" arrangements. According to paragraph 39 of the decision:

> " … Once treatment is established, however, it is carried out on a "shared-care" basis with the patient's local doctor. Prescriptions can be written by the specialist care centre or by the patient's local

> doctor. Regardless of who prescribes the drug, the funding comes from the patient's local Health Authority."

(As the Tribunal understands it, the cost of the treatment will ultimately be funded by the Primary Care Trust in which the patient's home is situated).

41. Where patients are treated at home, the prescription is usually sent by the consultant or GP directly to the home delivery/homecare services provider, who arranges for the prescription to be dispensed, delivers the drug and supplies any other necessary homecare services, including nursing.

42. Between 1993 and 1998 Genzyme used Caremark Limited ("Caremark"), a specialised provider of delivery/homecare services, as its distributor and service provider in the United Kingdom. Caremark delivered the drug to the patients' homes and supplied a range of supporting homecare services. Caremark also delivered to hospitals.

43. In 1998 Genzyme terminated its arrangements with Caremark and, following a review of delivery and homecare services providers, entered into a three year contract with Healthcare at Home. That contract was later revised and a new contract made dated 1 February 2000. Under the contract Healthcare at Home was appointed Genzyme's sole and exclusive distributor. Healthcare at Home provided deliveries to hospitals, and home delivery and homecare services to patients at home, in return for service fees. At the end of 2000, Genzyme informed Healthcare at Home of its intention to terminate the contract on notice, in accordance with its terms, with effect from 6 May 2001.

44. As already indicated (paragraph 17 above), in 2001 Genzyme set up its own in-house home delivery/homecare services provider, Genzyme Homecare. However, since May 2001 Genzyme has continued to supply Cerezyme to Healthcare at Home at the NHS list price. In practice, this is done by Genzyme supplying the hospital concerned (e.g. the Royal Free) at the NHS list price, who then re-supply the drug to Healthcare at Home at that price.

45. Accordingly, Healthcare at Home has, since May 2001, continued to supply home delivery/homecare services to Gaucher patients being treated at home, albeit without

earning a margin on these services (see paragraphs 112 to 120 below). Healthcare at Home has already ceased to supply Cerezyme to hospitals for use in hospital.

46. Both Genzyme Homecare and Healthcare at Home have registered pharmacies which dispense Cerezyme against the consultant or GP's prescription. Genzyme uses a pharmacy which is also a community pharmacy, but community retail pharmacies do not generally supply Cerezyme. Genzyme Homecare's distribution centre and pharmacy is in Oxford. Healthcare at Home's distribution centre and dedicated pharmacy is at Burton-upon-Trent. With minor exceptions home delivery/homecare services for Gaucher patients are currently available only from Genzyme Homecare or Healthcare at Home.

The present position

47. According to Genzyme, as at September 2003 there were 192 patients being treated with Cerezyme in the United Kingdom. Of these, 21 patients were being treated in hospitals. Since May 2001 deliveries to hospitals have been made by Genzyme Homecare.

48. Of the 171 patients receiving infusions at home, it appears that 154 are supplied by Healthcare at Home and 16 are supplied by Genzyme Homecare. 1 patient is supplied by Central Homecare, another homecare services provider, who obtains supplies of Cerezyme via a hospital. This supply is treated in the decision as *de minimis* (see footnote 186 to paragraph 162). As we understand it, deliveries of Cerezyme to individual patients are made at roughly six-week intervals.

49. According to Genzyme, approximately 116 patients self-infuse, of whom 107 are serviced by Healthcare at Home, 8 by Genzyme and 1 by Central Homecare. Some patients who self-infuse visit their GP to have the cannula inserted in the back of the hand, and then carry out the infusion process themselves.

50. Of the remaining 55 patients who are treated at home, some 42 have infusions administered by nurses supplied either by Healthcare at Home (37) or Genzyme Homecare (5). Some 13 patients have infusions administered by an NHS nurse, of whom 10 are supplied with Cerezyme by Healthcare at Home, and 3 are supplied by Genzyme

Homecare. Nursing visits are required approximately once a fortnight if the patient does not self-infuse.

51. The overall position is shown in Tables 1 to 3 as follows, omitting the one patient being supplied with Ceredase, and the one patient being supplied by Central Homecare.

Table 1

UK patient population being supplied with Cerezyme by either Genzyme Homecare or Healthcare at Home, September 2003

Total Patients	191
of which:	
In hospital	21
At Home	170
	191
Patients in Hospital	
Supplied by GH	21
Supplied by HH	0
	21
Patients at Home	
Supplied by GH	16
Supplied by HH	154
	170

Table 2

UK Patients receiving infusions of Cerezyme at home

Total patients at home	170
Patients at Home who self-infuse	115
of which:	
Supplied by HH	107
Supplied by GH	8
	115
Patients at Home Receiving Nursing Care	55
of which:	
Nurse supplied by HH	37
Nurse Supplied by GH	5
NHS nurse, drug supplied by HH	10
NHS nurse, drug supplied by GH	3
	55

Table 3

Supplies by Genzyme Homecare and Healthcare at Home respectively

Supplies by Genzyme Healthcare	
Total patients	37
of which:	
In Hospital	21
At home	16
	37
GH patients at home	
Self infusing	8
GH nurse supplied	5
NHS nurse	3
	16
Supplies by Healthcare at Home	
Total patients	154
of which:	
In hospital	0
At home	154
	154
HH patients at home	
Self infusing	107
HH nurse supplied	37
NHS nurse supplied	10
	154

Source: Annex 2 to Genzyme's final submissions, 6 October 2003. The number of self infusing patients has been corrected slightly by the Tribunal. Precise patient numbers will vary over time.

52. According to the decision, should the result of these proceedings be adverse, Healthcare at Home would almost certainly cease providing Cerezyme and homecare services to patients at home. Paragraph 120 of the decision states:

> " HH told the Director that, in order to remain a player in the provision of delivery of Cerezyme and provision of homecare services until the Director reaches a decision in this case, HH was prepared to run a loss making operation in the terms set out above. Should the current position continue, however, HH would cease providing delivery of Cerezyme and homecare services."

Actual or potential competitors to Cerezyme

53. As discussed in more detail later in this judgment, in March 2003 Zavesca (paragraph 29 (iii) above) obtained a market authorisation limited to use in the treatment of mild to moderate Gaucher disease in patients for whom Cerezyme is not suitable (paragraphs 143 to 146 of the decision). Zavesca, formerly known as Vevesca, and before that as OGT-918, is an orally administered treatment that does not require infusion. Zavesca is an SBT, rather than an ERT drug. It is manufactured by Oxford Glycosciences Ltd ("OGS"), based in Oxford, which is now owned by Celltech Group Ltd. OGS is active in researching and developing treatments for other LSDs.

54. Transkaryotic Therapies Inc ("TKT") based, like Genzyme Corporation, in Cambridge, Massachussets, is a leading biopharmaceutical company active in the development of treatments for LSDs. There is evidence, discussed later in this judgment, that TKT may commence human trials for an ERT product called GCB which, it is said, will be a direct competitor to Genzyme.

55. It is to be noted that one of TKT's products is Replagal, an ERT therapy for the treatment of Fabry disease, which competes directly with Genzyme's Fabrazyme. It appears that there are a number of legal disputes between Genzyme and TKT. We are told that Healthcare at Home undertakes the distribution of Replagal in the United Kingdom.

(3) ***The relevant regulatory regimes***

Marketing authorisations

56. Medicinal products as defined by Council Directive 2001/83/EC (OJ 2001 L311/67) require a marketing authorisation issued by the competent authority of a Member State, or an authorisation granted for the entire Community by the European Agency for the Evaluation of Medicinal Products ("EMEA") in accordance with Council Regulation 2309/93/EEC (OJ 1993 L214/1). Genzyme obtained individual marketing authorisations for Ceredase in various Member States. Genzyme applied for a Community marketing authorisation for Cerezyme on 10 May 1996. This was granted on 18 November 1997.

57. Under Article 13 of Council Directive 2001/83/EC a market authorisation may be granted more quickly than usual if "exceptional circumstances" exist. Exceptional circumstances

may arise, in particular, if the disease is so rare that it is impractical to carry out full clinical trials. Zavesca was apparently approved under this provision (paragraph 49 of the decision). Apparently proposals exist to introduce a "fast track" for granting market authorisation for certain drugs (paragraphs 51 to 61 of the decision).

Orphan Drugs

58. Some diseases, notably LSDs, are extremely rare and affect only a tiny proportion of the population. Because they occur so infrequently, there is a reduced incentive for phamaceutical companies to risk the cost of developing and bringing to market a medicinal product to diagnose, prevent or treat such a disease. Medicinal products for the treatment of such rare diseases are known as "orphan" drugs.

59. So-called "orphan drug legislation" has been passed in several jurisdictions, most notably the USA, but more recently in the European Community as well, to create additional economic incentives to foster orphan drug research and development. The European Community has made specific provision for orphan drugs in Regulation (EC) 141/2000, which came into force on 22 January 2000 (OJ 2000 L18/1). Article 1 of that Regulation provides that its purpose is "to lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products".

60. Under Article 3 of Regulation (EC) 141/2000, a product will be designated as an orphan medicinal product if it can be shown that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five persons in every 10,000 in the Community, or if it is unlikely that without incentives the marketing of the medicinal product in the Community would generate sufficient return to justify the necessary investment, and that no other satisfactory method exists for the diagnosis, prevention or treatment of the condition in question. According to Genzyme, there are more than 5,000 rare diseases which qualify for such a designation. They include various forms of cancer, infectious diseases, genetic diseases, metabolic diseases such as LSDs and various tropical diseases.

61. Pursuant to Article 8(1) of Regulation No. 141/2000, where a marketing authorisation is granted in respect of a product that has been accepted as an orphan drug, then, without prejudice to intellectual property law or any other provision of Community law, the Community and the Member States may not, for a period of 10 years, accept another application for a marketing authorisation, or accept an application to extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product. However, under Article 8(2) this period may be reduced to six years, if at the end of the fifth year it is established that the criteria set out in Article 3 are no longer met (for example, that the product is sufficiently profitable not to justify the maintenance of market exclusivity). In any event, by virtue of Article 9(3) of Regulation 141/2000, a marketing authorisation may be granted to another medicinal product for the same therapeutic induction if the holder of the marketing authorisation for the original medicinal product so consents, or if that holder is unable to supply sufficient quantities of the orphan product in question, or if the second applicant can establish that the second medicinal product is safer, more effective, or otherwise clinically superior.

62. In addition, sponsors of orphan drugs are accorded certain other advantages, such as advice from the EMEA as to how to conduct the necessary clinical trials, access to the EMEA centralised procedures, certain fee exemptions, and eligibility for EU funded research (Articles 6, 7 and 9 of Regulation (EC) 141/2000).

63. The Committee for Orphan Medical Products established under Article 4 of Regulation (EC) 141/2000 held its inaugural meeting on 17 August 2000. On that date six drugs, one of which was Cerezyme, were recognised as being orphan medicinal products “avant la lettre” - i.e. before the legislation had entered into force. However, these drugs could not be formally granted orphan medicinal product designation because they already had marketing authorisations at the time the legislation was adopted. One of the conditions to obtain designation as an orphan drug is that the request for such designation has to be filed before a marketing authorisation is applied for (Article 5(1) of Regulation (EC) 141/2000).

64. In the United States, the grant of orphan drug status under the relevant American legislation means that a drug has marketing exclusivity for seven years. Genzyme

obtained orphan drug status in the United States for both Ceredase and Cerezyme. That status expired in 2001.

65. In this appeal, Genzyme has laid considerable stress on Cerezyme's status as an orphan drug, and on the need to avoid regulatory action which might damage or destroy the incentives to develop orphan drugs.

Other licences

66. In addition to a marketing authorisation, in the United Kingdom further licences are required for the manufacture or packaging of a medicinal product, for dealing as a wholesaler in medicinal products, or for importing medicinal products.

The United Kingdom Pharmaceutical Price Regulation Scheme "PPRS"

67. The PPRS is a voluntary scheme agreed between the Secretary of State for Health and the Association of the British Pharmaceutical Industry ("ABPI") pursuant to section 33 of the Health Act 1999. It regulates the profit that companies may make from their sales of branded prescription medicines supplied to the NHS. Although participation in the scheme is voluntary, companies that do not participate in the scheme are subject to statutory regulation under sections 34 to 38 of the Health Act 1999 (see further paragraphs 261 to 275 below). Genzyme is a member of the current scheme established in 1999.

68. The objectives of the PPRS are:
    (i) to secure the provision of safe and effective medicines for the NHS at reasonable prices;
    (ii) to promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines; and
    (iii) to encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in the UK and other countries.

The current PPRS agreement lasts from 1999 to 2004.

69. The PPRS sets a limit on the rate of return (measured as a percentage return on capital employed) that a company can earn on its sales of branded prescription medicines to the NHS. The PPRS profit limit is applied across all the products that a company sells to the NHS, and is not applied to each product individually. Under the current PPRS scheme, companies are set a target rate of return on capital of 21%, with an upward margin of tolerance of 40% of the target. Companies exceeding the margin of tolerance (i.e. with a return on capital over 29.4%) are required to repay any excess to the DoH or reduce prices, or both.

70. The profitability of companies is monitored through detailed annual financial returns ("AFRs") submitted by the companies to the PPRS branch of the DoH. However, companies whose sales to the NHS are below £25 million (as is the case with Genzyme) do not have to submit detailed AFRs; such companies need submit only their standard statutory annual accounts. In consequence, their profitability is not closely monitored. The DoH can, however, request more detailed returns if circumstances demand it, for example, if a company wishes to increase prices.

71. Under the terms of the PPRS, a company is free to set the NHS list price of a new product i.e. a product involving a new active substance. However, if the return on capital of the company exceeds the ceiling of 29.4%, the company may be required to pay the surplus to the DoH or alternatively to reduce at least some of its prices to reduce its profits overall. The PPRS is not a cost-plus system of pricing where the price of each individual drug is calculated by adding together its individual costs plus an element of profit. Once prices are set, however, the PPRS restricts any increase. Under the current PPRS, a company may only apply for a price increase if its profits fall short of a return on capital of 8.5%.

72. In 1999 the DoH negotiated an across the board price cut on all branded medicines sold to the NHS of 4.5% (see further below). Companies were permitted to lower the prices of some products more than others provided the overall effect was that of a 4.5% price cut.

73. As the Tribunal understands it, the PPRS does not control the transfer price at which Cerezyme is sold by Genzyme Corporation in the USA to Genzyme for onward distribution and sale in the United Kingdom. At the time of the Decision, the transfer price was £2.50 per unit. However, according to Genzyme this has since been reduced. That reduction took place following the President's Order of 6 May 2003 suspending the direction on terms (see paragraph 128 below).

The NHS list price

74. The NHS list price is the price set by the manufacturer. In the typical case of drugs sold for dispensing by a retail pharmacy in the community (as distinct from drugs sold to hospitals), the drug manufacturer first sells the drug to a wholesaler, at a discount off the NHS list price. Such discount is conventionally 12½%, but may be less. Discounts offered by manufacturers to wholesalers may depend on the quantities of drugs purchased. The wholesaler, in a typical case, then resells to the retail pharmacist at any price up to the NHS list price. Again, however, the wholesaler may grant the pharmacist a discount off the NHS list price. The NHS list price forms the starting point for the reimbursement of the pharmacist by the Prescription Pricing Authority ("PPA") when the drug is dispensed by the pharmacist against a prescription written by a GP, normally on Form FP10. However, to take account of the fact that drugs may be sold to pharmacists by wholesalers or importers at prices below the NHS list price, arrangements exist to "claw back" the average difference between the NHS list price and the pharmacist's actual purchase price. "Zero discount" drugs, like Cerezyme, involve no clawback (see paragraphs 79 and 80 below).

75. It is important to bear in mind that the NHS list price is not, typically, an "ex-manufacturer" price, but is typically the price at (or below) which the wholesaler sells to the retail pharmacy, and at which the pharmacist is reimbursed by the PPA subject to any "claw back". It appears to be conventionally assumed that the manufacturer's NHS list price will be set so as to accommodate a margin of up to 12½% granted by the manufacturer to the wholesaler.

76. The OFT considers, in the decision, that the PPRS and the NHS list price are "inextricably linked" (paragraph 68), and that Homecare Services, as defined in the

decision, are not intended to be covered by the NHS list price (paragraphs 69-83 and 162 (ii)). Those conclusions are strongly contested by Genzyme.

Supplies to hospitals

77. Supplies to hospitals, as distinct from supplies destined to be dispensed by retail pharmacists, are not typically made at the NHS list price, but are made at an agreed discount off that price negotiated between the manufacturer and the hospital purchasing authority. Deliveries to hospitals may be made by wholesalers (in which case the manufacturer will allow a wholesale margin) or, in some cases, by the manufacturer direct.

78. As we understand it, sales of prescription drugs to the community are zero rated for VAT purposes. In the case of Cerezyme, this applies to sales to homecare delivery/service providers. However, sales of Cerezyme to hospitals are subject to VAT at the standard rate of 17.5%. As hospitals do not resell the drug when it is used in the hospital the hospital cannot recover the VAT (see paragraphs 89 and 90 of the Decision).

The Drug Tariff

79. The remuneration of pharmacists for the dispensing of drugs against a GP's prescription, normally on Form FP10, is principally governed by section 41 of the National Health Service Act 1977 and the National Health Service (Pharmaceutical Services) Regulations 1992 S.I. 1992 no. 662, as amended ("the 1992 Regulations") (see also paragraphs 276 to 280 below). Under these provisions, pharmacists receive dispensing fees. All prescriptions over £100 qualify for an additional "Expensive Prescription Fee" of 2% of the cost of the drug.

80. As regards the cost of the drug itself, retail pharmacies are reimbursed by the PPA for the cost of the drugs they have purchased, the intention being that the pharmacy should be reimbursed for the price of the drug "at cost". In practice, as mentioned in paragraph 74 above, many drugs are sold by wholesalers to retail pharmacies at less than the manufacturer's NHS list price. As we understand it (see Mr Derodra's witness statement of 11 October 2002 on behalf of Genzyme), in the typical case the pharmacist negotiates

a discount from the wholesaler, very often on an across-the-board basis, depending on how much the pharmacist has spent with a particular wholesaler in the month in question. To take account of this, the pharmacy is reimbursed at the NHS list price less a "clawback" determined by the PPA and published in the Drug Tariff in the context of an ongoing monitoring system known as "the Discount Inquiry". The clawback rate is not calculated on a per drug basis, but is a percentage applied to the pharmacist's total purchases in a particular month. For example, in October 2002 a pharmacy which dispensed items of a list value of £50,000 was subject to a clawback rate of 11.32%. However, certain drugs, known as "zero discount drugs" are reimbursed to the retail pharmacist at the NHS list price, it being recognised that the pharmacy does not normally obtain a discount off the NHS list price when it purchases such drugs. According to Mr Derodra, zero discount drugs typically have special features, such as cold chain delivery or high cost.

81. The Drug Tariff is made and published by the PPA under Regulation 18(1) of the 1992 Regulations. Part VIII of the Drug Tariff contains a "basic price" for named drugs approved by the Secretary of State. If no basic price is set out in Part VIII, the basic price is the manufacturer's list price (clause 8C of the Drug Tariff). Having dispensed the GP's prescription, the pharmacist is reimbursed at the applicable basic price, less the clawback percentage shown in the "Deduction Scale" in the Drug Tariff, except in the case of zero-discount drugs, to which no clawback is applied. In the case of Cerezyme the basic (i.e. reimbursement) price is Genzyme's list price, which is not subject to claw back. Although the terms "the Drug Tariff price" and the "NHS list price" are often used interchangeably, they are in fact distinct concepts.

82. As already stated, many prescriptions for Cerezyme are written by hospital consultants. Where the patient concerned is at home, the prescription is normally sent to Healthcare at Home or Genzyme Homecare for dispensing and onward supply of the drug and associated homecare to the patient. When those hospital prescriptions are dispensed by Healthcare at Home, or Genzyme Homecare, as the case may be, the hospital reimburses Healthcare at Home or Genzyme Homecare directly for the cost of the drug at the NHS list price. These arrangements lie outside the arrangements for reimbursing pharmacies by the PPA. Where, however, the prescription is written on a Form FP10 (for example, where the GP has a "shared care" arrangement with the responsible hospital consultant)

reimbursement is made to Healthcare at Home or Genzyme Healthcare by the PPA, again at the NHS list price. In relation to FP 10 prescriptions, the Expensive Prescription Fee is also payable.

The Fresenius/Caremark report and associated issues

83. In 1998 the then Monopolies and Mergers Commission (MMC) investigated and reported on a proposed merger between Fresenius AG (Fresenius) and Caremark: see the *Fresenius/Caremark* report, 9 March 1998. Fresenius and Caremark[4] were (and still are) companies active in providing services to patients who suffer from serious medical conditions and are treated for them at home. As already indicated, at the time of the *Fresenius/Caremark* report Caremark was Genzyme's distributor in the United Kingdom for Ceredase and Cerezyme, although Caremark was replaced by Healthcare at Home in May 1998 (paragraphs 42 to 43 above). The *Fresenius/Caremark* report contains discussion of the markets for various treatments or conditions which were then relevant to Caremark's business, including parenteral nutrition, enteral nutrition, immunoglobulin, Gaucher disease, infertility treatment, and beta interferon treatments for sufferers from multiple sclerosis.

84. It appears from the *Fresenius/Caremark* report that, until 1995, the homecare services for many of the treatments with which Caremark was then concerned were provided against GP prescriptions, the cost of any homecare services being included in the price of the drug (paragraphs 2.43 to 2.46 and 4.51 of the *Fresenius/Caremark* report). However, an instruction from the then NHS Executive in an executive letter EL(95)5, set out in Appendix 4.2 of the *Fresenius/Caremark* report, stated that in future packages of care at home in relation to certain patients should not be funded by GP prescriptions on Form FP 10, but should be provided on the basis of contracts between suppliers and the relevant health authorities. The patients concerned were patients with renal failure receiving continuous ambulatory peritoneal dialysis, cystic fibrosis patients receiving intravenous or nebulised antibiotics, cancer patients receiving intravenous chemotherapy agents, HIV patients receiving intravenous or nebulised anti-infectives, patients receiving total parenteral nutrition or various types of specialised enteral feed, thallassaemics receiving

[4] Caremark is now called Clinovia

desferrioxamine and patients receiving continuous anticoagulant treatment. As appears below, the relevance of the *Fresenius/Caremark* report and the significance, if any, of EL(95)5, has been the subject of argument before us: see paragraphs 281 to 287 below.

85. Both Genzyme and the OFT assert that the structure of homecare services has changed little since 1998. Both parties seek to support their case by reference to the *Fresenius/ Caremark* report. However, the evidence before the Tribunal is that the homecare sector is in the course of expansion and change, as discussed later in this judgment.

(4) ***The pricing and marketing of Ceredase and Cerezyme since 1993***

The arrangements with Caremark

86. Caremark was appointed by Genzyme as its distributor and service provider in the United Kingdom in 1993 (paragraph 42 above). Caremark delivered the drug to the patients' homes, and provided homecare services as required.

87. In 1993, the NHS list price for Ceredase was £2.97 per unit. A unit is one vial, with 200 vials to a pack. According to the decision, Genzyme initially sold Ceredase to Caremark at £2.67 per unit, which Caremark then resold to the NHS at the then list price of £2.97 per unit, funding the delivery and homecare services supplied out of the resulting margin of 30p. A letter of 26 March 1993 from Genzyme to Caremark cited in paragraph 106 of the decision states:

> "With regard to the community pharmacy supply of Ceredase via FP10 prescriptions, we intend that the price be £2.97 per unit to the customer and that you be charged £2.67 per unit. This difference will encompass your total distribution costs, together with the supply of ancillary items used in the non-hospital environment, the provision of nursing support by Caremark where deemed to be appropriate and other elements of service as discussed".

88. Apparently, soon afterwards, this arrangement was changed to the effect that Genzyme sold Cerezyme to Caremark at the NHS list price of £2.97 per unit, but Caremark received a service fee of 30p per unit from Genzyme.

89. At this time supplies sold direct to hospitals were sold at a hospital price of £2.67 per unit, plus VAT. The lower hospital price apparently reflected the fact that these supplies attracted VAT which was not recoverable by the hospital when the patient was infused in hospital (paragraph 90 of the decision).

90. In 1994 the NHS list price for Ceredase was increased to £3.09 per unit, and the hospital price was increased to £2.73 per unit plus VAT. Caremark's service fee was increased to 36p.

91. When Cerezyme was introduced in 1997, it was sold at the same price as Ceredase - i.e. £3.09 per unit. Since Cerezyme, like Ceredase, is sold in packs of two hundred vials, this gives a price per pack of £618.

The appointment of Healthcare at Home

92. As already indicated (paragraph 43 above) in May 1998, Genzyme terminated its arrangements with Caremark and entered into a new agreement with Healthcare at Home on 6 May 1998. Healthcare at Home purchased Cerezyme from Genzyme at the NHS list price of £3.09 per unit and resold to the NHS at £3.09 per unit for sales in the community, and at £2.73 plus VAT for sales to hospitals. Healthcare at Home was remunerated by Genzyme by reference to a scale of charges which depended on the level of care required by the patient, plus a management fee of 2½% and a fee for each nurse visit. In the case of sales to hospitals, the charges paid to Healthcare at Home by Genzyme were higher, to reflect the fact that the price at which Cerezyme was supplied to hospitals by Healthcare at Home (£2.73 per unit) was less than Healthcare at Home's purchase price from Genzyme (£3.09 per unit).

The correspondence with the Department of Health in 1999

93. In 1999, correspondence took place with the DoH in connection with Genzyme's admission to the PPRS and the effect on Genzyme of the across-the-board price cut of 4.5% then being sought by the DoH from all companies which were actual or prospective members of the PPRS (paragraph 72 above).

94. On 7 September 1999, Mr Cortvriend on behalf of Genzyme wrote to Dr Bratt of the DoH, PPRS branch, as follows:

> " … I refer to our phone conversation of earlier today during which we discussed the recent letter sent to Genzyme by J M Brownlee of the DoH PPRS branch.
>
> …
>
> Genzyme is not a member of the ABPI … Consequently we have not been party to any consultation regarding the PPRS. Our interpretation has been that the previous PPRS scheme was not applicable to those companies with a turnover of less than £20m in the UK. In any case we have not implemented a price increase in over four years.
>
> You commented that Cerezyme pricing may be unique. Our price of £618 per 200 unit vial is the price which our homecare provider, HealthCare at Home Ltd, supplies the product to the NHS. However this, as I pointed out, does not just include the price of the drug. Healthcare at Home provide extensive nursing support to many patients, even to the extent of three weekly visits to patients' homes to administer two hour infusions. In addition, home delivery and ancillaries such as water for injection, infusion pumps and lines, needles, swabs, etc. are all provided as part of this service, together with fridges for storage of drug etc.
>
> We discussed two issues for which we would like clarification. If Genzyme agrees to participate in the PPRS scheme as outlined in the letter, what opportunities are there for negotiation regarding the proposed 4.5% price decrease, based, in part, on the unique pricing as described above? Secondly, should we elect not to join the PPRS, how would the statutory price control, referred to in the 1999 Health Act, be implemented and would there be opportunities for negotiation in respect of this? …"

95. Dr Bratt replied to Mr Cortvriend on 14 September 1999, as follows:

> " .. In response to your letter of 7th September 1999, I can confirm that your company is subject to the PPRS and with sales of £16m you are also subject to the 4.5% price reduction. We have considered your submission regarding Cerezyme, and in the light of the pricing of this product I have the following proposal:
>
> You will be required to reduce that proportion of the list price representing the cost of the actual pharmaceutical by 4.5%. To ensure that we have evidence of this could you please provide a breakdown of the list price of Cerezyme? Given the Department's requirements to

demonstrate an audit trail, the price breakdown will have to be subsequently endorsed by your auditors…"

96. Following further correspondence, Mr Paul Foster, Genzyme's financial controller, wrote to Dr Bratt on 22 March 2000 outlining the basis on which Genzyme proposed to reduce the list price for Cerezyme, as follows:-

> "… The list price for the NHS represents two elements, firstly the cost of the pharmaceutical drug and secondly the costs of providing homecare assistance for patients whom have infusions in their home environment. The cost of homecare is dependent on the level of service provided, ranging from delivery of the drug and ancillaries and waste disposal to complete nursing assistance in the form of home visits.
>
> To compute the price of the drug (which solely attracts the 4.5% discount, as agreed in your letter of 14th September 1999) we have had to deduct the average cost of homecare.
>
> The calculation
>
> The average healthcare cost for the first nine months of 1999 was 33.9p. This represents the average of service levels from 4.06p to £1.05. As the average is near the lower end of the scale, the Genzyme management has thought it appropriate to build in a contingency of 20p to cover a likely shift of increased service levels for new patients. This gives a reduction of 11.5p per unit and corresponds to a reduction of price for the 200-unit vial from £618 to £595.
>
> See appendix for a detailed analysis."

97. On the basis of the above calculations, Genzyme's NHS list price was reduced from £3.09 per unit to £2.975 per unit. The calculations set out in Mr Foster's letter show that, according to Genzyme, the cost of the homecare services there referred to was calculated at 53.9p, including a contingency of 20p to take account of increased service levels in the future. On that basis, the "drug element" in the list price of Cerezyme was £2.55 per unit. It was to that figure (as opposed to £3.09) that the reduction of 4.5% required by the DoH under the PPRS was applied, giving a notional price reduction for the "drug element" from £2.55 per unit to £2.435 per unit. Taking £2.435 as the cost of the drug, plus 53.9p for home delivery and homecare services, gave a new NHS list price of £2.975 per unit (£595 per 200 unit vial). This methodology was apparently accepted by the DoH.

98. The hospital price remained unchanged at £2.73 plus VAT per unit.

The arrangements with Healthcare at Home in 2000

99. From 1 February 2000 the payment arrangements between Healthcare at Home and Genzyme were revised. Genzyme thereafter paid Healthcare at Home a fee of 39p per unit for hospital supplies, and 21p per unit for home supplies, plus a management fee of 2½%. The payment for hospital supplies equates to 14.5p per unit, since from 2000 Healthcare at Home bought Cerezyme from Genzyme at £2.975 per unit and resold to hospitals at £2.73 per unit, i.e. a discount of 24.5p. According to the decision (paragraph 114), as a result of these arrangements in 2001 Healthcare at Home was receiving a payment of some 28.4p per unit in respect of home based patients.

The termination of Healthcare at Home's contract

100. In the course of 2000, Genzyme decided to terminate its distribution agreement with Healthcare at Home, according to its terms, with effect from 6 May 2001 with a view to setting up its own "in house" delivery/homecare services provider in the form of Genzyme Homecare.

- *The letters of 12 June and 3 November 2000*

101. That decision was taken following discussions with Healthcare at Home. On 12 June 2000 Genzyme wrote to Healthcare at Home in these terms:

> "Following our discussions regarding the future role of Healthcare at Home in the provision of Cerezyme distribution and nursing services for Gaucher patients in the UK, I am now in a position to inform you of the decision.
>
> It has been decided that Genzyme Therapeutics will set up its own independent Homecare division to service current needs and for those that are in development.
>
> This service change comes into effect on 6 May 2001. Our decision is final, and we are currently in the process of obtaining the appropriate regulatory licenses to enable Genzyme to undertake this operation.
>
> Bringing homecare in-house is part of our strategic planning and does not reflect on the quality of service currently provided by you and your

team. I do appreciate the contribution that all of you at Healthcare at Home have made to this therapy area over the past two years. This has been an extremely difficult decision to make and I am sure you will be disappointed by this outcome."

102. On 3 November 2000 Genzyme wrote to Healthcare at Home in these terms:

> "As we mentioned yesterday we are giving Healthcare at Home formal notice (pursuant to clause 12.1) of the termination of the Agreement of 1 February 2000 effective May 5 2001. That notice is given by a separate letter which you will be receiving with this one.
>
> The Agreement has been terminated because Genzyme believes it is now appropriate to bring the management of the distribution of Ceredase and Cerezyme within the company in order that over the next few years the whole portfolio of single enzyme treatments which is being developed by Genzyme can be administered by our own medical department.
>
> The new therapies are of an extremely complex nature and will require intensive support and careful follow up and advice from the medical department. We expect to begin with the therapy for Fabry's disease in 2001 and to start studies on MPS1, for Hurler's disease in 2001 and dispensing that treatment in early 2002. These will be followed by two further therapies for enzyme deficiencies which we expect to market shortly afterwards.
>
> As with Gaucher's disease each group of patients is very limited in number and has very specialised requirements. Particular expertise will be needed for each of the therapies but whilst they treat different diseases they require the same essential medical knowledge - there are common issues to them all. For these reasons it makes both medical and commercial sense that the delivery of the therapies and the care of the patients should be handled directly by us.
>
> We are grateful for your assistance and help in the past three years; and we hope that you will continue to develop your successful business as you have done in the past".

103. In his witness statement of 22 October 2002 Mr Johnson of Genzyme emphasises that the arrangements with Healthcare at Home were also expensive for Genzyme, and that Genzyme had also encountered some problems with the service supplied by Healthcare at Home. In any event, according to Mr Johnson, the establishment of Genzyme Homecare made good commercial sense, especially with the introduction of Fabrazyme and other potential LSD therapies on the horizon.

- *The "proposal" document at the end of 2000*

104. A document entitled "Proposal for the Provision of Distribution and Homecare Nursing Services in the UK" was apparently prepared by Genzyme management in November 2000 in connection with the establishment of Genzyme Homecare and, in particular, the acquisition of premises at Oxford. The Executive Summary of this document states:

> "Currently all vials of Cerezyme in the UK are sold to a third party distributor - Healthcare at Home (H@H). The product is then either delivered to a hospital or a home environment for infusion. Genzyme pays in entirety the cost of homecare provision; it is included in the cost of Cerezyme to the NHS at the agreed price.
>
> Genzyme currently pay approx. 11.7% of revenue to H@H, by bringing homecare in-house we aim to reduce homecare costs to 6/7% after 5 years.
>
> Genzyme UK propose to develop an in-house homecare team dedicated to providing homecare services that will enable the management of appropriate dosing and protect our current business from potential competition.
>
> H@H are high maintenance, provide variable service levels and there is a general loss of control for Genzyme management.
>
> There is uncertainty of H@H's ability to successfully handle the nursing for the complex set of LSD pipeline products.
>
> To maximise cost savings and to provide optimal efficiency for product distribution we require a central location such as Oxford.
>
> To counteract any adverse public relations problems with physicians, DoH, patient associations and patients Genzyme UK will communicate strongly that the new service will provide the highest possible standard of care for patients, that we wish to introduce other therapies and harmonise the service.
>
> We have identified an appropriate Homecare Director who is currently head of Baxter's Homecare division which distributes all dialysis products and services to UK patients. We have also identified 2 pharmacists and a head of nursing.
>
> The financial benefits would be savings in 2001 of $103k and in 2002 they would be $1.379m. NPV would be $4.79m and the payback period would be early year three (16 year lease).

Over a five year period, when including Fabrazyme activity, we would benefit from cost savings of $6.6m (based on a 5 year lease) and $7.96m (based on a 16 year lease).

It is essential that we set up the Genzyme Homecare division at this time. The contract with H@H has been terminated, and we must have a decision at the very latest by 1 December 2000".

105. Paragraph 11 of this document under the heading "Summary" states as follows:

"*Homecare generally*:

- Homecare for the Gaucher patients has supported a >97% compliance on therapy
- It has provided us with the most accurate information on dosing and frequency in Europe
- It provides tremendous added value and would be a selling benefit in the face of competition

Homecare by Genzyme

- Reduces cost whilst maintaining service
- Puts Genzyme back in control - limits the failure rate
- Connects the company **with** the service (unlike the current situation)

- Pushes out competition, by providing a "shopping basket" of tailor-made services
- Raising the standard of care to superior levels

Oxford location

- Centralised and cost effective
- Easy access and located with all the services
- Minimal impact on running costs, with significant savings over time
- An ideal opportunity to raise awareness of Genzyme, particularly important in the face of TKT and OGS activity".

- The NSCAG meeting 13 February 2001

106. On 13 February 2001 Genzyme apparently informed the DoH of its intentions at a meeting with officials of the National Specialist Commissioning Advisory Group ("NSCAG") (see paragraph 39 above) of the DoH. Genzyme's own note of that meeting reads:

> "The rationale behind Genzyme's decision to set up its own in-house homecare service was explained to the team responsible for metabolic disorders at the DoH. Namely due to the complexity of Fabry's disease, and the potential safety issues with administering the replacement enzyme, (compared to Gaucher), it makes sense to set up our specialist service. This way Genzyme can establish a dedicated team to specialise and become experts in all clinical and physiological aspects of these rare disorders. By having a team specifically trained and dedicated to Genzyme's own needs without any form of commercial distraction, the standard of care available will be a major step forward in providing the back-up and support for both patients and clinicians.
>
> The feedback at the meeting was that this decision makes complete sense. The only question related to cost. By enhancing this service was there an increase in cost to the NHS? The funding of Homecare was then explained - Genzyme to pay for all aspects of providing Homecare and distribution, and that there would be no increase in costs to the NHS. They were satisfied with this answer."

107. Exactly what transpired at, and the significance of, the meeting of 13 February 2001, is in dispute between the parties: see notably Malcolm Johnson's witness statements of 28 August 2003 and 17 September 2003 on behalf of Genzyme, and the witness statement of Julia Stallibrass of 11 September 2003, Specialised Services Team Leader responsible for overseeing the work of the NSCAG commissioning group, filed on behalf of the OFT, mentioned later in this judgment.

The reactions of patients and clinicians

108. During March and April 2001 Genzyme informed the relevant hospitals and consultants, and also the Gaucher Association (patients association) that, following the termination of its agreement with Healthcare at Home, all orders for Genzyme would be handled by Genzyme Homecare through its new facility at Oxford as from 7 May 2001.

109. On 21 March 2001 the Gaucher Association prepared a memorandum expressing its concern regarding the replacement of Healthcare at Home by Genzyme Homecare. Those concerns were centred mainly on whether Genzyme Homecare's service would be as efficient as that of Healthcare at Home; whether the service provided by Genzyme Homecare would be, or would be perceived to be, as independent and impartial as that of Healthcare at Home; the maintenance of patient confidentiality; whether complaints

about any deterioration in service would be effective; and whether Genzyme would have an unfair competitive advantage in the event of new treatments becoming available for Gaucher disease.

110. On 29 March 2001 Professor Cox of Addenbrooke's Hospital sought advice about the propriety of Genzyme's decision from the Head of Medicine, Pharmacy and industry at the DoH. Professor Cox wrote to the DoH in these terms:

> "The Genzyme company has now announced that they are going to terminate the delivery and nursing service supplied by Healthcare at Home and will replace it with their own apparently independent but in-house Genzyme Homecare service.
>
> Genzyme tells us that with the waiving of 17.5% VAT this will be cost neutral but I am concerned that removal of the service from Healthcare at Home which is an independent service provider will lead to a lack of independence. I am concerned that confidential information regarding patients may be fed back inadvertently or inevitably through the sole licensed pharmaceutical supplier of the orphan drug Cerezyme to the Genzyme company. The clinical freedom for prescription of other drugs related to Gaucher's disease either available now or that will come on stream will be prejudiced by the sole provision of the service by the Genzyme company.
>
> Not only do I believe that this measure by Genzyme may create an unfair competitive commercial advantage for Genzyme over other suppliers and notably the current Healthcare at Home (who at present provide what our patients believe to be a satisfactory service), but inevitably difficulties may arise in the prescription of other agents - drugs from companies other than Genzyme. These companies may ultimately prove to be providers of better or at least comparable or complementary therapeutic agents. I believe that advice on the provision of treatment accompanied by nurses who supervise delivery of home intravenous therapy should be independent and impartial and that, despite assurances to the contrary, any in-house home service provided by the Genzyme company itself for its own drug could not maintain the appropriate level of independence.
>
> I have had discussion with the charity, the Gauchers Association, that represents the patients who receive this treatment and they join me in these concerns, as does the Director of the other adult Gaucher Centre nationally.
>
> I myself should like to know the legality and propriety of this move by Genzyme, for which there is to my knowledge no credible precedent for a pharmaceutical company. Your advice on the matter, however, would be most welcome. Since this action has been announced, the Genzyme

company is preparing to introduce its own home service very soon and for that reason the favour of an early reply when you have had an opportunity to fully consider this matter would be greatly appreciated. Thank you. I enclose the relevant announcement from the Genzyme company."

As the Tribunal understands it, that letter from Professor Cox dated 29 March 2001 was passed by the DoH to the OFT. Professor Cox copied that letter to Dr Mason at the OFT, to whom he also expressed his concerns.

111. On 18 April 2001, Christine Treherne, Principal Pharmacist at the Royal Free Hospital wrote to Genzyme to the effect that, so far as the Royal Free was concerned, supply of Cerezyme should continue through Healthcare at Home:

> "Following your visit to the Royal Free, I have had meetings with both Dr Mehta and John Farrell, Head of Pharmaceutical Services, and we have decided that the supply of Cerezyme, for Royal Free patients at home, should continue through Healthcare at Home, for the foreseeable future.
>
> I trust that you will continue to supply Healthcare at Home with appropriate stocks for our patients. I will forward the appropriate prescriptions for the next six months to them. Consequently, I would like to cancel the meeting we scheduled for tomorrow.
>
> I am in receipt of your letter of 24 March in relation to the supply of Cerezyme for patients with Gaucher's disease. I wish to make it clear that, after prolonged consideration of the matter, I would wish that the patients under my care should be supplied under the current arrangements by Healthcare at Home or, if necessary, by another free-standing agency, rather than supplied by Genzyme or an affiliated division thereof.
>
> I am also aware of the opinion of my colleage, Dr Atul Mehta, Director of the Gaucher's service at the Royal Free Hospital, who shares this view. I have also been given to believe that the patient organisation, the Gaucher's Association, has reservations about a monopoly arrangement for drug delivery and nursing services, as well as drug supply and share with them their concern".

Genzyme's decision to continue supplies to Healthcare at Home

112. Following a period in which it was unclear from whom Cerezyme was to be obtained, Genzyme stated in a letter to Healthcare at Home dated 25 April 2001, and in a general circular letter dated 11 May 2001, that it would continue to supply Healthcare at Home

with Cerezyme on similar terms to any other third party who may request supplies from Genzyme.

113. Accordingly, since May 2001 Genzyme has continued to supply Healthcare at Home with Cerezyme. These supplies are made at the same price as before - i.e. the NHS list price of £2.975 per unit, which is the price that Healthcare at Home subsequently charges the NHS. In practice, following a requirement by Genzyme that Healthcare at Home should supply it with a letter of credit, these supplies are sold by Genzyme to the Royal Free and Addenbrooke's hospitals, who then resell to Healthcare at Home, these purchases and sales all taking place at the NHS list price of £2.975.

114. When Healthcare at Home delivers the drug to the patient at home, it is then reimbursed by the NHS (either the PPA, or the purchasing hospital, as the case may be) at the same list price, i.e. £2.975 per unit[5]

115. However, Healthcare at Home does not receive any service or management fees from Genzyme, the NHS or any other source. It receives only dispensing fees, and the Expensive Prescription Fee, on prescriptions not written by hospital doctors. Apart from those fees, which relate to dispensing, Healthcare at Home's delivery/homecare services have operated from 6 May 2001 at no margin.

116. As regards supplies to hospitals, since May 2001 Healthcare at Home has been unable to continue to supply hospitals, since the hospital price is £2.73 plus VAT, whereas Genzyme is prepared to supply Healthcare at Home only at £2.975. Accordingly, since May 2001 hospital supplies have been made by Genzyme Homecare.

117. In June 2001, the Royal Free Hospital sought to purchase Cerezyme from Genzyme at the hospital price of £2.73 plus VAT per unit, for onward supply to Healthcare at Home to assist Healthcare at Home to supply homecare services to Gaucher patients at home under the care of the Royal Free. Because the patient was being treated at home, as distinct from in hospital, the Royal Free would have been able to recover the VAT. However, by a letter dated 25 June 2001 Genzyme pointed out to the Royal Free that the concessionary

[5] Although VAT is initially payable on these supplies, the VAT is recovered from Customs and Excise as an input on a zero-rated supply where the drug is used by the patient at home.

price to hospitals of £2.73 plus VAT per unit did not apply where the hospital was purchasing for resale and use outside the hospital setting. Hence a hospital who wishes to purchase Cerezyme for infusion outside the hospital has to pay the full list price of £2.975 per unit.

118. On 24 June 2001 Healthcare at Home asked Genzyme to supply it with Cerezyme on reasonable commercial terms, pointing out that it was standard industry practice for a wholesaler to operate on a margin of 12½% of the NHS list price with payment within 30 days. Healthcare at Home reiterated its request on 28 June 2001. As we understand it Genzyme did not reply to those letters. As already stated (paragraph 52 above), it appears that Healthcare at Home has been prepared to continue to supply home delivery/homecare services to Gaucher patients at home, at least temporarily, on an uneconomic basis, in the hope of a favourable outcome to the present case.

119. A number of documents in the Tribunal's file show that at various times between July and September 2001 Genzyme intimated to a number of NHS Trusts that Genzyme was no longer funding supplies of Cerezyme by Healthcare at Home, that Healthcare at Home's service was sustainable only in the short term, and that it would be more expensive for the NHS Trust concerned if they continued to deal with Healthcare at Home rather than Genzyme (letter from Leeds Teaching Hospitals NHS Trust 8 September 2001; HH notes of telephone conversations with NW Wales NHS Trust, 18 September 2001, and Royal Hospital for Sick Children, Edinburgh, 19 September 2001; letters from Genzyme to Cornwall and Isles of Scilly Health Authority 12 July 2001 and September 2001).

120. By letters dated 3 December 2002 to Clinovia Limited, 4 June 2003 to Calea UK, and 8 June 2003 to Central Homecare Ltd, all of whom are homecare services providers, Genzyme confirmed its willingness to supply these companies with Cerezyme on the same terms that it was willing to supply Healthcare at Home, i.e. at the NHS list price of £2.975 plus VAT per unit.

(5) ***The proceedings before the OFT***

Healthcare at Home's complaint to the OFT and request for interim measures

121. On 23 March 2001, Healthcare at Home complained to the OFT, alleging that Genzyme's announced intention to cease supplying Healthcare at Home from 5 May 2001, infringed the Chapter II prohibition, and requested the OFT to take interim measures under section 35 of the 1998 Act. The OFT also received, apparently via the DoH, a copy of Professor Cox's letter of 29 March 2001.

122. On 17 April 2001, the OFT served Genzyme with a notice under section 33 of the 1998 Act stating the OFT's intention to adopt an interim direction to the effect that, until the completion of the OFT's investigation, Genzyme would be required to continue to supply Healthcare at Home with Cerezyme on the terms of the existing agreement between the parties. Genzyme contends that the OFT's concern at this stage was a refusal to supply: it was to that issue that Genzyme's response of 2 May 2001 was directed.

123. On 11 June 2001, following representations by Genzyme and Healthcare at Home, the OFT decided not to give directions for interim measures, but to continue to investigate the matter.

The main proceedings before the OFT

124. On 31 July 2002, following the service of two notices under section 26 of the 1998 Act and other requests for information, the OFT served Genzyme with a notice under Rule 14 of the Director's Rules stating its intention to make a decision that the Chapter II prohibition had been infringed by Genzyme and to impose a penalty. Genzyme served extensive written representations in reply on 22 October 2002 and an oral hearing took place on 6 November 2002. Further written representations were made by Genzyme on 9 December 2002, 10 January 2003 and 26 February 2003.

125. The decision was adopted on 27 March 2003.

III. THE PROCEDURE BEFORE THE TRIBUNAL

(1) *The request for suspension*

126. On 3 April 2003 Genzyme submitted a request pursuant to Rule 32 of the Tribunal's Rules to suspend the effect of the direction pending the determination of an appeal against the decision, which Genzyme undertook to lodge with all due expedition.

127. Following a hearing on 16 April 2003 the direction was provisionally suspended by the President on the basis of various undertakings offered by Genzyme, the matter to be restored for further argument if a consent order could not in the meantime be agreed. In the event, no such agreement could be reached and, following a further hearing on 1 May 2003, the President (sitting alone under Rule 33(1) of the Tribunal's Rules) gave judgment on the request for suspension on 6 May 2003.

128. Pursuant to that judgment, the direction is suspended until the determination of the appeal or the Tribunal's further order, on the basis that Genzyme will in the meantime supply Healthcare at Home with Cerezyme at a small discount (of [ ]%) off the NHS list price. The full text of that judgment is set out at [2003] CAT 8.

(2) ***The main appeal***

129. Genzyme duly lodged a notice of appeal on 20 May 2003. The appeal, together with supporting documents and witness evidence, comprised some 27 files amounting to considerably in excess of 7,000 pages. The OFT lodged its defence on 2 July 2003. Case management conferences were held on 17 June, 31 July and 22 September 2003. At the second case management conference, Genzyme was granted permission to submit a reply which was lodged on 22 August 2003. In addition, the Tribunal put various questions to the parties which were dealt with in the course of the proceedings. The oral hearing was held in public over four days from 25 September 2003. Further witness statements were served on the Tribunal during the course of the oral hearing and two witnesses, Mr Michael John Brownlee, Head of the PPRS branch of the DoH, and Mr John Farrell, Head of Pharmacy Services for the Royal Free Hospital NHS Trust and a number of other NHS Hospital Trusts in London, gave evidence during the second day of the hearing.

130. The main pleadings are contained in the notice of appeal dated 20 May 2003, the OFT's defence dated 2 July 2003 and Genzyme's reply dated 22 August 2003.

131. Those pleadings were supplemented by Genzyme's skeleton argument for the oral hearing received on 12 September 2003, the OFT's skeleton argument of 19 September 2003, supplementary skeleton arguments on behalf of Genzyme dated 19 September 2003 and 22 September 2003, together with an outline of Genzyme's oral submissions dated 25 September 2003, an outline of the OFT's oral submissions dated 28 September 2003, together with the OFT's reply to the questions raised by the Tribunal of 22 September 2003, the transcripts of the hearings on 25, 26 and 29 September 2003, the OFT's supplementary submissions dated 2 October 2003, Genzyme's outline submissions in reply dated 6 October 2003, and the transcript of the hearing on that date.

132. Certain submissions on the law relating to the defence of objective justification and the relationship between decisions of the High Court and decisions of the Tribunal are contained in Genzyme's letter of 23 June 2003. The OFT's reply to certain legal questions raised by the Tribunal regarding the legal basis for EL(95)5 and the Secretary of State's powers under the 1992 Regulations (see paragraphs 79 to 85 above) were submitted on 20 August 2003 and 9 September 2003. Genzyme responded to those submissions in writing on 19 September 2003.

(3) ***Evidence before the Tribunal***

133. As noted above, a considerable amount of evidence has been placed before the Tribunal by all of the parties, but particularly by Genzyme. Accordingly, for completeness, we set out a list of the witness statements which have been submitted to, and considered by, the Tribunal. This list includes the evidence submitted by Genzyme to the OFT during the administrative procedure.

Evidence submitted by Genzyme to the OFT in response to the Rule 14 Notice

134. Witness statements from the following persons were submitted to the OFT by Genzyme:

- Dr Roscoe Brady, National Institute of Health, USA, 21 October 2002
- Dr Michael Hayes, Director of the Process Research Group, in the Cell and Protein Therapeutics R & D Department of Genzyme Corporation, 18 October 2002

- Dr Seng Cheng, R & D Department of Genzyme Corporation, 21 October 2002
- Dr Debra Barngrover, Vice President, Therapeutics Operation Management at Genzyme Corporation, 17 October 2002
- Henri Termeer, CEO, Genzyme Corporation, 22 October 2002
- Dr Alan Smith, Chief Scientific Officer and Senior Vice President, Research at Genzyme Corporation, 22 October 2002
- James Ollington, Senior Vice President, Therapeutics, responsible for LSD Product Development, Genzyme Corporation, 22 October 2002
- Paul Merrigan, Senior Director of Global Marketing for Cerezyme at Genzyme Corporation, 23 October 2002
- Dr Erik Tambuyzer, Vice President of Corporate Affairs, Europe, Genzyme Europe BV, 23 October 2002 and 21 February 2003
- Katie Starr, Senior Information Analyst, Genzyme Corporation, 21 October 2002
- Martin Cortvriend, Vice President of International Development, Genzyme UK Limited, 23 October 2002
- Malcolm Johnson, General Manager of Genzyme Therapeutics and a Director of Genzyme Limited, 22 October 2002
- Dominic Moreland, Director of the Genzyme Homecare Division of Genzyme UK Limited, 24 October 2002
- Julie Kelly, Senior Director of LSDs of Genzyme UK Limited, 23 October 2002
- Vivek Derodra, registered pharmacist employed by Genzyme UK Limited to run their community pharmacy based at Rose Hill, Oxford, 11 October 2002
- Dr Stephen Waldek, Consultant Renal Physician and Chairman of the Hospitals Medicines Management Group for the Hope NHS Trust Hospital Manchester, 18 October 2002.

135. In addition, expert evidence was also submitted on behalf of Genzyme to the OFT from two sources:

- A report by Dixon Wilson, Chartered Accountants, in relation to the pricing of Cerezyme, the financial profile for Cerezyme sales and distribution, the profitability

and financial position of Healthcare at Home and the terms of trade between Genzyme and Healthcare at Home

- A report prepared by Translucency Ltd on regulatory and structural issues in a publicly funded UK pharmaceutical sector relevant to the current case ("the Translucency Report").

136. At the oral hearing before the OFT, which took place on 6 November 2002, presentations were given by Dr Alan Smith, Dr Erik Tambuyzer, Malcolm Johnson and Julie Kelly. A copy of the transcript of that hearing was included in the documents submitted to the Tribunal with Genzyme's notice of appeal.

Evidence submitted during the application before the Tribunal for suspension of the direction

137. In its request for the direction to be suspended under Rule 32 of the Tribunal's Rules Genzyme submitted by way of background the witness statements of Henri Termeer, Dr Alan Smith and Malcolm Johnson, referred to above. In addition, Genzyme submitted further witness statements from Malcolm Johnson dated 2 April 2003 and Edward Perrott, partner at Taylor Vinters, solicitors for Genzyme, dated 30 April 2003.

138. Healthcare at Home, who intervened in the interim measures proceedings, also submitted two witness statements of Charles Walsh, the Chairman of Healthcare at Home, dated 30 April and 2 May 2003.

Further evidence submitted during the main proceedings before theTribunal

139. Further witness statements were submitted by Genzyme with its notice of appeal dated 20 May 2003 as follows:

- Professor Yarrow, Director of Regulatory Policy Institute in Oxford, and the senior economic adviser to OFGEM, 19 May 2003 and 5 June 2003. Attached to Professor Yarrow's first witness statement of 19 May 2003 was a detailed report on the economic aspects of the decision

- Richard Williams, Fellow of the Institute of Chartered Accountants in England and Wales, 19 May 2003
- Dominic Moreland, 16 May 2003
- Alastair Kent, director of the Genetic Interest Group, 14 May 2003
- Edward Perrott, 19 May 2003.

140. In response, the following witness statements were submitted by the OFT with its defence dated 2 July 2003:

- Michael John Brownlee, Head of Medicines, Pricing and Supply Branch in the Medicines, Pharmacy and Industry Group of the DoH, 30 June 2003
- John Farrell, Head of Pharmacy Services at the Royal Free Hospital NHS Trust, London, 20 June 2003
- Dr Gareth Jones, Director at Healthcare at Home, 1 July 2003
- Christopher Munro, barrister, of the Treasury Solicitor's Department, 2 July 2003
- Professor Cox, Consultant and Professor of Medicine in the University of Cambridge, based at the Addenbrooke's NHS Trust, 27 June 2003
- Atul Mehta, Consultant haematologist at the Royal Free NHS Trust, 27 June 2003.

141. Genzyme submitted further witness statements with its reply dated 22 August 2003 as follows:

- Professor Yarrow, 21 August 2003
- Richard Williams, 20 August 2003
- Dominic Moreland, 21 August 2003
- John Evans, Director of Pharmaceutical Services at Polar Speed Distribution Limited, two witness statements dated 28 July and 21 August 2003
- Dr Ashok Vellodi, consultant in metabolic disorders at Great Ormond Street Hospital, 21 August 2003
- Dr Stephen Waldek, Consultant Renal Physician and Chairman of the Hospitals Medicines Management Group for the Hope NHS Trust Hospital Manchester, 29 July 2003
- Dr Alan Smith, 19 August 2003
- Malcolm Johnson, 20 August 2003.

142. Further witness statements were submitted by Genzyme after service of its reply but before or during the oral hearing before the Tribunal:

- Malcolm Johnson, 17 September 2003
- Dominic Moreland, 24 and 28 September 2003.

143. Further witness statements were submitted by the OFT after service of its defence, but before or during the oral hearing before the Tribunal:

- Colin Pearson, Section Head in the DoH's Medicines, Pharmacy & Industry Group, 21 July 2003
- Dr Gareth Jones, 13 August and 26 September 2003
- Michael John Brownlee, 5 September 2003
- Julia Stalibrass, Specialised Services Team Leader of the team which incorporates the National Specialist Commissioning Advisory Group commissioning team at the DoH, 11 September 2003.

144. During the oral hearing, the OFT also disclosed to the Tribunal some correspondence by e-mail between the OFT case officer and the DoH during November and December 2002.

(4) ***The relief sought***

145. Genzyme seeks the following relief from the Tribunal:

- To set aside the decision and the direction in whole, alternatively in part
- To revoke, alternatively to reduce, the penalty imposed by the decision
- To make a declaration that Genzyme's conduct, which is alleged by the OFT to infringe the 1998 Act, does not infringe that Act
- Such other further relief as the Tribunal may consider appropriate.

(5) ***Summary of Genzyme's grounds of appeal***

146. The principal grounds of appeal are as summarised in the notice of appeal (pages 3 to 4) as follows:

- Market definition: according to Genzyme, the OFT has erred in law and fact by finding there to be two distinct relevant product markets, the so-called 'upstream' and 'downstream' markets. According to Genzyme, the relevant market is that for research, development, supply and distribution/delivery to hospitals and to patients at home and which relates to the drugs for the treatment of LSDs, drugs which can qualify for orphan drug protection under EU legislation. As regards the alleged downstream market, the OFT erred in defining it narrowly in relation to Gaucher disease only. Any downstream market extends to nursing homecare generally.

- Dominance: the OFT has erred in law and fact by finding that Genzyme is dominant in the alleged upstream market, and that there are barriers to entry to that alleged upstream market attributable to Genzyme's conduct. Even on that flawed market definition, the OFT ought to have found that Genzyme faces many actual and potential competitors on the LSD market, that entry barriers to that market are low or non-existent, and that Genzyme's conduct does not raise barriers to entry into that upstream market.

- Abuse: the OFT erred in law and fact in concluding that Genzyme has abused any dominant position by bundling or implementing a margin squeeze. In fact, the allegations posed by the OFT are no different to an allegation of refusal to supply, but any such abuse was dismissed at the interim measures stage before the OFT.

- Objective justification: the OFT has failed to establish that Genzyme's conduct was not objectively justified.

- The OFT's conduct of the investigation was inappropriate.

- The direction is unlawful: the direction goes beyond what the OFT's powers under section 33 of the 1998 Act and/or is inappropriate, unworkable, impracticable, unclear and would serve no purpose.

- The penalty is unlawful: since Genzyme did not commit any alleged infringement intentionally or negligently, the OFT had no power to impose a penalty under section

36 of the 1998 Act, or in any event should not have done so. Alternatively the penalty has not been properly calculated, includes impermissible elements and is grossly excessive in all the circumstances.

147. The notice of appeal, which runs to 130 pages, does not follow the order of the summary as set out above. In this judgment we have marshalled the arguments in the manner best suited to an understanding of the case. Although we have taken into account everything before us, it has not seemed to us necessary to set out in detail all the evidence we have received, or to set out more than a brief outline of the parties' arguments. We are grateful to all concerned for the hard work done on both sides in the preparation and presentation of this case.

IV THE BURDEN AND STANDARD OF PROOF

148. It is common ground that the legal burden of proof rests throughout on the OFT to prove the infringements alleged (see *Napp Pharmaceutical Holdings Ltd v Director General of Fair Trading* [2002] CAT 1 [2002] CompAR [13] *("Napp")*, at [100]), albeit that the OFT may properly rely on inferences or presumptions that would, in the absence of any countervailing indications, normally flow from a given set of facts: *Napp*, at [110] to [111].

149. As to the standard of proof, the Tribunal stated in *Napp* at [109]:

> "In those circumstances the conclusion we reach is that, formally speaking, the standard of proof in proceedings under the Act involving penalties is the civil standard of proof, but that standard is to be applied bearing in mind that infringements of the Act are serious matters attracting severe financial penalties. It is for the OFT to satisfy us in each case, on the basis of strong and compelling evidence, taking account of the seriousness of what is alleged, that the infringement is duly proved, the undertaking being entitled to the presumption of innocence, and to any reasonable doubt there may be".

150. We propose to follow the same approach. We bear in mind, however, that resolving the issues in the present case on such matters as relevant product market, dominance and abuse, may require a more or less complex assessment of numerous interlocking factors, including economic evidence. Such an exercise intrinsically involves an element of

appreciation and the exercise of judgment. On such issues it seems to us that the question whether the OFT has "proved" its case involves asking ourselves questions such as: Has the OFT established the underlying facts? Is the Tribunal satisfied that the OFT's analysis of the application of the Chapter II prohibition to those facts is robust and soundly based? If so, have the correct legal conclusions been drawn?

V RELEVANT PRODUCT MARKET AND DOMINANCE

A. THE FINDINGS IN THE DECISION

The upstream market

151. The OFT found, in the decision, that there is an "upstream" market for the supply of drugs for the treatment of Gaucher disease in the United Kingdom. That market is, according to the decision, the relevant product market for the purpose of assessing whether Genzyme has a dominant position (paragraphs 127 to 158).

152. According to the OFT, Genzyme is dominant, within the meaning of the Chapter II prohibition, on that "upstream" market for the supply of drugs for the treatment of Gaucher disease in the United Kingdom (see paragraphs 202 to 286). The basis for this conclusion is, in effect, that there are no other effective clinical substitutes for Cerezyme for the treatment of Gaucher disease save, to a minor extent, Zavesca (paragraph 29 (iii) above).

153. According to the OFT, from 1991 until the launch of Zavesca in March 2003, Genzyme had 100 per cent of the market for drugs for the treatment of Gaucher disease. Even following Zavesca's launch, Genzyme's market share will continue to be above 90% in the short to medium term (paragraphs 202 to 229 of the decision).

154. According to the decision, barriers to entry to the "upstream" market are high (paragraphs 230 to 255) and potential entry is not sufficiently certain and/or imminent to act as a constraint on Genzyme's market power in that market in the short to medium term (paragraphs 256 to 267, especially 262 and 267). According to the decision, neither the

buying power of the NHS (paragraphs 268 to 275) nor the PPRS (paragraphs 276 to 281) constrain Genzyme's market power.

The downstream market

155. The OFT also finds, in the decision, that there is a "downstream" market, namely the market for the supply of Cerezyme and the provision of delivery and related homecare services to the NHS: see paragraphs 159 to 191, especially 162 (ii), and 287 to 289 of the decision.

156. The OFT considers that Genzyme's pricing policy has the effect of completely foreclosing the downstream market to any delivery/homecare services provider other than the one appointed and reimbursed by Genzyme (paragraph 287). However, because at least temporarily Healthcare at Home remains in the downstream market, albeit at a loss, and continues to service the large majority of Gaucher patients receiving infusions at home, the Director finds that Genzyme Homecare is not currently dominant in the downstream market (paragraphs 288 to 289 of the decision).

Plan of this section

157. In the Tribunal's view it is convenient to deal together with the closely related issues of market definition and dominance in the "upstream" market alleged by the OFT. We summarise the parties' arguments on those issues in section B below, and set out the Tribunal's findings in section C. We deal with the issues relating to the "downstream" supply of homecare services in Part VI below.

B. ARGUMENTS OF THE PARTIES REGARDING THE RELEVANT PRODUCT MARKET AND DOMINANCE IN THE UPSTREAM MARKET

(1) ***Genzyme's arguments***

Relevant product market

158. Genzyme rejects the OFT's product market analysis. According to Genzyme, there is only one relevant product market in this case, which extends to the research, development, supply and distribution/delivery to hospitals and patients at home of drugs for the treatment of LSDs, which drugs qualify as orphan drugs.

159. By way of introduction, Genzyme emphasises the importance of maintaining economic incentives for the development of orphan drugs, as indicated in the witness statements of Mr Termeer and Dr Tambuyzer. According to Genzyme, the OFT's failure to grasp that economic incentives are necessary to ensure that research and development takes place for orphan drugs, or to investigate the orphan drug issue in this case, shows "a complete failure by the OFT to carry out a proper economic analysis of the market in which Genzyme operates".

160. The OFT's approach, argues Genzyme, would introduce major disincentives to developing orphan drugs, thus lessening, rather than strengthening, competition. In particular, on the OFT's approach, in almost every case an undertaking obtaining an orphan drug designation would automatically have a dominant position and thus be subject to the "special responsibility" of a dominant company. That would be contrary to the objectives of both the EU and the United Kingdom in promoting biotechnology.

161. Genzyme further submits, by reference to a number of witness statements, that LSDs should be treated "as a family" and not isolated into single diseases as the OFT has done. According to the website of TKT, one of Genzyme's principal competitors, LSDs "share common biochemical and clinical characteristics. The common nature of these disorders makes it important that they are considered collectively".

162. In particular, Genzyme argues, research takes place into LSDs as a family. Drug production methods and facilities, such as Genzyme's plant at Allston Landing, are not necessarily disease specific, and can be used for the production of a number of ERT drugs for treating different LSDs. Academic and practical study of LSDs by consultants and physicians takes place in relation to LSDs as a group; treatments for LSDs are marketed to the same group of consultants and physicians; and the hospitals specialising in Gaucher disease specialise in other LSDs as well.

163. Against that background, Genzyme submits that the relevant product market is a single one for the supply and delivery to hospitals and/or patients of drugs for the treatment of LSDs, whether by ERT or any other method of treatment.

164. In reaching the contrary conclusion, the OFT has not followed the Tribunal's guidance on determining the relevant product market in *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4 [2002] CompAR 167 ("*Aberdeen Journals (No.1)")*. In particular the OFT has ignored the views of market participants, and has relied inappropriately on cases decided under EC merger control provisions. Nor is it sufficient for the OFT simply to refer to the *Fresenius/Caremark* report, or to rely on statements by Healthcare at Home or TKT, without undertaking any further inquiries. According to Genzyme, the OFT's approach to the "upstream" market is wholly mechanistic, and ignores the dynamics of the market.

165. In response to the OFT's specific arguments set out in the decision, Genzyme submits, first, that the Anatomical Therapeutic Chemicals ("ATC") classification recognised by the World Health Organisation, and relied on at paragraphs 127 to 134 of the decision, is irrelevant.

166. Secondly, according to Genzyme, the OFT's reliance on the fact that Cerezyme and Zavesca are the only currently available treatments for Gaucher disease "does not assist at all in determining the structure and dynamics of the market in which Genzyme operates". The OFT's logic would give rise to a separate market for every new orphan drug, and lead to about 5000 separate markets and dominant positions. It is also incorrect for the OFT to rely on the European Commission's decision in *Ciba-Geigy/Sandoz* OJ 1997 L201/1, because that is a merger decision adopted in a different context.

167. Thirdly, as to supply-side substitutability, the one year test for new market entry on the supply side indicated, according to Genzyme, in paragraph 152 of the decision, is too short. It is also incorrect to consider merely the possibility of new drugs becoming available to Gaucher disease patients, without taking into account new treatments for other LSDs as well.

168. As regards Zavesca, that drug is already available. It is orally administered and does not require infusion. Even if Zavesca is only a complementary therapy to Cerezyme for some patients, it will potentially reduce sales of Cerezyme. Despite the present limited marketing authorisation for Zavesca, Genzyme submits that new patients with non-severe Gaucher disease, and existing patients unable or unwilling to continue to receive ERT, may be prescribed Zavesca. According to Genzyme, the likely impact of Zavesca on Cerezyme cannot be assessed at present, but the potential impact is dramatic. As with other orphan drugs, a change in consultants' prescribing habits may have a severe effect on market shares, virtually overnight.

169. In addition, Genzyme submits that TKT expects to introduce human trials for a drug to compete with Cerezyme, known as GCB, in the first half of 2004. TKT is already marketing Replagal, a treatment for Fabry disease, in competition to Fabrazyme. The OFT has not sufficiently verified the date of the launch of GCB, choosing to rely on limited information provided by TKT, which is not a disinterested party and is in litigation with Genzyme. In fact, TKT's announcement in its 10K Report for 2002, filed with the SEC, mentions forthcoming trials for GCB, and indicates that GCB will be cheaper than Cerezyme. The Royal Free has been involved with trials concerning the potential TKT product, according to a note of the OFT's conversation with Dr Mehta of 10 July 2001.

Dominance

170. Genzyme argues, in the alternative, that, even on the OFT's view of the market, it is not dominant in the upstream market. According to Genzyme, the OFT analysis of dominance at paragraphs 201 to 281 and 285 to 286 of the decision is flawed. The OFT has failed to carry out any proper market investigation.

171. As regards the OFT's assessment in the decision of existing competitors (paragraphs 202 to 225, market shares (226 to 229) and potential entrants (256 to 267), Genzyme submits, first, that the market for orphan and LSD drugs is highly dynamic, with an extraordinary rate of innovation. A successful treatment such as Cerezyme can be superseded very rapidly by the entry of a new drug. Accordingly no inference of dominance can be drawn from Genzyme's apparently high market share. The OFT has wrongly placed too much

emphasis on Genzyme's market share, contrary to the approach of the Spanish Supreme Court in Case R362/99 *Bacardi* judgment of 30 September 1999.

172. According to Genzyme, its position as a "first mover" has in fact encouraged competitive entry. Both OGS with Zavesca and TKT with GCB are now "hot on Genzyme's heels". Genzyme points out that an orphan drug may benefit from an accelerated procedure for obtaining market authorisation under Council Directive 2001/83/EC, as Zavesca did.

173. Indeed, according to Genzyme, the entry of Zavesca demonstrates that entry barriers are low. As already indicated Zavesca is likely to have an important competitive impact on Cerezyme. Low barriers to entry are also demonstrated by the potential competition from TKT's drug GCB. TKT does not see any barrier to entry and has recently expressed the view that "despite the well entrenched presence of Cerezyme, a major market opportunity still exists". (Conference call by executives of TKT, 31 March 2003). Furthermore, according to Genzyme, the OFT has not investigated whether other undertakings active in the LSD field are actual or potential competitors to Genzyme.

174. In addition, Genzyme contests the OFT's findings, at paragraphs 230 to 267 of the decision, that barriers to entry are high.

175. Genzyme argues that the matters relied on by the OFT at paragraph 231 of the decision, such as carrying out R&D, completing clinical trials, developing a manufacturing process, obtaining a manufacturing licence, and obtaining a marketing authorisation, are not barriers to entry but costs which are faced by all undertakings active in producing treatments for LSDs. The OFT has erred in equating the costs of entry with barriers to entry. These alleged barriers apply to Genzyme as much as to anyone else.

176. Furthermore Genzyme does not consider that its patent protection (paragraph 235 of the decision) is significant from the point of view of market entry. As already indicated, Genzyme's "first mover" advantage (paragraph 236), rather than being a barrier to entry is the reverse, since Genzyme's pioneering work has made new entry possible, as demonstrated by Zavesca and GCB. According to Genzyme, there is also no evidence that the small number of patients suffering from Gaucher disease impacts on the ability of new entrants to conduct clinical trials, as stated at paragraphs 236 to 237 of the decision.

The OFT has also overlooked the fact that trials of new drugs are not required to be carried out in the United Kingdom. Professor Cox considers that "perfectly satisfactory data can be obtained for well-designed studies" (paragraph 236 of the decision) while statements by Dr Mehta (meeting of 10 July 2001), Dr Wraith (meeting of 9 July 2001) and Dr Vellodi (note of telephone conversation dated 3 March 2003) support Genzyme's position. Similarly the alleged reluctance of doctors or patients to switch to a new treatment (paragraphs 238 to 239) is unsupported by evidence.

177. Genzyme concludes that the OFT has not properly investigated the question of barriers to entry. The evidence of both TKT and OGS supports the view that barriers to entry are not significant. Switching to these products is highly likely, particularly given the small patient numbers involved and the limited number of specialist consultants. The OFT's conclusion, at paragraph 240 of the decision, that barriers to entry into the market for the supply of drugs for the treatment of Gaucher disease are high, is thus incorrect.

178. Finally, Genzyme argues that at paragraphs 268 to 281 of the decision the OFT has failed to take account of the buyer power of the NHS, and the effects of the PPRS. Such power is shown by the imposition on Genzyme of a price cut in 1999 under the PPRS (see above). In addition, the Department of Health has statutory powers to fix prices for companies that are not members of the PPRS. The Department of Health also has the means to address the cost effectiveness of products through the National Institute for Clinical Excellence ("NICE"), through central purchasing by the Purchasing and Supplies Agency ("PASA"), by the use of specialist centres or advice through the National Specialist Commissioning Advisory Group ("NSCAG"), and by local tendering through Primary Care Trusts ("PCTs"). In particular, NSCAG is in a position to advise whether Cerezyme should still be funded when there are potentially cheaper alternatives such as Zavesca and GCB. Genzyme stresses that the NHS is the monopoly purchaser of drugs in the United Kingdom, and refers also to the Translucency Report of 24 October 2002 prepared on behalf of Genzyme.

179. Genzyme also relies on the evidence of Professor Yarrow, who argues that it is important to carry out the analysis of substantial market power (i.e. dominance) in a way that is linked to the alleged abuse, so that one can be satisfied that the power that is alleged to have been abused did actually exist. Professor Yarrow criticises the absence of any such

linkage in the decision, and in particular the absence of any discussion as to whether the NHS was in a position to exert its authority as a buyer to prevent the abuse alleged.

180. Professor Yarrow also considers that the OFT has underestimated the constraints imposed by the PPRS. Genzyme, as a single product firm, is constrained more severely by the PPRS than are multi-product firms who can spread the price restraints over a portfolio of products. The standard PPRS model is likely to be particularly disadvantageous to a one-product biotech company, with high research costs and a high cost of equity capital.

181. Finally, Professor Yarrow considers that the absence of a substitute drug for Cerezyme does not necessarily eliminate the buyer power of the NHS: a market consisting of a bilateral buyer/seller monopoly will typically produce a very different outcome from a market consisting of a monopoly seller/many buyers. Moreover, political or fiscal pressure may be exerted on pharmaceutical companies with a view to reducing drug prices. In this case, no one seems to have asked the NHS authorities to explore changes in the way homecare services are supplied to Gaucher patients with a view to securing better value for money.

182. Finally no valid inference can be drawn from the fact that Cerezyme was launched at the same price as Ceredase, particularly since the initial price of Cerezyme might well have been influenced by the constraints on future price rises imposed by the PPRS itself.

(2) ***The OFT's arguments***

Relevant Market

183. In its defence, the OFT maintains, essentially, that its position on market definition in the "upstream" market is correct for the reasons set out in the decision. The OFT updates the position as regards TKT with an witness statement from Mr Munro. The OFT rejects Genzyme's argument that the market is one for LSDs generally, essentially on the basis that Gaucher patients have an inflexible requirement for an effective treatment for Gaucher disease. As far as Gaucher patients and the relevant consultants are concerned, that demand can only be met by Cerezyme and, marginally, Zavesca.

Dominance

184. To establish dominance the OFT relies essentially on the matters set out in the decision at paragraphs 202 to 281, and makes the following additional points.

185. First, the OFT relies on statements by Professor Cox of 27 June 2003 and Dr Mehta of 30 June 2003 to confirm that Zavesca is only a second line treatment, and that Cerezyme remains the preferred standard of care for Gaucher patients. Secondly, in the context of barriers to entry, the OFT points out that the statements of Professor Cox and Dr Mehta support the conclusion that any new competitor to Cerezyme would face difficulties in finding a sufficient number of new patients "naïve to treatment" (i.e. who had not received treatment before) on whom to conduct clinical trials. Thirdly, the OFT relies on the witness statement of Mr Munro to show that the market entry of TKT with its new drug GCB is not imminent.

186. In relation to the alleged "buyer power" of the NHS, the OFT contends: (1) The NHS has no real alternative effective drug for treating Gaucher disease, even after the launch of Zavesca, which "makes it difficult for buyer power to have any real effect". (2) The history of supply of Cerezyme in the United Kingdom confirms that Genzyme has in practice been able to ignore requests from NHS doctors and the Gaucher Association to supply Cerezyme separately from Homecare Services. (3) Genzyme has maintained its prices for Cerezyme at the same level as for Ceredase, notwithstanding its apparent acceptance that Cerezyme is cheaper to produce than Ceredase. (4) Genzyme is acting contrary to the wishes of its NHS customers in seeking to deprive the NHS of the option of purchasing Homecare Services from third party suppliers and forcing Healthcare at Home out of the downstream market.

187. According to the OFT, bodies such as NICE, PASA, NSCAG or local PCTs are unable to exert any real competitive pressure on Genzyme, since there is no effective alternative to Cerezyme. Finally, the OFT considers that nothing in the PPRS affects Genzyme's autonomous conduct in such a way as to deprive Genzyme of its dominant position.

C. THE TRIBUNAL'S FINDINGS

(1) ***The relevant law***

188. In order to fall within the Chapter II prohibition, it must be established that the undertaking in question has a dominant position. As usually defined, a dominant position is:

> "a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by allowing it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers".

See Case 85/76 *Hoffman-La Roche v Commission* [1979] ECR 461, paragraph 38; Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-2969, paragraph 70.

189. The exercise of defining the relevant market forms part of the wider exercise of determining whether an undertaking has a dominant position for the purposes of the Chapter II prohibition, as the OFT itself points out at paragraph 125 of the decision.

190. As the Tribunal said in "*Aberdeen Journals (No. 1*) , cited above:

> "88. In order to determine whether, in any given case, an undertaking has the necessary degree of economic strength or, to use the more modern term, market power, so as to give rise to dominance, it is self-evidently necessary to define the market in which that market power is said to exist. As the Commission of the European Communities ("the Commission") has put it in paragraph 2 of its *Notice on the definition of relevant market for the purposes of Community competition law* ("the Commission's *Notice on Market Definition"*) OJ 1997 C372/5:
>
> "Market definition is a tool to identify and define the boundaries of competition between firms… The objective of defining a market in both its product and geographic dimension is to identify those actual competitors of the undertakings involved that are capable of constraining those undertakings' behaviour and of preventing them from behaving independently of effective competitive pressure."
>
> 89. The Director's Guideline on *Market Definition* OFT 403, March 1999, follows the same approach:
>
> "The approach described in this guideline is not mechanical, it is a conceptual framework within which evidence can be organised. The Director General will not follow every step described below in every

> case. Instead, he will look at the areas of evidence which are relevant to the case in question - and will often be constrained by the extent to which evidence is available. Market definition is not an end in itself, but rather a step which helps in the process of determining whether undertakings possess, or will possess, market power" (paragraph 1.5)."

191. As regards the question of how the relevant market is to be determined, in Case 6/72 *Continental Can v Commission* [1973] ECR 215, the Court of Justice said at paragraph 32:

> "… the definition of the relevant market is of essential significance, for the possibilities of competition can only be judged in relation to those characteristics of the products in question by virtue of which those products are particularly apt to satisfy an inelastic need and are only to a limited extent interchangeable with other products."

192. In Case 85/76 *Hoffman-La Roche v Commission* [1979] ECR 461, the Court of Justice said at paragraph 29:

> "The concept of the relevant market in fact implies that there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned." (paragraph 28).

193. In Case T-83/91 *Tetra Pak v Commission* [1994] ECR II-755 ("*Tetra Pak II*"), the Court of First Instance held at paragraph 63:

> "A preliminary point to note is that, according to settled case law, the definition of the market in the relevant products must take account of the overall economic context, so as to be able to assess the actual economic power of the undertaking in question. In order to assess whether an undertaking is in a position to behave to an appreciable extent independently of its competitors and customers and consumers, it is necessary first to define the products which, although not capable of being substituted for other products, are sufficiently interchangeable with its products, not only in terms of the objective characteristics of those products, by virtue of which they are particularly suitable for satisfying constant needs, but also in terms of the competitive conditions and the structure of supply and demand on the market (see the judgment of the Court of Justice in Case 322/81 *Michelin v Commission* [1983] ECR 3461, paragraph 37)."

194. Similarly, in Case T-504/93 *Tiercé Ladbroke v Commission* [1997] ECR II-923 the Court of First Instance held at paragraph 81:

> "According to settled case law, for the purposes of applying Article [82] of the Treaty, the relevant product or service market includes products or services which are substitutable or sufficiently interchangeable with the product or service in question, not only in terms of their objective characteristics, by virtue of which they are particularly suitable for satisfying the constant needs of consumers, but also in terms of the conditions of competition and/or the structure of supply and demand on the market in question (Case 31/80 *L'Oreal* [1980] ECR 3775, paragraph 25; Case 322/81 *Michelin v Commission [1983]* ECR 3461, paragraph 37; Case C-62/86 *AKZO Chemie v Commission* [1991] ECR I-3359, paragraph 51; Case T-30/89 *Hilti v Commission* [1991] ECR II-1439, paragraph 64, and Case T-83/91 *Tetra Pak v Commission* [1994] ECR II-755, paragraph 63)."

195. In the light of the case law of the Court of Justice and the Court of First Instance, the Tribunal concluded in *Aberdeen Journals* (*No. 1*), cited above, at paragraphs 96 and 97:

> "96. ….the relevant product market is to be defined by reference to the facts in any given case, taking into account the whole economic context, which may include notably (i) the objective characteristics of the products; (ii) the degree of substitutability or interchangeability between the products, having regard to their relative prices and intended use; (iii) the competitive conditions; (iv) the structure of the supply and demand; and (v) the attitudes of consumers and users.
>
> 97. However, this checklist is neither fixed, nor exhaustive, nor is every element mentioned in the case law necessarily mandatory in every case. Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to answer what, at the end of the day, are relatively straightforward questions: do the products concerned sufficiently compete with each other to be sensibly regarded as being in the same market? The key idea is that of a competitive constraint: do the other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm?"

196. The Tribunal followed the same approach in *Aberdeen Journals v Director General of Fair Trading*, judgment of 23 June 2003 [2003] CAT 12, ("*Aberdeen Journals (No. 2*)").

(2) ***The Tribunal's findings on relevant product market***

197. In the decision the OFT relies, first, on the ATC classification for pharmaceutical products used by the World Health Organisation and referred to by the European Commission in a number of decisions adopted in the context of Regulation (EC) 4064/89 on the Control of Concentrations between Undertakings OJ 1990 L 257/13, as subsequently amended (decision, paragraphs 127 to 133).

198. We agree with Genzyme that neither the ATC classification, nor the Commission's previous decisions applying that classification in merger cases, are determinative of the issue of market definition in the present case. Indeed, the decision itself points out that the ATC classification is only a "starting point" for an analysis in which other elements have to be considered (paragraph 134).

199. According to the decision, the key concept in market definition is interchangeability (paragraph 135). In view of the case law cited above, the OFT was in our view undoubtedly correct to concentrate its market analysis on the issue of interchangeability.

200. As the decision points out at paragraphs 136 to 140, the primary tool for judging interchangeability is "demand-side substitutability", i.e. the extent to which consumers are able to switch to substitute products, particularly in the event of a small but significant change in the relative price of the products concerned. The European Commission's *Notice on Market Definition*, cited above, puts the matter succinctly:

> ".. a relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use."

201. In our view it follows that the analysis of the relevant product market should start with the question of demand-side substitutability which the OFT discusses at paragraphs 139 *et seq* of the decision.

202. In the present case, it would appear self evident that there is a group of consumers, namely those suffering from Gaucher disease, who have a constant need for effective treatment for that disease. Similarly the clinicians responsible for these patients have a constant need to treat that disease. A treatment that does not treat Gaucher disease is of no use to a patient suffering from that disease, nor to the clinician responsible for the treatment of that patient. It follows, on the basis of the case law cited above, that in this case the relevant product market for the purpose of the Chapter II prohibition consists of effective treatments for Gaucher disease.

203. Genzyme has not contested the OFT's findings in paragraphs 141 and 142 of the decision that neither symptomatic treatments, nor bone marrow transplants, constitute effective treatments for Gaucher disease (see also paragraph 29 above). Those alternatives thus fall to be excluded from the relevant product market.

204. Genzyme has not contested the fact that, since the entry into force of the 1998 Act on 1 March 2000, and indeed well before that date, Cerezyme and its predecessor Ceredase, were the only treatments for Gaucher disease available in the United Kingdom until the launch of Zavesca on 3 March 2003.

205. As regards Zavesca, the OFT finds, at paragraphs 143 to 145 of the decision, that Zavesca can only be used on patients for whom ERT therapy is not suitable. According to the decision, Cerezyme will remain "the treatment of choice and the preferred standard of care" for Gaucher patients, while Zavesca will be "a second line treatment". An agreed statement of position by Gaucher specialists across Europe, set out in paragraph 144 of the decision, sets out the limited category of patients for whom Zavesca may be prescribed.

206. On that basis, while considering that it is arguable that Zavesca is not in the same market as Cerezyme, the OFT, in the decision, proceeds on the basis that the relevant market is one in which both Zavesca and Cerezyme compete (paragraph 146).

207. Genzyme, for its part, does not dispute that Zavesca is properly to be included in the relevant product market, but contends that the OFT has underrated the competitive significance of Zavesca. However, that is an argument which concerns primarily the issue of dominance, which we discuss below.

208. Genzyme further relies on the forthcoming launch by TKT of a new drug called GCB which, it says, is potentially a competing ERT-based substitute for Cerezyme. It appears to the Tribunal that, if and when launched, GCB could potentially be in the same relevant product market as Cerezyme. However, the question of when, or even if, GCB is likely to be launched, is a matter that goes to the issue of dominance, discussed below.

209. There is no evidence before the Tribunal to show that drugs suitable for treating other diseases (for example other LSDs) are suitable for the treatment of Gaucher disease. Similarly there is no evidence that any drugs other than Cerezyme, and to a limited extent, Zavesca, have marketing authorisations for the treatment of Gaucher disease, or are likely to obtain such authorisation, with the possible future exception of GCB.

210. On the basis of the foregoing, in our view the relevant product market comprises only drugs indicated for the treatment of Gaucher disease (currently only Cerezyme and Zavesca), as the OFT found in paragraphs 149 and 153 of the decision.

211. Genzyme, however, argues that the relevant market is a quite different market, namely the market for the drugs for the treatment of LSDs. According to Genzyme, pharmaceutical companies active in the orphan drugs field do research across a range of LSDs; the activities of R&D, production and marketing are applicable to LSDs as a family; the methods of treatment are the same; production facilities are not disease specific; academic and practical studies by consultants and others cover LSDs as a group; and hospitals specialise in LSDs as a group. Both Genzyme and companies such as TKT regard themselves as active in this wider market, as TKT's website indicates.

212. The OFT, in the decision, responds to this argument in two ways. First, at paragraph 156, the OFT contends that Genzyme's arguments "do not address the question of the absolute lack of demand-side substitution between treatments of different LSDs. A patient suffering from Gaucher's disease cannot be treated with a drug for any LSD other than Gaucher's disease". Secondly, at paragraph 157, the OFT considers that Genzyme's arguments do not address the question of whether a supplier of a drug for the treatment of an LSD other than Gaucher disease could begin supplying a treatment for Gaucher disease in the short term without incurring significant additional cost or risk. According to the OFT, the need to carry out clinical trials, and to obtain a marketing authorisation, precludes a supplier of another LSD from switching to producing an LSD drug for the treatment of Gaucher disease in the short term.

213. In our view, both those arguments are correct. First, there is no getting away from the fact that there is no available alternative treatment for Gaucher disease other than Cerezyme, and to a minor extent Zavesca. Secondly, there is no evidence that any drug

currently authorised for the treatment of another LSD could obtain a marketing authorisation for Gaucher disease within any reasonably foreseeable timescale. We add, incidentally, that as we read it, paragraph 152 of the decision is not based on a one year time frame, as Genzyme's notice of appeal suggests, but on the combined duration of clinical trials and market authorisation procedures, which are likely to last for a number of years.

214. It may well be that, in a general sense, biopharmaceutical companies such as the Genzyme Corporation and TKT see themselves as rivals in the research, development, production and marketing of predominantly orphan drugs, across a range of LSDs, based notably on ERT. We also accept that research techniques leading to the development of an ERT based drug for one disease may be transferable to research into possible ERT based drugs for other diseases; that production facilities may be adaptable; and consultants and hospitals treating LSDs may be interested in a company's products across a range of treatments.

215. Indeed, those matters are not seriously disputed by the OFT. The question to be answered, however, is what is the *relevant* product market for the purposes of the Chapter II prohibition - i.e. the market that it is relevant to consider for the purpose of assessing whether Genzyme has market power?

216. In simple terms, an undertaking's market power will depend on whether the consumers or users of the product have any alternatives available to them. It is thus the market in which substitutes are, or are not, available that is the *relevant* market for the purpose of addressing the issue of dominance. In the present case sufferers from Gaucher disease have no other alternatives available to them. That remains true irrespective of whether there is in some looser, non technical, sense a wider "market" for LSDs in general. It follows that in this case the *relevant* upstream market for the purposes of the Chapter II prohibition is the market for drugs for the treatment of Gaucher disease. We did not read Professor Yarrow's evidence as disagreeing with this approach.

217. Although, as the Tribunal said in *Aberdeen Journals (No.1),* at paragraphs 103 and 104, contemporary documents showing how an undertaking views its competitors may constitute important evidence on the question of market definition, each case depends on

its own factual circumstances. In that case the internal documents evidencing predatory conduct by Aberdeen Journals were relevant on the facts. In this case, however, we do not think the rather general comments on the TKT website undermine our conclusions that in this case the specific *relevant* market for the purpose of assessing dominance is that of drugs for the treatment of Gaucher disease.

218. As regards Genzyme's general arguments about orphan drugs, we accept that in a field such as orphan drugs a typical pattern may well involve the emergence of a drug which for the time being is the only available treatment for a particular disease, either as a result of the terms of a marketing authorisation under Article 8 of Regulation No. 141/2000, or as a result of intellectual property rights, or as a result of superior scientific expertise. Such a product monopoly may be an appropriate outcome when it is based on research, innovation, risk taking and entrepreneurial skill. The Tribunal does not see the existence of such a monopoly for a certain period of time as necessarily anti-competitive in itself. In broad terms, the Tribunal also accepts Genzyme's argument that orphan drugs are unlikely to be developed effectively unless there are sufficient economic incentives to do so.

219. In our view, however, those considerations are not relevant to the concept of market definition used in order to determine dominance under the Chapter II prohibition. It is clear from the case law cited above that the issue of market definition depends primarily on the question of substitutability, and not on the matters raised by Genzyme. Nor, in the Tribunal's view, is it conceptually absurd that, in a sector such as pharmaceuticals, or even in a sub-sector such as orphan drugs, there may be a large number of small relevant markets in which there is a dominant supplier. Consumers in small markets are, in our view, just as entitled to the protection of the Chapter II prohibition as are consumers in larger markets. That applies particularly to persons suffering from a disease for which there is only one treatment, irrespective of whether the disease itself is rare or not.

220. The points that Genzyme makes about the need to encourage orphan drug development go, it seems to us, not to the issue of dominance, but to the issue of abuse, and, in particular, to the question of the scope of the "special responsibility" of a dominant undertaking in circumstances such as those at issue in the present case. We come to that question later in this judgment.

221. We therefore conclude that, in the decision, the OFT correctly identified the relevant market as being the market for drugs for the treatment of Gaucher disease.

(3) ***The Tribunal's findings on dominance***

Market Shares

222. In this case, throughout the period of infringement and until the launch of Zavesca on 3 March 2003, Genzyme had 100% of the relevant product market, i.e. the market for drugs for the treatment of Gaucher disease. Genzyme has not seriously contested the OFT's conclusion at paragraph 229 of the decision that, even following Zavesca's entry, Genzyme's share of the market for drugs for the treatment of Gaucher disease will continue to be significant and probably above 90% in the short to medium term.

223. That conclusion seems to us to be reinforced by the limitations on Zavesca's marketing authorisations which are set out, without serious challenge by Genzyme, at paragraphs 207 to 225 of the decision. The evidence of Professor Cox and Dr Mehta has confirmed to the Tribunal the role of Zavesca as a second line treatment only.

224. The evidence before the Tribunal as to GCB, as set out in Mr Munro's witness statement, is that the launch of that product is, at the earliest, possible in 2006 or 2007. Whether GCB will be launched in Europe is, in itself, uncertain.

225. In most circumstances, in the Tribunal's view, a market share of 90% or above, which has continued throughout the period of infringement and is likely to continue for several years, will be sufficient, depending on the circumstances, to infer the existence of dominance: see *Napp*, cited above, at paragraphs [156] to [160], and *Aberdeen Journals (No. 2)*, cited above, at [310], and the cases there cited. See also Case T-65/98 *Van den Bergh Foods v. Commission*, judgment of 23 October 2003, at paragraph 154.[6]

[6] Although this case was decided after the close of oral argument, we refer to it in this judgment only to the extent that it reiterates the previous case law.

226. However, contrary to Genzyme's submission, in this case the OFT did not base itself simply on market shares, but examined also barriers to, and the likelihood of, new entry, as well as the buying power of the NHS and the effect of the PPRS.

Barriers to entry

227. As regards the present case, at paragraph 231 of the decision the OFT points out that a competing supplier wishing to launch an alternative treatment for Gaucher disease has to complete the lengthy and risky processes of R&D, clinical trials, development of production, obtaining a manufacturing licence and obtaining a marketing authorisation. We agree with the OFT that, although not insurmountable, these processes represent "a significant hurdle" for anyone contemplating entering the market.

228. Genzyme itself emphasises the amount of investment required for, and the risks associated with, the development of orphan drugs. This, combined with the small size of the market under consideration, and the lengthy process - probably four years or more - before a drug, once developed, can be brought to the market, demonstrate in our view that there are significant barriers facing any competitor who wishes to enter the market for drugs for the treatment of Gaucher disease. The fact that, as Genzyme argues, all pharmaceutical companies face similar barriers, does not mean that such barriers do not exist.

229. A further element specific to the present case is the difficulty any new entrant faces in finding sufficient patients on whom to conduct clinical trials, as the decision states at paragraphs 236 and 237. In his witness statement before the Tribunal, Professor Cox points out that new clinical trials will be difficult in the future, as most patients are already on Cerezyme. Although, for example, trials abroad can be conducted, in Professor Cox's view, it is difficult to plan well designed trials. Dr Mehta's view is that it could be quite difficult for a competitor to develop a new drug, in that patients will not be available for trials on new treatments, and patients and physicians will be reluctant to switch. According to Dr Mehta, Genzyme thus has "a large natural advantage" from being first in the market. Dr Mehta also points out that Genzyme was mistaken in suggesting that the Royal Free Hospital had been engaged in trials for TKTs product,

now GCB. The trials involved Replagal, which is a treatment for Fabry disease, not for Gaucher disease. We see no reason to disagree with that evidence.

230. As regards the arguments put forward by Genzyme, we can see, as the OFT accepts at paragraph 250 of the decision, that orphan drugs legislation may have gone some way to reducing barriers to entry. We can also see that the relatively small number of consultants active in this field may be more easy to target and persuade than, for example, a large number of GPs; and that Genzyme's success may have encouraged others to consider entering the market, as the OFT acknowledges at paragraph 247 of the decision.

231. However, as the OFT points out at paragraph 242 of the decision, in considering barriers to entry in the context of dominance, "the issue is whether entry barriers are sufficiently low that the behaviour (and in particular pricing) of a firm with a high market share is constrained by the threat of new entry": see OFT Guideline 415, *Assessment of Market Power*, September 1999. In this case, we can see no evidence that Genzyme's behaviour in the market, whether as to pricing or otherwise, has been constrained by the threat of new entry.

232. On the contrary, the factors identified by the OFT, including the size of the investment needed to develop a new product (paragraph 243), the risk involved (paragraph 242), the timescale (paragraph 244), and the uncertainty of any return on investment (paragraph 245) seem to us to support the OFT's conclusion, at paragraphs 240 and 255 of the decision, that barriers to entry into the market for the supply of drugs for the treatment of Gaucher disease are high, over at least the short to medium term.

233. In these circumstances, the Tribunal does not feel that the reported remark of Dr Wraith, who treats children suffering from Gaucher disease at the Royal Manchester Children's Hospital, at a meeting with the OFT on 9 July 2001, to the effect that "entry by another competitor would not be difficult", outweighs the cumulative evidence considered above. That reported remark is unsupported by any detailed reasoning, or by a witness statement.

234. Mr Farrell, who was cross-examined on this point, disagreed with Dr Wraith's reported view. We accept Mr Farrell's evidence on this issue.

235. The reference to Dr Vellodi's position in footnote 246 to paragraph 217 of the decision does not seem to us to support Genzyme. On the contrary, that footnote merely indicates that clinical trials for Zavesca in connection with the treatment of children with Gaucher disease, in conjunction with Cerezyme, are in contemplation.

236. As to Genzyme's assertion that OGS with Zavesca, and TKT with GCB, are "hot on Genzyme's heels", we regard that as an exaggeration. As the decision itself points out, at paragraph 254, Zavesca, although benefiting from "exceptional circumstances" under Directive 2001/83/EC, went through five years of clinical trials and then took another seventeen months to receive a marketing authorisation. Even now, that authorisation is extremely limited. As to TKT, we have already indicated that the evidence is that the launch of that product is at least some years away. Moreover, even if Dr Tambuyzer may be right that obtaining marketing authorisations may be quicker in the future, we do not think that that is likely to lower the barriers to entry in this case to any material extent.

237. In our view the fact that, over a period of some ten years, one or two producers have sought to surmount barriers to entry, and have even succeeded in doing so in a minor way (as is the case with Zavesca) does not show that barriers to entry to this market are low. For the reasons already given, we consider that barriers to entry to the market for drugs for the treatment of Gaucher disease are high in the short to medium term.

238. As to potential future entrants, dealt with at paragraphs 256 to 267 of the decision, we have already indicated that the evidence is that TKT's GCB drug will not be available, if at all, until 2006 or 2007 and that the launch of GCB in Europe is uncertain. That evidence confirms the OFT's view, in the decision, that the date of late 2004 mentioned in paragraph 257 may not be realistic, and that, in any event, it is by no means certain that GCB will ever be launched in the United Kingdom: see generally paragraphs 257 and 263 of the decision.

239. We are not aware of any evidence that supports the view that there are other competing products whose entry into the market for Gaucher disease is imminent, or even likely over the short or medium term. We have no reason to doubt the OFT's findings on this point at paragraphs 260 to 267 of the decision.

240. The combination of Genzyme's high market shares, the lack of alternative products, and the high barriers to entry discussed above in our view point overwhelmingly to the conclusion that Genzyme is dominant in the market for drugs for the treatment of Gaucher disease, as the decision finds. Indeed, for all practical purposes Genzyme has a monopoly in that market.

Buyer power

241. Genzyme, however, argues that it is not dominant because of the effects of the PPRS and the position of the NHS as a monopoly purchaser. According to Genzyme, the NHS has numerous means to address the cost effectiveness of its products, a view which is supported by Professor Yarrow.

242. The OFT concludes, at paragraphs 268 to 275 of the decision, that the NHS does not have sufficient countervailing buyer power to negate Genzyme's dominant position. The essential reason for this conclusion is that the lack of effective substitute products makes it difficult for buyer power to have any real effect (paragraph 268). That, says the OFT, is supported by various instances in which Genzyme has ignored the wishes of its customers (paragraphs 269 and 271). The OFT does not consider that Genzyme is constrained by the PPRS (paragraphs 276 to 281).

243. The Tribunal accepts that, self evidently, the vast majority of pharmaceuticals supplied in the United Kingdom are supplied to the NHS. Similarly, in the United Kingdom, virtually all supplies of Cerezyme are made to the NHS. On the other hand, Genzyme is, in effect, a monopoly seller of Cerezyme, virtually the only available drug for the treatment of Gaucher disease. In our view the question is whether, in those circumstances, the NHS has sufficient countervailing power to negate Genzyme's dominant position and, in particular, to establish that Genzyme is not able to behave, to an appreciable extent, independently of its competitors, its customers and ultimately of its consumers within the meaning of the *Hoffman La Roche* test (paragraph 188 above). To analyse where the balance of power lies as between Genzyme and the NHS, we first briefly summarise the structure of the NHS. We then go on to consider the specific circumstances in which prescribing and purchasing decisions are taken in the present

case, the evidence of Genzyme's conduct, and the various suggested powers that have been raised in the argument before us.

- *The structure of the NHS*

244. For practical purposes the basic structure of the NHS in England is set out in the National Health Service Act 1977 ("the 1977 Act"), as amended and supplemented by the Health Act 1999 ("the 1999 Act"). Similar arrangements apply in Scotland, Wales and Northern Ireland.

245. Under section 2 of the 1977 Act, the Secretary of State has the broad duty of providing a comprehensive health service designed to secure improvement in the physical and mental health of the people of England and Wales, and in the prevention, diagnosis or treatment of illness, and for that purpose to provide or secure the effective provision of services in accordance with the 1977 Act. Section 2 gives the Secretary of State wide general powers to secure the discharge of the duties imposed by the Act. Section 3 sets out further more specific duties. Section 17 of the 1977 Act empowers the Secretary of State to give directions to various NHS bodies, including Strategic Health Authories, Special Health Authorities, Primary Care Trusts, and NHS Trusts. In addition, sections 33 to 39 of the 1999 Act confer powers on the Secretary of State to agree voluntary schemes such as the PPRS and to control prices and profits in certain specified circumstances (paragraphs 67 to 73 above and paragraphs 261 to 275 below). The reimbursement of pharmacists is governed by section 41 of the 1977 Act (paragraphs 79 to 82 above and paragraphs 276 to 280 below). The role of the Secretary of State is discharged through the DoH, which has responsibility for the overall policy, planning and budget of the NHS.

246. The "NHS" does not, however, exist as a corporate entity. In practice, the operation of the NHS is devolved to numerous executive or advisory bodies or agencies. These include, notably, the following:

- Special Health Authorities, which include such bodies as the PPA, which is responsible for the reimbursement of pharmacists and the publication of the Drug

Tariff (paragraphs 79 to 82 above), and NICE, which provides guidance on best clinical practice.

- Strategic Health Authorities which, since 2002, are responsible for developing strategic plans for 28 areas in England.

- PCTs, which are responsible for providing and funding health services in their local areas. There are over 300 PCTs in England, accounting for around 75% of the total NHS budget.

- NHS Hospital Trusts, which are responsible for providing hospital services and healthcare in their local areas. Some hospital trusts, such as Addenbrooke's, the Royal Free, Great Ormond Street and Royal Manchester Children's Hospital in the present case (paragraph 39 above), provide specialised services for patients from all over the United Kingdom suffering from particular diseases. These services are normally funded by the PCT in which the patient resides.

- Executive Agencies, which include the NHS Purchasing and Supply Agency ("NHSPASA"), which advises on purchasing and procurement policy and contracts on a national basis for certain NHS contracts, mainly those of strategic importance.

- Other advisory bodies, including the NSCAG (paragraphs 39 and 106 above), which advises the Secretary of State on the best arrangements for securing specialist services, particularly in the case of rare and expensive treatments.

247. However, as far as we can see none of the bodies mentioned in paragraph 246 above have any specific powers to require Genzyme to alter the pricing practices at issue in the present case, and the contrary has not been suggested. In our view, therefore, the question of whether the NHS has any countervailing buyer power in the face of Genzyme's dominant position largely depends on (i) the factual circumstances in which prescribing and purchasing decisions are actually taken in the case of drugs for the treatment of Gaucher disease; (ii) evidence about Genzyme's actual conduct in the market, and the ability of the NHS to respond to that conduct; and (iii) the relevance of the various other suggested powers which have featured in the argument before us.

- Prescribing and purchasing decisions in the case of drugs for the treatment of Gaucher disease

248. Despite the large superstructure of strategic, executive and advisory bodies described above, the clinical decision to prescribe Cerezyme for a patient suffering from Gaucher disease is taken locally by the responsible clinician at one of the four specialist centres already mentioned, namely Addenbrooke's, The Royal Free, Great Ormond Street or the Royal Manchester Children's Hospital. As we understand it, the clinician concerned takes that decision entirely on medical grounds, in the best interests of the patient. The funding is then undertaken by the patient's local PCT.

249. In the present case, when presented with a patient suffering from Gaucher disease - which is a serious and potentially life-threatening illness - the clinician who wishes to treat or alleviate the patient's pain and suffering has in practice little or no clinical alternative than to prescribe Cerezyme. Similarly, once Cerezyme has been prescribed, the patient is dependent on continuing supplies of that drug for his health and wellbeing. It is very difficult to imagine circumstances in which a patient suffering from Gaucher disease could or would be refused treatment with Cerezyme on non-medical grounds, despite the expense of that drug. Thus, in practice, once the prescribing decision is taken by the clinician, the NHS - in the form of the patient's local PCT - has little option but to fund the product.

250. In those circumstances, in our view, even though the NHS is the only purchaser of Cerezyme, its bargaining position is relatively weak in the face of Genzyme's monopoly in the supply of that drug. If the NHS wishes to treat the highly vulnerable patients concerned, it has no alternative but to deal with Genzyme. Zavesca is of no more than marginal importance, given its limited market authorisation, and GCB is some years away.

251. We recognise that "the NHS", or some constituent part of it, could if it so wished discuss with Genzyme aspects of its pricing policies which give rise to concern (see for example paragraphs 286, 542 to 543 and 613 below). However, in our view four factors (i) Genzyme's product monopoly; (ii) the dependence on Cerezyme of the prescribing

physicians; (iii) the largely decentralised structure of the NHS; and (iv) the lack of any specific statutory powers (see below) combine in this case to leave Genzyme in a dominant position vis-à-vis the NHS for the purposes of the Chapter II prohibition. That in our judgment is confirmed by the way in which Genzyme has, in effect, been able to impose on the NHS certain of the pricing and distribution arrangements at issue in the present case.

- *The evidence as to conduct*

252. As far as pricing is concerned, as emerges from our analysis below of the PPRS, Genzyme, like other pharmaceutical companies, has had, in practice, complete freedom to set the initial price of both Ceredase and Cerezyme. Cerezyme was launched at the same price as Ceredase, although the former was cheaper to produce (paragraph 270 of the decision). There is no evidence that the NHS ever had any ability to influence the prices set for those drugs. The across-the-board price reduction that the DoH sought from all pharmaceutical manufacturers in 1999 is not in our view relevant. That was a "one-off" situation, and applied to all pharmaceutical companies, rather than being specific to Genzyme.

253. Similarly, with the sole exception of a concessionary price to hospitals, apparently introduced in 1993 because of VAT considerations (paragraph 90 of the decision) Genzyme has not been prepared to sell Cerezyme at anything other than the NHS list price. There has been no discounting of Cerezyme, as one might expect to occur in a competitive market. Cerezyme is not traded through normal pharmaceutical wholesalers.

254. An even more striking picture emerges when considering Genzyme's arrangements regarding home delivery and homecare services. It is apparent from evidence before the Tribunal that since 2001 there has been, and is, a significant demand, both from the patients represented by the Gaucher's Association, and from the relevant clinicians, to have an alternative supplier to Genzyme Homecare for homecare services, and in particular to be serviced by Healthcare at Home rather than by Genzyme Homecare. The existence of that demand is apparent from Tables 1 to 3 above, and from the evidence of Professor Cox of Addenbrooke's, Dr Mehta of the Royal Free, and Mr Farrell, Head of Pharmacy Services at the Royal Free: see paragraphs 108 to 111 above.

255. However, Genzyme has been prepared to supply Healthcare at Home and other homecare delivery/service providers only at the NHS list price, effectively giving Healthcare at Home no margin between its buying and selling price, other than dispensing fees. Genzyme must have been aware that such a policy ran a substantial risk of forcing Healthcare at Home out of business, thereby depriving the clinicians and patients concerned of the choice that they clearly wish to have, see paragraphs 117 to 120 above. That, in the Tribunal's view, is evidence of Genzyme's ability to disregard the wishes of its consumers and users, which is the hallmark of dominance.

256. In the Tribunal's view, it is particularly striking that, by its letter of 21 June 2001, Genzyme was able to insist that the hospital price for Cerezyme charged to the Royal Free Hospital applied as a concessionary matter only when Cerezyme was used to infuse a patient in the hospital, and not when a patient under the care of the Royal Free was infused at home (paragraph 117 above). Such a price differential, depending on the location of use of a particular product, is in our view a classic indication of monopoly power.

257. Thus the very state of affairs which forms the subject matter of the present case itself indicates the ability of Genzyme to disregard the wishes of its customers and consumers. Similarly, Genzyme is in a position to dictate the terms upon which it is prepared to supply Cerezyme to homecare service providers wishing to compete with Genzyme Homecare. Moreover, the foregoing facts show a clear linkage between the dominant position for which the OFT contends and the facts giving rise to the alleged abuse. That in our view meets the concern expressed by Professor Yarrow to the effect that the question of dominance should be examined in the context of the abuse in question.

258. Finally, the existence of Genzyme's market power is expressly confirmed by the evidence of Mr Farrell, who pointed out, in his witness statement, that the Royal Free Hospital has no choice but to deal with Genzyme on its own terms, since there is no alternative supplier: see e.g. paragraphs 46, 48, 53 and 58 of his witness statement, which were not seriously challenged in cross-examination. Mr Farrell confirmed in evidence to the Tribunal that he saw himself in a weak bargaining position vis-à-vis Genzyme, in the absence of any alternative supplier:

PROF GRINYER: In your written statement in paragraph 58, you seem to be implying that you do not, at your operating level, see yourself as having countervailing buying or monopsony power as a big buyer against a monopoly like Genzyme, where you have a uniquely efficacious treatment, just one, and you are unable to persuade them to unbundle and so on.

Q. This is a correct interpretation?
A. That is correct.
Q. Do you think that moving to a more networking and more reasonable procurement sort of collaboration, consortia, will actually change that or not?
A. It is something we would be asking for, and if we went to tender it is something we would be putting in the tender document.
Q. But if you are tendering just for one product ---

A. That is a difficulty, and that is the difficulty we find ourselves in in this particular case. If there is only one product there is no point in tendering." (Transcript Day 2, pp 61-62)

We accept that evidence.

Were there any relevant statutory powers or other means of constraining Genzyme's market power?

259. Nonetheless, we have considered whether there existed, within the NHS system, any statutory powers or other means of constraining Genzyme's behaviour which might be argued to negate Genzyme's dominant position. The four matters which have been raised, one way or another, in these proceedings are (a) the PPRS, (b) the Secretary of State's reserve powers under the Health Act 1999, (c) the powers to control pharmacists' remuneration under Part II of the 1997 Act and (d) administrative action along the lines of EL(95)5.

260. For the following reasons we conclude that there were in this case no relevant statutory powers or other potential means available to the NHS capable of negating Genzyme's dominant position.

(a) The PPRS

261. The PPRS is a voluntary scheme agreed between the Secretary of State and the pharmaceutical industry in the United Kingdom under powers now contained in section 33 of the Health Act 1999. As emerges from the description of the PPRS set out at paragraphs 67 to 73 above, that scheme is not designed to control the prices of individual drugs, still less the distribution arrangements of particular drugs. The principle is one of an overall control on profits, based on a permitted rate of return for a company's NHS business as a whole, across its range of licensed medicinal products.

262. In its judgment in *Napp*, cited above, where a similar point arose, the Tribunal said at paragraph 164:

> "In our view the case law on the existence of a dominant position, cited above, directs our attention to the competitive situation in the market place, and in particular to whether the allegedly dominant undertaking is able to "prevent effective competition being maintained on the relevant market". As seen from the foregoing, the PPRS does not have a direct effect on Napp's freedom to conduct itself as it wishes in the market for oral sustained release morphine. As regards the issue of dominance, the effects of the PPRS are at most remote and indirect…"

263. At paragraphs 167 to 168 of *Napp* the Tribunal said:

> "167. In Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-2969 the Court of First Instance rejected the appellant's plea that its policy on offering certain rebates was in accordance with the policy of the Irish government in the following terms:
>
> "If anti-competitive conduct is required of undertakings by national legislation or if the latter creates a legal framework which itself eliminates any possibility of competitive activity on their part, Articles 81 and 82 do not apply. In such a situation, the restriction of competition is not attributable, as those provisions implicitly require, to the autonomous conduct of the undertakings … Articles 81 and 82 may apply, however, if it is found that the national legislation does not preclude undertakings from engaging in autonomous conduct which prevents, restricts or distorts competition …"
>
> 168. In our view nothing in the PPRS affects Napp's autonomous conduct in such a way as to deprive Napp of its dominant position, as the Director found in paragraphs 122 to 136 of the decision. Moreover, on Napp's argument virtually the entire pharmaceutical industry of the United Kingdom would be outside not only the scope of the Chapter II prohibition but also Article 82 of the Treaty. The

decisions of the Commission cited by the Director at paragraph 137 of the decision are contrary to that point of view".

264. In our view a similar analysis applies in this case. The existence of the PPRS does not affect, in any respect relevant to this case, Genzyme's ability to conduct itself in the market place as it wishes. The present case concerns the arrangements for the distribution of Cerezyme to delivery/homecare service providers. That is nothing to do with the PPRS.

265. One effect that the PPRS may have at some future time could be to limit Genzyme's overall return on capital on its NHS sales of licensed medicinal products as a whole, i.e. Cerezyme, Fabrazyme and other products. Again, we do not see that possibility as relevant in the present case.

266. In our view, however, even the prospect of some kind of future profit control is extremely distant, for two reasons. First, at present Genzyme's turnover falls below the threshold of £25 million at which detailed financial returns are required annually. In practice, therefore, as Mr Brownlee told us, there is at present no routine control over whether Genzyme's NHS pharmaceuticals business is or is not within the overall permitted limits on return on capital as calculated under the specific rules of the PPRS. Secondly, in any event, Genzyme's profits in the United Kingdom are substantially dependent on the transfer price for Cerezyme charged by Genzyme Corporation in the USA to Genzyme in the United Kingdom. In our view the setting of that transfer price could give Genzyme flexibility when seeking to remain within the overall limits of profitability envisaged by the PPRS. In our view it does not, therefore, necessarily follow that Genzyme's profitability is constrained by the PPRS, and still less that Genzyme may be more constrained than other companies, as Professor Yarrow suggested.

267. In any event, the distant future prospect of some kind of overall control on Genzyme's profitability under the PPRS does not seem to us to have a material impact on Genzyme's market power in relation to its conduct in the supply of homecare services that is in issue in this case. Similarly the distant possibility that the PPRS might at some stage impact on future price increases for Cerezyme, does not seem to us to have any bearing on the issues in this case either.

268. Lastly, the negotiations between Genzyme and the DoH in 1999, already referred to, formed part of the across-the-board price reduction which the DoH sought from all pharmaceutical companies in 1999. Although relevant background in the present case, that correspondence does not in our view demonstrate any relevant constraint upon Genzyme's market power in relation to Genzyme's decision to include homecare services in the NHS list price for Cerezyme, and to sell Cerezyme to third party home delivery/ homecare service providers only at that list price.

(b) *The reserve powers under sections 33 to 38 of the 1999 Act*

269. Under section 33(1) of the 1999 Act the Secretary of State may make a voluntary scheme for (a) limiting the prices charged or (b) limiting the profits arising from the supply of health service medicines, as defined. That is the statutory basis for the existing PPRS. If the acts or omissions of any scheme member show that "in the scheme member's case, the scheme is ineffective for either of the purposes mentioned in subsection (1)", then under section 33(4) the Secretary of State may serve a notice determining that the scheme is not to apply to that scheme member. Under section 33(5), the Secretary of State must set out his reasons and accord the scheme member the opportunity to make representations before excluding that member from the scheme.

270. Under section 34(1)(a), the Secretary of State has power to "limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine". Under section 34(1)(b), the Secretary of State has power to "provide for any amount representing sums charged by that person for that medicine in excess of the limit to be paid to the Secretary of State within a specified period". However, under section 34(2), those powers are not exercisable in relation to any manufacturer or supplier who for the time being is a member of a voluntary scheme. The same applies to the making of a statutory scheme for limiting prices or profits under section 35: see 35(7).

271. The effect of these provisions, in our judgment, is that the Secretary of State has no power to "limit prices" or control profits of health service products under the 1999 Act for as long as the relevant supplier is a member of the PPRS, which is the case with Genzyme.

272. An existing member of the PPRS can, however, only be removed from that scheme if it is shown under section 34(1) that the PPRS is "ineffective" as regards that member for the purposes of limiting prices or controlling profits within the meaning of section 33(1), following the procedure envisaged by section 33(5). Mr Brownlee, understandably enough, was somewhat unclear in his evidence as to the scope of these powers, especially since, as Mr Brownlee pointed out, the Secretary of State has never attempted to use them.

273. In our judgment, since Genzyme is a member of the existing PPRS, the powers under section 34(1) to "limit prices" could not be exercised unless Genzyme was first excluded from the PPRS under section 33(4) and (5). However, as far as we know, Genzyme is fully complying with the existing provisions of the PPRS. Genzyme has not sought to increase the price of Cerezyme without the consent of the DoH, and has not breached the limit of profitability imposed by the PPRS. In our view it would be difficult for the Secretary of State successfully to show that the PPRS was "ineffective" as regards Genzyme within the meaning of section 33(4) as long as Genzyme was fully compliant with the provisions of the PPRS.

274. In any event, we think it unlikely that the power to "limit prices" referred to in section 34(1) could have been intended by Parliament to be used for the collateral purpose of controlling the anti-competitive practices of "bundling" and "margin squeeze" alleged in the present case. In our view, the statutory purpose of sections 33 to 38 of the 1999 Act, read as a whole, is to control *excessive* profits or prices for branded health service products, and not to control other practices, such as those at issue in the present case, which are more appropriately dealt with under the Chapter II prohibition of the 1998 Act.

275. We therefore conclude that neither the PPRS nor the reserve powers to control prices or limit profits under the 1999 Act affect Genzyme's dominant position in any relevant respect.

(c) *The Secretary of State's powers regarding the reimbursement of pharmacists*

276. Under regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992 ("the 1992 Regulations") made under section 41 of the 1977 Act the Secretary of State has power to determine the reimbursement paid to pharmacists by the PPA pursuant to the Drug Tariff. A similar power of determination appears to exist under section 7(4) of the Health and Social Security Act 1984 ("the 1984 Act").

277. In the course of these proceedings the Tribunal raised with the parties the question of whether these powers could be used to secure the "unbundling" of the list price of Cerezyme, so that the drug itself and the supply of homecare services were remunerated separately. In its submissions dated 9 September 2003 the OFT rejected that suggestion. Genzyme has developed little detailed argument on this point, contenting itself with only general observations in paragraph 54 of its submissions of 19 September 2003.

278. We are satisfied that the possible exercise of the Secretary of State's powers under the 1992 Regulations, or section 7(4) of the 1984 Act, does not have any bearing on Genzyme's dominant position in the supply of drugs for the treatment of Gaucher disease, nor would the exercise of those powers represent a realistic alternative solution to the issues arising in the present case.

279. The issue that presents itself in the present case is Genzyme's ability to sell Cerezyme to third parties only at the NHS list price, while itself supplying not only Cerezyme but also home delivery and homecare services for that same list price, thus giving rise to the alleged abuses of "bundling" and margin squeeze found in the decision. However, as the OFT points out, the 1992 regulations are concerned with the reimbursement of *pharmacists* under the Drug Tariff not with controlling the prices of *manufacturers*. Nothing in the Secretary of State's powers regarding the reimbursement of registered pharmacists under the Drug Tariff permits the regulation of the individual manufacturer's list price, or the discount, if any, that an individual manufacturer grants off that list price, or the component parts of the manufacturer's list price. The Drug Tariff is concerned with the reimbursement of the *pharmacist*, not the price charged by the manufacturer.

280. We thus see force in the OFT's submissions of 8 September 2003 that the statutory provisions affecting the Drug Tariff were not intended to confer power on the PPA to seek to control prices set by manufacturers in individual cases by the "back door" route of limiting the *pharmacist's* right to reimbursement, and that the legal and practical problems of seeking to do so could be very great indeed. Morever, as the OFT points out, in the present case around 60% of the prescriptions in question are hospital prescriptions, which in any event fall outside the provisions for reimbursing pharmacists under the Drug Tariff pursuant to the 1992 Regulations.

(d) *EL95(5)*

281. It has also been submitted by Genzyme that many of the issues in the present case could have been resolved by the issue of administrative guidance along the lines of the circular EL95(5), which required the relevant health authorities to acquire certain treatments involving "packages of care" on a contract basis, rather than on the basis of a prescription written by a GP on Form FP10 (see paragraph 84 above). We consider that this argument does not negate the existence of Genzyme's dominant position.

282. As we read EL95(5), which is set out in full in appendix 4.2 of the *Fresenius/Caremark* report, that document constitutes, essentially, internal administrative guidance issued by the NHS Executive in England and Wales as to how certain medical treatments involving certain "hi-tech" homecare products and services should be acquired and funded within the framework of the NHS as it existed in 1995. However, EL95(5) is not, and could not be, a direction *to the manufacturers or suppliers in question* as to how such products or services should be supplied or priced.

283. As we understand it, the problem addressed by EL95(5) was that at that time certain types of treatment including "packages of care" (i.e. the supply of the drug, plus the necessary equipment) for certain home based patients were being authorised by FP10 prescriptions written by GPs, the cost of which was being borne by the budgets applicable to Family Health Service Authorities. In order to put the acquisition and funding of such services on what is described as "a more consistent and sensible basis", it was decided that, in future, certain types of treatment involving "packages of care" should be acquired on the

basis of contracts with suppliers entered into by District Health Authorities or NHS Trusts, rather than on the basis of prescriptions written by GPs.

284. The effect of this change was that the cost of such treatment would in future be borne on the budgets of the then District Health Authorities, rather than on those of the then Family Health Service Authorities. The main treatments affected by this change were home dialysis for patients with kidney failure, various kinds of intravenous treatments for patients suffering from cystic fibrosis, cancer or HIV, parenteral nutrition (the administering of a patient's nutrition directly into the blood stream), infusions of desferrioxamine for patients suffering from Thalassaemia, and certain continuous anti-coagulant treatments administered by infusion. Treatments for Gaucher disease were not affected.

285. The main purpose of EL95(5) was thus to move the acquisition of the "packages of care" in question from a "prescription basis" to a "contract basis". As far as we can see, EL95(5) was not particularly directed towards ensuring that the contracts, when entered into, were necessarily "unbundled", with separate prices for the drug and the home care services respectively. Indeed, it appears that, at the time of the *Fresenius/Caremark* report, under the new contracts many health authorities simply continued to use their previous supplier without much change from the previous arrangements: see e.g. paragraph 2.150 of that report.

286. Transposing the above to the present case, we accept that it would in theory be possible for the NHS or its constituent parts to seek to change the purchasing arrangements for the supply of Cerezyme and associated homecare services by putting contracts out to tender, and perhaps inviting tenderers to quote separate prices for the supply of the drug, and the supply of homecare services respectively. Such a change could, in theory, be suggested by any one or more of the four specialist centres treating Gaucher disease, no doubt in consultation with the PCTs and other relevant authorities concerned. The DoH could, in theory, it seems to us, issue a circular to the four specialist centres, intimating that that should be done.

287. These possibilities, however, overlook the fact that Genzyme is a monopoly supplier. For the reasons already given at paragraphs 252 to 258 above, we have no evidence to

suggest that Genzyme could be compelled to change its pricing arrangements for Cerezyme against its will. Mr Pearson of the Clinical and Cost Effectiveness Branch of the DoH states in an e-mail dated 30 June 2003, and confirmed in his witness statement of 21 July 2003:

> "So far as I am aware, we do not have the legal power to require a company to separate the drug price from other constituent elements of a homecare service.
>
> Generally, we would attempt to do so by negotiation with the appropriate supplier(s), but we would have little chance of success if there are no competitive products or other suppliers with access to the same product"

That view is supported by Mr Farrell, who pointed out (paragraph 258 above) "if there is only one product there is no point in tendering".

288. In those circumstances it does not seem to us that the administrative possibility of a circular along the lines of EL95(5) affects the existence of Genzyme's dominant position.

Conclusion on buying power

289. For the above reasons, the Tribunal finds that, notwithstanding its very large size the existence of "the NHS" as a monopoly purchaser does not undermine the OFT's conclusion that Genzyme has a dominant position in the supply of drugs for the treatment of Gaucher disease. Such "buyer power" as the NHS may have, at least potentially, does not in our view deprive Genzyme of its dominant position for the purposes of the Chapter II prohibition.

Conclusions on Dominance

290. For all these reasons we are entirely satisfied that Genzyme enjoys a dominant position in the supply of drugs for the treatment of Gaucher disease, as found by the OFT in the decision.

VI THE DOWNSTREAM SUPPLY OF HOMECARE SERVICES

A. THE FINDINGS IN THE DECISION

291. According to the OFT, there is a "downstream" market for the sale of Cerezyme and the delivery of homecare services to the NHS (paragraphs 159 to 191). This market has two segments, a "wholesale" segment and a "Homecare Services" segment (see paragraphs 162 (ii), first indent, and 183 of the decision).

292. According to the decision the "wholesale" segment comprises the delivery of Cerezyme and sales support to hospitals. In this segment no other supporting services are provided, since the patient is in the care of the hospital. Currently only Genzyme Homecare is active in this wholesale segment (paragraphs 162 (ii), 163, 175 and 182-183 of the decision).

293. According to the decision, in the "Homecare Services" segment of the downstream market, delivery/homecare service providers dispense Cerezyme against a prescription and deliver it to a patient's home. The level of service may range from dispensing, home delivery, emergency helpline and provision of accessories (when the patient is self infusing), to comprehensive care, including taking complete charge of the infusion, teaching the patient to self-infuse, providing a 24 hour helpline, supplying and monitoring accessories such as syringes or fridges, and advising on storage (see paragraphs 34 and 162 (ii) of the decision).

294. Rejecting Genzyme's argument that delivery of Cerezyme is not part of any downstream market (paragraphs 165 to 172), the OFT concludes that the home delivery of Cerezyme and the provision of homecare services may properly be considered together under the description "Homecare Services" (paragraph 172 of the decision).

295. In determining whether Homecare Services for patients who receive an infusion of Cerezyme at home constitute a separate market, the OFT considers that an undertaking can only be active in the Homecare Services segment of the downstream market if it can obtain supplies of Cerezyme at a price which enables it to offer Homecare Services, as defined, on a viable basis. In this case, Genzyme is prepared to sell to Healthcare at Home (or other delivery/homecare service providers) only at the same price at which Genzyme Homecare itself sells Cerezyme and Homecare Services to the NHS - i.e. at the

NHS list price of £2.975. It follows, according to the OFT, that it is impossible for any other independent delivery/homecare service provider to operate a viable business offering homecare services in competition with Genzyme Homecare. Similarly, because Homecare Services are included in the NHS list price, the NHS has no incentive to obtain such services from an independent provider, at what would inevitably be an extra cost (paragraphs 173 to 180 of the decision). According to the OFT, a similar argument applies to wholesaling (paragraphs 181 to 182).

296. The OFT therefore concludes (at paragraph 183) that there is a separate relevant "downstream" market which at most consists of two segments, namely the delivery of Cerezyme to hospitals (wholesaling) and the home delivery of Cerezyme and the provision of homecare services to the patients concerned (Homecare Services). The OFT rejects Genzyme's contrary arguments at paragraphs 184 to 191 of the decision.

B. THE ARGUMENTS OF THE PARTIES

(1) ***Genzyme's arguments***

Unrealistic market definition

297. As regards the "downstream" market identified by the OFT at paragraphs 159 to 191 of the decision, Genzyme submits that the OFT's market definition does not reflect any economic reality, nor the particularities of the pharmaceutical market, the Drug Tariff or the PPRS, and is unsupported by evidence. Genzyme contests whether any such downstream market exists. Nowhere in the decision is there any definition of a "homecare services" market or any investigation or analysis of what such a market might comprise.

298. More particularly Genzyme submits that there is no basis for including either delivery to hospitals, or delivery to patients at home, in any "downstream" market. Delivery is associated with the supply of the drug, and is not a "downstream" activity. The only "downstream" activity conceivably relevant to this case is the supply of home nursing services.

299. However, according to Genzyme, there is no separate market for the supply of home nursing services to Gaucher patients, merely a market for the supply of home nursing services generally. The OFT's conclusion that there is a separate market for the supply of Homecare Services for Gaucher disease, as distinct from a market for home nursing services, is contrary to the *Fresenius/Caremark* report, and to Healthcare at Home's evidence to the MMC that "it would be very difficult for a pure service provider to build a profitable business in only one treatment". According to Genzyme, the market for home nursing services is not disease specific.

The delivery issue

300. As regards the question whether delivery is a separate activity, which is dealt with at paragraphs 165 to 172 of the decision, Genzyme argues that the delivery of Cerezyme relates to the supply of the drug and is not part of "homecare services", however defined. Transport of Cerezyme to the hospital is part of the normal supply chain. Transport of Cerezyme to the patient's home is no different in principle from the normal case of delivery of a drug to a retail pharmacy, except that in the case of Cerezyme dispensing takes place before delivery to the patient's home, whereas in the normal case dispensing takes place when the patient collects the drug from the pharmacy. Genzyme's system of delivery is simply the most efficient way of delivering the drug to the patient's home in a cold chain delivery system, which also involves the supply of a refrigerator, the provision of ancillary products such as needles, and the removal of waste products. Moreover, delivery is included in the Drug Tariff price of pharmaceutical products.

301. According to Genzyme, any delivery service would be capable of undertaking this type of cold chain delivery, and undertakings such as Polar Speed and Healthcare Logistics do so. The fact that Genzyme's drivers are appropriately trained, carry out stock checks, and remove waste does not mean that such a delivery service can be separated from the supply of the drug, or that it is disease specific.

302. Genzyme, in its reply, also draws attention to a tender document issued by the Royal Free Hospital in relation to haemophilia patients, annexed to Mr Farrell's statement. That tender document draws a distinction between dispensing and cold chain delivery on the one hand, and nursing care on the other. Genzyme's argument that there is a "natural

split" between delivery and nursing services is further supported, notably, by the fact that two thirds of Gaucher patients self-infuse and thus do not receive nursing services; by the evidence of Mr Evans of Polar Speed; and by the evidence of Dr Jones of Healthcare at Home, who indicates that Healthcare at Home has used Polar Speed as a sub-contractor.

303. Excluding delivery from the downstream market, Genzyme considers that the only homecare involved in any downstream market in this case is the provision of nursing services. However, as already stated, about two thirds of Gaucher patients in the United Kingdom are trained to self-infuse. According to Genzyme, self-infusion is not a particularly complicated operation. For such patients no nursing services, and hence no "homecare" is required. Even when nursing services are required, such nursing is not disease specific, since any competent nurse could do it: see the OFT's note of the meeting with Dr Mehta, 10 July 2001. There is also no doubt, according to Genzyme, that Healthcare at Home operates in a "home nursing" market of which Gaucher patients form a tiny proportion.

304. In addition, Professor Yarrow argues on behalf of Genzyme that there is no substitutability as between the various operations considered by the OFT to fall within the definition of Homecare Services (distribution/delivery, dispensing, equipment, advice, nursing). Accordingly, such services can be treated as one market only if they are complementary. However, there is no analysis in the decision as to whether such products are complementary, and the mere fact that such services are, in a specific case, supplied by one undertaking (decision, paragraph 163) is not sufficient to place all the activities in the same relevant market. Moreover, nursing is either not supplied at all or, if it is supplied, can and is undertaken by another supplier, e.g. the NHS. In Professor Yarrow's view, it follows that "homecare" should be defined on a narrower basis than that adopted in the decision. In any event, argues Professor Yarrow, delivery and associated activities are to be regarded as being in a separate market from nursing services.

305. Specifically on the issue of delivery, Professor Yarrow states on behalf of Genzyme that:

> "The reality is that, whilst Cerezyme is a (high cost) triumph of front-line science, home delivery of a product where there is a temperature-maintenance issue is closer in technology to

> Domino's Pizza, the milkman, and home delivery of chilled and frozen foods by Sainsbury's or Tesco".

In Professor Yarrow's view, activities such as retrieval of packaging, waste disposal etc. are most naturally classed as part of distribution/delivery, and are not much different from "picking up the empties" on a milk round. The supply of fridges is part of delivery, while the supply of other ancillary equipment (e.g. syringes), while less clear cut, are de minimis in any event. Advice and support to patients are akin to pharmacy activities, but these can be expected to be remunerated by dispensing fees. According to Professor Yarrow, that leaves only nursing activities which can properly be described as "homecare". Such activities affect only a small number of Gaucher patients.

Homecare Services to Gaucher patients

306. As regards the OFT's finding, at paragraphs 174 to 180 of the decision, that the downstream market is limited to Homecare Services to Gaucher patients, Genzyme argues that, whatever the definition of "homecare services", such services form part of a wider market for homecare services generally, particularly nursing services generally.

307. According to Genzyme, the OFT's analysis of demand-side substitution based on a hypothetical price rise in homecare services supplied to Gaucher patients at paragraph 174 of the decision is misconceived, because no Gaucher patient is ever faced with a price increase for services which are funded by the NHS. The MMC adopted the correct approach at paragraph 2.71 of the *Fresenius/Caremark* report, in indicating that market definition depends on the ease and speed with which a producer of one product or service is able to offer another in response to a price rise or the opportunity to offer the service at lower cost. That is exactly what Healthcare at Home did in 1998 when it was awarded the Genzyme contract.

308. Genzyme denies that the potential for supply-side substitution in any downstream market is prevented by Genzyme's policy of "making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme", as alleged by the OFT in paragraph 177 of the decision. According to Genzyme, the NHS Drug Tariff price for Cerezyme includes delivery to the pharmacy, or to a patient. It does not, however, include any element for nursing care. According to Genzyme, home nursing is provided

by Genzyme "at its own cost where needed and free of charge". That does not, however, prevent others from supplying such services if so desired. The NHS supplies its own homecare in many cases through community nurses or care services sourced from another supplier. Genzyme points out that the Royal Free uses the services of Healthcare at Home, and that some PCTs or hospital trusts are moving to "block contracting" for homecare provision.

309. On behalf of Genzyme Professor Yarrow also criticises the OFT's finding in the decision that there is a downstream market limited to the provision of homecare services to Gaucher patients. According to Professor Yarrow, such an approach appears to define the relevant market by reference to the alleged abuse, which is to confuse two separate issues. In any event, there is no analysis of the cost of providing homecare services, or of income from dispensing fees. Moreover, any analysis of supply side substitutability should be carried out at *competitive prices*, in order to avoid the so called "Cellophane Fallacy". What the OFT has done here is to define the downstream market incorrectly on the basis of a price which is assumed to be the abusive, rather than the competitive, price.

310. According to Professor Yarrow, while it is admittedly harder for private companies to provide homecare services for the subset of the market being treated with Cerezyme, the relevant question should be whether Genzyme's activities have substantial foreclosure effects on the market for homecare services generally, to which the answer is plainly in the negative. In *Fresenius/Caremark*, the MMC was more cautious than the OFT suggests.

311. Although Professor Yarrow states that he is not saying that the OFT's assessment of market power in the downstream market is necessarily "holed beneath the waterline by the Gaucher-only approach", it does seem to him that such an approach contains various pitfalls. Apart from confusing the question of market definition with the question of abuse, Professor Yarrow considers that the OFT's approach overlooks the fact that Genzyme is itself potentially a buyer of homecare services, and can consider whether to engage an independent provider, or provide such services itself.

Wholesaling

312. As regards the wholesaling function referred to in paragraph 163 of the decision, Genzyme submits that there is no wholesaling of Cerezyme, and the test of a hypothetical price rise purportedly applied at paragraph 175 of the decision is divorced from reality. Similarly, the suggestion, left open at paragraph 182 of the decision, that there could be a separate product market for the wholesale supply of Cerezyme to four hospitals treating just over 20 patients is ludicrous, according to Genzyme.

(2) ***The OFT's arguments***

313. As regards the "downstream" market, the OFT maintains, on the basis of the evidence of Mr Farrell and numerous documents before the Tribunal, that "home delivery" forms an integral part of Homecare Services, as defined in the decision, and cannot be separated as Genzyme suggests. As regards Genzyme's argument that there is a broad "downstream" market for homecare nursing services, the OFT does not dispute that delivery/homecare service providers could, in principle, provide services for a range of conditions (decision, paragraphs 173 to 180). However, because Genzyme controls access to Cerezyme, and because its pricing policy in practice excludes third party delivery/homecare service providers from servicing Gaucher patients, it is necessary to consider delivery/homecare services for Gaucher patients separately from other delivery/homecare services for other conditions, as the MMC did in the *Fresenius/Caremark* report.

C. THE TRIBUNAL'S FINDINGS ON THE "DOWNSTREAM" SUPPLY OF HOMECARE SERVICES

Preliminary observations

314. Genzyme has argued the following principal issues:

(i) Whether there is any downstream market limited to the supply of services to Gaucher patients being treated with Cerezyme, or whether, as Genzyme contends, the only relevant downstream market is that for homecare services generally for patients requiring treatment at home, of whom Gaucher patients comprise a miniscule proportion.

(ii) Whether, in any event, any such downstream market is, as Genzyme contends, limited to the supply of nursing services, and excludes the delivery of the drug, which operation belongs to the upstream supply of the drug itself.

315. We observe, first, that the question of how far the supply of homecare services to Gaucher patients constitutes a separate "market" for the purpose *of deciding whether Genzyme is dominant in that market* does not strictly speaking arise, since it is not alleged that Genzyme is dominant in the downstream market identified in the decision (paragraphs 287 to 289). Indeed, it is common ground that it is only Genzyme's alleged dominant position in the upstream market, already discussed, that could have been abused in this case.

316. Secondly, on this part of the case there seems to us to be a considerable amount of common ground between the parties. The OFT does not deny that there is in general terms a market for "homecare services" which is supplied by various companies who specialise in providing such services (for example, Healthcare at Home, Clinovia (formerly Caremark), Central Homecare) and by certain drug manufacturers who also offer homecare services primarily in association with their own products (for example Baxter, Nutricia).

317. Nor does the OFT deny that there are companies who offer "delivery services" or "nursing services". Similarly, the OFT does not deny that it is, in the abstract, possible to imagine different elements of certain homecare services being supplied by different companies, depending on the illness concerned. For example, for some types of illness there may be no particular reason why the manufacturer should not supply the drug, another company the delivery, and yet a third company the nursing services, and so on. However, says the OFT, that is not typically the case with Gaucher disease.

318. In our view, there is very little doubt that there is, in a general sense, a market for "homecare services" for a wide variety of illnesses ranging from haemophilia to HIV. That market is supplied by Healthcare at Home and other specialised companies. Indeed, Mr Farrell emphasised in his evidence to us the growing importance of such a homecare services market. However, the existence of such a wider market - not seriously disputed before us - is in our view of very limited relevance in the present case. The issue in the

present case is whether Genzyme has abused its dominant position in the upstream market by preventing a segment of the downstream market for homecare services - namely the supply of homecare services to Gaucher patients - being supplied by anyone other than Genzyme. In our view that matter goes primarily to the issue of abuse, and does not depend on defining the precise ambit of the "downstream" market.

319. For completeness, however, we address the issue of the downstream market in this section of the judgment, at paragraphs 365 to 367 below.

320. Thirdly, we observe that the decision does not find an abuse in relation to what is described as the "wholesale" segment of the downstream market, i.e. the supply of Cerezyme to hospitals. In those circumstances we think it unnecessary to consider further any issues that may arise in relation to paragraphs 162(i), 162(ii), first indent, 163, 173, 175, 182 and 183 of the decision in so far as those paragraphs deal with wholesaling.

321. Against that background, there are four issues which in our view should be dealt with at this stage. These issues are:-

(1) What activities are properly included as "homecare services" in this case?

(2) Is there a demand from Gaucher patients at home for "homecare services" which is separate from, albeit ancillary to, the supply of the drug alone?

(3) Is Genzyme in a position to foreclose that supply?

(4) Is there a separate market for Homecare Services to Gaucher patients?

(1) *What activities are properly included as homecare services in this case?*

322. The homecare services with which this case is concerned are described in paragraph 162(ii) of the decision in these terms:

> "When the Cerezyme is purchased for infusion at the patient's home, the delivery/homecare services providers dispense the drug against a prescription and deliver it to the patient's home. In this case, the level

> of service may range from dispensing, home delivery, emergency help-line and provision of accessories (when the patient self-infuses) to comprehensive care, which might include any one or more of the following: taking complete charge of the infusion, training the patient to self-infuse, providing a 24-hour help-line, supplying and monitoring the need for accessories (e.g. fridges, syringes, etc.) and, among other things, advising on storage of the drug."

323. Similar descriptions of the services in question are set out in paragraphs 34 and 396, sub-paragraph 3, of the decision.

324. Genzyme's argument (see paragraphs 297 to 312) is, essentially, that delivery cannot properly be included within "homecare services" for the purposes of this case; that the only relevant "homecare services" properly so called are nursing services, which are supplied to only a small number of Gaucher patients; and that the constituent elements of the homecare services relied on by the OFT could be supplied by companies other than homecare providers such as Healthcare at Home. In particular, argues Genzyme, there are many suppliers of delivery services and nursing services who could easily undertake these services in relation to Cerezyme. Professor Yarrow further argues that home delivery of Cerezyme is analagous to home delivery of a pizza and that waste disposal is similar to picking up the empties on a milk round.

- The evidence as to the services concerned

325. The Tribunal has considerable evidence about the homecare services with which this case is concerned, including the witness statement by Julie Kelly of 23 October 2002, Julie Kelly's presentation to the OFT of 6 November 2002, Dominic Moreland's statements of 24 October 2002, 23 August 2003 and 28 September 2003, all on behalf of Genzyme, and Mr Farrell's statement of 30 June 2003, on behalf of the OFT, as well as Mr Farrell's oral evidence before the Tribunal. We have also seen literature produced by Genzyme Homecare (see Genzyme Homecare's Homepack), Healthcare at Home, and Central Homecare (see exhibit JF3).

326. We find Mr Farrell's description in his witness statement, which was not challenged in cross-examination, the most helpful. Mr Farrell, basing himself on the service provided by Healthcare at Home, sets out what he describes the provision of homecare services in

terms of "a number of integrated service elements" including (a) the operation of a registered pharmacy; (b) a customer care operation, to ensure that the patients are fully and properly attended to; (c) a logistics operation, in particular to ensure cold chain validation and the prompt and timely delivery of the refrigerated product; and (d) in the case of Gaucher disease, nursing services as well.

327. As regards first the pharmacy, Mr Farrell states:

> "25. The provider's registered pharmacy is a critical element of the overall service. In the first instance, when a provider is engaged, the provider's pharmacist and other relevant staff (including the customer care officer) will typically meet with the hospital's key staff and establish their exact requirements for the group of patients who are to receive the care. If there are patients with particular needs, these are identified.
>
> 26. All drug products are dispensed by the provider's pharmacist from registered premises, against Royal Free prescriptions. The pharmacist carries out a clinical check before dispensing any prescription, by reference to information in the patient's office file and notes, as well as in the current prescription itself.
>
> 27. Each patient receives a "Patient Information Folder" which contains the names and contact details of the customer care officials and of other key personnel of the provider, including the pharmacist, as well as the delivery drivers and 24-hour on-call cover. The patients can call the pharmacist if they have questions about their drug therapy, such as any adverse reactions. The pharmacist, like the other staff of the provider, maintains a close liaison with the hospital, and ensures that any clinical care issues which crop up with a patient are relayed back promptly.
>
> 28. The pharmacy element of homecare/delivery services immediately distinguishes them from the "thousands" of distribution services referred to by Genzyme as being equivalent..."

328. As to customer care services, Mr Farrell states:

> "29. It is a vital feature of homecare/delivery services that the provider must be sensitive to the needs and concerns of individual patients, who are being treated in their home environment. The provider should be constantly alert to ensure that the patient receives a smooth and trouble-free service, and to deal with any worries that a patient or his/her family might raise.

30. We expect that the provider will, in the first instance, ensure that contact is made with each patient to introduce and explain the service, and to ascertain his or her individual needs. Healthcare at Home creates an "information pack" for each of the patients, which contains:

    (a) a letter of welcome and introduction;
    (b) an information leaflet and a help-line number;
    (c) a patient file setting out relevant treatment details; and
    (d) a delivery schedule for the home delivery of drugs.

31. As part of the ongoing service, Healthcare at Home patients are often called prior to delivery to confirm the relevant date and time. If a patient calls up at any time with a problem, this is directed in the first instance to the individual with the relevant expertise within Healthcare at Home (for example, a nurse or pharmacist). The provider must be astute to pass on any clinical care concerns that may arise to a member of the hospital team dealing with the patient concerned, without any delay."

329. As to logistics, which essentially comprise cold storage, stock control, cold chain delivery and the removal of clinical waste, Mr Farrell states:

"32. Drugs such as Cerezyme require monitored cold storage. The provider needs to have in place rigorous cold chain procedures to ensure that the drug reaches the patient's home in perfect condition. If it does not, there can be serious consequences. Accordingly, the warehousing facility must have suitable controls, all products must be shipped to patients in insulated, "validated" cold-chain packaging (i.e. checked to show that the correct temperature will be reliably maintained within the necessary parameters during transport), and full cold-chain and batch tracing records have to be kept. This requires careful planning for each delivery, particularly if a refrigerated van is not used, because an extended length of time in transporting the drug can undermine the reliability of the cold chain.

33. The provider has to be able to monitor the stock levels for each patient continually, bearing in mind his or her individual requirements. Deliveries have to be made within very narrow time windows, never left unattended, and conform to the individual schedule of the patient.

34. In contrast to the drivers of pharmaceutical distributors or wholesalers, home delivery drivers have to undertake a special training programme, and their competence continually monitored. To become a Healthcare at Home driver in particular, all applicants have to:

    (a) submit to a police check;
    (b) have an interview with the nursing manager;
    (c) sign a confidentiality agreement; and

(d) undergo training and regular assessment to ensure that they follow written procedures governing cold chain monitoring and compliance, and the handling and delivery to patients of sensitive prescription drugs. The training includes unpacking items and transferring them (with permission) into the patient's refrigerator. It also includes stock level monitoring, stock rotation based upon the principle of "first expiry - first use", the checking of refrigerator performance and the removal of clinical waste.

35. Healthcare at Home has male and female delivery staff available, who need to be smartly dressed and carry personal photo identification. The staff need to be ready and able to respond properly to any issues that may be raised by patients, and astute to refer their own observations and matters of any concern back promptly to an appropriate individual within the provider's organisation, so that further action can be taken. In some cases, the level of trust built up between patients and the delivery drivers is such that the patients even give out their house keys to them so that they can deposit the drugs in the specialist fridge if the patient is not at home …

36. The collection, removal and disposal of clinical waste from patients (which often includes used needles and syringes, and could also include drug residues within the packaging), is in itself an important and costly function. It has major public health implications."

330. Mr Farrell emphasises how dangerous the management of clinical waste can be, and considers that Professor Yarrow has not fully understood this.

331. As regards nursing services, Mr Farrell states that, for Gaucher disease, nursing services form an integral part of the package of care. He continues:

"38. … the provider's nursing staff is given special training on the service and product being provided. Healthcare at Home's nurses are recruited from the senior grade levels, starting at F and G. None are locums, and all of them are qualified to perform intricate IV procedures. The nurses attend internal and external training to maintain and increase their knowledge and skills, and need to be assessed as competent to care for the patients in question. Healthcare at Home formally documents their competencies, and reassesses them yearly.

39. The provider's nurses visit patients as their needs require. With Gaucher patients, this will generally include an initial phase of educating patients and/or a parent or carer, on how to administer infusions. These are often given on a weekly or fortnightly basis. In some cases, there is a need for continuing care and support of the patient and in some other cases there is an occasional need. The

nurses fill out clinical evaluation forms whenever they visit patients and these are passed to the relevant clinician at the hospital (Dr Mehta at the Royal Free) for him to review".

332. In his witness statement Mr Farrell emphasises that the quality of service which a homecare/delivery service provider gives the patient is crucial. For that reason, Mr Farrell and members of his team have carried out detailed inspections of Healthcare at Home's premises from time to time.

333. In his oral evidence Mr Farrell said this:

> "A. Homecare can range from a variety of inclusive and integrated services …
>
> In particular, homecare services are provided to patients who may in the past have been either in-patients in hospital or have long-term chronic conditions which can be managed now within the community, within the primary care setting. The context of homecare has evolved in order to enable these patients to be managed within that care setting.
>
> In that context, it ranges from the dispensing, supply and management of medicines to those patients and it may be more than one drug - it may be a number of different drugs - to the full provision of nursing care within the context of homecare. That will largely depend upon the extent of the patient's condition.
>
> In that there may be a population of patients who are eligible for homecare, they may not all at any one time require full nursing care. It is a dynamic situation, because these patients' condition can vary and they may need to be stabilised. Therefore, nursing care may be required. When patients are stabilised, then a dispensing, delivery and drug management service will be a more appropriate level of service. But there has to be that level of integration within the homecare provider in order to be able to move between different elements of homecare.
>
> The other point to identify is this. I have already said that the patient may be in receipt of more than one drug and, indeed, some of these enzyme disorders from which patients suffer run in families, so there may be more than one sibling in receipt of the medicine also. It is, we think, sensible to try and have the same homecare provider providing a service to a particular family or patient group. That is what I understand by that.
>
> Q. That is very clear. As you were talking, you used the word "integrated" more than once.

A. Yes.

Q. I think I understood you to refer to dispensing, delivery, what you described as drug management and in many but not necessarily all cases or at all times a nursing service as well, or at least the ability to provide it if it became necessary; are those elements what a homecare service provider will be typically providing in your experience?

A. Yes, sir, that is correct".

334. It seems to us from the material before us that Mr Farrell's description of the services involved is fair and balanced, and we accept it.

335. Furthermore, Mr Moreland, in his witness statements of 24 October 2002 and 29 September 2003, explains how he set up Genzyme Homecare and the components of the service provided. He emphasises the expertise of the pharmacy staff he recruited, the highly trained nurses employed by Genzyme (Grade G and above), the extensive training the nurses receive and the training courses the drivers are sent on. Mr Moreland also explains the sequence of events when homecare services are provided. The decision to move from the hospital setting to homecare is taken by the prescribing physician, under whose clinical control the patient remains at all times. The prescribing physician will then arrange for the patient to be registered with the relevant homecare services provider, and request homecare nursing as required. If the homecare services provider is Genzyme Homecare, the prescription is sent by the physician to Genzyme. The Genzyme pharmacist then dispenses against the prescription and transfers the drugs and ancillaries into the care of one of the three Genzyme drivers, who deliver in unmarked estate cars. Genzyme's Patient Service Coordinator rings the patient to arrange a convenient delivery time. Genzyme has a two hour window for delivery, but in almost all cases delivers within 15 minutes of the start of the window. Cerezyme itself is transported in pharmaceutical grade polystyrene porters capable of maintaining the required temperature for 72 hours. The drivers also check the refrigerator at the patient's home (provided free by Genzyme), check and rotate the stock as necessary, and supply necessary ancillaries (saline bags, vials of water, needles, infusion tubing, local anaesthetic cream, swabs, antiseptic wipes, sharps bins and syringes). As we understand it, an individual delivery of Cerezyme may be worth some £10,000. Mr Moreland emphasises the importance of

Genzyme Homecare being in a position to arrange the whole of the product supply chain, so that the patient always has sufficient supplies of Cerezyme with a guaranteed cold chain system of packaging and delivery, quality assured by Genzyme Quality Assurance Department.

336. Thus, the evidence we have is to the effect that the operations of Genzyme Homecare are, in their essentials, very similar indeed to those of Healthcare at Home as described by Mr Farrell. Genzyme Homecare seems to us to operate an integrated home delivery/homecare service, in which the operations of pharmacy, customer care, logistics and, where relevant, nursing are closely coordinated. See for example "Homecare News" published by Genzyme in November 2001, Genzyme's specification for homecare services to Gaucher patients for the Royal Manchester Children's Hospital, 6 August 2001 and Genzyme's "Homepack" at Annex 2 to Julie Kelly's statement of 23 October 2002.

337. To give some further examples, Julie Kelly emphasised in particular the importance of the pharmacy in her presentation to the OFT on 6 November 2002:

> "Homecare constitutes many compartments and pharmacy is one of those. This is a very important division, because it is this division that is responsible for pharmaco-vigilance, for safety and for storing the product. Cerezyme and Fabrazyme and the other lysosomal therapies are extremely expensive. They are complex in how they have to be reconstituted and there is a very key issue as to how they get stored. They have to be kept refrigerated and handled very carefully. Our pharmacy department makes sure that the medical community understand this. There is a very short chain of command. If a doctor rings up or a pharmacist rings up and speaks to our pharmacist they can have direct access. If they have a query, which happens once every two or three weeks 'I left my drug out of the fridge', 'I have reconstituted it with the wrong dilutant', 'what can I do' - immediately we can get back, because of this short chain of command. These people are employed by Genzyme and can access these very important departments."

338. As regards home delivery, Genzyme's home delivery service is described in "Homecare News" under the heading "More than just a delivery service".

339. The specification of 6 August 2002 for the Royal Manchester Children's Hospital states:

> "One of our core tenets is the importance of maintaining a named, one to one relationship with the Homecare Service driver, nurse and coordinator. Patients will speak to and meet the same person each time they deal with Genzyme Homecare."

340. A further description is set out in Genzyme's Homepack, which stresses the integration of the home delivery services with the other elements of the homecare package offered by Genzyme Homecare, and the fact that the Homecare Services driver is part of the team, together with the Service Co-ordinator and Nurse: see pages 2184, 2185, 2192 and 2193 of the Tribunal's bundle. It is stated by Genzyme at p. 2193:

> "Our Homecare Service drivers will often be invited into patient's homes to assist with the storage of drugs and ancillaries. Where this is the case, and with the patient's express permission they will inspect the condition of the fridge, rotate the stock, check expiry dates and enquire of any malfunction that may affect the integrity of the product and summarise their findings during the visit. This will be fed back to the hospital or community team where appropriate."

341. Dominic Moreland stated in his statement of 24 October 2002 that:

> "Our drivers are also sent on training courses; they have been given therapy training courses which, though less intensive than those undergone by our nurses, nonetheless give them a thorough grounding in field [sic] of Gaucher and Fabry diseases and their treatment. They also attend advanced driving courses and receive regular Health and Safety updates."

342. Julie Kelly said in her statement of 23 October 2002 that:

> "The delivery drivers are another important point of contact between the patient and the homecare service provider, as they may see a patient more regularly than a nurse does (for example, where the patient is independent and self caring). For this reason, Genzyme Homecare has chosen their delivery drivers for their care experience or for personal qualities which make them particularly well suited to the role. The head delivery driver is a former paramedic/ambulance driver."

That evidence is essentially confirmed in Dr Jones' witness statement of 13 August 2003, at paragraph 11.

343. As regards nursing, Julie Kelly said in her statement of 23 October 2002:

> "54. The provision of homecare is a very serious responsibility. If a patient is being treated in the hospital environment, he sees his physician on a regular basis and can raise any issues or questions with him or with

> nursing staff. If the patient is being treated in the home environment, he will see his doctor much less regularly. The role of the nurse is therefore very important; the nurse must pick up on any problems or difficulties and report these back to the physician. Knowledge of the disease process and the impact of treatment is therefore crucial; a nurse needs to be aware of what factors must be reported and what factors are associated with the disease and require intervention. Genzyme's nursing team has the advantage of having a patient rather than a commercial focus, and the nurses are trained to an extremely high level on the disease and the product. They are regularly assessed on their competency".

(see also as regards nursing paragraphs 11, 41 and 42 of Mr Moreland's statement of 22 October 2003).

- *Conclusions to be drawn from the evidence*

344. We conclude on the basis of the evidence, first, that the supply of homecare services to Gaucher patients involves a series of close and continuous relationships, essentially tripartite in nature, between the consultant/hospital, the homecare services provider and the patient. The consultant and hospital retain clinical responsibility for the patient and are thus rightly and legitimately concerned to ensure that the homecare services are properly and effectively supplied to the patient. The homecare services provider is responsible to the consultant/hospital for those services, but equally has, as Genzyme itself has stressed, a close relationship with the patient, whether via the delivery drivers, the nurses, or the 24 hour help-line provided. The patient, for his part, looks both to the consultant/hospital, and to the homecare services provider, for care, and for his or her physical and psychological wellbeing.

345. Secondly, although comprising a series of successive operations, the activities involved in homecare are closely associated with each other. The prescription goes from the clinician directly to the homecare services provider, who is expected to carry out all the operations required. In the normal case both the hospital and the patient will need to be satisfied that the closely related aspects of pharmacy, customer care, logistics and nursing are being carried out in an efficient and coordinated way. It follows, in our judgment, that the effective supply of homecare services to Gaucher patients will normally involve the supply of an integrated package. In the normal case the hospital and/or patient will expect all of these services to be supplied by, or under the aegis of, the homecare services provider.

346. Although it is true that certain parts of the package may sometimes be 'outsourced' (e.g. by the homecare provider using a community pharmacy for dispensing, or occasionally sub-contracting delivery, or using NHS or agency nursing services), we think it unlikely that a homecare provider would be able to offer an effective service to Gaucher patients unless he were able to ensure that all the constituent elements of the package were provided as a cohesive whole. That has been the mode of operation of all the providers which have been concerned with Gaucher patients, namely Caremark, Healthcare at Home and Genzyme Homecare. We have no evidence that it would be commercially feasible to operate in a significantly different way. The coordinated nature of the service is specifically stressed in the literature of Healthcare at Home, Genzyme Homecare and Central Homecare.

347. Thirdly, we entirely reject Genzyme's argument that home delivery is not to be regarded as part of homecare services for the purposes of the present case. In our view, the cold chain home delivery of Cerezyme from the homecare service provider's pharmacy to the patient is the central feature of the homecare service provider's function. That function takes place in conjunction with the other functions of pharmacy, warehousing and stock monitoring in controlled conditions, and also involves the collection and disposal of clinical waste, 24 hour help-line and so on. All those functions have to be closely coordinated and executed in timely fashion to meet the needs of individual patients. Drivers have to be appropriately trained, able to respond to patients' concerns, and to report back matters upon which action is required.

348. As the OFT points out at paragraphs 164 to 166 of the decision, home delivery has always been a central feature of the services provided by Caremark, Healthcare at Home and Genzyme Homecare itself, and was stressed to be part of the service provided in Genzyme's correspondence with the DoH in 1999 (see paragraphs 93 et seq above). The evidence we have already referred to confirms that home delivery is a core part of the service offered by the homecare services provider. As Mr Farrell said in evidence "part of the homecare service is delivery of the drug, and if the patients are all over the country we need to find a mechanism for doing that" (Day 2, p.58).

349. Moreover, in the light of the evidence set out above, we do not accept that there is an analogy in the present case with the operations of pizza delivery vans, milkmen or similar "low tech" operations, as Professor Yarrow suggests.

350. As far as nursing services are concerned, it is true that not all Gaucher patients require nursing, and that some nursing is provided by NHS nurses, although in the latter case on a smaller scale than Genzyme suggests (see Tables 1 to 3 above). On the other hand, where nursing is required, in the majority of cases nursing is supplied by the homecare services provider rather than the NHS, as occurs in 42 out of the 55 current cases in which nursing is provided (Table 2 above). Moreover, a patient who is not being nursed at any particular moment, may have needed nursing in the past, and may need it again in the future, for example where respite care is needed. As Mr Johnson of Genzyme explained in his witness statement of 20 August 2003:

> "the needs of the patients [are] to be managed on a case by case basis and the degree of individual nursing care could change or vary depending on their disease state or personal circumstances".

Mr Farrell's evidence, cited at paragraph 333 above, is to the same effect.

351. In these circumstances it seems to us that any home delivery/homecare services provider serving Gaucher patients must be in a position to offer nursing services as part of the package in order to service those patients for whom nursing is required. In practice, Caremark, Healthcare at Home and Genzyme Homecare have always offered nursing as part of the package. Although in one sense home delivery and nursing are separate activities, in this case the demand from customers (the hospital) and consumers (the patient) is such that a homecare services provider must be in a position to supply both home delivery and, where required, nursing, as part of a single service.

352. We specifically reject Genzyme's attempt to separate nursing from other elements of the homecare services here in issue. It is clear to us from Mr Farrell's oral evidence that, desirable though it may one day be for nursing services for Gaucher patients to be provided by the district nursing service of the NHS, that day lies considerably in the future, at best. As Mr Farrell told us, all the patients at home coming under the aegis of the Royal Free and requiring nursing are nursed by an independent homecare services

provider (in fact Healthcare at Home). In Mr Farrell's view, the provision of such a nursing service is as much a part of the integrated operation of homecare services provision as any other element of the service. Although it is conceptually possible to visualise nursing being provided by a supplier other than the supplier of the drug (as occurs where NHS nurses are used) it seems to us that, in practice, that is not likely to be a feasible option in many cases. Genzyme's correspondence with the DoH in 1999, which refers to "extensive nursing support" (7 September 1999) and "complete nursing assistance" as being part of the service offered by Healthcare at Home, is to the same effect (see paragraphs 94 to 96 above).

353. In these circumstances we conclude that the homecare services relevant for the purposes of this care are those which are defined, in our view correctly, as Homecare Services at paragraph 162(ii) and 172 of the decision, including both home delivery and nursing. These services normally comprise a series of closely coordinated operations supplied in an integrated way, by or under the aegis of a single home delivery/homecare services provider.

354. We regard Genzyme's attempt to play down what is necessary to be an effective homecare services provider, and to disaggregate the service it supplies into its component parts, as not in accordance with the facts. The kind of delivery service offered by a company such as Polar Speed does not seem to us comparable to the homecare services here under consideration. Nor are Genzyme's arguments consistent with those Genzyme presented to the DoH in 1999, its own literature and a number of Genzyme's own statements indicated above.

(2) ***Is there a demand for the supply of home delivery/homecare services to Gaucher patients at home which is separate from, albeit ancillary to, the supply of the drug?***

355. We are satisfied that there is a separate and identifiable economic demand to meet the needs of patients suffering from Gaucher disease for the home delivery of Cerezyme together with associated homecare services - i.e. for Homecare Services as defined in the decision. The demand arises from those Gaucher patients who are not hospitalised and for whom treatment at home is a viable option.

356. That demand has historically been met by dedicated home delivery/homecare services providers. The first such provider was Caremark, followed by Healthcare at Home. The demand is still met predominantly by Healthcare at Home (Tables 1 to 3 above). In so far as the demand for home delivery/homecare services to Gaucher patients is now partly met by Genzyme, it is relevant that Genzyme has not sought to operate by simply supplying Cerezyme ex-factory, but has established Genzyme Homecare as a separate division, precisely in order to offer bespoke, coordinated home delivery and homecare services to Gaucher patients in need of such services. Other suppliers such as Central Homecare are apparently capable of supplying the same kind of service.

357. In our view, therefore, there is a separate demand for the supply of Homecare Services as defined in the decision, to Gaucher patients at home. In our view that demand is capable of being met, and is normally met, by specialised home delivery/homecare service providers (whether in-house or third party). In our view those services are distinct from, albeit closely related to, the supply of Cerezyme alone.

(3) ***Is Genzyme in a position to foreclose the supply of home delivery/homecare services to Gaucher patients?***

358. For the reasons already given, in the vast majority of cases a patient suffering from Gaucher disease has only one choice of treatment available to him, namely Cerezyme. For Gaucher patients being treated at home, there is no possibility of any alternative treatment not involving the use of Cerezyme. Thus, from the point of view of the demand side, at present there is no realistic possibility of homecare services being supplied to Gaucher patients otherwise than together with the supply of Cerezyme. (See also similar observations by the MMC at paragraphs 2.70 to 2.71, and 4.125 of the *Fresenius/Caremark* report, cited at paragraphs 187 and 176 of the decision respectively).

359. From the point of view of the supply side, there are in theory a number of potential suppliers of homecare services to Gaucher patients, as the decision accepts at paragraph 177. However, in our view it is self evident that a provider of home delivery/homecare services is able to provide such services to Gaucher patients only if he is in a position to obtain supplies of Cerezyme. Furthermore, a provider of such home delivery/homecare services will in practice be able to provide such services to Gaucher patients only if he

can obtain supplies of Cerezyme at a price that enables the provision of homecare services to be economically viable.

360. Genzyme is the only source of supplies of Cerezyme. It follows that Genzyme, if it wishes, is potentially in a position to foreclose the provision of home delivery/homecare services to Gaucher patients by anyone other than Genzyme itself, either by refusing to supply Cerezyme altogether, or by doing so on terms and conditions which prevent any third party home delivery/homecare services provider from providing such services on an economically viable basis.

361. As the decision points out at paragraphs 178 to 180, a similar conclusion was reached by the MMC in the *Fresenius/Caremark* report. In that report the MMC considered various situations in which the supplier of the drug or feed in question was in a position to foreclose the supply of homecare services by third parties, for example by supplying homecare services himself "in-house", or by establishing preferential relationships with particular suppliers. Furthermore, where the homecare service was included in the list price of the drug, the MMC recognised that homecare services could viably be supplied by third parties only if the supplier of the drug either granted the homecare provider a discount off the list price, or made a payment to the homecare provider to cover the cost of its services. In those circumstances, according to the MMC, the drug or feed provider was able to limit supply side substitution (i.e. the entry of other homecare providers) or foreclose such entry altogether (see paragraphs 2.75, 2.78 and 4.128 of that report, cited in paragraphs 178 to 180 and 186 of the decision. Note also paragraphs 2.46 and 4.97 of the MMC report).

362. Indeed, in the case of Gaucher disease, the MMC attributed to Caremark, Genzyme's then distributor, a share of 95 - 100 per cent of "homecare sales" for the treatment of Gaucher disease: see tables 4.4 to 4.7 of the MMC report.

363. Although in the *Fresenius/Caremark* report the MMC's analysis was apparently based largely on the then distinction between 'prescribed' and 'contracted' services considered in that case (see e.g. paragraphs 1.4 and 1.5 of that report), in the present case Genzyme's potential ability to foreclose third party providers of homecare services does not seem to us to depend on whether the NHS chooses to purchase Cerezyme and the associated

homecare services on prescription, or under some other kind of contractual arrangement or tendering procedure. Whatever purchasing system is used, Genzyme in our view would still be in a position, if it so chose, to prevent third parties from offering to provide the NHS with home delivery/homecare services for Gaucher patients, by the simple expedient of not supplying Cerezyme to third parties, or supplying such third parties with Cerezyme at a price which rendered it uneconomic for those third parties to provide homecare services. Although nursing could theoretically be provided by a supplier other than the home delivery supplier, in practice the hospital will look to the home delivery supplier to provide the nursing where it is needed, except where an NHS nurse is used (paragraphs to 350 to 352) above.

364. In this respect, as we see it, Genzyme's position is little different from that of any other monopolist who controls an "upstream" product which is an essential input to the supply of a product or service needed for a "downstream" activity. Whether Genzyme has in fact sought to supply the "upstream" product (Cerezyme) at a price which precludes or forecloses competition in the "downstream" supply of homecare services, and whether any such foreclosure is an abuse, are, however, separate issues, which we discuss in the next section of this judgment.

(4) ***Is there a separate market for homecare services for Gaucher patients?***

365. For the above reasons we find that there is a separate demand to meet the needs of Gaucher patients, for whom no other treatment is available, for the supply of Homecare Services as defined in the decision, including the home delivery of Cerezyme and the supply of nursing where necessary. The supply of such services is a separate economic activity, distinct from the supply of the drug alone. Genzyme is in a position, if it so chooses, to foreclose that supply by third parties by the pricing practices it adopts in relation to Cerezyme. In our view such supply forms a discrete segment of the wider market for homecare services which Genzyme is in a position to monopolise for as long as there is no alternative treatment for Gaucher disease.

366. In so far as we need to express a view as to whether that discrete segment is properly described as a separate downstream "market" or "sub-market", our view is that, on the specific facts of this case, it is correct to describe the segment of the wider homecare

services market which consists of Homecare Services to Gaucher patients as a "market" or "sub-market" in its own right. Although we take into account Professor Yarrow's comment that it is, in the abstract, potentially confusing to define "the market" by reference to the behaviour said to constitute the abuse, that is not in our view a compelling criticism of the OFT's approach at paragraphs 173 to 183 of the decision.

367. As the OFT points out in the decision, from the point of view of Gaucher patients at home and the clinicians responsible for their welfare, there is no demand-side substitution because there is no other way of treating Gaucher disease other than by supplying Cerezyme and the associated Homecare Services. The MMC took the same view in the *Fresenius/Caremark* report (see paragraph 358 above). On the supply side, although there are in theory various potential suppliers of homecare services to Gaucher patients, in our view the relevant downstream product is the integrated package of Homecare Services which we have already described in paragraphs 344 to 354 above. In practice no homecare services supplier will be able to supply that integrated package of Homecare Services to Gaucher patients unless they are able to obtain Cerezyme from Genzyme on economically viable terms (paragraphs 359 to 363 above). In those specific circumstances, namely the lack of any demand-side substitution, and the constraints affecting supply-side substitution resulting from Genzyme's monopoly over Cerezyme, we think it is correct to speak of a downstream "market" for the supply of Homecare Services to Gaucher patients, that market being a distinct sub-market of a wider homecare services market. Again, that approach seems to us consistent with that of the MMC in *Fresenius/Caremark* (paragraphs 361 to 363 above).

VII ABUSE: THE DECISION AND THE ARGUMENTS OF THE PARTIES

A. THE FINDINGS IN THE DECISION

368. At paragraphs 293 and 396 of the decision the OFT finds:

> "… that Genzyme has abused its dominant position in the upstream market by, without objective justification
>
> (i) making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, thereby reserving to itself (or to an

undertaking acting under contract for Genzyme) the ancillary but separate activity of providing Homecare Services; and

(ii) adopting a pricing policy following the launch of Genzyme Homecare which results in a margin squeeze;

with the effect of

(i) foreclosing the Homecare Services segment of the downstream market; and

(ii) raising barriers to entry to the upstream market"

369. Homecare Services are defined in paragraphs 162(ii) and 396.3 of the decision: see paragraphs 344 to 354 above.

The Bundling Abuse

370. The first of the two alleged abuses is that Genzyme has "made the NHS pay" a price for Cerezyme which includes "Homecare Services", thereby reserving to itself (or to an undertaking acting under contract for Genzyme) the ancillary or separate activity of providing homecare services.

371. The OFT considers that the NHS list price for Cerezyme includes not only the cost of the drug, but also the cost of Homecare Services as so defined. According to the OFT, Genzyme's abuse consists, essentially, in requiring the NHS to purchase Homecare Services as a condition of purchasing Cerezyme, which is equivalent to a tie-in. According to the OFT, such practices have been consistently regarded by the Court of Justice and the European Commission as an abuse: see paragraphs 295 to 300 of the decision.

372. According to the OFT, the practice of selling Cerezyme at the NHS list price, including Homecare Services, forecloses the possibility of other home delivery/homecare service providers supplying Gaucher patients.

373. The essence of the OFT's reasoning is set out in paragraphs 302 to 307 of the decision as follows:-

"302. As a result of this pricing policy, when the NHS purchases Cerezyme (for use in the community or in hospitals), it automatically pays for the Homecare Services. Therefore, if the NHS wished to purchase Homecare Services from anyone other than Genzyme (or an undertaking acting under contract for Genzyme) it would have to pay for the Homecare Services twice: first to Genzyme, as part of the inclusive price of the drug and Homecare Services, and then to the independent delivery/homecare services provider, as reimbursement for the Homecare Services. It is, therefore, of no interest to the NHS to purchase the Homecare Services from anyone other than Genzyme.

303. The fact that currently the NHS can purchase the Homecare Services not only from Genzyme, but also from HH, does not alter the conclusion set out in the previous paragraph. This is because, while currently the NHS has a choice between receiving Homecare Services from Genzyme Homecare or from HH, this choice is only available as a result of HH's temporary decision not to charge the NHS for the Homecare Services and to operate at a loss. It is clearly not economic to operate a loss-making business indefinitely. According to HH, the only reason it continues to offer Homecare Services is to retain its contacts with the NHS and its Gaucher patients, awaiting the outcome of the Director's investigation. In the absence of the Director's investigation into Genzyme's behaviour, HH would not currently be providing Homecare Services and, therefore, the only choice for the NHS would be Genzyme Homecare (unless the NHS were willing to pay for the Homecare Services twice).

304. As stated above, an undertaking with a dominant position in a market may abuse such a position if it leverages its market power from a market in which it is dominant into a separate but related market, with the effect of foreclosing the related market to other competitors. This can be achieved where an undertaking which is dominant in one market (here, the supply of drugs for the treatment of Gaucher disease) makes customers pay for a product or service in a separate but related market (here, the provision of Homecare Services in the Homecare Services segment of the downstream market) in which the undertaking does not have market power or where it is more vulnerable to competition.

305. Genzyme's practice of including Homecare Services in the price of the drug, effectively deprives the NHS of the option to purchase Cerezyme independently from the Homecare Services in normal competitive conditions. This enables Genzyme to reserve to itself (or to an undertaking acting under contract for Genzyme) the separate but ancillary activity of providing Homecare Services (i.e. the Homecare Services segment of the downstream market). This ancillary activity could, under normal competitive circumstances, be undertaken by an

independent third party acting alone (e.g. a delivery/homecare services provider which provides specialised home delivery and homecare services for a range of complex conditions).

306. Genzyme's policy, which is a form of tying, effectively makes Genzyme a compulsory trading partner (i.e. Homecare Services provider) for the NHS in the Homecare Services segment of the downstream market. In addition, it prevents competition in that segment where entry would otherwise be relatively easy and where Genzyme is trying to establish its position (Genzyme only entered this segment itself in May 2001).

307. Genzyme's tying policy ultimately leaves the NHS with no real choice of Homecare Services provider and, as such, abusively exploits the NHS, and through it, the patients. The fact that the Homecare Services are provided by Genzyme itself (through Genzyme Homecare) or through a third party acting under contract for Genzyme (e.g. Caremark or HH until 5 May 2001), is irrelevant. In either case, the customer (the NHS) and the consumer (the patients) are deprived of choice over the source of supply from other parties because the NHS is effectively tied (through Genzyme's pricing policy) to receive the Homecare Services from Genzyme or an undertaking acting under contract for Genzyme."

374. According to the OFT, there is no doubt that the NHS would wish to have a choice of home delivery/homecare services provider: paragraph 308 of the decision.

375. At paragraphs 312 *et seq* of the decision, the OFT replies to Genzyme's arguments that there was no "bundling" because (i) the NHS list price includes both the supply of the drug and its delivery to patients, and cannot therefore be "a bundled price"; (ii) nursing services are provided by Genzyme "free of charge"; and (iii) it is not an abuse for the supplier of a product to supply that product directly instead of using wholesalers, distributors or other third parties.

376. The OFT rejects the first of these arguments at paragraph 312 of the decision on the grounds that the NHS list price is not intended to cover the cost of delivering the drug from the pharmacy to the patient's home, for the reasons given in paragraphs 68 to 83 of the decision.

377. The OFT rejects the second of these arguments at paragraphs 313 to 329 of the decision, essentially on the grounds that if "homecare" is restricted to "nursing" then in many cases the NHS is paying for a service that is not, in fact, provided; that homecare services should properly be considered as including home delivery services, and not just "nursing

services"; that the NHS is not free to out-source its services for the reasons given in paragraphs 302 et seq of the decision; and that Genzyme's argument that "homecare" is provided at no cost to the NHS is entirely inconsistent with Genzyme's submissions to the DoH in 1999.

378. As to the third argument, the OFT considers that the abuse is not Genzyme's decision to supply Cerezyme directly, but the practice of reserving the supply of homecare services exclusively to itself: see paragraph 330 of the decision.

379. The OFT further argues that the bundling of the price of Cerezyme, with the consequence that only Genzyme is in a position to offer Homecare Services, has the effect of raising barriers in the "upstream market" of drugs for the treatment of Gaucher disease: see paragraphs 331 to 346 of the decision. According to the OFT, a supplier of a new drug for the treatment of Gaucher disease needs to have access to the patients. However, such access is made more difficult if the supply of Cerezyme is tied to Homecare Services because patients wishing to change to an alternative treatment would be required not only to switch to the new drug, but also to a new home delivery/homecare services provider, which would be very difficult. This, argues the OFT, raises the already high barriers to entry even further.

380. Finally, the OFT rejects Genzyme's argument that it is for the OFT to prove that Genzyme's policy was without any objective justification. In any event, the OFT considers that there is no objective justification. Genzyme has submitted no convincing evidence of any such justification, in particular there is no evidence that Genzyme's method of distributing Cerezyme is the "most cost effective for the NHS". In any event, says the OFT, this is for the NHS, not Genzyme, to decide.

The Margin Squeeze Abuse

381. The OFT states at paragraph 364 of the decision:

> "364. A pricing policy operated by a vertically integrated dominant undertaking may infringe section 18 of the Act. This might occur where a vertically integrated undertaking which is dominant in the upstream market operates a pricing policy which does not allow reasonably efficient competitors in the downstream market a margin sufficient to enable them

> to survive in the long term. This pricing behaviour is known as 'margin squeeze'."

In support of that finding, the OFT relies on the various communications and decisions of the European Commission, set out in paragraphs 365 to 369 of the decision.

382. According to the OFT, an abuse arises in this case because there is no difference between the NHS list price at which Genzyme sells Cerezyme to the NHS, and the NHS list price at which Genzyme is prepared to sell Cerezyme to third party home delivery/homecare service providers. Genzyme is thus subjecting its competitors in the supply of homecare services to Gaucher patients to a margin squeeze by preventing such competitors from earning a margin sufficient to enable them to survive in the long term.

383. According to the OFT, Genzyme Healthcare acquires Cerezyme at the transfer price of £2.50 per unit[7] and sells it to the NHS at the list price of £2.975 per unit, including the cost of homecare services. However, Genzyme sells Cerezyme to third parties such as Healthcare at Home at the same list price of £2.975 per unit, with the consequence that such third parties have no margin with which to compete with Genzyme Homecare. After referring to criteria set out in the European Commission's Telecommunications Access Notice, OJ 1998 C265, the OFT concludes at paragraph 377 of the decision:

> "377. The Director therefore considers that Genzyme's pricing policy prevents independent delivery/homecare service providers, no matter how efficient, from operating in the homecare services segment of the downstream market. HH will eventually be forced to leave this segment of the market, as it cannot continue to sustain losses indefinitely. The effects of this will be particularly serious, as HH's exit will leave Genzyme Homecare as the monopoly supplier of homecare services, in a segment of the downstream market which is completely closed to competition."

384. The OFT considers that Genzyme knew that its policy would have the effect of forcing Healthcare at Home out of the supply of homecare services to Cerezyme patients (paragraph 378 of the decision). The OFT further considers that Genzyme's view that the OFT's essential allegation is one of refusal to supply is mis-conceived (paragraph 381).

[7] This price has apparently reduced since the decision.

385. Finally, the OFT considers that the margin squeeze abuse, like the bundling abuse, raises barriers to entry in the upstream market, for the reasons given in paragraphs 331 to 350 of the decision (paragraph 382). The OFT considers that there is no objective justification for the margin squeeze abuse (paragraphs 383 to 385 of the decision).

B. GENZYME'S ARGUMENTS ON ABUSE

General

386. Genzyme submits that the OFT has mischaracterised practices as abusive which in fact represent normal competitive activity in the atypical but highly dynamic LSD and orphan drug market. In particular, the OFT's decision is entirely contrary to the EU's objective of providing incentives for orphan drugs such as Cerezyme to be brought to market.

387. According to Genzyme, the applicable law is that set out in Case 85/76 *Hoffman-La Roche* [1979] ECR 461, cited at paragraph 292 of the decision, which provides that an abuse can only take place where there has been "recourse to methods different from those which condition normal competition". Genzyme's distribution policy is a method of normal competition, as evidenced by the fact that the MMC raised no objection to it in the Fresenius/Caremark report. Moreover, as a matter of law it is not an abuse for the supplier of a product to choose to supply it to the market directly, rather than through wholesalers, distributors or other third parties, as Case C-7/97 *Oscar Bronner* [1998] ECR I-7791 makes clear.

388. According to Genzyme, in essence the OFT's complaint against Genzyme is not bundling but refusal to deal. Indeed, this is what the OFT originally argued at the interim measures stage. As a matter of law, bundling is simply a less stringent form of tying and tying is in turn regarded as the corollary of a refusal to supply. Accordingly, the case law on tying and bundling must be seen in the light of the decision of the Court of Justice in *Bronner*. The principles of that case are summed up by Advocate General Jacobs at paragraphs 56 to 69 of his opinion. In particular, Advocate General Jacobs concludes that it is not sufficient that an undertaking's control over a facility should give it a competitive advantage (paragraph 65): the mere fact that by retaining a product for its own use a

dominant undertaking enjoys an advantage over a competitor cannot justify requiring access to it (paragraph 57).

389. The opinion of Advocate General Jacobs was followed by the Court of Justice at paragraph 39 of its judgment in *Bronner*, where the Court said that only in exceptional circumstances can a refusal to supply constitute an abuse. The same approach has been applied by the High Court in *Getmapping v Ordnance Survey* [2002] UKCLR 410, at [33]-[40]. Furthermore, Case 238/87 *Volvo v Veng* [1988] ECR 6213 supports Genzyme's position.

390. Genzyme also relies on OFT Decision No. CA98/07/2003 *Refusal to supply unprocessed holographic photopolymer film: E.I. du Pont de Nemours & Company and Op. Graphics (Holography) Limited* of 9 September 2003, in which the OFT rejected a complaint of refusal to supply by a dominant undertaking. According to Genzyme, it is implicit in that decision that the OFT accepted that DuPont's distribution policy was not one "which no rational and fair person could justify": and the same must be the case for Genzyme.

391. According to Genzyme, applying *Bronner*, there is no justification in the present case for depriving Genzyme of the right to choose its trading partners, particularly given the very substantial investment in Cerezyme made by Genzyme, and the strong need to give incentives for orphan drug production. The mere fact that Genzyme controls access to Cerezyme is an insufficient basis for intervention by the OFT; it is the NHS, not other homecare service providers, who is the customer in this case. The regulation of drug pricing is a matter for the DoH, not the OFT.

392. According to Genzyme, it was an error of law for the OFT to fail to apply the "*Bronner* refusal to deal principles". Had it done so, it would have found that Genzyme's decision to supply homecare itself is perfectly legitimate and not an abuse. In any event, a number of other pharmaceutical companies follow practices very similar to Genzyme, as indicated by paragraph 2.40 of the *Fresenius/Caremark* report, Mr Derodra's evidence as regards Nutricia, and the information contained in Mr Moreland's witness statement of 24 September 2003. The OFT has wholly failed to examine this issue, or to include any description of the homecare services market in the decision.

393. It cannot be right, according to Genzyme, that Genzyme, alone out of pharmaceutical companies should be obliged to supply "any Tom, Dick or Harry" with Cerezyme, especially when no such obligation would apply to Genzyme's rival TKT with Replagal.

394. In its closing submissions, Genzyme emphasised in particular that the pricing issues with which this case are concerned are a matter of DoH/NHS policy, rather than competition law. The OFT's approach runs counter to the policy of H M Government not to over-regulate the pharmaceutical industry, as explained by Mr Brownlee (Transcript Day 2, p.20) and to encourage companies such as Genzyme to invest in the United Kingdom economy, as Genzyme has with a new manufacturing plant for another product near Haverhill.

The Bundling Abuse

395. Genzyme rejects the OFT's case on bundling, set out at paragraphs 294 to 363 of the decision, on the basis that it is simply not possible for Genzyme to bundle the price of homecare with the price of Cerezyme. The Drug Tariff price for Cerezyme is for the supply of the drug and its delivery to patients. It does not include any price for homecare, which is supplied free of charge by Genzyme.

396. Genzyme argues, on the basis of the Translucency Report prepared on its behalf, that "the NHS Drug Tariff price does not include any separate element for the supply of home healthcare services". That, says Genzyme, is confirmed by Professor Yarrow in witness statements of 19 May and 21 August 2003. Professor Yarrow considers that the NHS Drug Tariff price is by definition the price that the NHS pays the relevant pharmacist in reimbursement for his purchase of the drug, and not in reimbursement for any other services. Hence, says Professor Yarrow, "the notion that the Drug Tariff price includes homecare services does not make any sense". Similarly, the evidence of Richard Williams, an expert on the PPRS and related matters, in statements of 19 May and 20 August 2003, is to the effect that there is no justification for the OFT's claim that there is a constituent element within the Drug Tariff price for the provision of homecare services.

397. Contrary to the findings of the OFT at paragraphs 68 to 83 of the decision, Genzyme considers that the NHS Drug Tariff price and the PPRS are not "inextricably linked" in the way suggested by the OFT. As explained by Professor Yarrow and Mr Williams, they are distinct regimes, the PPRS to control the profitability of manufacturers, and the NHS Drug Tariff price to control the reimbursement of pharmacists. The PPRS controls prices only indirectly, through controlling profits and does not break the NHS list price down into individual components. For a zero discount drug such as Cerezyme, the pharmacist is reimbursed at his cost of purchase at the NHS Drug Tariff price, and not for any other services. The Translucency report at 7.3.7 confirms that there is no mechanism within the Drug Tariff price for securing a separate price for homecare services.

398. According to Genzyme, the OFT's findings, at paragraphs 68 to 83 of the decision, to the effect that the NHS list price is not intended to cover the cost of delivery of the drug to the patient's home, are misconceived. This conclusion is based on statements by Mr Brownlee about the PPRS taken out of context. In the quotations relied on by the OFT at paragraphs 70 to 74 of the decision, Mr Brownlee was referring to the operation of the PPRS in the typical case of distribution by a wholesaler to a community pharmacy. In the present case, although Cerezyme could be delivered to a local pharmacy, delivery to the patient's home is likely to be more efficient. Hence there is no reason why delivery of the drug to the patient's home should not be taken into account under the PPRS. Mr Williams considers that the cost of such delivery could be included in the costs allowable under the PPRS. The evidence of Mr Brownlee before the Tribunal and the disclosure of e-mails dated 11 December 2002 passing between the DoH and the OFT supports that conclusion. Moreover, since the NHS list price normally includes delivery, the cost of delivery to the patient's home should be regarded as included in the NHS list price. Such delivery is not an 'extra', but a more efficient substitute for delivery to a community pharmacy. In any event, Genzyme's total 'homecare' costs are likely to be below the normal costs of the traditional wholesaling function.

399. As regards the 1999 negotiations with the DoH, Genzyme accepts that it sought to reduce the effect of the expected across the board price cut of 4.5% especially since, unlike other pharmaceutical companies, it did not have the option of minimising the effect of that price cut by reducing discounts to wholesalers. However, the outcome of the 1999 negotiations does not imply that there is a 'stand alone' price for the drug and a separate, stand alone

price for delivery and nursing. Genzyme submits that it was "only engaging in a cost allocation exercise for the purpose of negotiating a lower reduction of its NHS drug tariff price". Professor Yarrow considers that these negotiations were a "horse trade" and that the price £2.43 per unit which resulted from the negotiations can only be regarded as an ex-manufacturer price, rather than an NHS list price. Both Professor Yarrow and Mr Williams consider that it was erroneous of the DoH to permit Genzyme to base its 1999 price cut on what was, in effect, an ex-manufacturer price rather than on its NHS list price. Indeed, Genzyme accepts, at paragraph 143 of its skeleton argument of 12 September 2003, that the DoH should not have accepted the arguments put forward by Genzyme in 1999.

400. As regards nursing services, Genzyme submits that nursing homecare is not included in the price of Cerezyme but is provided at no cost to the NHS. That is supported by the facts that: (i) there are a number of patients who receive treatment in hospital where Genzyme Homecare delivers Cerezyme to the hospital but supply no nursing care; (ii) most patients taking Cerezyme at home administer it themselves, so again there is no nursing care; (iii) NHS community nurses look after many of those patients that do require nursing; (iv) the NHS is entirely free to outsource that nursing by contract to a third party other than Genzyme; and (v) those few patients who receive homecare nursing, other than from an NHS nurse, do so at no cost to the NHS.

401. Moreover, according to Genzyme the many authorities relied upon by the OFT in the decision are not in point and do not concern facts similar to the present case. For instance, the OFT refers to three cases, namely Commission Decision IV/30.178 *Napier Brown/British Sugar* OJ 1998 L 284/41, Case 311/84 *CBEM - Telemarketing v CLT and IPB* [1985] ECR 3261 ("Télémarketing") and Commission Decision IV/31043 *Tetra Pak II* OJ 1992 L 72/1, where the dominant undertaking was in a position, through its control of access to a raw material or its control of equipment, to foreclose any competition downstream. By contrast, Cerezyme is in no sense a raw material (unlike industrial sugar in *Napier Brown/British Sugar*) and homecare is in no sense a product derived from Cerezyme. Homecare is a separate activity and is not dependent on Cerezyme, as is demonstrated by the fact that HH supplied homecare before it was awarded the Cerezyme contract and continues to do so. There are numerous suppliers of delivery or homecare services who are not foreclosed from supplying the thriving homecare services market.

402. In support of Genzyme's arguments Professor Yarrow makes a number of points. Some of these appear to us more relevant to the direction, dealt with later in this judgment, than to the issue of abuse. Professor Yarrow does, however, criticise the OFT for failing to consider the different operations in the supply chain (manufacturer to wholesaler, wholesaler to pharmacy and pharmacy to retail customer) and the different prices applicable at each stage. The NHS list price is applicable only at the last of these stages, and is neither an ex-manufacturer nor an ex-wholesaler price. According to Professor Yarrow, the NHS list price covers the cost of supplying the drug to a location convenient to the patient, which is what Genzyme does in a cost-effective way. No 'extra' supply is involved. Although it might be logical to require Genzyme to supply at a wholesale price, paragraph 330 of the decision excludes that possibility, according to Professor Yarrow.

403. Since, according to Professor Yarrow, delivery must be taken to be included in the NHS list price, that leaves only nursing as possibly "bundled". But nursing is not in any way reserved to Genzyme, and could be supplied by anyone, including the NHS itself, which does so. It is common commercial practice to give customers the option of taking extra services included in the price (e.g. help with packing at the supermarket checkout) where the cost is small and it is inconvenient to charge separately. According to Professor Yarrow, nursing probably accounts for less than 1.0% of the NHS list price. Moreover, it cannot be argued that Genzyme is "making the NHS pay" unless it is shown that the price of the drug would fall if the service was not supplied; but that is not demonstrated.

404. According to Professor Yarrow, Genzyme has no interest in excluding third party suppliers, since it wants homecare to be supplied as efficiently and cheaply as possible. Furthermore, there is no convincing evidence that Genzyme's practices could affect entry into the upstream market, where a degree of reluctance on the part of patients or clincians to switch suppliers is likely to occur in any event.

The Margin Squeeze Abuse

405. Genzyme disputes the OFT's findings on margin squeeze, set out at paragraphs 364 to 385 of the Decision, as a matter of law and of fact. According to Genzyme, this

allegation is, like that of bundling, an attempt by the OFT to "recycle" the original, but abandoned, allegation of refusal to supply.

406. According to Genzyme, the OFT has erred in law by basing itself on guidelines and case law that are inappropriate to the facts of this case. For instance, Case T-5/97 *Industries des Poudres Spheriques* [2000] ECR II-3755, concerned an allegation of an abusively high price for a raw material which the complainant wished to process into a derived product. Commission Decision 76/185/ECSC *National Carbonising Company Limited* OJ 1976 L 35/6, and *Napier Brown/British Sugar*, cited above, are both cases where the undertaking in question was dominant both upstream and downstream. In this case, the OFT's finding is that Genzyme is not dominant in the downstream market.

407. Moreover, the OFT's reliance on telecommunications guidelines is misplaced. These concern the principles on which access to a single fixed network must be granted, which is a completely different situation. Indeed, the OFT publication *The application of the Competition Act 1998 in the Telecommunications Sector*, OFT 417, has been recognised to be sector specific by the Tribunal (see *Freeserve.com v Director General of Telecommunications* [2003] CAT 5, [193]).

408. As regards the OFT's reliance upon footnote 306 of its decision in Case No. CA/98/20/2002 *BSkyB*, in support of its argument "that there is no need for a company to be dominant in both the raw material and derived product markets to operate a margin squeeze", the footnote in *BSkyB* does not cite any authority. According to Genzyme, that would mean that any dominant undertaking would be under an obligation to supply its product to all would-be retailers of that product. That is wrong as a matter of law: see *Bronner*, cited above.

409. Even if there were a "downstream" market, as alleged by the OFT, Genzyme would be under no obligation to supply Cerezyme at a wholesale price to Healthcare at Home or anyone else, as the OFT accepted at the interim measures stage.

410. Genzyme also submits that the saving made by the hospital on VAT is an accepted method of funding homecare, as Mr Farrell confirms at paragraph 13 of his witness statement. That explains Clinovia's apparent willingness to buy Cerezyme at the NHS

list price referred to at paragraphs 32 to 37 of Mr Moreland's witness statement of 22 August 2003. Moreover, the OFT has also failed to take into account income from dispensing fees and the Expensive Prescription Fee. Professor Yarrow emphasises that the OFT has made no calculation as to what an appropriate margin would be. In its closing submissions, Genzyme emphasised that the calculation of an appropriate margin would be a complicated exercise which has not been undertaken by the OFT.

The alleged foreclosure of Homecare Services

411. Genzyme rejects the OFT's allegations of foreclosure of the supply of homecare services which are set out at paragraphs 301 to 330 of the decision in relation to bundling, and paragraphs 370 to 381 in relation to margin squeeze.

412. Genzyme's case is that there is no foreclosure through bundling, however the downstream market is defined. For the reasons already given, there is no bundling, hence there can be no foreclosure effect. Moreover, Healthcare at Home's continued expansion in providing nursing and delivery services (2,000 homecare patients in 2001, now 5,000 homecare patients) shows that there is no foreclosure. As to delivery services not involving nursing, there is simply no evidence at all in the decision in relation to any alleged foreclosure effect. In fact, many undertakings, for instance Healthcare at Home, Polar Speed and Healthcare Logistics, provide cold chain delivery services for pharmaceuticals.

413. Even on the OFT's downstream market definition, there could be no foreclosure in relation to nursing services for (i) the patients receiving infusions of Cerezyme in hospital; (ii) the patients who self-infuse, and do not have homecare nursing; (iii) the patients receiving homecare from NHS community nurses; or (iv) those patients who switch to an oral treatment such as Zavesca, where there is no homecare. Any such foreclosure effect could therefore only be insignificant, affecting no more than 15% of all Gaucher patients. Such a minimal level of "foreclosure" is well below what is needed to establish an abuse contrary to the Chapter II prohibition.

414. As regards the alleged foreclosure through margin squeeze, according to Genzyme Cerezyme is not a necessary ingredient to enable Healthcare at Home to enter the

homecare market, since Healthcare at Home had done so prior to its contract with Genzyme, and continues to be active in that market. Moreover, the OFT's reliance on principles developed in relation to ensuring competitive service provision over a telecommunication network (see paragraphs 375 to 376 of the decision) is inappropriate in relation to the orphan drug field where the competitive structure is entirely different. In conclusion, submits Genzyme, any foreclosure there may be in this case is insignificant in terms of patients affected, duration or economic effect.

The alleged foreclosure through raising barriers to entry in the upstream market

415. As regards the OFT's allegations regarding the raising of barriers in the upstream market (paragraphs 331 to 350, and 382 of the decision) Genzyme submits that this allegation is based upon the OFT's theory as summarised at paragraph 350 of the decision that:

> "patients could be switched to a new treatment more easily if the supplier of the drug did not determine, directly or indirectly, the identity of the delivery/homecare services provider".

416. However, according to Genzyme, this allegation is not backed up by sufficient evidence. First, OGS and TKT are both on the point of entry to this market. Secondly, no foreclosure could take place in relation to OGS's Zavesca since it is an oral treatment not requiring homecare.

417. In any event, Genzyme submits that the statements of Professor Cox and Drs Waldek and Lee, relied on at paragraphs 334 to 338 of the decision, are selective and taken out of context.

418. In relation to Professor Cox's evidence that patients "may be swayed by non-clinical considerations such as liking a particular homecare service provider" (see paragraph 336 of the decision) Genzyme submits that this alleged effect is wholly unquantified. Indeed, the only figures referred to by Professor Cox concern one occasion "when a local physician changed the homecare service provider for three of his patients" (see paragraph 334 of the decision). According to Genzyme, even Professor Cox would contemplate changing the homecare services provider once every two or three years.

419. In relation to Dr Waldek's evidence, the OFT omitted to quote evidence from his statement of 18 October 2002 which clearly contradict the OFT's case:

> "I can see no merit in the contention that restriction on the homecare service provider may effect the entry of new drugs in the upstream market. I know almost all the physicians specialising in the field of metabolic disorders. This body of physicians is readily approachable, and any new contender wanting to enter this field of therapeutics would have no difficulty in discussing with those physicians trials for newly introduced therapies, and, if those therapies proved effective, use of them" (emphasis added by Genzyme).

420. In relation to Dr Lee's evidence, Genzyme submits that the OFT omitted reference to the fact that Dr Lee stated in a telephone conversation in August 2002 that "as long as there is a means of getting the drug delivered to the patient, [Dr Lee] did not see that the in-house delivery of Cerezyme would have any effect on the physician's decision [as to which drug to prescribe]".

421. Moreover, according to Genzyme the OFT has failed to refer to the views of Dr Wraith, who said on 9 July 2001 that entry by another competitor would not be difficult. Dr Wraith also stated in an e-mail of 8 August 2002 with the OFT that:

> "When it comes to prescribing a particular product that would be my choice, and that would not be influenced by the presence or absence of homecare - it would be based on what was the right medication for that individual person".

In its reply on this issue, Genzyme relies on further witness statements by Dr Vellodi of 21 August 2003 and Dr Waldek of 29 July 2003.

422. In these circumstances Genzyme submits that no foreclosure in the upstream market has been established to the requisite standard of proof. Hence Genzyme had no need to cross-examine on this point. Moreover, the question regarding the identity of the homecare service provider which, according to paragraph 359 of the decision, was never put to Drs Waldek, Lee and Wraith, was not put by the OFT either, when interviewing Professor Cox, Dr Mehta or Dr Wraith.

423. In any event, according to Genzyme the OFT's argument that it will be more difficult for a competitor to get a new drug to market, because switching the treatment will mean switching the homecare service provider to whom the patient may have formed an "attachment", is self-contradictory. This argument would simply mean that, if homecare services were not supplied by Genzyme, patients and clinicians would become captive customers of a different homecare service provider.

424. Finally, Genzyme submits that it is impossible to see how there would be any foreclosure as regards the delivery service element. There is no evidence that the identity of a delivery driver bringing boxes of Cerezyme and ancillaries and collecting packaging and waste every 4-8 weeks could possibly influence of patient's choice of drug, still less that of a clinician.

Objective Justification

425. Genzyme submits, in any event, that it is objectively justified in not using wholesalers and distributing Cerezyme via Genzyme Homecare, and "in providing homecare at no cost". The OFT has erred in law by failing to apply the correct legal test for establishing lack of objective justification as summarised by Laddie J in two recent judgments: *Getmapping plc v Ordnance Survey* [2002] UKCLR 410 at [52] and *Suretrack Rail Services Ltd v Infraco JNP Ltd* [2003] UKCLR 3 at [26].

426. According to Genzyme, the burden of proof lies with the OFT to show that an alleged abuse is incapable of objective justification. Genzyme rejects the OFT's attempt, at paragraph 352 of the decision, to distinguish those judgments on the basis that they related to an interim relief application in the course of private litigation. The concept of abuse is an objective one (see *Hoffmann-La Roche*, cited above, at [91]) which does not vary according to whether the issue is before the courts or the competition authorities.

427. In supplementary submissions dated 23 June 2003, Genzyme submitted that the burden of proof of lack of any objective justification is on the OFT throughout, including the administrative procedure: see the Tribunal's judgment in *Napp Pharmaceuticals* [2002] CompAR 13 at [100], *Suretrack* at [26], Case 311/84 *Telemarketing* [1985] ECR 3261 at [26], and Case T-30/89, *Hilti v. Commission* [1991] ECR II-1439, on further appeal in Case C-53/92P [1994] ECR I-667. In rebutting the OFT's contention, at paragraph 353 of the

decision, that section 60 of the 1998 Act provides a justification for departing from the approach of the High Court, Genzyme submits that other tribunals such as VAT tribunals do not regard themselves as free to ignore the High Court. According to Genzyme, the Tribunal is bound by the decisions in *Suretrack* and *Getmapping*.

428. As to the substance of the OFT's case on lack of objective justification, Genzyme rejects the OFT's reliance on correspondence from 1996 and 1997 relating to Caremark (see paragraphs 356 to 360 of the decision) since that correspondence does not address Genzyme's current distribution policy. That correspondence related to Genzyme's decision to use Caremark as the then most cost-effective solution, but Genzyme first switched to using another third party, Healthcare at Home from 1998 to 2001, and has now concluded that it is most efficient in terms of cost and quality control to distribute and supply homecare itself. The NHS was kept informed of Genzyme's plans, Mr Johnson having specifically informed NSCAG at the meeting of 13 February 2001, a meeting which was both preceded and followed by correspondence between Genzyme and NSCAG. Since the NHS has raised no objection, it is not for the OFT to do so. The NHS could easily adopt a contract system along the lines of EL95(5), if it so wished.

429. As regards the margin squeeze abuse, Genzyme contends that the objective justification for the price of Cerezyme to a pharmacy, including HH's pharmacy, is that it is the NHS Drug Tariff price. According to Genzyme it is ludicrous to suggest that a price based on the NHS Drug Tariff price lacks objective justification.

430. In the alternative, although Genzyme submits that it is under no obligation to put forward a positive case in relation to objective justification, Genzyme submits that its conduct is objectively justified for a number of reasons:

431. First, the price for Cerezyme is set under the NHS Drug Tariff. The price includes distribution, normally to the pharmacy (for patients not being treated in hospital) but because there are so few patients prescribed Cerezyme, and because it requires cold chain delivery and is expensive, it makes no sense for Cerezyme to be delivered to high street pharmacists for collection by the patient. It is not irrational for Genzyme not to use wholesalers. In fact, wholesaling would be inappropriate and irrational for the delivery of Cerezyme to the four

hospitals and approximately 170 homes. Nor is it irrational for Genzyme not to use a third party distributor.

432. According to Genzyme, a number of other manufacturers, e.g. Aventis, Baxter and Wyeth, have arrangements similar to Genzyme. Mr Moreland provides further details in his witness statement of 24 September 2003. Genzyme notes that the MMC apparently raised no objection to Nutricia's decision in 1997 to bring its distribution and homecare in-house (see paragraph 2.60 of the *Fresenius/Caremark* Report). Both Mr Johnson and Mr Moreland state that they were aware at the time that other companies were in direct charge of their homecare services. Moreover, in the present case, the DoH raised no objection to Genzyme's decision from a medical or commercial point of view, save that it wanted reassurance that it would not involve any increase in cost: see the meeting with NSCAG of 13 February 2001. Indeed, Dr Wraith's view, in his statement of 9 July 2001, was that "it was logical that Genzyme should take the service in-house".

433. As regards the specific reasons for Genzyme not wishing to entrust distribution or nursing services to Healthcare at Home, Genzyme submits that Healthcare at Home is the distributor and homecare supplier for TKT for Replagal, which competes with Genzyme's Fabrazyme in the treatment of Fabry disease. Furthermore, TKT is launching GCB, a competitor to Cerezyme, and Genzyme has reservations about entrusting the distribution and service provision to the same undertaking that is providing the same services to a direct competitor.

434. Secondly, Genzyme contends that bringing homecare in-house will ensure higher standards, higher quality and more cost-effective service. For example, Genzyme can ensure that adverse events are reported by nurses, and that deliveries are not sub-contracted to inappropriate delivery firms. Bringing homecare in-house will remove Genzyme's dependence on third parties, ensure compliance with pharmaco-vigilance requirements, and ensure a service that will specialise in LSD treatments, including Fabrazyme and Aldurazyme. That in turn will ensure more effective feedback from Genzyme's own nurses treating LSD patients at home. Genzyme relies on the witness statements of Malcolm Johnson of 22 October 2002, Dominic Moreland of 24 October 2002 and Julie Kelly of 23 October 2002. Genzyme's pharmaco-vigilance obligations are explained in more detail in Mr Moreland's witness statement of 28 September 2003.

435. Genzyme considers, in particular, that it can provide a better, more cost effective and responsive homecare nursing service than that provided by a company such as Healthcare at Home, or by a specialised delivery service such as Polar Speed. Bringing the service in-house ensures that Genzyme can see that the job is done properly, in particular by exercising better control over the nurses who are carefully and individually selected by Genzyme. This is particularly significant for treatments such as Fabrazyme, where feedback from nurses is important. By using Genzyme Homecare, the cost of providing the services in question will be less than the cost of employing a third party distributor such as Healthcare at Home. Genzyme also relies on various cost estimates in Mr Williams' second witness statement of 20 August 2003.

436. According to Genzyme the reference in the November 2000 proposal (paragraph 104 above) to "pushes out competition by providing a shopping basket of tailor-made services" is a legitimate reference to meeting competition on the LSD market. In so far as the statements of Professor Cox and Dr Mehta may imply that Genzyme Homecare may seek to influence the level of dosing, Genzyme submits that that allegation is inadmissible, since it has never been previously raised. In any event the allegation is strongly denied.

437. Genzyme emphasises that when it decided to take 'homecare services' "in-house" in 2001, it acted on legal advice. Although the OFT now says that its arrangements have been illegal since the Act came into force on 1 March 2000, the OFT does not explain how Genzyme could then have terminated its distribution with Healthcare at Home. Indeed, at the time of the interim measures proceedings in April 2001 the OFT was seeking to compel Genzyme to supply Healthcare at Home on the same terms as before. Genzyme also emphasised the adverse consequences of Cerezyme losing the status of a zero discount drug.

438. For all these reasons, submits Genzyme, there is no basis for interfering with Genzyme's freedom to choose its own trading partners.

C. THE OFT'S ARGUMENTS ON ABUSE

439. The OFT emphasises, first, the cumulative nature of the two alleged abuses, which enable Genzyme to monopolise the supply of Homecare Services as defined in the decision. According to the OFT, the "bundling abuse" chokes off demand from the hospitals, whereas the "margin squeeze" abuse chokes off supply from other healthcare providers. 'Homecare Services', according to the OFT, are part of the care provided to the patient under the aegis of the responsible clinician. It is fundamental to this case, submits the OFT, that the choice of homecare provider should lie with the clinician responsible for the patient's care, and not with the drug manufacturer, Genzyme. In addition, the abuses here in question make it more difficult to introduce new drugs for the treatment of Gaucher disease since (1) Genzyme would not be prepared to allow Genzyme Homecare or any other third party under contract to Genzyme to supply delivery/homecare services for a competing drug (2) clinicians will be more reluctant to switch treatment for their patients if this means also switching the delivery/homecare services provider (3) doctors' ability to try various available treatments on patients without having to switch the homecare services provider will be impeded.

The bundling abuse

440. According to the OFT, the first issue as regards the bundling abuse seems to be whether Genzyme actually does charge an inclusive price for the drug and for ancillary Homecare Services for Gaucher patients. On that issue, the OFT rejects Genzyme's argument that there are in fact two principal, and discrete, elements to homecare, namely: (i) delivery of the drug to the patient's home, which is paid for out of the NHS Drug Tariff price, and (ii) nursing care for patients who do not self-administer the drug, which is "supplied free of charge" by Genzyme.

441. On the contrary according to the OFT, Homecare Services comprise an integrated package of elements, including specialist delivery and clinical waste collection services, specialised nursing care, a customer helpline, pharmacy services and logistics. Homecare services themselves amount to a distinct specialist field in which there are a number of competing independent companies who market their services (in particular HH, Clinovia and Central Homecare). The services are provided flexibly to the patients concerned according to their individual and varying requirements.

442. Moreover, the OFT rejects Genzyme's argument that home delivery can be "most naturally classified as part of distribution/delivery" to a community pharmacy and is "not much different to 'picking up the empties' on a milk round", with the implication that no foreclosure will occur (see in particular Professor Yarrow's evidence). The OFT relies on paragraphs 169 to 172 of the decision, on the evidence of Mr Farrell, on the witness statements of Julie Kelly and Dominic Moreland of 23 and 24 October 2002 respectively, and on Genzyme's own literature. According to Dr Jones' witness statement of 13 August 2003 the use of delivery companies such as Polar Speed is quite exceptional.

443. Moreover, according to the OFT, payment for this package of services is bundled together with the cost of the drug itself, but in normal circumstances it would not be. The OFT rejects Professor Yarrow's argument that the governing principle of reimbursement for pharmacists is that the NHS Drug Tariff price covers delivery to a location where the drug is conveniently made available to the patient, and that in the case of Cerezyme, this location is the patient's home. According to the OFT, this view is contradicted by the evidence of Mr Brownlee. According to Mr Brownlee at paragraph 21 of his witness statement of 30 June 2003:

> "[t]he operating assumption of the PPRS in primary care is that the supply to patients of medicines manufactured by PPRS members is through wholesalers and community pharmacists that dispense the medicines to patients in the pharmacy".

Mr Brownlee continues at paragraph 22 of the same witness statement dated 30 June 2003:

> "If any member of the 1999 PPRS was to inform the DoH that the NHS list price for one of its drugs included an element relating to home delivery to patients, then, for the purposes of the PPRS, we would be interested in whether this was simply a replacement for the normal wholesaling function, and covered the basic delivery of the drug to the patient. If so, that element of the price would be subject to the 4.5 per cent price cut required by the 1999 scheme, just as would the traditional wholesaling margin. Where, on the other hand, the home delivery service was a more complex operation for the patient, involving value added elements, we would look at the specific circumstances in more detail and may conclude that such components were not a normal element of the NHS list price. The latter situation arose in the case of Genzyme, who successfully argued that a part of the NHS list price for Cerezyme related to the provision of home care services, and that these fell outside what the NHS list price was normally intended to cover."

444. Similarly, Mr Brownlee states that in 1999 he did not consider Genzyme's activities, as described by Genzyme, to be equivalent to the normal wholesaler function or "basic delivery of the drug": see Mr Brownlee's statement of 5 September 2003. Genzyme's operations are in fact very different to the 'box shifting' operations of wholesalers described in Mr Johnson's evidence at the oral hearing of 6 November 2002. Both Genzyme Homecare and Healthcare at Home provide significant additional services beyond the point where the drug is dispensed in their respective pharmacies.

445. Moreover, according to the OFT, Genzyme's claim that the NHS list price for Cerezyme does not cover nursing care services, since these are supplied "free of charge" is contradicted by all the evidence, and in particular the statements made by Genzyme to the DoH in 1999/2000, set out in paragraphs 95 to 103 of the Decision.

446. The OFT further rejects Professor Yarrow's argument that Genzyme's statements to the DoH in 1999 cannot be taken at face value, because the negotiations with the DoH were only a "horse trade". The OFT relies on the evidence of Mr Brownlee, at paragraphs 25 to 34 of in his witness statement of 30 June 2003.

447. The OFT also rejects Genzyme's argument that any "bundling" could not foreclose the home delivery of Cerezyme because there are many thousands of businesses who could undertake that function. First, home delivery is not a 'no frills' service: it cannot be divorced from the integrated service that only companies such as Healthcare at Home provide. Secondly, Genzyme's argument overlooks the fact that the NHS would not be willing to pay twice for the same service, once to Genzyme and once to the independent provider. Despite the possible VAT saving, the purchaser is still facing a bundled price and has no incentive to acquire the homecare services from anyone other than Genzyme.

448. The OFT further rejects Genzyme's claim that only a small proportion of Gaucher patients are in a position to receive nursing care from independent homecare services providers, so that the impact of any bundling practices must be *de minimis*. This argument also rests on the false premise that "nursing homecare" forms a discrete service, whereas it is clear that it is supplied as part of the overall service provided by companies such as Genzyme Homecare and Healthcare at Home. All Gaucher patients who receive

their treatment at home receive that flexible, wider service. All the Gaucher patients in the UK who are treated at home may require nursing assistance, at least from time to time.

449. The OFT maintains its assessment, at paragraphs 331 to 350 of the decision, that the abuse has an effect on the upstream market since the already high barriers to entry for potential suppliers of new drugs for the treatment of Gaucher disease are raised even higher by the "significant added difficulties in switching patients over to a new drug requiring homecare if this meant also changing the service provider". According to the OFT, that assessment is confirmed by Professor Cox at paragraphs 20 to 22 of his witness statement of 17 June 2003, and by Dr Mehta at paragraph 22 of his witness statement of 30 June 2003. The OFT is of the view that the opinions on this subject of Drs Waldek, Wraith and Lee, which might seem to support Genzyme's case, are of little weight since: (a) only Dr Wraith is a Gaucher specialist; (b) those doctors were not asked to consider the question whether the need to switch the patient's homecare service provider, as well as the drug, could affect the specialist's choice of treatment for the patient; (c) Genzyme has taken out of context the various statements of Dr Waldek, Dr Lee and Dr Wraith; (d) the point is not addressed by Dr Vellodi in his witness statement of 21 August 2003; (e) Dr Waldek was not apparently shown the witness statements of Professor Cox and Dr Mehta; and (f) Genzyme did not seek to cross-examine Professor Cox and Dr Mehta. In addition, statements in Genzyme's business proposal document of November 2002 (paragraph 104 above) show that Genzyme was fully aware of the strategic importance of controlling the supply of homecare services as a means of reinforcing its monopoly in the supply of drugs for the treatment of Gaucher disease.

450. According to the OFT, the decision sets out at paragraphs 294 to 300, and in footnote 355, the relevant EC jurisprudence establishing the relevant principles against which to analyse Genzyme's inclusive pricing behaviour: see in particular *Telemarketing*, at paragraph 27 of the judgment.

451. This case is a classic example of such an abuse, submits the OFT. Moreover, *Duales System Deutschland*, OJ 2001 L1661, cited above, shows at paragraphs 114 to 115 that there is no need to impose a formal tying requirement, if the economic effect of the

practice in question is to bind the customer to use the service. Both that decision, and *Napier Brown/British Sugar*, show that the principle is not limited to situations in which the supplier is also dominant in the downstream market. Moreover, in *Napier Brown/British Sugar*, referred to at paragraph 297 of the decision, the relevant abuse was not British Sugar's refusal to supply the raw material for making refined sugar, but British Sugar's practice of insisting on supplying sugar to customers together with the service of delivery of the sugar (see paragraphs 69 to 72 of that decision). According to the OFT, the *Bronner* decision, relied on heavily by Genzyme, is of no relevance to the present case. Even if, contrary to the OFT's submission, this case should be analysed as a constructive refusal to supply, the result is the same, according to the OFT: see also Case T-111/96 *Promedia v. Commission* [1998] ECR II-2937, at paragraph 139.

452. Finally, on this part of the case, the OFT submits that it is irrelevant that there is no substantial foreclosure of the overall homecare market. Access to Cerezyme at an economically viable price is essential to any homecare service/delivery provider who wishes to supply homecare services to Gaucher patients. Genzyme, by its pricing policy, has foreclosed the possibility of any other provider offering homecare services to Gaucher patients.

Lack of objective justification for the 'bundling' abuse

453. Finally, the OFT maintains its position, set out at paragraphs 356 to 362 of the decision, that there is no objective justification for the bundling abuse. The OFT considers that Genzyme has raised four additional points in the Notice of Appeal, namely that (a) Genzyme's practice enables it to keep costs to the NHS down (b) the NHS is content with Genzyme's pricing, and could have forced Genzyme to unbundle (c) it is normal for the NHS Drug Tariff price to cover the cost of delivery to a location convenient to the patient and (d) the policy followed by Genzyme will facilitate research in orphan drugs. The OFT disagrees with these arguments.

454. As to the argument that Genzyme's pricing practice enables it to control costs to the NHS, the OFT refers to paragraphs 356 to 362 of the decision. Genzyme is currently forcing the NHS, as the price for choosing its own Homecare Services provider, to remunerate Genzyme for a service that Genzyme does not actually provide. This is contrary to

Community law: Case C-340/99 *TNT Traco v Post Italiane* [2001] ECR I-4109. In any event, any cost savings or efficiences achieved by Genzyme Homecare accrue entirely to the monopolist, Genzyme, and not to the NHS.

455. It is fundamentally wrong, according to the OFT, that Genzyme, rather than the clinician, should be able to dictate the nature and quality of the service to be provided. Mr Farrell's oral evidence to the Tribunal is to the same effect. The OFT also relies on difficulties alleged by Clinovia in relation to the Royal Berkshire Hospital referred to in Mr Munro's witness statement.

456. Secondly, there is no basis for Genzyme's claim that the NHS is content. First, the NHS is not a single trading entity; it is a collection of different parts which exercise different functions, and which cannot be relied upon to act as an effective counterweight to anti-competitive behaviour by drug companies. As far as the PPRS branch of the DoH is concerned, the issue of bundling was not addressed in 1999. Mr Brownlee confirms that the DoH cannot compel a company such as Genzyme to "unbundle" its prices to promote competition on behalf of the NHS except to the extent that the profit limits set under the PPRS are exceeded.

457. As far as Hospital Trusts are concerned, there is no evidence that they are content with Genzyme's practices. Indeed, it is clear from Mr Farrell's witness statement that he is decidedly against Genzyme's pricing practices – see paragraphs 46 (the absence of alternatives for the NHS), 52 to 53 (the impediment that inclusive pricing creates to block contracting) and 57 to 58 (the Trusts' inability to force Genzyme to unbundle its price) of that statement.

458. EL(95)5 was an executive letter directed at current GP prescribing practices and health authorities, and does not bear on the question whether the NHS would be able to secure any "un-bundling".

459. As far as Genzyme's dealings with NSCAG in February 2001 are concerned, it cannot reasonably be inferred that NSCAG gave any kind of approval to Genzyme's pricing policy: see the witness statement of Julia Stallibrass of 11 September 2003.

460. Finally, the legislation relating to orphan drugs is intended to create the appropriate environment for research and development. There is no basis for asserting that companies producing orphan drugs should be allowed to engage in abusive pricing practices. In fact, according to the OFT there were complaints from the Gaucher Association about the activities of Caremark and Genzyme's pricing policy from 1995 onwards.

The margin squeeze abuse

461. The OFT submits, first, that it is clear that a dominant undertaking can commit an abuse on a neighbouring market where it is not dominant – see paragraph 296 of the decision, citing Case C-333/94 P *Tetra Pak II* [1996] ECR 5951, and the decision of the Court of First Instance in Case T-83/91 *Tetra Pak II* [1994] ECR II 7455, at paragraph 115. The "margin squeeze" principle, first enunciated in *National Carbonising,* cited above, (relied on at paragraph 364 and footnote 425 of the Decision), is simply an instance of such a pricing abuse, and of the general principle which emerges from *Télémarketing* and Case 6/72 *Commercial Solvents v. Commission* [1974] ECR 223. Contrary to Genzyme's assertions, there was no indication in *National Carbonising* that it was a necessary condition of the abuse for the National Coal Board to be dominant in the downstream market as well as the upstream market. Such a condition would be quite superfluous where, by virtue of its control over the terms on which an essential input (such as Cerezyme) is made available to suppliers in the downstream market, a dominant undertaking upstream is able to foreclose competition to its own downstream operation (see also paragraph 178 of *Industrie des Poudres Sphériques,* cited above, referred to at footnote 430 of the decision).

462. Secondly, the OFT submits that the OFT and EC Commission guidelines in the telecommunications sector, referred to in paragraphs 365 to 367 of the decision, are not sector specific: see, in particular, paragraph 6 of the EC Commission's guidelines. Similarly, the principles relating to margin squeeze were outlined in general, and not sector specific terms, at paragraphs 201 to 202 of the CAT's judgment in *Freeserve*, cited above.

463. As regards Genzyme's claim that the OFT decided at the interim measures stage that Genzyme has no obligation to supply Cerezyme to Healthcare at Home or to anyone else, the OFT denies that it had so decided: it had merely decided not to order interim measures. In any event, in this case Genzyme is supplying Healthcare at Home. The sole issue is as to the terms upon which it should do so.

464. As to Genzyme's argument that it has no power to foreclose the wider homecare market, according to the OFT the essential point is not whether Genzyme has the power to force independent providers such as Clinovia or Healthcare at Home altogether out of the business of providing homecare for patients suffering from a range of conditions other than Gaucher disease, such as HIV/AIDS or haemophilia. The point is that Genzyme does have the power, via a margin squeeze, to force independent providers such as Healthcare at Home out of providing Homecare Services for patients with Gaucher disease, and to reserve (i.e. monopolise) that particular activity for itself. Moreover, nothing in the *Fresenius/Caremark* report supports Genzyme's position, according to the OFT.

465. As regards Genzyme's argument that Genzyme Homecare is not an equivalent provider of homecare/delivery services to Healthcare at Home, the OFT submits that Genzyme Homecare is a separate division of Genzyme, and in a comparable position to Healthcare at Home.

Lack of objective justification for the margin squeeze abuse

466. As regards Genzyme's claim that it is standard practice to charge the NHS list price for Cerezyme to Healthcare at Home as a pharmacy, the OFT considers that this fundamentally misses the point of the margin squeeze issue: see paragraph 385 of the decision. Healthcare at Home is not simply a standard community pharmacy, which receives the appropriate reimbursement and remuneration for dispensing activities in accordance with prevailing NHS administrative arrangements. Genzyme provides no justification for its practice of supplying Cerezyme to Healthcare at Home, a provider of Homecare Services, at the same price as Genzyme Homecare sells the drug *and* the Homecare Services to the NHS.

467. Moreover, according to the OFT it should be noted that: (i) the cost to Healthcare at Home of its home delivery service for patients is not reimbursed out of the NHS list price: the cost to Healthcare at Home of the home delivery service, which is carried out subsequent to the point of dispensing, needs to be separately remunerated; (ii) as Mr Brownlee's witness statement makes clear at paragraph 41, the Expensive Prescription Fee is intended by the authorities only to contribute towards the costs incurred by a pharmacy as a result of a three month delay in payment by the PPA; (iii) as Mr Walsh's witness statement of 30 April 2003 makes clear, the majority of the prescriptions for Gaucher patients are hospital prescriptions, as opposed to prescriptions reimbursed by the PPA, and do not attract the Expensive Prescription Fee; (iv) Genzyme has at all times been fully aware that the decision to charge Healthcare at Home the full NHS list price for the supply of Cerezyme while charging the same price to the NHS for the drug and Homecare Services, was calculated to lead to the elimination of Healthcare at Home from the provision of Homecare Services for Gaucher patients. This is demonstrated by (a) the standard letters written by Mr Moreland to consultants and hospital pharmacists in April 2001 stating: "… it has become apparent that we must be in a position to transition your patients to our service by 7 May 2001"; (b) the letter of 12 July 2001 from Mr Moreland to Ms Price of the Cornwall and Isles of Scilly Health Authority, "Genzyme will no longer fund the provision of homecare by other companies. If the Health Authority wishes to continue using them, funding for the provision of such services must be secured from other sources"; (c) Mr Moreland's evidence that the 2002 budget for Genzyme Homcare was prepared on the basis that all patients would be transferred to Genzyme Homecare.

468. As regards Genzyme's argument that certain other pharmaceutical companies have in-house homecare operations, the OFT accepts that there is nothing objectionable in that per se. However, in relation to the three companies which are specifically relied upon by Genzyme, namely Aventis, Baxter and Wyeth, the OFT refers to Mr Farrell's witness statement, at paragraphs 14 to 17 and 45 to 48, where he explains that, in the case of these companies (which, in particular, supply competing haemophilia treatments), the hospital does not have to use their in-house operations for the supply of homecare for patients if it does not wish to do so. The hospital is free to use an independent homecare provider such as Healthcare at Home on an economic basis (and currently does so). The position with Genzyme is totally different because there is *no* effective choice in the matter, and

because Genzyme is taking steps to eliminate the only existing independent provider of Homecare Services for Gaucher patients from the market and to prevent further market entry. The OFT also relies on Mr Farrell's oral evidence to the effect that situations comparable to the present situation are extremely rare (Day 2, pp 37 to 38 and 40 to 46), and on the evidence of Dr Jones in his witness statement of 26 September 2003.

469. The OFT rejects Genzyme's argument that it should not have to entrust the distribution of Cerezyme to an undertaking that is providing the same services to a competing drug company: see also Mr Farrell's evidence, Day 2, p.67. The OFT also refers to paragraph 16 of the witness statement of Dr Jones of 26 September 2003 on that point, and to Dr Jones' understanding that Healthcare at Home does not have an exclusive arrangement with TKT as regards Replagal.

470. According to the OFT, the provision of Homecare Services is an aspect of the treatment of Gaucher patients, rather than merely a distribution function for a product. It is a matter for the clinicians responsible for the patients' care to decide upon the most appropriate arrangements for homecare service provision, and not for the drug manufacturer. Moreover, this argument ignores the fact that Genzyme is not refusing to supply Healthcare at Home, on the grounds that this would, in itself, be inappropriate. Genzyme is prepared to supply Cerezyme to Healthcare at Home. What is in issue are the terms as to price on which it is willing to do so.

471. As regards Genzyme's claims that the use of Genzyme Homecare for the provision of Homecare Services will ensure higher quality standards, the OFT submits that this is not borne out by the facts. According to the OFT, if such significant advantages for the NHS were forthcoming, then the NHS would surely support Genzyme fully in its action. However, the potential loss of Healthcare at Home as an independent provider of Homecare Services, in favour of Genzyme Homecare, is a source of serious concern to both of the two leading consultants involved in the care of all adult Gaucher patients in the United Kingdom, Dr Mehta and Professor Cox, as well as to the Gaucher's Association: see their paper of 21 March 2001. That concern arises from the inherent tension that exists between the commercial interests of the drug manufacturer, and the best interests of the patients from the point of view of clinical care. There is also the difficulty of switching to any new drug for Gaucher disease requiring homecare if this

also means switching the patient's Homecare Services provider. Both clinicians have also emphasised that the drug companies' views on the appropriate dosage for patients may not necessarily accord with the views of the clinicians.

The burden of proof on objective justification

472. Finally, the OFT rejects Genzyme's assertion that the OFT must itself adduce evidence in order to demonstrate that the dominant undertaking's behaviour is incapable of being justified, in the sense that no rational and fair person could justify it.

473. First, the OFT submits that the facts and matters which could justify a breach of the Chapter II prohibition would normally be within the knowledge of the dominant undertaking. As a matter of common sense, it would be strange if the OFT were obliged to exercise investigatory powers on its own initiative in order to hunt for a possible justification for the dominant undertaking's behaviour.

474. Secondly, the OFT notes that "[i]n Napp, the Tribunal expressly did not exclude the possibility that, on some issues, the appellant might well have an evidential burden to overcome: see paragraph [111]". The OFT further refers to the Tribunal's judgment in *Aberdeen Journals (no.2)*, cited above, where the Tribunal referred, at paragraphs 357 and 358 of the judgment, to the possibility that, exceptionally, a dominant firm in a predatory pricing case "may be able to rebut the presumption of abuse".

475. As to Community law, neither *Telemarketing* nor *Eurofix/Bauco/Hilti*, cited above, support Genzyme's position. According to the OFT, it is the task of the dominant undertaking to show objective justification. The OFT relies notably on Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-2769 at paragraph 189; Case T-83/91 *Tetra Pak II v Commission* [1994] ECR II-755, at paragraphs 126 to 127 and 137 to 141; Case C-395/87 *Ministere Public v Tournier* [1989] ECR 2521, at paragraph 38; and Case T-128/98 *Aeroports de Paris v Commission* [2000] ECR II-3929, at paragraphs 200 to 203.

476. As regards the judgments of Laddie J in *Getmapping* and *Suretrack*, both cited above, the OFT submits that those cases are not relevant. In any event, according to the OFT, it would be incompatible with section 60 of the 1998 Act for the Tribunal to prefer a High

Court decision in an interlocutory application to the consistent jurisprudence of the Community courts.

VIII THE TRIBUNAL'S FINDINGS ON ABUSE

The OFT's essential case

477. The essential case made by the OFT in the decision is as follows. As regards the *bundling abuse*, the OFT argues that Genzyme supplies Cerezyme at the NHS list price (currently £2.975 per unit). According to the OFT, the effect of that is that it is uneconomic for the NHS to acquire Homecare Services from anyone other than Genzyme, or an undertaking under contract to Genzyme, because the NHS would thereby be paying twice over for the supply of the Homecare Services: once in the price of the drug, and then again to an independent homecare services provider. That, says the OFT, effectively ties the NHS to Genzyme in respect of Homecare Services, and excludes, in practice, any third party from supplying Homecare Services to Gaucher patients, as would occur in normal competitive conditions.

478. As regards the *margin squeeze abuse*, the OFT argues that since May 2001 Genzyme has supplied Cerezyme to the NHS at the NHS list price, while supplying other homecare services providers at the same list price, £2.975 per unit. The effect of that is that other homecare service providers have no margin with which to compete with Genzyme Homecare, and are effectively eliminated from the supply of Homecare Services to Gaucher patients.

479. The OFT emphasises the interrelationship between the two alleged abuses. The bundling abuse, argues the OFT, effectively prevents the NHS from seeking a homecare services provider other than Genzyme Homecare, while the margin squeeze abuse prevents other homecare service providers from offering their services to the NHS on economically viable terms.

480. According to the OFT, both those abuses foreclose the downstream market for homecare services. In addition it is more difficult for competitors to enter the upstream market for the supply of drugs for the treatment of Gaucher disease. Since the supply of Homecare

Services is effectively tied to Genzyme Homecare, a new competitor would face the additional hurdle of persuading the patient to switch not only to a new drug, but also to a new homecare services provider. According to the OFT, that additional hurdle further raises the already high barriers to entry to the upstream market for drugs for the treatment of Gaucher disease.

481. In this section we first set out the relevant law (A). We then deal with certain matters relating to the NHS list price, the PPRS and the Drug Tariff (B). We then consider the bundling abuse standing alone (C), followed by the margin squeeze abuse (D). We then address the issue of objective justification (E) and the alleged effect in the upstream market (F), before summarising our conclusions (G).

A. THE RELEVANT LAW

482. In case 85/76 *Hoffman-La Roche v. Commission* [1979] ECR 46, the Court of Justice said at paragraph 91:

> "The concept of abuse is an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition".

483. In case 322/81 *Michelin v. Commission* [1983] ECR 3451, the Court of Justice said at paragraph 57:

> "A finding that an undertaking has a dominant position is not in itself a recrimination but simply means that, irrespective of the reasons for which it has such a dominant position, the undertaking concerned has a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market."

See also cases C-395/96P and 396/96P *Compagnie Maritime Belge v. Commission* [2000] ECR I-1365, at paragraph 37.

484. It is thus clear from the case law from the Court of Justice and the Court of First Instance that a dominant firm may, by virtue of its "special responsibility" be deprived of the right to follow a course of conduct which would not necessarily be objectionable if that course of conduct were followed by a non-dominant undertaking: see e.g. Case T-83/91 *Tetra Pak v. Commission* [1994] ECR II-775, at paragraph 137, Case 111/96 *ITT Promedia v. Commission* [1998] ECR II-2937 at paragraph 139, and Case 65/98 *Van den Bergh Foods Limited v. Commission*, judgment of 23 October 2003 at paragraph 159. In particular, a dominant firm is prohibited from eliminating a competitor and from strengthening its position by recourse to means other than those based on competition on the merits: *Van den Bergh Foods,* cited above, at paragraph 157.

485. An abuse has been found, in particular, where a dominant undertaking seeks, without objective justification, to "tie" the supply of a product or service to the supply of another product or service, so that the customer cannot obtain one of the products without at the same time purchasing the other. See, for example, case T-83/91 *Tetra Pak v Commission* [1994] ECR II-775, at paragraphs 135 and 137, upheld on appeal in Case 333/94P *Tetra Pak v Commission* [1996] ECR 5951, at paragraph 37. See also, for example, *Eurofix-Bauco-Hilti* OJ 1988 L65/19, upheld on appeal in Case T-30/89 *Hilti v. Commission* [1991] ECR II-439, on further appeal in Case C-53/92P [1994] *Hilti v. Commission* ECR I-667.

486. A particular example of an abusive practice tending to eliminate a competitor occurred in Case 311/84 *CBEM Télémarketing v. CLT and IPB* [1985] ECR 3261 (*Télémarketing)*. In that case, Centre Belge was a telemarketing organisation which advertised on the Luxembourg television station CLT. The Centre Belge advertisements showed the Centre Belge telephone number, which customers would call if they wanted to purchase the products shown in the advertisements. After the expiry of the relevant agreement, CLT refused to accept any further advertisements involving telemarketing unless the telephone number shown was that of its own advertising agent, Information Publicité, thereby excluding Centre Belge. The Court of Justice held at paragraphs 25 to 27 of its judgment:

> "25. In order to answer the national court's second question, reference must first be made to the aforesaid judgment of 6 March 1974 [Cases 6 and 7/73 *Commercial Solvents v. Commission* [1974] ECR 233], in which the court held that an undertaking which holds a

> dominant position on a market in raw materials and which, with the object of reserving those materials for its own production of derivatives, refuses to supply a customer who also produces those derivatives, with the possibility of eliminating all competition from that customer, is abusing its dominant position within the meaning of Article 86.
>
> 26. That ruling also applies to the case of an undertaking holding a dominant position on the market in a service which is indispensable for the activities of another undertaking on another market. If, as the national court has already held in its order for reference, telemarketing activities constitute a separate market from that of the chosen advertising medium, although closely associated with it, and if those activities mainly consist of making available to advertisers the telephone lines and team of telephonists of the telemarketing undertaking, to subject the sale of broadcasting time to the condition that the telephone lines of an advertising agent belonging to the same group as the television station should be used amounts in practice to a refusal to supply the services of that station to any other telemarketing undertaking. If, further, that refusal is not justified by technical or commercial requirements relating to the nature of the television, but is intended to reserve to the agent any telemarketing operation broadcast by the said station, with the possibility of eliminating all competition from another undertaking, such conduct amounts to an abuse prohibited by Article [82], provided that the other conditions of that article are satisfied.
>
> 27. It must therefore be held in answer to the second question that an abuse within the meaning of Article [82] is committed where, without any objective necessity, an undertaking holding a dominant position on a particular market reserves to itself or to an undertaking belonging to the same group an ancillary activity which might be carried out by another undertaking as part of its activities on a neighbouring but separate market, with the possibility of eliminating all competition from such undertaking."

487. In *Commercial Solvents*, referred to in paragraph 25 of *Télémarketing*, Commercial Solvents was dominant in the supply of raw materials for the production of a downstream product, ethambutol. Zoja was a producer of ethambutol who obtained its raw materials from Commercial Solvents. When Commercial Solvents decided itself to commence the downstream manufacture of ethambutol, it ceased to supply the raw materials to Zoja, thus preventing the latter from competing with Commercial Solvents in the downstream supply of ethambutol. The Court of Justice held at paragraph 24 of its judgment that Commercial Solvents had abused its dominant position:

> "24. … an undertaking being in a dominant position as regards the production of raw material and therefore able to control the supply to manufacturers of derivatives, cannot, just because it decides to start manufacturing these derivatives (in competition with its former customers) act in such a way as to eliminate their competition which in the case in question, would amount to eliminating one of the principal manufacturers of Ethambutol in the common market. Since such conduct is contrary to the objectives expressed in Article 3(f) of the Treaty and set out in greater detail in Articles [81] and [82], it follows that an undertaking which has a dominant position in the market in raw materials and which, with the object of reserving such raw material for manufacturing its own derivatives, refuses to supply a customer, which is itself a manufacturer of these derivatives, and therefore risks eliminating all competition on the part of this customer, is abusing its dominant position within the meaning of Article [82]…"

488. *Commercial Solvents* was applied by the European Commission in *Napier Brown/British Sugar* OJ 1988 L284/1. In that case British Sugar's refusal to supply Napier Brown with industrial sugar solely on the grounds that Napier Brown intended to re-package that sugar and sell it on the retail market in competition with British Sugar was held to be an abuse: see paragraphs 61 to 64 of the Commission's decision.

489. Cases such as *Commercial Solvents*, *Télémarketing* and *Tetra Pak II* demonstrate that it may well be an abuse for an undertaking which is dominant in one market to act without objective justification in a way which tends to monopolise a downstream, neighbouring or associated market. That is confirmed by the decision of the Court of Justice in Case C-18/88 *GB Inno* [1991] ECR I-5941, where the court referred to *Télémarketing* with approval in a case where the monopoly operator of a telecommunications system effectively reserved to itself the supply and maintenance of equipment for the network. As the OFT points out at paragraphs 296 and 304 of the decision, the abuses found in the case law essentially involve a company which is dominant in one market extending its monopoly into a separate or related market to the exclusion of competitors who would otherwise be able to compete in that separate market. If the elimination of competition in the related market is not the result of competition on the merits, then an abuse may be found.

490. In accordance with *Télémarketing*, such an abuse may occur in particular, where a dominant undertaking seeks to reserve to itself the supply of services that are ancillary to

the supply of the dominant product. In *Napier Brown/British Sugar*, cited above, the Commission also found, on the basis of *Télémarketing*, that British Sugar's policy of delivered pricing was abusive, since the effect of that pricing policy was to reserve to British Sugar the separate but ancillary activity of delivery, to the exclusion of competition from independent transport undertakings: see paragraphs 69 to 72 of the Commission's decision.

491. A further particular example of the same general principle may occur where an undertaking that is dominant in an upstream market supplies an essential input to its competitors in a downstream market, on which the dominant company is also active, at a price which does not enable its competitors on the downstream market to remain competitive. Such a practice is called a "margin squeeze" or "price squeeze": see Case T-5/97 *Industrie des Poudres Sphériques v. Commission* [2000] ECR II-3755, at paragraph 178. Thus in *National Carbonising Company*, OJ 1976 L36/6 the National Coal Board supplied coking coal for the manufacture of coke both to its own subsidiary, National Smokeless Fuels, and to an independent company National Carbonising. National Smokeless Fuels and National Carbonising were competitors in the downstream market for coke, which was derived from the coal supplied by the National Coal Board. National Carbonising complained that the price it had to pay the National Coal Board for coal was too high to enable it to sell coke competitively at the price charged by National Smokeless Fuels. The Commission held, at paragraph 14 of its decision, that:

> "an undertaking which is in a dominant position as regards the production of a raw material (in this case coking coal) and therefore able to control its price to independent manufacturers of derivatives (in this case, coke) and which is itself producing the same derivatives in competition with these manufacturers, may abuse its dominant position if it acts in such a way as to eliminate the competition from these manufacturers in the market for derivatives. From this general principle the services of the Commission deduced that the enterprise in a dominant position may have an obligation to arrange its prices so as to allow a reasonably efficient manufacturer of the derivatives a margin sufficient to enable it to survive in the long term."

492. Again, in *Napier Brown/British Sugar*, cited above, Napier Brown purchased industrial sugar from British Sugar, repackaged it, and sold the repackaged sugar on the retail sugar market in competition with British Sugar. However, British Sugar's retail selling prices were too low to cover the cost of transforming its industrial sugar for sale on the retail

market. In those circumstances, the Commission found that the margin between British Sugar's industrial and retail selling prices was insufficient to enable a reasonably efficient competitor such as Napier Brown to remain in the retail sugar market. Referring to the *National Carbonising* case, the Commission found that British Sugar's conduct was abusive: see paragraphs 65 to 66 of the Commission's decision.

493. As the decision points out at paragraphs 365 to 367, and 375 to 376, a margin squeeze may potentially occur in the telecommunications sector, where third parties may be dependent on the incumbent supplier for access to the latter's network. However, in our view, contrary to Genzyme's submissions, the possibility of an abusive "margin squeeze" is not confined to telecommunications, as demonstrated by decisions such as *National Carbonising* and *British Sugar*.

494. A particular aspect of the foregoing principles is the doctrine of "essential facilities". Thus in *Port of Rødby* OJ 1994 L55/52, the Commission, basing itself on *Télémarketing*, stated at paragraph 12 of the decision that:

> "An undertaking that owns or manages and uses itself an essential facility, i.e. a facility or infrastructure without which its competitors are unable to offer their services to customers, and refuses to grant them access to such facility is abusing its dominant position. Consequently, an undertaking that owns or manages an essential port facility from which it provides a maritime transport service may not, without objective justification, refuse to grant a shipowner wishing to operate on the same maritime route access to that facility without infringing Article [82]".

495. A somewhat extreme example of the same approach in the field of intellectual property rights occurred in the *Magill* case (cases C-241/91P and C-242/92P *RTE and ITP v. Commission* [1995] ECR 743). In that case certain television companies, relying on their copyright under national law in the information used to compile listings for television programmes, refused to supply such information to the prospective publisher of a weekly television guide covering all television channels. Upholding the decision of the Court of First Instance that such conduct was abusive, the Court of Justice said at paragraphs 53 to 56 of the judgment:

> "53. Thus the appellants who were, by force of circumstances, the only sources of the basic information on programme scheduling

> which is the indispensable raw material for compiling a weekly television guide, gave viewers wishing to obtain information on the choices of programmes for the week ahead no choice but to buy the weekly guides for each station and draw from each of them the information they needed to make comparisons.
>
> 54. The appellants' refusal to provide basic information by relying on national copyright provisions thus prevented the appearance of a new product, a comprehensive weekly guide to television programmes, which the appellants did not offer and for which there was a potential consumer demand. Such refusal constitutes an abuse under heading (b) of the second paragraph of Article [82] of the Treaty.
>
> 55. Second, there was no justification for such refusal either in the activity of television broadcasting or in that of publishing television magazines …
>
> 56. Third, and finally, as the Court of First Instance also upheld, the appellants, by their conduct, reserved to themselves the secondary market of weekly television guides by excluding all competition on that market (see the judgment in Joined Cases 6/73 and 7/73 *Commercial Solvents v. Commission* [1974] ECR 223, paragraph 25) since they denied access to the basic information which is the raw material indispensable for the compilation of such a guide."

496. In Case 238/87 *Volvo v Veng* [1988] ECR 6211, the Court said that the refusal to grant a licence for the manufacture of spare parts covered by a registered design could constitute an abuse only if the conduct consisted of "the arbitrary refusal to supply spare parts to independent repairers, the fixing of prices for spare parts at an unfair level or a decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation" (paragraph 9).

497. The limits of the doctrine of essential facilities have recently been explored by the Court of Justice in *Bronner*, cited above, which is relied on heavily by Genzyme. In that case, Oscar Bronner published a daily newspaper in Austria that had 4 to 6 per cent of the market in terms of circulation and advertising respectively. Mediapoint, the largest daily newspaper publishing group in Austria, had 47 per cent of the circulation and 42 per cent of advertising revenue, but was able to reach 71 per cent of all newspaper readers. Mediapoint operated the only home delivery system for newspapers in Austria. Bronner asked Mediapoint to undertake the home delivery of its (Bronner's) daily newspapers through Mediapoint's home delivery system in return for reasonable remuneration.

Bronner claimed that Mediapoint's refusal to do so was an abuse of a dominant position, since Bronner was unable, by reason of its small circulation, either alone or in combination with other newspaper publishers, to set up and operate its own home delivery scheme in economically reasonable conditions. Bronner relied primarily on the doctrine of "essential facilities" derived from the judgment of the Court of Justice in the *Magill* case. Bronner also relied on *Commercial Solvents* and *Télémarketing*, cited above.

498. The Court rejected Bronner's argument. On the question whether Mediapoint's refusal to allow Bronner access to its home delivery system for newspapers was an abuse, the Court said at paragraphs 38 and 41 to 46:

> "38. Although in *Commercial Solvents v Commission* and *CBEM*, cited above, the Court of Justice held the refusal by an undertaking holding a dominant position in a given market to supply an undertaking with which it was in competition in a neighbouring market with raw materials (*Commercial Solvents v Commission*, paragraph 25) and services (*CBEM*, paragraph 26) respectively, which were indispensable to carrying on the rival's business, to constitute an abuse, it should be noted, first, that the Court did so to the extent that the conduct in question was likely to eliminate all competition on the part of that undertaking. (…)
>
> 41. Therefore, even if that case law on the exercise of an intellectual property right were applicable to the exercise of any property right whatever, it would still be necessary, for the *Magill* judgment to be effectively relied upon in order to plead the existence of an abuse within the meaning of Article [82] of the Treaty in a situation such as that which forms the subject matter of the first question, not only that the refusal of the service comprised in home delivery be likely to eliminate all competition in the daily newspaper market on the part of the person requesting the service and that such refusal be incapable of being objectively justified, but also that the service in itself be indispensable to carrying on that person's business, inasmuch as there is no actual or potential substitute in existence for that home delivery scheme.
>
> 42. That is certainly not the case even if, as in the case which is the subject of the main proceedings, there is only one nationwide home delivery scheme in the territory of a Member State and, moreover, the owner of that scheme holds a dominant position in the market for services constituted by that scheme or of which it forms part.
>
> 43. In the first place, it is undisputed that other methods of distributing daily newspapers, such as by post and through sale in shops and at kiosks, even though they may be less advantageous for the distribution

of certain newspapers, exist and are used by the publishers of those daily newspapers.

44. Moreover, it does not appear that there are any technical, legal or even economic obstacles capable of making it impossible, or even unreasonably difficult, for any other publisher of daily newspapers to establish, alone or in cooperation with other publishers, its own nationwide home delivery scheme and use it to distribute its own daily newspapers.

45. It should be emphasised in that respect that, in order to demonstrate that the creation of such a system is not a realistic potential alternative and that access to the existing system is therefore indispensable, it is not enough to argue that it is not economically viable by reason of the small circulation of the daily newspaper or newspapers to be distributed.

46. For such access to be capable of being regarded as indispensable, it would be necessary at the very least to establish, as the Advocate General has pointed out at point 68 of his Opinion, that is is not economically viable to create a second home-delivery scheme for the distribution of daily newspapers with a circulation comparable to that of the daily newspapers distributed by the existing scheme."

499. The foregoing cases are, in our view, illustrative of the general principles we must apply in accordance with section 60 of the 1998 Act. Whether, in the light of these principles, Genzyme's conduct amounts to an abuse depends on the particular facts of the present case. We revert to the foregoing case law in Section D below.

B. THE "NHS LIST PRICE" AND RELATED ISSUES

500. In this case, the competition issues that arise seem to have become to some extent enmeshed in the complexities of the NHS system. In particular, considerable confusion seems to have surrounded the three distinct notions of the "NHS list price", the "Drug Tariff price" and the "PPRS", which we have attempted to explain at paragraphs 67 to 82 above. We begin, therefore, by clarifying these matters in so far as they are relevant to the arguments put to us on the issue of abuse.

501. As regards, first, the NHS list price, it is common ground that no statutory definition exists of "the NHS list price", nor of what the "NHS list price" includes. In our view, the most that can be said is that the NHS list price is in practice the price determined by the manufacturer at which the drug concerned is to be purchased by the pharmacist in a

community pharmacy and, it is assumed, handed to the patient at the pharmacy. Hence, the NHS list price is not, in the standard case, the price that the manufacturer receives, because the NHS price is normally set so as to accommodate a wholesaler's margin. To put it another way, the NHS list price is in practice regarded as covering the cost of delivering the drug to the community pharmacy. The NHS list price is thus to be distinguished from the 'ex-manufacturer' price which in the standard case will normally be the NHS list price less a wholesaler discount of up to 12½%. To complicate matters still further, the NHS list price will not necessarily even be the price that the community pharmacist pays, because the wholesaler and the pharmacist may negotiate between them a discount off the NHS list price, except in the case of zero discount drugs (see paragraphs 74 to 75 above).

502. Beyond that, we are not persuaded that there is any rule or practice under the NHS system which identifies the elements that may or may not be included by the manufacturer in the initial setting of the NHS list price, or which precludes the manufacturer from taking into account, when setting his initial NHS list price, any element of cost or profit that he wishes.

503. Secondly, we do not think that we can safely infer from the PPRS what Genzyme's NHS list price for Cerezyme should, or should not, include.

504. The PPRS does not in general control the setting of *individual list prices*, still less the costs of individual products, but operates a control over a company's permitted level of *overall profits*. The scheme does not control the setting of the initial list price and does not require the PPRS branch to be informed of the initial list price of a new active substance, although many companies in fact do so; nor does the PPRS branch know what actual transaction prices are for individual drugs (Mr Brownlee, Day 2, pages 7-9). That control on profits is across the board, on a company's branded NHS business as a whole, rather than on individual products (see paragraphs 67 to 73 above). Save in exceptional circumstances, the PPRS monitors only companies which have a turnover of United Kingdom sales of branded pharmaceutical products of more than £25 million annually. Companies below that limit, such as Genzyme, do not have to submit detailed Annual Financial Returns ("AFRs"). Where the PPRS controls apply, the costs taken into account in measuring profits are not assessed on a "per product" basis, but again relate to

across-the-board expenditures, for example on R&D, production, marketing etc. as shown on the relevant AFRs. According to Mr Brownlee, the PPRS branch only rarely has to deal with the prices of individual products, perhaps for example if a price increase is sought, but then "only in a fairly limited way" (Day 2, page 11). In the specific case of Genzyme, there has never been any suggestion of Genzyme seeking a price rise, or exceeding the profit limit applicable under the PPRS. There is no evidence that the initial price for either Ceredase or Cerezyme was affected by the PPRS.

505. We accept that there are some links between the PPRS and the NHS list price. For example, once an initial NHS list price is set, that price cannot be increased without the consent of the DoH. However, we are unpersuaded that the PPRS and the NHS list price are sufficiently linked – let alone "inextricably linked" as suggested by paragraphs 68 and 82 of the decision - so as to enable firm conclusions to be drawn as to what costs the NHS list price is intended to cover.

506. Thirdly, even if the operation of the PPRS could by inference throw light on what may be included in the NHS list price, we are not satisfied that the workings of the PPRS support, for the purposes of *this* case, the OFT's conclusion, at paragraphs 75 and 83, last sentence, of the decision, that the NHS list price "is not intended to cover the cost of delivering the drug from the pharmacy to the patient's home", nor the conclusion at paragraph 163 (ii), last sentence, that "the NHS list price paid by the NHS for a drug is not intended to cover the cost of homecare delivery and provision of homecare services".

507. The OFT's conclusion that the NHS list price does not cover home delivery of Cerezyme to the patient is apparently based mainly on the statements as to the workings of the PPRS made to the OFT by Mr Brownlee recorded at paragraph 74 of the decision. At paragraph 82 of the decision the OFT states that the head of the PPRS (Mr Brownlee) is "a very reliable expert on matters related to the NHS list price and the PPRS" and that his evidence about the working of the NHS list price is "more reliable than any other evidence put to [the OFT] on this matter".

508. However, at paragraph 74 of the decision Mr Brownlee is reported as commenting on a statement in the Translucency report, set out at paragraph 72 of the decision, to the effect that "the NHS price also covers, de facto, the costs of delivering the medicine to the

patient". At paragraph 74 of the decision Mr Brownlee comments in relation to that statement:

> "We are not aware that the components of 'the NHS list' price have been defined. The last sentence of the above statement would be correct if understood in the following context. The operating assumption of the PPRS in primary care is that the supply to patients of medicines manufactured by scheme members is through wholesalers and community pharmacists that dispense the medicines to patients in the pharmacy."

509. As we read the decision, what Mr Brownlee is quoted as saying at paragraph 74 relates to what may be described as "the standard case" of supply by a manufacturer to a wholesaler to a community pharmacy. What Mr Brownlee is saying at paragraph 74 is that, in such a standard case, the NHS list price is normally assumed to cover the cost of the manufacture and distribution of the product through wholesalers "up to the point of delivery to the pharmacy where it is dispensed by the pharmacist *and collected by the patient*", to use the words of the OFT itself at paragraph 74. However, in our view Mr Brownlee is *not* saying what the NHS list price would necessarily cover in a *non-standard* case, such as the present.

510. In the present case, not only is there no wholesaling function of the classic kind but, more importantly, Cerezyme is not delivered to a community pharmacy *for collection by the patient*. From Genzyme's premises in Haverhill, Cerezyme is first transported to two central points, namely Burton-upon-Trent (Healthcare at Home) and Oxford (Genzyme Homecare). Genzyme's pharmacy at Rosehill, although a community pharmacy, does not operate as a point of collection by the patient in relation to Cerezyme. From Burton-upon-Trent and Oxford, respectively, Cerezyme is then delivered direct to Gaucher patients' homes all over the country. Although Cerezyme is dispensed in the pharmacies of Healthcare at Home and Genzyme Homecare at Burton-upon-Trent and Oxford respectively, in relation to Cerezyme those pharmacies do not perform the role of a community pharmacy. Cerezyme cannot be conveniently collected by the overwhelming majority of Gaucher patients from either of those locations, even if collection by the patient would otherwise be a feasible option, which we doubt.

511. Thus, whereas *in the standard case* the distribution chain is complete when the product reaches the community pharmacist, save for the actual handing over to the patient, *in the case of Cerezyme* the dispensing operation in the central pharmacy takes place at a much earlier stage in the distribution chain, at a stage where the product has yet to be delivered to a location convenient to the patient. In the case of Cerezyme, that location is the patient's home. Hence, in this case, what Mr Brownlee refers to at paragraph 74 of the decision as "the operating assumption of the PPRS" - i.e. delivery by a wholesaler to a community pharmacy – is wholly inapplicable.

512. It seems to us, if we may say so, that the decision falls into error at paragraphs 75, 78, 80 and 82 in applying Mr Brownlee's remarks, made in the context of the standard case of distribution from manufacturer to wholesaler to the community pharmacy, to the quite different facts of the present case. The use of the word "the pharmacy" at paragraphs 75 and 82 without the qualifying adjective "community" obscures the fact that the pharmacies of Healthcare at Home and Genzyme Homecare perform, in relation to Cerezyme, a quite different role from that of the traditional community pharmacy.

513. The evidence of Professor Yarrow and Mr Williams is to the effect that the home delivery of Cerezyme (including, according to Professor Yarrow such items as the supply of fridges, ancillary items and waste disposal) should be regarded as included in the NHS list price on the grounds that such operations in effect replace, in an economically efficient way, the distribution function which the NHS list price is conventionally regarded as including. In Professor Yarrow's words, the underlying principle is that the NHS list price covers the cost of delivery to a location convenient to the patient. In response to that evidence Mr Brownlee, in his witness statement of 30 June 2003, was in our view rightly circumspect. Mr Brownlee stated that if home delivery "was simply a replacement for the normal wholesaling function" he would regard that as covered by the NHS list price, but that the situation would have to be examined in more detail "if the home delivery service was a more complex operation for the patient, involving value added elements…" (paragraph 22). Mr Brownlee took essentially the same view in his evidence before us: see Day 2 at pages 13-14).

514. Mr Brownlee and his colleague Mr Kullman took the same position in e-mails dated 11 December 2002. Although the sequence of the relevant e-mails is not easy to follow, it

appears to be the case that on 11 December 2002, Mr Kullman of the PPRS branch responded to an enquiry from the OFT's case officer about what the NHS list price was intended to cover. In response to the OFT's question:

> "1. What does the "NHS list price" cover (i.e. does it cover the cost of the drug? does it cover the cost of delivery of the drug to wholesalers? does it cover the cost of delivery of the drug to patients? does it cover any other element?)"

Mr Kullman told the OFT:

> " … However, the scheme is not specific on what may or may not be included as part of distribution costs. Distribution normally covers the cost of delivering the product from the manufacturer or wholesaler. If a company's distribution costs are high (e.g. as a result of including the cost of delivery to the patient), the level allowed might be restricted and might result in excess profits being repaid.
>
> It is important to note that the Department receives no information on the costs of individual products, only in aggregate on a company's portfolio of products sold to the NHS".

In response to the OFT's question:

> "2. Please consider and comment on the accuracy of the following statement. In particular, the underlined sentence:
>
> The NHS list price is intended to cover the cost of the pharmaceutical, together with manufacturer's profit which is constrained to a maximum by the PPRS. The NHS list price also covers, de facto, the costs of delivering the medicine to the patient."[8]

Mr Kullman replied:

> "I am not aware that the "NHS list price" is defined but would not disagree with the above statement."

515. That exchange prompted the OFT case officer to put a further question to Mr Brownlee on 11 December 2002 in these terms:

> "As I have just explained in the telephone, I wanted to make sure that I understood correctly David's statement in relation to my question

[8] In the copy of the e-mail provided to the Tribunal, no sentence was in fact underlined.

> regarding whether the NHS list price 'covers, de facto, the costs of delivering the medicine to the patient'.
>
> You have explained that although there is no legal definition of what the NHS list price covers, the PPRS works on the assumption that the medicine is delivered to a pharmacy where it is then collected by the patient on presentation of a prescription. In this context, it would be correct to say that the NHS list price covers "the costs of delivering the medicine to the patient". However, the NHS list price does not cover the cost of delivering a medicine to a patient's home.
>
> I would be grateful if you could let me know if my understanding above is correct."

516. Mr Brownlee replied to that question as follows:

> "I am content with your understanding except for the last sentence in the third paragraph. It is perfectly correct to say that the PPRS is based on the assumption that medicines are dispensed to patients by community pharmacists. We have not had to consider a case where medicine is delivered to patients' homes and I am not prepared to say that in no case would we accept this. It would depend upon the case the company put to us. The position would be I suspect that assuming the product was a new one the company would be able to decide its own price. Provided that the total turnover of the company was £25 million or more it would submit an annual return and in examining this we would look at its distribution costs. We would strip out costs that were outside the scheme – which could and I suspect would include delivery to the patient at home in most cases – and if this put the company above the profit threshold it would have to pay the excess. However, in situations like this we look at the facts of the specific case before we make a decision. When sufficient examples are presented we issue guidance after discussion with the ABPI. In the absence of specific examples therefore I am not prepared to say that there are no circumstances in which we would allow some at least of home delivery costs."

517. It seems to us that the statements in paragraphs 75 and 82 of the decision, which are said to be based on the views of Mr Brownlee, to the effect that as regards Cerezyme the NHS list price "is not intended to cover the cost of delivering the drug from the pharmacy to the patient's home" do not fully reflect the much more cautious view expressed by Mr Brownlee, both in the e-mails of 11 December 2002 and in his witness statement of 30 June 2003. Mr Brownlee confirmed to us in his evidence, he did not want "to lay down in

the abstract hypothetical benchmarks" (Day 2, page 12). We gained the impression from Mr Brownlee's evidence that there was a considerable degree of flexibility within the PPRS, with give and take in the relevant negotiations (page.11).

518. As regards the further question whether nursing costs may properly be included in the NHS list price, Mr Williams expresses the view in his statement of 19 May 2003 that such costs would not be an allowable cost under the PPRS, particularly since there is "no specific category within an AFR to place this particular type of service expenditure". However, it is common ground that this issue has never before arisen, and that the present case is a "non-standard" case. In those circumstances, it is not surprising that the standard AFR does not deal with it.

519. More importantly, in our view Mr Williams is in danger of falling into the same error, namely to reason across from the PPRS in order to infer what it is or is not permissible to include in the NHS list price. In our view, such an exercise is particularly questionable where one is trying to draw conclusions from hypothetical assumptions about how the PPRS might work if applied in the future, to circumstances that have not yet arisen, in a case in which "the usual operating assumption" of the PPRS does not apply.

520. We remind ourselves that the question of the treatment of nursing costs under the PPRS could arise only at some future date, and only then if, hypothetically (i) Genzyme's turnover in NHS branded medicines exceeded £25 million, with the consequence that Genzyme needed to submit an AFR and (ii) it was suspected that the United Kingdom profit Genzyme was making on its total sales of branded medicines to the NHS was in excess of the permitted return on capital of some 29 per cent. Only then would the question arise as to whether, in calculating Genzyme's overall profit, the nursing costs in relation to Cerezyme were, or were not, an allowable cost in computing that overall profit.

521. Mr Williams acknowledges that, apart from certain costs that are absolutely disallowed (such as gifts and hospitality) the guiding principle of the PPRS is whether the relevant costs "are reasonable in the light of accepted commercial practice": see paragraph 9.3 of the PPRS. However, under paragraph 9.4 of the PPRS, when assessing the reasonableness of a company's costs the DoH will have regard to "any special features of the company's operation". In all those circumstances, we are not persuaded on the

material before us that, in the special circumstances of this case, the nursing costs of Cerezyme would necessarily be disallowed for the purposes of the PPRS.

522. In addition, the OFT argues that Homecare Services cannot be included in the NHS list price for Cerezyme because the Drug Tariff envisages that the pharmacist will be reimbursed for the cost of the drug, and will not be reimbursed for any other services rendered subsequent to the point of dispensing unless they are specifically set out in the Drug Tariff. We are not persuaded by this argument.

523. The Drug Tariff does not, as the OFT itself points out, regulate the manufacturer's NHS list price, but only controls the price at which the pharmacist is reimbursed. The Drug Tariff does not control the components of the NHS list price, which is left to the manufacturer to determine (see paragraphs 79 to 82, and 279 above). In any event, again it seems to us inappropriate to reason from the standard case with which the Drug Tariff is concerned (namely where a pharmacist dispenses a drug against an FP10 prescription and hands it over the counter to the patient or someone on his behalf), to the non-standard case we are concerned with here. In the present case, the pharmacy does not perform the traditional role of the community pharmacy, and is situated at a different point in the distribution chain at a location which is not convenient for the patient. Moreover, as the OFT again points out, the majority of prescriptions for Cerezyme are written directly by hospital doctors in circumstances where the pricing of the Drug Tariff does not apply.

524. We note, in this connection, that according to the *Fresenius/Caremark* report, the practice of including various ancillary homecare services in the NHS list price was common for treatments involving enteral nutrition, immunoglobulin, the parenteral administration of hormone treatment for women at home, treatment at home for multiple sclerosis using beta interferon, and Gaucher disease. Indeed it is said at paragraph 2.43 of that report that in these cases "the price of the drug is set high enough to cover the cost of the equipment and services required for the home use of the drug" (see also paragraphs 4.51 and 4.91). Those examples suggest to us that it is not in itself contrary to any NHS rule or practice to include homecare services in the NHS list price. There is some evidence that this practice continues for some products (e.g. paragraph 605 below).

525. Finally on the issue of what the NHS list price is intended to cover, we are not concerned to decide whether the correspondence between Genzyme and the DoH in 1999 resulted in the correct application of the PPRS, although we note that Genzyme now considers that its approach at that time was incorrect. Our impression is that, at the time, the responsible official, Dr Bratt, no doubt with many other pressing matters to deal with, suggested a pragmatic solution on the basis of what Genzyme told him, without investigating in any detail Genzyme's operations or necessarily reflecting at any length on analogies between Genzyme's operations and the standard case. The one firm conclusion we do feel able to draw from the 1999 correspondence is that Dr Bratt, as a responsible official of the PPRS, who had apparently consulted Mr Brownlee, at least briefly, did not object in principle to Genzyme selling Cerezyme to the NHS at a list price which included Homecare Services.

526. For those reasons, we find that the conclusions in the decision to the effect that Homecare Services are not, under the NHS system, properly included in the NHS list price, are not proved on the evidence before us. We now turn to consider the two alleged abuses in more detail.

C. THE BUNDLING ABUSE STANDING ALONE

527. As regards the bundling abuse it is convenient, analytically, to begin by considering that abuse in isolation, during the period 1 March 2000 to May 2001. During that period, "bundling" is the only abuse alleged.

528. First, there is no doubt in our mind that Genzyme's NHS list price for Cerezyme of £2.975 per unit includes the cost of Homecare Services as defined in the decision. Genzyme itself argues that such a price includes home delivery, including the supply of ancillaries such as fridges, needles etc. and waste disposal.

529. As to nursing we have already found, at paragraphs 350 to 352 above, that nursing forms an integral part of Homecare Services. We further reject Genzyme's suggestion that nursing is supplied to the NHS "free of charge". The cost of nursing is one of the costs

incurred by Genzyme and that cost falls to be recovered out of the list price for Cerezyme charged by Genzyme. That is expressly confirmed by the correspondence between Genzyme and the DoH in 1999. Thus Mr Cortvriend said in his letter of 7 September 1999:

> "[The price of £618 per 200 unit vial] does not just include the price of the drug. Healthcare at Home provide extensive nursing support to many patients, even to the extent of three weekly visits to patients' homes to administer two hour infusions."

On 22 March 2000 Mr Foster of Genzyme said:

> "The list price for the NHS represents two elements, firstly, the cost of the pharmaceutical drug and secondly the costs of providing homecare assistance for patients whom have infusions in their home environment. The cost of homecare is dependent on the level of service provided, ranging from delivery of the drug and ancillaries and waste disposal to complete nursing assistance in the form of home visits.
>
> To compute the price of the drug (which solely attracts the 4.5% discount, as agreed in your letter of 14 September 1999) we have had to deduct the average cost of homecare".

530. We therefore approach this part of the case on the basis that the cost of Homecare Services is included in the NHS list price for Cerezyme. There is thus a "bundled" price in the sense in which that term is used in the decision.

531. For the reasons already given at paragraphs 344 to 354 above, we also accept that Homecare Services as defined in the decision are properly to be regarded as an integrated package of services which are customarily supplied by specialist homecare service providers such as Healthcare at Home, Clinovia, Central Homecare and others.

532. Furthermore, for the reasons already given at paragraphs 355 to 357 above, we accept that the supply of Homecare Services is an independent economic activity which is separate from, albeit ancillary to, the supply of Cerezyme alone.

533. We also accept that the "bundling" together by a dominant undertaking, in one inclusive price, of separate but ancillary products or services may constitute an abuse where the

effect is to eliminate or substantially weaken competition in the supply of those ancillary products or services. That seems to us to follow from the general principles discussed in section A above, in particular cases such as *British Sugar/Napier Brown*, cited above.

534. Contrary to Genzyme's submissions, it does not seem to us an essential ingredient of such an abuse that the dominant undertaking should be dominant in both the upstream and downstream markets concerned, although that will often be the case. In any event, in this case Genzyme is in a position potentially to exclude Healthcare at Home and other homecare services providers, as we have already found at paragraphs 358 to 367 above, and would have already done so but for these proceedings. In those circumstances it does not seem to us that the OFT has to wait until Healthcare at Home has actually been eliminated from the market before the Chapter II prohibition is applicable, as the OFT finds at paragraph 303 of the decision.

535. However, it seems to us that closer analysis is required before one can draw the conclusion that it is sufficiently proved that the inclusion of Homecare Services within the NHS list price for Cerezyme was, in and of itself, necessarily an abuse in the period from March 2000 to May 2001.

536. First, for the reasons given in section B above, it is not proved before us that Genzyme is in breach of NHS rules or practices in including Homecare Services in the NHS list price for Cerezyme, nor that Genzyme is in breach of any provision of the Drug Tariff or the PPRS.

537. The allegation that, under the NHS rules, it is impermissible to include Homecare Services in the NHS list price for Cerezyme appears to us to be a central plank in the OFT's findings at paragraphs 301 to 330 of the decision: see notably paragraphs 309 to 312 (especially the last sentence of 312) and 325 of the decision, referring back to paragraphs 68 to 83 and 162 (last sentence). Since we have found, in section B above, that that allegation is not proved, we feel that there is a doubt as regards the reasoning followed by the OFT in paragraphs 309 to 330 of the decision.

538. Secondly, the OFT's argument, at paragraph 302 of the decision, that the NHS would have to pay "twice over" in order to acquire Homecare Services from anyone other than

Genzyme contains, it seems to us, a further premise. The further premise is that Genzyme not only supplies Cerezyme to the NHS at a price which includes Homecare Services, but also that Genzyme is not prepared to supply any other homecare services provider with Cerezyme at a price sufficiently below the NHS list price to enable any other homecare services provider to supply Homecare Services on an economic basis. In other words, the essential allegation, it seems to us, is not just that Cerezyme is sold to the NHS at a list price which includes Homecare Services, but that no lower price (what may be loosely called at this stage of the analysis an ex-manufacturer price) is made available to third party homecare service providers.

539. During the period March 2000 to May 2001, Genzyme sold Cerezyme to the NHS at the NHS list price of £2.975 per unit, and paid Healthcare at Home service and management fees of approximately 28.4p per unit for providing Homecare Services. The NHS thus acquired Homecare Services at what the decision describes as the "bundled price" included in the list price of Cerezyme. However, because Genzyme in effect paid Healthcare at Home to provide Homecare Services, the NHS did not pay "twice over" to acquire those services: they were simply included in the price of Cerezyme.

540. It seems to us, therefore, that the OFT's case on abuse in the period March 2000 to May 2001 must depend on the argument that had the NHS wished to purchase Homecare Services in the period between March 2000 and May 2001 from anyone other than Healthcare at Home, it would have been faced with the difficulty of having to pay "twice over", assuming that, in these hypothetical circumstances, Genzyme would have been prepared to sell Cerezyme to another homecare services provider only at the NHS list price.

541. However, we have no evidence that, during this period, the NHS wished to acquire Homecare Services from anyone other than Healthcare at Home; indeed the contrary seems to be the case. There is also no evidence that, during this period, the NHS approached Genzyme, either to seek a choice of Homecare Services provider, or to propose any change in the pricing of Cerezyme, for example to suggest that homecare services might be priced separately from the drug.

542. Moreover, the evidence is that Genzyme has followed the practice of including Homecare Services in the NHS list price for Cerezyme for many years, effectively since the introduction of Ceredase. The NHS has known about Genzyme's practice in this regard since the beginning. No specific objection to this pricing practice was taken by the DoH when it was specifically informed in 1999. According to the *Caremark/Fresenius* report, such a practice was not entirely uncommon where homecare services were supplied in conjunction with certain drugs, at least during the 1990s, see paragraph 84 above. There is some evidence that such a practice continues in relation to some drugs where homecare services are also supplied: e.g. paragraph 605 below.

543. Thirdly, even if Genzyme had appreciated in the period March 2000 to May 2001 that its practice of bundling Homecare Services within the list price of Cerezyme was potentially abusive, we are unpersuaded that there was at that time an obvious mechanism which Genzyme ought to have used to achieve the "unbundling" of Homecare Services. Thus, although in principle, in our view, Genzyme could, during that period, have offered a separate price for Homecare Services and a (lower) ex-manufacturer price for Cerezyme, as far as we can see there would, in these circumstances, have been no mechanism for Genzyme to be reimbursed for the cost of Homecare Services, other than by entering into contracts with the relevant hospitals and PCTs. However, there is no evidence that, in the period March 2000 to May 2001 any hospital or PCT sought any such contractual arrangement. Whatever the precise scope of the "special responsibility" of a dominant undertaking, we are reluctant to hold that Genzyme acted in breach of its special responsibility during the period March 2000 to May 2001 when its only customer, the NHS, passively acquiesced in Genzyme's practice, and raised neither complaint nor criticism in that regard.

544. Similarly, we have no evidence that during the period March 2000 to May 2001 any other Homecare Services provider sought to acquire Cerezyme from Genzyme at a discount from the NHS list price. There is, in addition, the further circumstance that during the period March 2000 to 7 May 2001 the contract between Genzyme and Healthcare at Home dated 1 February 2000 provided that Healthcare at Home was Genzyme's sole and exclusive distributor for products for the treatment of Gaucher disease. We note that there is no explicit reasoning in the decision in support of the view, advanced by the OFT

in its submissions dated 29 September 2003, that by virtue of the Chapter II prohibition Genzyme should have been prepared to act in apparent breach of that agreement by offering Cerezyme to homecare services providers other than Healthcare at Home. In any event in our view the OFT's submissions of 29 September 2003 sit somewhat uncomfortably with the OFT's initial position at the time of the interim measures proceedings, which was to the effect that the agreement with Healthcare at Home should be enforced in accordance with its terms (paragraph 122 above).

545. It is true that, at paragraph 308 (iv) of the decision, the OFT relies on an incident in 1996 when Fresenius apparently sought supplies of Ceredase. Similarly, the OFT, at paragraphs 355 to 360 of the decision, and in submissions before us, placed reliance on various suggested complaints and reservations about Genzyme's pricing between 1995 and 1997 when Caremark was Genzyme's homecare services provider, including letters from Professor Cox to Genzyme dated 11 June and 19 September 1996. However, those matters antedate the coming into force of the Act in March 2000, and do not seem to us to be sufficiently close in time to the issue we have to decide to enable us to place much reliance upon them as regards the period March 2000 to May 2001. In any event, those matters relate primarily to Caremark, with whom Genzyme ceased to deal in 1998. In relation to Fresenius' request in 1996, there appears to be no written record of what Genzyme's response was. We are, therefore, unpersuaded that these matters alter the fact that the NHS displayed an essentially passive attitude in the period March 2000 to May 2001.

Conclusion on the "Bundling abuse" standing alone

546. In these circumstances we accept, in principle, the OFT's case, set out at paragraphs 302 to 307 of the decision, that, in the period between 1 March 2000 and 7 May 2001 Genzyme's practice of including the price of Homecare Services in the NHS list price for Cerezyme could have had the anti-competitive effect of preventing the NHS from using other homecare services providers, other than Healthcare at Home, to provide homecare services to Gaucher patients.

547. However, we doubt whether, in respect of *that* period, it is sufficiently proved that Genzyme's potentially anti-competitive conduct is to be characterised as an abuse for the purposes of the Chapter II prohibition, having regard to the facts that, during *that* period

(a) there is no evidence that the NHS sought an alternative provider to Healthcare at Home, or that any other homecare services provider sought to obtain Cerezyme from Genzyme on discounted terms or otherwise;

(b) the NHS knew of, and acquiesced in, Genzyme's practice of including Homecare Services in the NHS list price of Cerezyme;

(c) it is not shown that Genzyme acted contrary to any aspect of the NHS system in including Homecare Services in the NHS list price for Cerezyme; and

(d) it is not obvious how Genzyme would have been remunerated for the supply of Homecare Services had it "unbundled" the list price of Cerezyme, other than by virtue of a separate contract with the relevant hospital or PCT, but no body on behalf of the NHS ever sought or suggested any such separate contract.

548. In all these circumstances the effect on competition of Genzyme's "bundling practice" in the period March 2000 to May 2001, although theoretically established, is not proved to have had a sufficient adverse effect on competition, in the particular circumstances of this case, to be characterised as an abuse for the purposes of the application of the Chapter II prohibition.

D. THE PERIOD SINCE MAY 2001: THE MARGIN SQUEEZE ABUSE

549. The situation which prevailed in the downstream supply of Homecare Services to Gaucher patients between May 2001 and March 2003 may be summarised thus:

- Genzyme Homecare supplied Cerezyme to the NHS for the treatment of Gaucher patients at home at a price of £2.975 per unit

- Genzyme Homecare supplied Cerezyme to Healthcare at Home, and was prepared to supply other homecare service providers, for the treatment of Gaucher patients at home at the same price of £2.975 per unit

- The price of £2.975 per unit at which Genzyme Homecare sold Cerezyme both to the NHS and to other homecare service providers during this period included the supply of Homecare Services

- Genzyme Homecare, as a division of Genzyme Limited, acquired Cerezyme from Genzyme Corporation at a transfer price of £2.50 per unit (paragraph 371 of the decision)

- It follows that Genzyme Homecare was in a position to earn a margin of some £0.475 per unit on sales of Cerezyme including Homecare Services to the NHS

- Healthcare at Home, having acquired Cerezyme from Genzyme Homecare at £2.975 per unit, resold Cerezyme and provided Homecare Services to the NHS at the same price of £2.975 per unit[9]

- It follows that Healthcare at Home, unlike Genzyme Homecare, was not in a position to earn any margin on the supply of Homecare Services to the NHS

550. We also accept the OFT's view that in order to compete with Genzyme Homecare, it would be very difficult for other homecare providers to charge the NHS more than £2.975 per unit.

551. As regards Healthcare at Home's nil margin between the buying price and the selling price of Cerezyme, it is true that when Cerezyme is sold on FP10 prescriptions Healthcare at Home earns an Expensive Prescription Fee (paragraph 79 above). FP10 prescriptions represent about 40% of Healthcare at Home's business. The Expensive Prescription Fee is 2% of the value of the drug provided. That fee is intended to reimburse the pharmacy for the delay in payment of some three months by the PPA. We accept that the Expensive

[9] We ignore for simplicity the purchasing arrangements between Healthcare at Home, the Royal Free and Genzyme mentioned at paragraph 113 above

Prescription Fee will make some contribution to the financing costs incurred by Healthcare at Home. Nonetheless, that fee is not intended to contribute to other costs incurred by Healthcare at Home in providing homecare services.

552. In our view, in those circumstances it is likely to be wholly uneconomic for Healthcare at Home to provide homecare services at no effective margin between its buying and selling price of Cerezyme. We therefore accept that Genzyme's pricing policy constitutes a margin squeeze, the effect of which is to force Healthcare at Home to sustain a loss in the provision of Homecare Services to Gaucher patients. We also accept that no undertaking, regardless of how efficient it may be, could trade profitably in these circumstances in the downstream supply of homecare services, as the OFT found at paragraphs 376 and 377 of the decision.

553. We also accept that if Genzyme's pricing policy since May 2001 continues unaltered, it is likely that Healthcare at Home will exit the market, as the OFT finds at paragraph 377 of the decision (see also paragraphs 52 and 118 above).

554. In those circumstances we share the OFT's conclusion that the effect of Genzyme's margin squeeze is to monopolise the supply of Homecare Services to Gaucher patients in favour of Genzyme, and to eliminate any competition in the supply of such services to Gaucher patients, as the OFT also found at paragraph 377 of the decision.

555. Furthermore, in our view Genzyme's pricing policy has, since May 2001, been intended to achieve the result of monopolising the supply of Homecare Services to Gaucher patients in favour of Genzyme Homecare, as the OFT found at paragraph 378 of the decision. Genzyme must have appreciated that the inevitable result of its pricing policy would be to force Healthcare at Home to exit the market and to make it virtually impossible for any other homecare services provider to provide homecare services for Gaucher patients in competition with Genzyme Homecare: see also paragraph 119 above, and the correspondence there cited.

556. Looking at the matter from the point of view of the NHS, to obtain homecare services from anyone other than Genzyme Homecare since May 2001 would have involved the NHS in paying a price above £2.975 per unit, in order to remunerate the homecare

services provider in question. That in our view would be extremely difficult to justify. In any event, since Genzyme's price of £2.975 per unit already includes the cost of Homecare Services, the NHS would be, in these circumstances, be paying for Homecare Services which it was not receiving, and then paying again for a homecare services provider to supply the services already included in the price of the drug.

557. At one stage in the argument Genzyme suggested that it could still be economical for a hospital to purchase Cerezyme at £2.975 from another homecare services provider because it could recover the VAT on that purchase when a patient was infused at home, and that saving could be used to fund the homecare services in question. That argument overlooks the fact that, in those circumstances, the hospital would still be paying Genzyme for the cost of Homecare Services which Genzyme was not providing, and then additionally having to remunerate the homecare services provider for Homecare Services already 'paid for' in the drug price. Moreover, if the hospital were able to acquire Cerezyme from a homecare services provider other than Genzyme Homecare for infusion in the community, as we understand it there would be no VAT payable in the first place. In our view in those circumstances it is artificial to regard the hospital as "saving" the VAT. In any event, even assuming a VAT saving, we do not think that Genzyme's pricing policy can be defended on the grounds that the NHS should be expected to forego a VAT saving that would otherwise be available to it.

558. In the light of the foregoing it is abundantly clear to us that Genzyme's pricing policy since May 2001 has been adopted with the intention of reserving to Genzyme Homecare the supply of Homecare Services to Gaucher patients, in the expectation of eliminating all competition from Healthcare at Home and other homecare services providers in the supply of such services. Had it not been for the willingness of Healthcare at Home to remain in the market pending the determination of these proceedings, Genzyme would in our view have already succeeded in establishing Genzyme Homecare as the monopoly supplier of Homecare Services to Gaucher patients.

559. Subject to the issue of objective justification, which we consider below, such conduct seems to us to fall plainly within the concept of an abuse of the kind established by the Court of Justice at paragraph 27 of its judgment in *Télémarketing*, namely that

> "… an abuse within the meaning of Article [82] is committed where, without any objective necessity, an undertaking holding a dominant position on a particular market reserves to itself or to an undertaking belonging to the same group an ancillary activity which might be carried out by another undertaking as part of its activities on a neighbouring but separate market, with the possibility of eliminating all competition from such undertaking.."

560. As to the particular nature of the abuse here in question, in our view the facts that (a) Genzyme sells Cerezyme to the NHS at a list price which includes Homecare Services and (b) sells Cerezyme to other homecare providers at that same list price, give rise to an abusive margin squeeze within the principles of *Napier Brown/British Sugar* and *National Carbonising*, cited above at paragraphs 491 and 492. As already indicated (paragraph 534 above) we do not accept Genzyme's argument that those cases are distinguishable on the grounds that, in those cases, British Sugar and the National Coal Board respectively were dominant in both the upstream and downstream markets.

561. For the reasons we have already given the bundling of "Homecare Services" within the NHS list price of Cerezyme is not itself proved to be an abuse. In our view, from May 2001 onwards Genzyme's practice of bundling the cost of Homecare Services within the NHS list price for Cerezyme facilitated the margin squeeze abuse, which in turn would inevitably eliminate competition in the supply of Homecare Services to Gaucher patients.

562. We entirely reject Genzyme's argument that there is no relevant "elimination of competition" in this case because Healthcare at Home and other providers are not eliminated from the wider homecare services market. The effect of Genzyme's conduct is potentially to eliminate Healthcare at Home and other providers from the supply of Homecare Services to Gaucher patients. In our view, Gaucher patients, as consumers, although small in number, are fully entitled to the protection of the Chapter II prohibition, entirely dependent, as they are, on Cerezyme. In our opinion, Genzyme's "special responsibility" as a dominant firm extends to such patients, even though they constitute only a small sub-market within a wider homecare services market.

563. As Advocate General Jacobs points out in paragraphs 58, 59 and 61 of his opinion in *Bronner*, cited above, the ultimate purpose of Article 82 of the Treaty is to safeguard the interests of consumers. In our view, the same applies under the Chapter II prohibition.

The fact that patients suffering from other diseases requiring homecare services such as haemophilia or multiple sclerosis are not affected by Genzyme's actions is in our view entirely irrelevant to the analysis. As we have already found, the integrated nature of the package of homecare services required by Gaucher patients means in practice that all other suppliers of homecare/home delivery (including nursing) services are excluded from supplying Gaucher patients by virtue of the pricing policies pursued by Genzyme.

564. We also specifically reject Genzyme's argument that the only foreclosure relevant to this case relates to the minority of patients receiving nursing care, of whom only 37 are currently supplied by Healthcare at Home (see tables at paragraph 57 above). For the reasons set out at paragraphs 350 to 352 above, we think it incorrect to separate nursing from other aspects of the integrated package that constitutes homecare services. The foreclosure in this case in our view affects the entire supply of Homecare Services to Gaucher patients (see also pargraph 315 of the decision).

565. Genzyme, however, argues that this case should be seen in terms of a "refusal to supply", an allegation that Genzyme says was abandoned by the OFT at the interim measures stage, but is now being "recycled". According to Genzyme, applying the principles of *Bronner* (see paragraphs 497 to 498 above) no abuse can be established.

566. We do not regard the fact that the OFT did not proceed to take an interim measures direction against Genzyme (see paragraph 123 above) as amounting to the "abandonment" of any particular allegation against Genzyme. In this case, having not proceeded to make an interim measures direction, the OFT undertook a further investigation and, following the issue of a Rule 14 notice adopted the present decision, the scope of which is different from the earlier proposed interim measures direction. We do not see that process as the "recycling" of "abandoned" allegations.

567. As to Genzyme's contention that this case is a case of refusal to supply, the first difficulty that we have with that argument is that Genzyme has not refused to supply Healthcare at Home, but has continued to do so since May 2001. As Mr Moreland said in his fourth witness statement of 28 September 2003, "Genzyme has never refused to supply Cerezyme to other homecare service providers". Similarly, Genzyme's letters to other homecare suppliers confirm that there has been no refusal to supply: paragraph 120. We

do not therefore see this case in terms of an abusive refusal to supply, but in terms of an abusive margin squeeze.

568. Even if it were accepted that Genzyme's pricing policy on homecare services is a form of constructive refusal to supply, we do not think that the case of *Bronner* assists Genzyme.

569. First, the facts of *Bronner* are in our view a long way from the present case. In *Bronner* a smaller newspaper publisher, Oscar Bronner, claimed to be entitled, by virtue of Article 82 of the Treaty, to the use of the home delivery system of the allegedly dominant newspaper group Mediaprint. The analogy here would be if a competitor of Genzyme sought the right to use the facilities of Genzyme Homecare for the home delivery of a rival product. This case, however, presents precisely the *opposite* scenario; other homecare service providers do *not* wish to use Genzyme's system for supplying homecare services, but wish to supply homecare services independently.

570. Second *Bronner*, as we read it, turned largely on the so called "essential facilities" doctrine, which is concerned with the circumstances in which a company owning or controlling a specific facility such as, typically, a harbour, an airport, or a telecommunications network, may be obliged to allow third parties to use that facility in return for reasonable remuneration (paragraphs 494 to 495 above). As we read the judgment, the essence of the decision of the Court of Justice in *Bronner* is that there is no obligation on a dominant newspaper undertaking to make available to other newspapers a nationwide home delivery distribution network which the dominant firm has created for its own use unless it is established (i) that access to such a network is *essential* to enable other newspapers to compete in the newspaper market, and (ii) that other newspapers have *no realistic possibility* of creating an alternative system of home delivery: see paragraphs 41 to 46 of the judgment, cited in paragraph 498 above. In the present case, by contrast, a homecare services provider wishing to supply homecare services in competition with Genzyme Homecare is entirely dependent on being able to obtain supplies of Cerezyme on reasonable terms and has no alternatives available: see paragraphs 358 to 367 above.

571. Thirdly we note that in relation to *Télémarketing* and *Commercial Solvents,* the Court of Justice pointed out, at paragraph 38 of *Bronner*, that those cases involved the refusal by a

dominant undertaking to supply an undertaking with which it was in competition in a neighbouring market with goods or services which were indispensable to the rival's business, with the effect of eliminating all competition on the part of that undertaking. Applying that principle to the present case, we find that Genzyme's policy in relation to Cerezyme is likely to eliminate all competition on the part of Healthcare at Home and other homecare services providers in relation to the supply of Homecare Services to Gaucher patients. That in our judgment is sufficient to establish the abuse here in question. In particular, we see nothing in *Bronner* to suggest that the Court intended to overturn its previous decisions in *Télémarketing* and *Commercial Solvents*. Both of those cases were in our view much closer on the facts to the present case than *Bronner*, involving as they did a dominant undertaking establishing an in house operation to compete in a downstream sector while at the same time seeking to exclude from that downstream sector an existing customer of the dominant enterprise. The analogy with the present case seems to us to be rather close.

572. Fourthly, the passages from the opinion of Advocate General Jacobs on which Genzyme relies seem to us to be largely concerned with the ambit of the doctrine of essential facilities and the balance that is necessary to be struck when dealing with that issue. It does not seem to us that Advocate General Jacobs was intending to throw doubt on the Court's decisions in *Commercial Solvents* and *Télémarketing*, nor on decisions of the Commission such as *Napier Brown/British Sugar*, cited above, referred to in paragraph 44 of his opinion.

573. We note in particular that Advocate General Jacobs emphasises the importance of taking into account the interests of consumers in the downstream market, since "it is detriment to the consumer, whether direct or indirect, with which Article 82 is concerned" (paragraphs 58 and 59). Advocate General Jacobs considers that Article 82 is likely to apply where "the dominant undertaking's final product is sufficiently insulated from competition to give it market power" (paragraph 58) or where "access to a facility is a precondition for competition on a related market for goods or services for which there is a limited degree of interchangeability (paragraph 61) or where "a dominant undertaking's monopoly over a product … may lead to permanent exclusion of competition on a related market (paragraph 64) or where "the dominant undertaking has a genuine stranglehold on the related market". It seems to us that, unlike *Bronner*, those kinds of considerations apply

in the present case, where Genzyme is in a position to foreclose any competition in the supply of Homecare Services to Gaucher patients.

574. Nor do we regard the OFT's decision in *du Pont* of 9 September 2003 (see paragraph 390 above) as supporting Genzyme. That decision concerned a situation where the dominant supplier was proposing to cease production of the relevant intermediate product, unprocessed holographic photopolymer film (HPF) and to withdraw itself from the downstream market (HPF holograms for graphic arts applications) in which it was in competition with the complainant. That, in effect, was the opposite of the situations which prevailed in *Commercial Solvents* and *Télémarketing*.

575. In all the circumstances we conclude that, since May 2001 Genzyme has adopted a pricing policy which results in a margin squeeze with the effect, or potential effect, of foreclosing the supply of Homecare Services to Gaucher patients. In our view, that conduct constitutes an abuse by Genzyme of its dominant position, subject to the question of objective justification now discussed in Section E.

E. OBJECTIVE JUSTIFICATION

Issues relating to proof

576. Genzyme argues, principally on the basis of two interlocutory judgments in the Chancery Division, *Suretrack* and *Getmapping*, that it is for the OFT to show, in the decision, that Genzyme's conduct is incapable of being objectively justified, and that the OFT has failed to discharge that burden.

577. In our view, at the stage of the decision, the OFT is bound to consider the issue of objective justification, and in particular any arguments put forward by the dominant undertaking. We do not exclude the possibility that, depending on the circumstances, it may be proper for the OFT to consider the issue of objective justification on a wider basis, for example to take account of a previous decision of the Court of Justice, or where the decision in question may have wide ramifications, but that is essentially a matter for the OFT. We accept, in principle, the OFT's submission that it does not have to deal in the decision with all the possible objective justifications for a particular course of conduct

that could conceivably be, but have not been, raised by the dominant undertaking. In the first place, the facts and matters relating to objective justification are likely to lie primarily within the knowledge of the dominant undertaking. In the second place it would, in our view, be incorrect to require the OFT "to prove the negative" in respect of matters that have not even been raised before it.

578. At the stage of an appeal to the Tribunal, the dominant undertaking may raise further matters of objective justification. In our view, at that stage, the Tribunal must be satisfied that the conduct in question is not objectively justified. Leaving aside such possibilities as the Tribunal raising matters itself, it is essentially in our view for the dominant undertaking to put forward the matters that it relies on by way of objective justification, for the OFT to put forward its arguments in rebuttal, and for the Tribunal to decide whether it is satisfied that the conduct is not objectively justified. That approach, it seems to us, is in line with the decisions of the Court of Justice and the Court of First Instance cited by the OFT (see paragraph 475 above). Thus, to give but one example, in *Aeroports de Paris v. Commission*, cited above, the Court of First Instance held that, where there was a difference between fees charged by the dominant airport operator (AdP) to different service providers

> "If AdP imposes different rates of fee on those service providers, it must therefore establish the existence of objectively different situations or circumstances capable of justifying that disparity of treatment" (paragraph 202).

579. According to the Court of First Instance, that approach did not "reverse the burden of proof". It was for the Commission to establish that the relevant service providers were being charged differential fees: it was then for the airport operator to show that the difference was objectively justified: see paragraphs 200 to 203 of the judgment. See also the judgment of the Court of Justice in *Ministere Public v. Tournier*, cited above, at paragraph 38.

580. As to the interlocutory judgments in *Suretrack* and *Getmapping*, it is not for the Tribunal to express a view as to what threshold a private claimant must reach in order to obtain interim relief in the High Court in a private action based on Article 82 or the Chapter II prohibition. In our view, that is a quite different matter from the issue which the Tribunal

has to address, namely what are the OFT's obligations when taking an infringement decision under the 1998 Act, and how the Tribunal should approach the matter in an appeal under section 46, having regard to section 60 of the Act. Here the Tribunal is dealing with final relief, not interim relief. On those grounds we find that *Suretrack* and *Getmapping* are distinguishable from the present case. We also note that, in accordance with general principle, interlocutory decisions of the High Court do not, by their nature, necessarily reflect that Court's final view on an issue such as where the burden of proof would lie on a full trial of the action. In those circumstances we do not need to express a view as to any respective "hierarchy of authority" as between decisions of the Tribunal and decisions of the High Court.

581. We do not accept, therefore, that in adopting the decision the OFT has misunderstood or misapplied the burden of proof as regards objective justification.

The matters raised as objective justification

582. Genzyme argues that its policy is objectively justified because:

(i) The OFT's approach is contrary to the EU's objectives in developing orphan drugs

(ii) Genzyme's NHS list price is a price to a pharmacy, i.e. the Drug Tariff price. A price based on the Drug Tariff price is by its nature objectively justified

(iii) It is not an abuse to bring an activity "in house", or to supply the market directly rather than through intermediaries

(iv) The in-house supply of Homecare Services by Genzyme is an efficient and cost effective solution

(v) Other companies follow policies similar to Genzyme's

(vi) There is no basis for requiring Genzyme to deal with "any Tom, Dick or Harry"

(vii) Pricing issues such as the present are a matter of policy for the DoH, not for the OFT

(viii) The NHS has been kept informed throughout and has raised no objection

(ix) Healthcare at Home distributes products for Genzyme's competitor TKT

(x) Distribution by Genzyme enables Genzyme to comply with its pharmo-vigilance obligations

(xi) Any other solution would jeopardise Cerezyme's position as a zero discount drug

(xii) Genzyme acted on legal advice

General

583. We observe first that Genzyme's arguments on objective justification relate partly to various claimed benefits of its pricing policy which ultimately accrue to Genzyme. However, in our view the concept of "objective justification" does not fall to be applied in terms of benefits which accrue to the dominant undertaking, but in terms of the general interest, and particularly the interests of customers and consumers which the Chapter II prohibition is intended to protect.

584. Secondly, in this case, the evidence we have is that "homecare" for Gaucher patients forms part of the treatment for the disease, which is provided as a result of a decision by the responsible clinician, who remains responsible for the patient throughout the treatment. That is why Mr Farrell, for example, goes to great lengths to ensure that the Royal Free's homecare services provider of choice, Healthcare at Home, is in fact able to meet the quality standards the Royal Free requires (see paragraphs 326 to 333 above) see also Mr Farrell's oral evidence, Day 2 at p.57). Moreover, at the end of the day it is the NHS which must meet the cost of the treatment, including homecare services.

585. In those circumstances it seems to us that, in principle, the choice of Homecare Services provider should rest with the responsible clinicians and NHS authorities, and should not be dictated by the pricing policy followed by the monopoly manufacturer of the drug. In normal competitive conditions the clinicians/NHS would have that choice. In our view it is in principle for the responsible clinicians and the NHS, rather than Genzyme, to determine what is in the best interest of the NHS (see paragraph 361 of the decision). To the extent that Genzyme's pricing policy leads to the opposite result, depriving clinicians

and patients of choice, we have difficulty in seeing how that policy can be objectively justified.

(i) Orphan Drugs

586. The abuse here in question cannot, it seems to us, be justified by Genzyme's arguments in relation to orphan drugs. We note that the rights accorded to orphan drugs under Article 8(1) of Regulation 141/2000 (paragraph 61 above) are "without prejudice to … any other provision of Community Law". For the reasons already given, we have no reason to suppose that Article 82 would not be applicable to Genzyme's margin squeeze abuse if the necessary effect on inter State trade were established, and we see no reason why the Chapter II prohibition should not be equally applicable. We note, in particular, that the orphan drugs legislation is rightly directed to encouraging investment in the research and development of orphan drugs, but we see no compelling reason why a manufacturer such as Genzyme, who already has a monopoly on the product, should, on the basis of the orphan drugs legislation, also have a monopoly on the methods of distribution of the product, or the supply of services necessary for the home treatment of the patients concerned. Indeed, to the extent that Genzyme's pricing policy may have some inhibiting effect on the entry into the United Kingdom market of new drugs for the treatment of Gaucher disease (see section F below), there may be some negative effect on the marketing in the United Kingdom of a second orphan drug for the treatment of that disease.

(ii) The Drug Tariff price

587. As to Genzyme's argument that the list price for Cerezyme is automatically justified because it is the Drug Tariff price (see paragraph 384 of the decision), we note, in particular, that Genzyme has consistently argued that the NHS list price is a delivered price. However, in this case, Genzyme is offering to supply other homecare providers at a list price which *includes* the cost of Homecare Services, notwithstanding that in such a case (i) Genzyme itself has not incurred the cost of supplying Homecare Services, including home delivery; and (ii) those other Homecare Services providers have, in addition, to fund the cost of themselves supplying Homecare Services, including home delivery. We do not regard such a situation as in any way responding to what would

normally occur in a competitive market, nor can we see any justification for charging a delivered price where there has been no delivery to persons who, having paid a delivered price, then themselves have to undertake, at their expense, the delivery in question.

(iii) and (iv) Bringing Homecare Services "in-house"

588. Genzyme's evidence is to the effect that it set up Genzyme Homecare in order, among other reasons, to save costs and improve efficiency, to create an organisation capable of providing homecare services across a range of LSDs including Fabry disease, and to ensure that the Homecare Services provided to Gaucher patients were provided safely and efficiently, particularly from the nursing point of view: see paragraphs 101 to 105 above.

589. As we see it, there can be no objection under the 1998 Act to Genzyme setting up its own in-house operation, Genzyme Homecare, to provide Homecare Services to Gaucher patients, nor to Genzyme terminating its previous distribution agreement with Healthcare at Home. We stress in particular that this appeal is not concerned with any private disputes there may be between Genzyme and Healthcare at Home. We also accept Genzyme's sincerity in wishing to ensure a sound and safe service for Gaucher patients.

590. However, those considerations do not, in our view, entitle Genzyme to adopt a pricing policy which has as its object and effect to secure a monopoly of the supply of Homecare Services to Gaucher patients in favour of Genzyme Homecare. That, in our view, emerges clearly from *Commercial Solvents* and *Télémarketing*, cited above. In both these cases, the dominant undertaking had terminated arrangements with a previous customer (*Commercial Solvents)* or a previous distributor (*Télémarketing),* had set up its own "in-house" operation, and then sought to secure a monopoly in favour of that in-house operation in the downstream activity concerned. The Court of Justice held that that was an abuse where the effect was, as here, to eliminate all competition in respect of the downstream activity concerned, here the ancillary but separate activity of Homecare Services. We see nothing in *Bronner* which puts in doubt that approach.

591. In the present case, any other view could mean that the choice of Homecare Services provider for Gaucher patients was made by Genzyme, and not by the clinician concerned or the NHS. As we have already said (paragraph 584 above) homecare constitutes part of the treatment of the patient, and the choice of Homecare Services provider should in principle rest with the clinician/NHS. That is because the primary responsibility for the patient's care rests with the clinician, not with Genzyme, and because in normal competitive conditions the customer is entitled to choose from whom to acquire the product or service that he needs. Mr Farrell's evidence shows us that hospitals such as the Royal Free have safeguards in place so as to be able to determine the healthcare provider they wish to use, and to ensure that patient care meets the necessary standard.

592. As the decision itself states (paragraph 361) it is not for Genzyme to determine what is in the best interests of the NHS or to pre-empt the choice by the NHS of the most cost effective means of purchasing the drug, having regard perhaps to the various different possibilities mentioned by Mr Farrell at paragraphs 44 to 53 of his witness statement.

593. We also point out that in normal competitive conditions suppliers would be seeking to respond to customers' different requirements, and cost savings would be passed on to the customer. Here Genzyme has not responded to customers' wishes and any cost savings there may be accrue entirely to Genzyme and not to the customer.

594. Finally, we comment briefly on paragraph 330 of the decision where, in response to Genzyme's argument that "it is not an abuse for the supplier of a product to choose to supply it to the market directly rather than through wholesalers, distributors and third parties", the OFT said that the bundling abuse set out in the decision "is not Genzyme's decision to supply Cerezyme directly and not through Healthcare at Home or any other third party". That observation was made in the context of the bundling abuse so that, strictly speaking, we do not need to deal with it here. In so far as the OFT meant by that observation that it was not an abuse for Genzyme to set up Genzyme Homecare and itself supply Homecare Services, the OFT is in our view undoubtedly correct, and that is how we interpret paragraph 330 of the decision. Although paragraph 330 of the decision is perhaps phrased somewhat ambiguously, we do not take that paragraph to mean that it is not an abuse for Genzyme to act in a way that tends to prevent Homecare Services being supplied by third parties. That interpretation of paragraph 330 could be quite contrary to

the basic thrust of the decision, both in relation to the alleged bunding abuse (see paragraphs 301 to 307) and to the margin squeeze abuse (see paragraphs 370 to 381). We do not think therefore that any point in Genzyme's favour arises from paragraph 330 of the decision.

595. For those reasons we conclude that Genzyme's decision to bring homecare in-house, and the commercial and other considerations which led to that decision, do not constitute an objective justification for the margin squeeze abuse.

(v) Do other companies follow similar practices?

596. Genzyme, relying mainly on the evidence of Mr Derodra and Mr Moreland's witness statement of 24 September 2003, and on the *Fresenius/Caremark* report, submits that other companies have arrangements similar to Genzyme. Genzyme also strongly criticises the OFT for having failed properly to investigate this aspect of the case.

597. We observe, first, that there is no evidence before the Tribunal that any other pharmaceutical company has operated a margin squeeze of the kind here under consideration.

598. Secondly, Mr Farrell's evidence, upon which Genzyme had the opportunity to cross examine, is that in only one other case had Mr Farrell come across a pharmaceutical company which included the cost of homecare services in the cost of the drug and insisted that the Royal Free used that company's approved homecare services provider. Mr Farrell regarded such a situation as atypical and very rare (Day 2, pp. 37-38, 65).

599. Thirdly, as regards the other examples referred to by Genzyme, these do not appear to us to support Genzyme's case.

600. Those examples cover, first, various companies engaged in the supply of enteral or parenteral feeds. The first of these is a company called Nutricia, which in paragraph 2.60 of the *Fresenius/Caremark* report was reported as taking homecare services "in house". The fact that the MMC made no adverse comment on that fact is not, in our view, surprising, since Nutricia was not under investigation in that enquiry. It appears from Mr

Moreland's third witness statement that Nutricia tenders for the supply of enteral and parenteral services in the area of the local NHS Trust concerned, which suggests to us that competition in this area exists.

601. Enteral feeds are feeds where the patient is fed by a tube directly into the stomach. The companies concerned appear to be Abbott, Nutricia, Fresenius and Novartis. Mr Jones' evidence is that there are no specialist homecare companies operating in this area. However that may be, we have no evidence that any of those companies has a dominant position, nor that any such company has operated a margin squeeze, nor as what the technical requirements for the supply of enteral foods may be.

602. As regards parenteral feeds, these are feeds given to the patient intravenously. According to Mr Farrell, the Royal Free buys parenteral solutions from Pharmacia, manufactures the feeds itself, and then uses the hospital's homecare services provider. Both Baxter and Fresenius are apparently active in the supply of parenteral feeds also. Such evidence as we have suggests that parenteral feeds are not a comparable case to Cerezyme. Again, we have no evidence as to dominance, and none to suggest the operation of a margin squeeze or the exclusion of independent homecare service providers.

603. A number of companies are concerned with the supply of immunoglobin, including Alpha, Baxter and Novatis. As regards immunoglobin, Mr Farrell's evidence is that there are tendering arrangements which relate separately to the homecare service and to the supply of the drug, and that it is possible to buy the latter separately (Day 2, pp.40-41). That suggests to us that competitive market forces operate here. We also note that the *Fresenius/Caremark* report at paragraph 4.105 indicates that although at that time Alpha and Baxter had brought immunoglobin homecare services in-house, they were still prepared to supply Caremark at a discount.

604. In relation to treatments for haemophilia the views of Aventis, Baxter, Bayer, Grifols (now the owners of Alpha) and Wyeth are to the general effect that the manufacturers, although offering their own homecare services, are prepared to see their products supplied by independent homecare providers: see Mr Farrell's witness statement at paragraphs 44 to 50.

605. In the case of drugs for the treatment of multiple sclerosis, Mr Farrell's evidence is that although three suppliers, Schering, Biogen and Scorio, sell at a "bundled" price, the Royal Free has a choice of homecare provider (Day 2, p.44).

606. A practice similar to that in issue in the present case is apparently followed by Genzyme in relation to Fabrazyme, and TKT in relation to Replagal. In the case of Replagal, Healthcare at Home is the homecare services provider. Mr Jones on behalf of Healthcare at Home denies that that is an exclusive arrangement. We have no evidence on which to base a finding one way or the other of dominance in the market for the treatment of Fabry disease, but in this case the NHS would appear at least to have the choice of two competing suppliers and, at least to some extent, an independent homecare service provider.

607. None of the other examples referred to by Mr Moreland seem to us sufficiently clear to enable us to draw any relevant conclusions.

608. In summary, it appears to us that, with the possible exception of the one other company referred to by Mr Farrell (paragraph 598 above), Genzyme's position is unique in that it has both a monopoly in the supply of the upstream product, Cerezyme, and has pursued policies tending to give it, the drug manufacturer, a monopoly in the downstream supply of Homecare Services to Gaucher patients being treated with that drug..

609. Although in the examples discussed above, some manufacturers have in-house homecare operations, with that one exception no manufacturer appears to exclude independent homecare service providers in circumstances comparable to those of Cerezyme. In any event, in almost all cases there are several competing drug manufacturers.

610. As to the OFT's investigation of this aspect of the case, we accept that it would have provided useful background had the OFT more fully informed itself of the various arrangements applicable to the supply of homecare services generally to the NHS. However, we do not think the omission to do so on the part of the OFT affects the legality of the decision, given that the OFT was concerned with the practices of a specific dominant undertaking in the particular circumstances of the present case. Moreover the

Tribunal considers that it has sufficient material before it to enable the Tribunal to deal properly with the arguments advanced by Genzyme.

611. In all these circumstances, we conclude that the practices of other companies do not assist to establish an objective justification for the margin squeeze abuse here in question.

(vi) Any "Tom, Dick or Harry"

612. As already mentioned, Genzyme is already supplying Healthcare at Home on a large scale and has offered to supply Clinovia, Calea and Central Homecare. We know of no other homecare service providers who would be likely actively to seek supplies of Cerezyme. In our view the question of supplying any "Tom, Dick or Harry" simply does not arise in this case. In any event, if the NHS has approved a homecare services provider as capable and competent to provide Homecare Services to Gaucher patients, we do not think that, absent exceptional circumstances, it would be for Genzyme to oppose the choice that the customer, the NHS, had made.

(vii) and (viii). The matter is not for the OFT, but is an issue of policy for the DoH, which has not expressed dissatisfaction with Genzyme's conduct

613. We accept Genzyme's argument that whether the NHS should seek a price for Homecare Services separate from the price of the drug, whether there should be tendering, block contracting, or other purchasing arrangements, is a matter of policy to which the NHS might properly address itself. We also note that, in the period up to May 2001, the NHS was apparently content with the then arrangements. Moreover, for whatever reason, the NHS has never, in fact, sought a separate price for Homecare Services.

614. However, that said, it is the OFT's responsibility under the 1998 Act to enforce the Chapter II prohibition so as to maintain an effective competitive structure in the market. In this case there is conduct of an anti-competitive kind by a dominant undertaking, which threatens the elimination of competition in the submarket for the supply of Homecare Services to Gaucher patients. In such circumstances the OFT is, in our view, fully entitled to intervene. Similarly, in our view the DoH is entitled to refer to the OFT conduct which tends to the elimination of competition, the OFT in our view being the

appropriate body to deal with such conduct under the competition law regime now established in the United Kingdom (see also paragraph 274 above). In any event, the margin squeeze abuse with which we are here concerned relates primarily to the terms on which Genzyme is prepared to deal not with the NHS itself, but with other homecare service providers. The terms on which Genzyme deals with other homecare service providers is not in our view solely "a policy issue for the NHS", but a matter which the OFT is entitled to investigate under Chapter II of the Act.

615. As to possible acquiescence on the part of the NHS, it is true that no objection to Genzyme's policy appears to have been raised between the coming into force of the Act and May 2001. We have already taken that into account in finding that no abuse is established prior to that date. There is also no evidence that the NHS ever objected to Genzyme offering a "bundled price", but on the other hand we have not found an abuse in that regard. It also appears that NSCAG raised no objection to Genzyme bringing Homecare Services "in-house" at the meeting of 13 February 2001, on the basis of Genzyme's explanations (paragraphs 106 and 107 above). However, it appears from paragraph 15 of Ms Stallibrass' witness statement of 11 September 2003 that NSCAG did express doubts at a later meeting of 27 June 2001 when it was more fully apprised of the situation. More importantly in our view, both Professor Cox of Addenbrookes in his letter of 29 March 2001, and the Royal Free Hospital (Dr Mehta and Mr Farrell) in its letter of 18 April 2001 made it perfectly clear that they were extremely unhappy with Genzyme's proposal (paragraphs 109 to 101 above). The Royal Free and Addenbrookes are together responsible for treatment of virtually the entire adult population of Gaucher patients. In those circumstances we find it difficult to place much weight on the initial reaction of the NSCAG representatives of 13 February 2001. In our view it must have been clear to Genzyme by mid-2001 at the latest that its principal customers, the Royal Free and Addenbrookes, were opposed to the course it wished to follow.

616. On those grounds we find that Genzyme's margin squeeze abuse since May 2001 cannot be dismissed as being solely a matter of policy for the NHS, and that there is no relevant acquiescence by the NHS in relation to that abuse.

(ix) Healthcare at Home distributes products for TKT

617. At present Healthcare at Home distributes Replagal, which is a competitor to Fabryzyme in the treatment of Fabry disease. That would not, in itself, in our view be a justification for a dominant undertaking such as Genzyme refusing to supply Healthcare at Home with Cerezyme and, indeed, Genzyme has not done so. We can see no justification for Genzyme maintaining the margin squeeze abuse – which applies to all homecare services providers, not just Healthcare at Home – on the basis that one of those providers may deal with a competitor's products. Nor do we understand Genzyme's pricing policy to be based on that consideration.

618. Indeed, in our view, it is the essence of the service provided by an independent homecare services provider that such a provider should be able to deal with the products of different manufacturers, some of them competing, so that the interests of the patients are fully safeguarded under the supervision of the relevant clinician. Mr Farrell's evidence at paragraphs 44 to 50 of his witness statement is to the effect that it is not normal usage in this industry for a manufacturer to refuse to allow a homecare services provider supply a rival product. Even if there were such a usage, it does not follow that it would be applicable in the case of a dominant undertaking such as Genzyme (see paragraph 484 above). See also Mr Farrell's evidence on this point, Day 2, p.67.

(x) Pharmacovigilance obligations

619. As to Genzyme's arguments based on its pharmacovigilance obligations under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 SI 1994 no. 3144, as we understand it all pharmaceutical manufacturers have similar obligations, but that does not entitle a pharmaceutical manufacturer to eliminate all competition in the distribution of its product. More fundamentally, since March 2001 the majority of Gaucher patients at home have been serviced not by Genzyme Homecare but by Healthcare at Home, without apparent prejudice to Genzyme's pharmacovigilance obligations. Moreover, as Genzyme itself points out, it has never refused to supply other homecare service providers. In those circumstances we can see no convincing argument to justify the margin squeeze here in question on the basis of Genzyme's pharmacovigilance obligations.

(xi) Cerezyme as a zero discount drug

620. As we understand it, Cerezyme is currently designated a zero discount drug, and it would require a decision by the PPA, after consulting pharmacists' interests, to include Cerezyme in the 'discount inquiry' which determines the overall rate of clawback when reimbursing community pharmacists for drug purchases.

621. Even assuming that, in the future, Genzyme continued to maintain an NHS list price which included Homecare Services, in this case (i) the pharmacies of Genzyme Homecare and Healthcare at Home do not play the usual role of a community pharmacy in relation to Cerezyme, (ii) the position of Cerezyme is wholly atypical, (iii) any discounted price offered by Genzyme to a homecare services provider who maintained an in-house pharmacist would not represent a "profit" on the drug which the clawback is intended to prevent, but rather a margin to cover the cost of supplying homecare services. In all these circumstances we can see no proper reason for Cerezyme to be included in the discount inquiry or clawback arrangements. In any event, the majority of sales of Cerezyme, being hospital prescriptions, are not funded by the PPA and thus lie entirely outside the regime for reimbursing pharmacists.

(xii) Legal Advice

622. Genzyme has quite properly not produced any legal advice it received, and we do not know what questions were asked or what assumptions were made in the giving of any such advice. An assertion by a dominant undertaking that it took unspecified legal advice cannot in our view amount to an objective justification for conduct that is otherwise an abuse.

Conclusion on objective justification

623. In all those circumstances we find that the margin squeeze abuse operated by Genzyme between May 2001 and March 2003 is not objectively justified.

F. EFFECT ON THE UPSTREAM MARKET

624. Genzyme argues, on the basis notably of the evidence of Dr Waldek and others, and the matters summarised at paragraphs 415 to 424 above, that the OFT has not established the alleged effect of foreclosure of the upstream market alleged at paragraphs 331 to 350 and 382 of the decision

625. The foreclosure of the downstream supply of Homecare Services as a result of Genzyme's margin squeeze in our view is sufficient to establish the alleged abuse in this case. Our findings in relation to the upstream market do not therefore affect the existence of an abuse, only whether that abuse has an aggravating effect on competition in the upstream market.

626. In that regard we have already found that there are relatively high barriers to entry to the upstream market: see paragraphs 227 to 237 above. The relatively small number of Gaucher patients is itself one of the barriers to entry in the upstream market (see paragraph 229 above) as the OFT held at paragraphs 237 to 239 and 331 to 333 of the decision.

627. However, we also note, that research and development of orphan drugs, particularly in the sphere of biotechnology, takes place on a worldwide basis. Although we have no precise figures, the United Kingdom is only a small part of the world market. We think it unlikely that the current marketing arrangements for drugs for the treatment of Gaucher disease in the United Kingdom would have any significant effect on the willingness of research based pharmaceutical companies worldwide to develop new drugs for the treatment of Gaucher disease.

628. The question then is whether Genzyme's policy in relation to the supply of Homecare Services would have any inhibiting effect on the ability of another manufacturer successfully to enter the market for drugs for the treatment of Gaucher disease in the United Kingdom once a new drug had been developed.

629. There would be no such effect if, as is the case with Zavesca, any new treatment did not require home infusion, As we have already found, the only new infusion-based drug we have evidence about is GCB, the launch of which in the United Kingdom is at best some years away.

630. It seems to us unlikely in the extreme that Genzyme Homecare would be prepared to distribute a rival infusion-based product for the treatment of Gaucher disease, especially if that product were cheaper than Cerezyme or produced by Genzyme's rival TKT.

631. In our view, if a more efficacious, more convenient or cheaper infusion-based alternative to Cerezyme were to be developed in the future, there would be keen interest among the relevant consultants to use, or at least try out, any such new treatment, if only to reduce the high cost of using Cerezyme. Presumably bodies such as NSCAG and local PCTs would be interested in reducing costs where possible.

632. How far the introduction of such a new treatment would be made more difficult if Genzyme Homecare were the monopoly supplier of Homecare Services is not easy to assess or quantify.

633. In relation to infusion based drugs, it is true that, whoever the homecare provider is, a patient may be reluctant to change treatment. We can also accept that, if a change of treatment is otherwise desirable, it may be more difficult to persuade a patient to change if the change means a change of the homecare service provider as well. However, as Genzyme points out, that would apply whoever the homecare provider was.

634. We can see, however, that if homecare services are provided by an independent homecare services provider such as Healthcare at Home, it would in all probability be possible to introduce a new treatment without necessarily having to change the Homecare Services provider.

635. Professor Cox, in his witness statement of 27 June 2003 expresses the view that changing homecare provider in circumstances where he was considering switching treatment could definitely affect the choice of treatment, especially in the case of vulnerable patients requiring infusion assistance, particularly since "a very intense relationship can be built up between patients and their homecare providers". Dr Mehta, at paragraph 22 of his witness statement of 30 June 2003 also stresses that prescribing decisions have to take into account the patient's viewpoint. In Dr Mehta's view, if there is a change not just of the drug, but also of the arrangements for treatment "from the delivery driver that he or

she meets each time, to the assisting nurse with whom a relationship may have been built up and with whom the patient is content, this is not an insignificant matter". In oral evidence Mr Farrell said that if a supplier was using its own homecare company and a new product became available, there would be a difficulty unless the supplier were prepared to continue using their homecare services company to supply the competitor's drug (Day 2, p.56). This is also a matter about which the Gaucher Association expressed concern in its letter of 21 March 2001 (paragraph 109 above).

636. On the other hand, Mr Farrell also envisaged a tendering procedure in which the homecare services provider could change every other year (Day 2, p.32). Similarly, Dr Waldek and Dr Lee (specialising in Fabry disease) and Drs Vellodi and Wraith (treating children with Gaucher disease) do not, in their various statements, take the position that the introduction of a new treatment would be more difficult as a result of the need to change the homecare services provider. We take that evidence into account. We note, however, that Dr Waldek, treating sufferers of Fabry disease, in his statement of 18 October 2002, does not seem to address directly the problem of the attachment factor, nor how far that would be an obstacle to switching patients to a new treatment. The same is true of his statement of 29 July 2003. The same comment applies to the witness statement of Dr Vellodi of 21 August 2003. Dr Lee's statement is limited to a telephone conversation of 8 August 2002 and the note of the meeting with Dr Wraith on 9 July 2001 does not focus on that particular point.

637. Our conclusion on this issue is that we do not feel able to discount the views of Professor Cox and Dr Mehta. Our principal reason is that those clinicians are together responsible for treating almost all adult Gaucher sufferers in the United Kingdom. They have been involved, directly or indirectly, by the issues raised in this case from an early stage, and have addressed the present issue in their witness statements. We note also that, in its "proposal" of November 2000 Genzyme itself saw the creation of Genzyme Homecare as a strategy which "pushes out competition, by providing a shopping basket of tailor made services". In our view, it is a reasonable inference that Genzyme considered that the creation of Genzyme Homecare would make it more difficult for competitors to Cerezyme to enter the market. We also see force in the OFT's argument that if Homecare Services to Gaucher patients were supplied only by Genzyme, it would be more difficult

for clinicians even to experiment with new or complementary treatments requring homecare services.

638. On the other hand, when it comes to the clinician choosing a new infusion treatment, especially a treatment equally efficacious but significantly cheaper than Cerezyme, in our view the effect of the "attachment factor" as an additional barrier to entry is likely to relate mainly to those dependent on home nursing.

639. Our overall conclusion, on the balance of the evidence, is that if Genzyme were to succeed in monopolising the downstream supply of Homecare Services, that would probably have some adverse effect on the ability of a new treatment for Gaucher disease to establish itself in the United Kingdom over a reasonable timescale, but the additional foreclosure effect in the upstream market is unlikely to be as great as that suggested by the OFT in the decision.

G. CONCLUSION ON ABUSE

640. For the foregoing reasons we conclude that Genzyme has abused its dominant position in the period from 7 May 2001 to the end of March 2003 by, without objective justification, adopting a pricing policy following the launch of Genzyme Homecare which has resulted in a margin squeeze, with the effect of foreclosing the downstream supply of Homecare Services.

641. We find that the bundling abuse is insufficiently proved, either up to 7 May 2001 or since that date. However, the practice of bundling facilitated the margin squeeze abuse.

642. In our view it cannot be suggested that there is no abuse as regards the period from May 2001 onwards because the Tribunal has not found an abuse in the period from March 2000 to May 2001. First, we have made no positive finding that Genzyme's policy of bundling prior to May 2001 was lawful under the Chapter II prohibition. We have merely found that, on the evidence before us, the OFT has not met the necessary standard of proof to establish an abuse during that period, for the reasons set out above. Secondly, and by contrast, it is established in our view to the necessary standard of proof that Genzyme has pursued a policy likely to lead to elimination of competition in the supply

of Homecare Services from May 2001, by charging what is, in effect, a delivered price to other homecare services providers in circumstances where Genzyme had undertaken no home delivery or services, and those other providers still had themselves to bear the on-cost of home delivery and associated homecare services, thereby imposing a margin squeeze. That conduct commenced only in May 2001. Thirdly, and in contrast to the period prior to May 2001, there is clear evidence that from May 2001 Genzyme has been acting contrary to the clearly expressed wishes of its principal customers (in particular the Royal Free and Addenbrooke's Hospital), as well as its users as represented by the Gaucher Association: see paragraphs 109 to 111 above. Fourthly, whereas the alleged bundling abuse concerns Genzyme's price to the NHS, the margin squeeze abuse concerns Genzyme's pricing policy vis-à-vis its competitors, and involves, in our view, a clearcut abuse within the principles of *Télémarketing*.

IX THE OFT's INVESTIGATION

643. Finally, Genzyme has made numerous criticisms, for example in section G of its Notice of Appeal, and section C of its outline submissions in reply, of the OFT's investigation. Genzyme argues notably that the OFT has not sufficiently examined the case or assessed the evidence objectively, adopted an unacceptable position in the interim measures proceedings, and at times conducted the administrative proceedings oppressively. In the context of the appeal, says Genzyme, the OFT has not presented the matter in a balanced way, has adopted an inappropriate tone, failed to disclose e-mails between the NHS and the OFT, and sought to "shore up" its position with late witness statements.

644. In so far as these complaints go to the merits of the case against Genzyme, which most of them do, matters going to the merits have already been covered exhaustively in this judgment. As regards procedural issues, we do not think that any procedural point arises from the administrative procedure which affects the legality of the decision. In any event, before the Tribunal, Genzyme has had a full opportunity to put its case and to call or to cross-examine any witness it wished. The Tribunal is of the view that it has all the material it needs to decide the issues that have arisen, including on such matters as the practices followed in other areas where homecare is provided. The DoH e-mails, it is true, provided confirmation of the DoH's views, but did not in our view alter the tenor of

the existing witness statements. There does not seem to us any basis for suggesting that Genzyme has not had a fair hearing.

X THE DIRECTION

A. THE DIRECTION

645. The Direction is set out at paragraph 23 above. Paragraph 1 of the Direction requires Genzyme to bring to an end the infringements found at paragraph 388 of the Decision. Paragraph 2 of the Direction provides that, in relation to Homecare Services as defined in paragraph 3

> " 2.1 the price at which Genzyme supplies Cerezyme and Ceredase to the National Health Service shall be, in respect of each drug, a stand-alone price for the drug only that is exclusive of any Homecare Services that may be provided; and
>
> 2.2 the price at which Genzyme supplies Cerezyme and Ceredase to third parties shall be, in respect of each drug, no higher than the stand-alone price for the drug only as agreed between Genzyme and the Department of Health."

646. In paragraph 393 of the decision the OFT points out that in the negotiations with the DoH in 1999 the "drug element" in the price of Cerezyme was identified at £2.43 per unit. The OFT considers that £2.43 per unit is "the implied stand-alone drug only price" charged by Genzyme for the purposes of the 1999-2004 PPRS. Paragraph 394 of the decision states:

> "The price of £2.43 per unit of Cerezyme is a price agreed between the DoH and Genzyme. the OFT acknowledges that any future alteration of this price is entirely a matter for negotiation between Genzyme and the DoH".

B. THE PARTIES' ARGUMENTS

647. Without prejudice to its arguments on the substance, Genzyme strongly criticises the Direction. Genzyme repeats a number of its previous arguments to show that the Direction is wholly unjustified, would act as a disincentive to the development of orphan drugs, and would introduce an element of regulation inimical to the policy of the United Kingdom towards the pharmaceutical industry. In more concrete terms, Genzyme

submits that the figure of £2.43 per unit was never "agreed" with DoH as a "stand alone" price for the drug in 1999. The 1999 correspondence reflected simply "horse trading" negotiations in the context of the 4.5% price cut to be imposed on companies who adhered to the new PPRS then being introduced. Secondly, in any event a reduction in the NHS list price for Cerezyme would simply result in a lower price for Cerezyme. It could not be a "stand alone" price for the drug in the sense suggested by the OFT because the NHS list price already includes the cost of delivery to a location convenient to the patient, for the reasons given by Professor Yarrow and Mr Williams. The cost of nursing is borne by Genzyme and is free to the NHS. The NHS list price is not an ex-manufacturer price, and paragraph 330 of the decision shows that the OFT is not intending to create an ex-manufacturer price. Moreover, there would be no mechanism under the NHS system for reimbursing the cost of "Homecare Services" if the Direction were implemented.

648. As regards the possibility, reflected in the President's interim order of 6 May 2003 and discussed during the hearing, of Genzyme allowing a discount off the NHS list price of Cerezyme to bona fide homecare services providers, Genzyme has a number of criticisms. Genzyme criticises in particular the OFT's proposed direction, in its supplementary submissions dated 2 October 2003, in which the OFT suggested that Genzyme should make Cerezyme available to third party providers "at a price set at a sufficiently low level that it would enable a reasonably efficient provider to make a reasonable profit on the supply of Homecare Services".

649. According to Genzyme, such a direction is too vague and depends on assessments of what is "sufficiently low", "reasonably efficient", "a reasonable profit", and what is included in "Homecare Services". It is unclear who would make those assessments, on what criteria, on what evidence, and who would be involved. A single "across the board" percentage is unsatisfactory, because there is no mechanism for separating the costs of nursing and delivery, or for taking into account the fact that some patients are more expensive to service than others (because they are further away or require nursing). There should be a lower discount for "delivery only" than for "delivery and nursing" and even then margins would vary unacceptably for patients that are further away, or have different doses, or do not require nursing. Moreover it is assumed that the NHS would continue to accept

£2.975 per unit as the NHS list price for reimbursement of pharmacists and that there would be no "clawback".

650. Moreover, the OFT denied seeking such a direction at paragraph 330 of its decision, and the Tribunal in consequence has no powers to impose such a direction. The direction is so vague that it is outside the powers conferred by the 1998 Act. Separate arrangements would need to be made with PCTs across the country. No consideration has been given to the terms of which such supplies might be made, in particular as regards Genzyme's pharmacovigilance allegations. It would be unfair if Genzyme, alone of all producers of pharmaceutical products for which homecare is provided, is "required to wholesale".

651. Nor is it clear that such a solution would be better in terms of transaction costs, given that the NHS list price already covers delivery, so that the only extra cost relates to nursing. To "unbundle" in these circumstances may not achieve significant cost savings: see paragraph 4.66 of the *Fresenius/Caremark* report. Tendering procedures in this area are largely untried, and may be subject to EU rules. Moreover, a direction requiring a discount on the current list price cannot be supported by the reasoning in the decision, and was not subject to the Rule 14 procedure.

652. The OFT argues, in its defence, that it is clearly established that Homecare Services are included in the price of Cerezyme. The Direction is a requirement to "unbundle" the price of Homecare Services. That is a perfectly practicable and workable requirement, as Mr Farrell explains at paragraphs 18 to 19 and 54 to 56 of his witness statements. In the OFT's view, the Direction is sufficiently clear. It would ensure that suppliers such as Healthcare at Home were properly remunerated for supplying Homecare Services. The OFT cannot see any reason why the Direction would adversely affect the development of orphan drugs. Other drug manufacturers, according to the OFT, give the NHS the option of purchasing their drugs separately from the provision of delivery/homecare services. It was always plain, during the administrative procedure, that the OFT envisaged £2.43 as the 'stand alone' price for the drug.

653. In supplementary submissions dated 3 October 2003 the OFT accepted that one alternative direction would be to require Genzyme to sell Cerezyme to independent providers at a discount off the NHS list price.

C. THE TRIBUNAL'S FINDINGS

654. We have found that Genzyme has abused its dominant position by imposing a margin squeeze abuse in the period from May 2001 to March 2003. We have not found Genzyme's practice of "bundling" the supply of Homecare Services within the list price of Cerezyme to be an abuse in and of itself, but we have found that that practice facilitated the margin squeeze abuse in the period from May 2001 onwards.

655. In accordance with the Act, the margin squeeze must now be terminated.

656. There are two ways in which the margin squeeze abuse may be terminated. One way is by Genzyme voluntarily adjusting its arrangements in agreement with the NHS. The other way is by a direction under section 33 of the Act, made either by the OFT or the Tribunal.

657. As regards the latter possibility we accept that since we have not found that "bundling" is, in itself an abuse, the Direction set out in paragraph 396 of the decision needs to be reconsidered. Such a re-consideration is, in our view, also appropriate in the light of the examination of the issues that has now taken place before the Tribunal.

658. We also add for completeness that we are unpersuaded that it can properly be inferred from the correspondence with the DoH in 1999 that Genzyme agreed a "stand alone" price for Cerezyme of £2.43 per unit. First, that correspondence took place in the context of negotiations about the application of the rules of the PPRS to the specific case of Cerezyme. Given the comparatively slight involvement of PPRS officials with individual list prices, and the relatively superficial consideration which Dr Bratt was able to give to the matter, for quite understandable reasons (see paragraph 525 above), we do not think an "agreement" of the kind referred to in paragraph 394 of the decision can be inferred. Secondly, whatever may be implicit in the 1999 correspondence, we do not think it can be inferred that "the NHS list price" of Cerezyme was to be £2.43 per unit, because the concept of the NHS list price implies, at least in normal circumstances, a delivered price rather than an ex-manufacturer price: see paragraph 501 above. Thirdly, for the reasons given by Professor Yarrow, we can see that the concept, in paragraph 2.1 of the existing

direction that "the price at which Genzyme supplies [Cerezyme] to the National Health Service shall be "a stand alone price for the drug only that is exclusive of any Homecare Services" raises possible difficulties under the NHS system, given that where the NHS reimburses a pharmacist at a list price, that list price would in practice include an element for the cost of delivery.

659. We add that if, pursuant to the Direction, the list price to "the NHS" does not include Homecare Services, there remains the question of how Homecare Services are to be separately remunerated. Since it appears to be common ground that that aspect would have to be negotiated, it appears to us doubtful whether the Direction is sufficiently precise to be enforceable in its present form.

660. If, for those reasons, the existing Direction needs to be reconsidered, there are two procedural possibilities. The first possibility is for the Tribunal to set aside the Direction, and to remit the matter of the Direction to the OFT, pursuant to paragraph 3(2)(a) of schedule 8 of the 1998 Act (see paragraph 10 above). The second possibility is for the Tribunal itself "to give such direction … as the OFT could itself have given" under paragraph 3(2)(d) of that schedule (see also paragraph 3(2)(e)). In our view, in a case such as the present, the Tribunal would have jurisdiction under those provisions to substitute a new direction, provided that the parties had the opportunity to make representations to the Tribunal equivalent to the opportunity they would have had had the matter been remitted to the OFT.

661. In the present case, however, there is an intermediate possibility, namely to invite Genzyme and the relevant NHS representatives and, as necessary, individual homecare services providers, to see if a negotiated solution can be reached, before the Tribunal decides either to remit under paragraph 3(2)(a), or to make its own direction under paragraph 3(2)(d) of Schedule 8 of the 1998 Act.

662. The Tribunal proposes, in the first instance, to adopt that course. First we observe that in this case feelings, perhaps understandably, seem to have been running rather high, and a period of calm and reflection may help to resolve matters. Secondly, it seems to us that the issues that have arisen in this case arise partly from the complex nature of the purchasing structures applicable under the NHS. An opportunity for Genzyme to

negotiate in a sensible way with the relevant DoH purchasers – who would we imagine in the first instance be Mr Farrell and his equivalent colleagues at other hospitals – would we hope restore normal commercial relations for the first time since the rupture leading to this case occurred in May 2001. In that connection we would hope that the interests of the patients in seeing this matter resolved will be taken fully into account by all concerned. We also trust that not only Genzyme Limited, but also Genzyme Corporation, share our view that a solution to this dispute should now be found.

663. As to the parameters within which such negotiations could take place, it seems to us that such a solution could be found in three possibilities, either alone or in combination.

664. First, we have found that the practice of bundling facilitated the margin squeeze abuse, although not constituting an abuse in itself. In our view, there would be nothing to prevent Genzyme from negotiating with the relevant hospitals (and if necessary PCTs) to charge a price for Cerezyme alone, and a separate price for Homecare Services when supplied by Genzyme Homecare. The 'drug only' price, effectively equivalent to an ex-manufacturer price, would then be made available to other homecare services providers and to Genzyme Homecare on comparable terms, enabling other service providers to compete with Genzyme Homecare on an equal basis. The hospitals, if they wished, would then be able to negotiate direct with homecare service providers, including Genzyme Homecare.

665. The second possibility would be for Genzyme to continue to charge "the NHS" the existing list price for Cerezyme, but again to make available to bona fide homecare service providers the equivalent of an "ex-manufacturer" price. Such a price would take into account the fact that in relation to those supplies Genzyme would not be incurring the cost of delivery and of associated Homecare Services.

666. The third possibility would be to build on the existing hospital price (of £2.73 per unit) and simply drop (or by order of the Tribunal prohibit) the requirement imposed in Genzyme's letter to the Royal Free of 25 June 2001 to the effect that that price applies only where the patient is infused inside, as distinct from outside, the hospital. Again, in neither case is Genzyme incurring the cost of Homecare Services.

667. We do not accept that any of these three possibilities raise the difficulties which Genzyme suggests.

668. First, it is in our view primarily Genzyme's responsibility, and that of its parent company, to find the means to bring the margin squeeze abuse to an end. A direction is necessary only if Genzyme is unwilling or unable to find a solution. We find it hard to accept that Genzyme, advised as it is by a distinguished team, would be unable to find a solution if it had the will to do so.

669. Secondly, we have already dealt with paragraph 330 of the decision at paragraph 594 above. Even if, contrary to our view, the ambiguity in that paragraph could be construed in the manner suggested by Genzyme, at this stage of the proceedings it is necessary to bring the abuse to an end, and it is for Genzyme to do so. The three possibilities indicated above represent default solutions that the Tribunal may have to impose if the matter is not otherwise resolved.

670. Thirdly, although it is true that with any product some customers will be more expensive to service than others, we do not see at this stage any compelling reason for having different drug prices for different levels of Homecare Services provided by third parties. The appropriate solution and in our view the one that most nearly reflects normal competitive conditions is for negotiations to be based, as a starting point, on the average cost of providing Homecare Services. Nor do we think that the matter is affected by the Expensive Prescription Fee, which is simply an extra payment designed to compensate for delays in PPA reimbursement procedures.

671. For the reasons already given, we are unpersuaded that what is proposed is likely to be affected by the arrangements for zero discount drugs (paragraph 620 and 621 above) or by Genzyme's pharmacovigilance obligations (paragraph 619 above).

672. As to the alleged "vagueness" and "uncertainty" in what is proposed, the Tribunal accepts that, in default of agreement, it would be necessary to make a precise direction. However, the Tribunal does not accept that that would be difficult to do, given the amount of information in the material before us. We give some examples of the information that is

already to hand. Paragraph 112 of the President's judgment on interim measures of 6 May 2003 also gives examples.

673. First, the correspondence with the DoH in 1999 gives figures for the cost of homecare, which result in a figure of 54p per unit. That figure, however, includes a figure of 20p as "a contingency". Excluding that latter figure as a contingency which has not in fact arisen, the average cost of Homecare Services would be 34p, just over 11 per cent of the list price of £2.975 per unit. Subtracting this from the list price would give a price of £2.64 per unit.

674. When the contract with Healthcare at Home was terminated in 1999 the average remuneration of Healthcare at Home per patient at home under that agreement, admittedly criticised by Genzyme as over generous, was some 28.4p per unit, about 9.5 per cent of the list price. Similarly the margin allowed by Genzyme to Caremark in 1993 was of a similar order, about 10% per cent of the list price. Subtraction of 28.4p from the list price would give an ex-manufacturer price of £2.69 per unit.

675. As we understand it, the conventional wholesaler discount is 12½%, but we recognise that this may be the upper end of the "standard case", and not that involving Homecare Services.

676. The figures given in the Dixon Wilson report of 18 October 2002 also suggest that 10% of the list price would cover costs and overheads of Homecare Services.

677. The hospital price of £2.73 per unit represents a discount of about 24p, or about 8% of the list price.

678. These figures suggest that, at first sight, the matter of an ex-manufacturer price lies within a relatively narrow range.

679. In the above circumstances the Tribunal proposes to make no order at this stage as to the Direction, but to adjourn that issue for six weeks to allow negotiations to take place. Following those negotiations the matter will be restored before the Tribunal for argument

as to whether the matter of the Direction should be remitted to the OFT or decided by the Tribunal, if no agreement is reached. We trust that an agreement can be reached.

X1 THE PENALTY

A. THE PENALTY

680. At paragraphs 397 to 443 of the decision, the OFT found that Genzyme's infringements were committed intentionally or negligently within the meaning of section 36(3) of the 1998 Act and imposed a penalty of £6,809,598. The OFT's case on intent or negligence is set out at paragraphs 403 to 406 of the decision in respect of bundling and paragraphs 407 to 410 in respect of margin squeeze.

681. That penalty is calculated by a series of Steps in accordance with *The Director General of Fair Trading's Guidance as to the Appropriate Amount of a Penalty,* OFT 423, March 2000. Under Step 1, the OFT takes Genzyme's turnover in the supply of Cerezyme including Homecare Services in the financial year to 31 December 2002, namely £19,954,985, and applies a percentage of 7% to that figure, to reflect the seriousness of the infringement. That gives a "starting point" under Step 1 of £1,396,848.

682. Under Step 2, the starting point may be increased to take account of the duration of the infringement. The OFT considers that the duration is three years. For infringements lasting more than one year, OFT 423 permits the "starting point" figure to be multiplied by the number of years of the infringement. Multiplying £1,396,848 by three gives a figure of £4,190,544 under Step 2. Under Step 3, that figure may be further adjusted to reflect, in particular, the importance of deterrence. In order that the penalty should act as an effective deterrent to Genzyme, Genzyme Corporation and other undertakings, the OFT has increased the penalty under Step 3 by £2 million, to give a figure of £6,190,544.

683. Under Step 4 the figure may be further adjusted by aggravating or mitigating factors. The OFT considers that it was an aggravating factor for Genzyme to adopt its policy of margin squeeze after it was aware of the OFT's investigation. In consequence, the OFT has increased the figure under Step 4 by 10%, giving a figure of £6,809,598. The OFT does

not consider that there are any mitigating factors. In the result, the penalty is fixed at £6,809,598.

B. THE PARTIES' ARGUMENTS

684. Genzyme submits, in the alternative to its arguments on the substance, that it has not acted intentionally or negligently, so that there is no jurisdiction to impose a penalty under section 36(3) of the 1998 Act. Genzyme submits, notably, that it must be shown that Genzyme knew or ought to have known that its acts or practices "were not legitimate, amounted to abuses and were not objectively justified in the sense of being irrational". Genzyme denies awareness of its dominance and of the fact that its policies would have the effect of preventing price competition in Homecare Services. The OFT's case on intent or negligence is inadequate. In the light of the *Fresenius/Caremark* report, Genzyme could not have known that its practices were objectionable. The OFT accepted Genzyme's policy at the interim measures stage. Bundling was not raised until November 2001, and the margin squeeze abuse was first identified only in the Rule 14 notice in July 2002. Genzyme acted on legal advice in deciding not to grant Healthcare at Home a further distribution agreement.

685. In the further alternative Genzyme submits that the penalty is excessive and that there should not be any penalty in this case, even if Genzyme has committed any abuse, which is denied.

686. Genzyme submits that, as a matter of discretion, no penalty should be imposed, having regard to the benefits that flow from Genzyme's development of orphan drugs; to "unfairness and imbalance" in the administrative proceedings, and the higher legal costs therby incurred; to the abandonment of the interim measures proceedings; to Genzyme's cooperation with the OFT investigation; and to Genzyme's willingness to continue supplies to Healthcare at Home during these proceedings.

687. As regards the figure of 7% used by the OFT at Step 1, Genzyme argues that its United Kingdom turnover is £18,928,315. The OFT figure includes Ireland. Moreover, the OFT has not evaluated the different aspects of Genzyme's conduct separately, nor taken into account the approval of the MMC and DoH of its practices, nor the relative level set in

the *Napp* case, nor the benefits deriving from Genzyme's research and development. As to duration, Genzyme argues that time should not run until Genzyme could reasonably have been aware of the infringement (31 July 2002 as regards the margin squeeze), and that the two abuses should be considered separately. As to Step 3 of the OFT's calculations, Genzyme objects to the OFT taking into account the position of Genzyme Corporation, to the size of the additional penalty for deterrence, and to the fact that such a penalty will, according to Genzyme, send out an inappropriate signal. As to aggravating factors, Genzyme submits that the OFT has ignored the Tribunal's guidance at [514] of *Napp*, has wrongly treated the launch of Genzyme Homecare as an aggravating factor, especially as Genzyme had no warning that the margin squeeze could be an abuse before July 2002, and has wrongly applied the uplift for aggravating factors to both infringements. Genzyme also relies on the mitigating factors which are rejected in the decision.

688. The OFT submits that the conditions for imposing a penalty are met, that the calculations are correctly made, and that the penalty imposed is fully justified.

C. THE TRIBUNAL'S FINDINGS

Intentionally or negligently

689. In *Napp*, cited above, at [453] to [455], the Tribunal held that in order to impose a penalty, the OFT does not have to decide whether the infringement was committed intentionally *or* negligently, so long as it is satisfied that the infringement is *either* intentional or negligent. The question of whether the infringement was intentional *or* negligent goes, at most, to mitigation.

690. As to the meaning of "intentionally" or "negligently", at [456] and [457] of *Napp* the Tribunal said:

> "456. As to the meaning of "intentionally" in section 36(3), in our judgment an infringement is committed intentionally for the purposes of the Act if the undertaking must have been aware that its conduct was of such a nature as to encourage a restriction or distortion of competition: see *Musique Diffusion Français*, and *Parker Pen*, cited

> above. It is sufficient that the undertaking could not have been unaware that its conduct had the object or would have the effect of restricting competition, without it being necessary to show that the undertaking also knew that it was infringing the Chapter I or Chapter II prohibition: see *BPB Industries and British Gypsum*, cited above, at paragraph 165 of the judgment, and Case T-29/92 *SPO and Others v Commission* [1995] ECR II-289, at paragraph 356. While in some cases the undertaking's intention will be confirmed by internal documents, in our judgment, and in the absence of any evidence to the contrary, the fact that certain consequences are plainly foreseeable is an element from which the requisite intention may be inferred. If, therefore, a dominant undertaking pursues a certain policy which in fact has, or would foreseeably have, an anti-competitive effect, it may be legitimate to infer that it is acting"intentionally" for the purposes of section 36(3).
>
> 457. As to "negligently", there appears to be little discussion of this concept in the case law of the European Community. In our judgment an infringement is committed negligently for the purposes of section 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition: see *United Brands v Commission*, cited above, at paragraphs 298 to 301 of the judgment. For the purposes of the present case, however, we do not need to decide precisely where the concept of "negligently" shades into the concept of "intentionally" for the purposes of section 36(3), nor attempt an exhaustive judicial interpretation of either term.

691. The Tribunal applied those observations in *Aberdeen Journals (No. 2)*, cited above, at [484] to [486].

692. In view of Genzyme's virtual monopoly and the Tribunal's findings in section V above, we accept the OFT's findings at paragraph 401 of the decision that Genzyme could not reasonably have been unaware that it had, or would foreseeably be found to have, a dominant position for the purposes of the Chapter II prohibition.

693. We also accept the OFT's finding at paragraph 408 of the decision that:

> Genzyme knew (in the sense that it could not have been unaware) that charging the same price for Cerezyme to its competitors in the downstream market, as that charged for Cerezyme and Homecare Services to the NHS, would prevent any other potential provider of Homecare Services from viably offering such Homecare Services to the NHS."

In our view such a consequence is plainly foreseeable. Whereas Genzyme Homecare was supplying the NHS with Cerezyme at a list price that included home delivery and other homecare services, it was supplying third party homecare providers at that same price, although not incurring the cost of home delivery and other homecare services. Third party homecare providers then had to incur themselves the additional on cost of home delivery and other homecare services, even though those elements were already included in the price they had paid. In these circumstances we accept the OFT's finding at paragraph 409 of the decision that:

> "Genzyme, therefore, knew that its anti-competitive pricing policy would ensure that its only competitor, HH, would not be able to operate in the Homecare Services segment of the downstream market and that no independent delivery/homecare services provider could enter such segment. Consequently, Genzyme, the dominant supplier of drugs for the treatment of Gaucher disease, would become the only Homecare Services provider in the Homecare Services segment of the downstream market where entry is completely foreclosed".

694. Indeed, it seems to us abundantly clear that Genzyme's whole strategy was predicated on the assumption that Genzyme Homecare would in due course take over the entire supply of Homecare Services to Gaucher patients. That strategy was supported by the comments in the correspondence referred to in footnote 444 of the decision, which are to the effect that if the NHS authorities wished to continue to deal with Healthcare at Home they (the NHS authorities) would have to find the necessary additional funding: see paragraph 119 above.

695. At the very least, in our view Genzyme could not have been unaware that its margin squeeze abuse would have the effect of eliminating competition from other providers in the supply of Homecare Services.

696. It follows in our view that Genzyme committed the margin squeeze abuse intentionally, or at least negligently, for the purposes of section 36(1) of the 1998 Act. We do not accept that Genzyme's intention or negligence dates only from the Rule 14 Notice issued on 31 July 2002. In our view the potential anti-competitive consequences in the downstream supply of Homecare Services were plain from May 2001 onwards when Genzyme's margin squeeze abuse commenced. We stress that it is not "the launch of

Genzyme Homecare" which constitutes the abuse, but the margin squeeze abuse which accompanied that launch.

697. In those circumstances it is unnecessary to decide whether Genzyme Homecare must also have been aware of the potential effects in the upstream market alleged in the last sentence of paragraph 409 of the decision.

The amount of the penalty

698. In *Napp*, cited above, at [497] to [499], and again in *Aberdeen Journals (No. 2)*, cited above at [489], the Tribunal took the view that it was not bound by the OFT's guidance in OFT 423 as to the amount of the penalty, but would fix the penalty in the light of the Tribunal's own appreciation of the seriousness of the infringement.

699. In so far as it concerns the margin squeeze abuse, we share the OFT's view, set out at paragraphs 416 to 419 of the decision, that Genzyme's conduct constitutes a serious infringement of the Chapter II prohibition. That conduct was in our view intended to exclude all competition in the supply of Homecare Services and, but for the OFT's intervention, would in all probability have succeeded in doing so. We consider, for the reasons already given, that Genzyme was aware that that was the foreseeable result of its conduct, but nevertheless persisted in that conduct deliberately. The resulting situation, in which for two years no rival homecare services provider has been in a position to earn an effective margin on the supply of Homecare Services, is in our view a serious distortion of competition. So too, in our opinion, is the charging, by a monopoly supplier of a product, of a price to third parties which includes the downstream supply of ancillary services, when no such services are provided to those third parties, with the intention of making it impossible for those third parties to compete with the monopoly supplier of the product in the supply of such ancillary services. It is also clear to us that such a policy was pursued by Genzyme despite the wishes of the principal hospitals responsible, and of the Gaucher Association.

700. We acknowledge that there is some reduction in the seriousness of the infringement found by the OFT resulting from the fact that we have not found the bundling abuse proved. However, in our view the principal distortion of competition occurred by way of the

margin squeeze abuse from May 2001 onwards, that abuse also being facilitated by the bundling of the price of Cerezyme.

701. We also accept that the evidence supports a less serious effect on competition in the upstream market than the decision suggests (see paragraphs 624 to 639 above), with the result that, in our view, it is difficult to support the emphasis given to this factor in paragraphs 416 to 418 of the decision.

702. On the other hand, and despite the very small market with which this case is concered, we agree with the OFT at paragraph 418 of the decision that in assessing the seriousness of the infringement account must be taken of the fact that this case concerns a pharmaceutical product and ancillary services for the treatment of patients suffering from a potentially life threatening disease that requires treatment throughout the patient's life. (See also *Napp*, cited above, at [525]).

703. As regards duration, we accept that the result of our findings is to reduce the period of abuse from three years to two years, and that in the latter period there is one abuse rather than two abuses. Nonetheless the effect on competition was in our view more serious in the latter period.

704. In this case, as a result of the OFT's intervention, it is difficult to show that Genzyme has made a significant gain from the infringement. In the event, most Gaucher patients being treated at home have been serviced by Healthcare at Home since 2001. There is no evidence of any identifiable effect on the upstream market during the period of the infringement. It is not evident that the NHS itself has suffered significant financial loss. Any losses incurred by Healthcare at Home are a matter for such civil remedies as may be available. On the other hand, had Healthcare at Home not survived in the market, Genzyme would have succeeded in monopolising Homecare Services, and that in our view is a serious matter.

705. Moreover, in our view the OFT was right to consider the question of deterrence (paragraphs 427 to 428 of the decision). Enforcement by way of deterrent penalties is an important aspect of the 1998 Act: see *Napp* at [502] and *Aberdeen Journals (No.2)* at [492].

706. In our view, as the Tribunal stated in *Napp* at [507] to [509], the penalty is not to be fixed in terms of the 'gain' to the infringing party, but in terms of the sanction appropriate for the conduct, having regard to the need for deterrence. In this case we recognise the need to take into account a factor for deterrence, particularly given the size of Genzyme Corporation, and to dissuade other undertakings that may be contemplating similar practices. However, in the specific context of the NHS, we think that an abuse of the kind here under consideration would be less likely to occur in the future if "the NHS" itself or its constituent parts were able to develop a somewhat clearer framework for the remuneration of homecare services supplied to patients at home.

707. As regards the specific points made by Genzyme, we fully recognise Genzyme's ground breaking achievement in developing an infusion based ERT drug for the treatment of Gaucher disease, but we doubt whether that is a matter that is properly relevant in mitigation of the abuse here in question. We note, however, Mr Farrell's evidence that Genzyme's ethical standards are high (Day 2, p 59) and also Dr Vellodi's evidence that the standard of care supplied by Genzyme Homecare to children at home is excellent. We do not doubt the professionalism and dedication of those responsible for Genzyme Homecare.

708. As to paragraph 436 of the decision, where the OFT treats as an aggravating circumstance the fact that the margin squeeze abuse began at a time when Genzyme was aware of the OFT's investigation, we think that any "aggravation" there may be is to some extent counterbalanced by the facts that at that time (May 2001) the OFT had discontinued the interim measures proceedings, and that it was not until July 2002 that the Rule 14 notice was served. Genzyme did at least maintain supplies to Healthcare at Home, so a choice of homecare services provider was maintained during the period of infringement, albeit only because Healthcare at Home decided to remain in the market.

709. Taking all the above considerations into account, and taking the broad approach indicated in *Napp* at [535] and *Aberdeen Journals (No. 2)* at [489], we think it proper to reduce the penalty on Genzyme. Making a broad assessment of the seriousness of the infringement on all the material now before the Tribunal, and in light of the findings of the Tribunal set out above, we think that the appropriate penalty is £3 million.

710. We therefore fix the penalty at £3 million.

XII CONCLUSIONS AND ORDERS

711. For the above reasons the Tribunal unanimously decides:

(1) Paragraphs 293 (i) and 386(i) of the decision, which find that Genzyme's practice of including Homecare Services in the NHS list price for Cerezyme is an abuse of a dominant position contrary to the Chapter II prohibition, are set aside

(2) The last indent (ii) of paragraphs 293 and 386 of the decision, which refer to raising barriers to entry in the upstream market are to be read subject to the Tribunal's findings in paragraphs 624 to 639 above.

(3) The Direction set out in paragraph 396 of the decision is to remain suspended for a period of six weeks from the date of this judgment on the terms set out in the President's order of 6 May 2003, or until further order of the Tribunal, subject to any application that may be made by a party in case no. 1013/1/1/03(R).

(4) The parties shall, by a date not less than six weeks after this judgment to be fixed by the Registrar, file reports with the Tribunal as to the result of negotiations regarding the pricing of Cerezyme and Homecare Services: see paragraphs 661 to 679 above.

(5) The Tribunal's decision as to the Direction (including the remittal of the Direction to the OFT or the substitution of a new Direction by the Tribunal) is reserved until after the filing of the reports referred to in paragraph (4) above, and such further hearing of the parties as may be necessary.

(6) A penalty of £3 million is imposed on Genzyme Limited in substitution of the penalty set out in the decision.

Christopher Bellamy Peter Grinyer Graham Mather

Charles Dhanowa
Registrar Delivered in open court, 11 March 2004