[2003] CAT 8

IN THE COMPETITION
APPEAL TRIBUNAL

Case: 1013/1/1/03 (IR)

New Court
Carey Street
London WC2A 3BZ

6 May 2003

Sir Christopher Bellamy
(President)

GENZYME LIMITED

Applicant

-and-

THE OFFICE OF FAIR TRADING

Respondent

Supported by

HEALTHCARE AT HOME LIMITED

Intervener

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

Mr Jon Turner (instructed by the Office of Fair Trading) appeared for the Respondent

Mr Ben Tidswell (instructed by Messrs Ashurst Morris Crisp) appeared for the Intervener

JUDGMENT ON INTERIM RELIEF (Non-confidential version)

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

General background

1. This is an application by Genzyme Limited ("Genzyme") for an order under Rule 32 of the Tribunal's Rules suspending, pending the hearing of Genzyme's substantive appeal, certain directions against Genzyme made by the Director General of Fair Trading ("the Director") contained in decision no. CA 98/3/03 made on 27 March 2003 ("the Decision") under section 18 of the Competition Act 1998 ("the 1998 Act").

2. Section 18(1) of the 1998 Act provides:

> "18.-(1) Subject to section 19, any 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-
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> (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
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> (b) limiting production, markets or technical development to the prejudice of consumers;
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> (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 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 subsection (1) is referred to in this Act as "the Chapter II prohibition"."

3. In the Decision of some 123 pages the Director finds that Genzyme has abused a dominant position in the market for the supply of drugs for the treatment of Gaucher disease in the United Kingdom. The circumstances are broadly as follows.

4. Genzyme is a subsidiary of a US company Genzyme Corporation, which is a leading biotechnology company with a worldwide turnover of some US $1,300 million. Genzyme Corporation has developed a drug called Cerezyme, which it supplies to Genzyme, its United Kingdom subsidiary, at a transfer price. Genzyme's annual United Kingdom turnover in Cerezyme is around […]. Genzyme's total United Kingdom turnover is some £65 million annually.

5. Cerezyme is used for the treatment of Gaucher disease. Gaucher disease is a lysosomal storage disorder ("LSD"). LSDs are a form of metabolic disorder. Gaucher disease is a rare form of inherited enzyme deficiency disorder, which impedes sufferers' ability to degrade waste materials that accumulate in white blood cells. The symptoms associated with the most common form of the disease (known as Type 1) may include an enlarged spleen and liver, bleeding and bruising problems, bone pain, demineralization, and fractures. These symptoms may vary from mild to severe and may appear at any age and may be potentially life threatening. Since 1998 Genzyme has largely replaced an earlier drug for the treatment of Gaucher disease called Ceredase, which was also produced by Genzyme Corporation. Currently there are about 180 sufferers from Gaucher disease in the United Kingdom being treated with Cerezyme. Treatment for each patient currently costs the NHS some £100,000 a year.

6. Cerezyme is an enzyme replacement therapy ("ERT") drug. ERT involves a patient being administered replacement enzymes which degrade the stored waste materials in the white blood cells. ERT is the preferred and, according to the Decision, the only tried and effective treatment. According to the Decision (at paragraph 207) from 1991 to 3 March 2003 Genzyme was the only supplier of drugs for the treatment of Gaucher disease (initially Ceredase and from 1998 onwards, Cerezyme).

7. On 3 March 2003, another drug, Zavesca, was granted what appears to be a limited marketing authorization, for patients with mild to moderate Gaucher disease for whom ERT is not suitable (Decision, paragraph 209). There is no evidence, of which I am aware, that Zavesca is at the moment a substitute for the treatment of the 180 patients who are currently being treated by Cerezyme. For the purpose of these interim proceedings, I shall assume provisionally that Cerezyme is the only available drug for the treatment of these existing patients.

8. Cerezyme is administered through intravenous infusion (i.e. via a drip), as was its predecessor Ceredase. Originally Ceredase could only be administered in hospital but from about 1994 it became possible for Ceredase to be delivered to the patient's home and administered there. Administration is either by the patient himself who has been trained to do this, or by the parent of a child sufferer who has been so trained, or by a nurse. This possibility of self-administration obviates the need for the patient to go to hospital.

9. In the United Kingdom all patients diagnosed with Gaucher disease are referred to the Royal Free Hospital, London, or Addenbrooke's, Cambridge or, in the case of children, to Great

Ormond Street or Royal Manchester Children's Hospital. 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."

10. It appears that from 1993 to 1998 Genzyme appointed Caremark Limited ("Caremark"), a specialized provider of delivery/homecare services to sufferers from various diseases, as Genzyme's sole distributor and service provider for delivery/homecare services in the United Kingdom. At that time Ceredase was apparently sold to the NHS at £[…] per unit and Caremark received a margin (later a service fee) of 30p per unit for the home delivery/services it provided. From 1994 the price of Ceredase to the NHS went up to £3.09 per unit and Caremark's margin or service fee increased to 36p.

11. In 1998 Genzyme terminated its agreement with Caremark and entered into a new distribution agreement with Healthcare at Home Limited ("HH"), who are the intervener in these proceedings. HH is a specialist provider of delivery and home care services to patients suffering a range of diseases but who can be treated and/or cared for at home.

12. Between 1998 and 2000 HH was reimbursed by Genzyme for the services it provided according to a scale of charges linked to the service provided, plus a management fee of […] per cent and a payment for each nursing visit. Those arrangements were simplified in 2000, into two categories, for hospital and home-based patients respectively. Table 2 to paragraph 114 of the Decision states that the unit charge paid to HH by Genzyme was […]p in respect of home-based patients, plus a management fee of […] per cent. The list price of Cerezyme at that time was £3.09 per unit.

13. At that time the list price to hospitals was a concessionary price of £[…] per unit plus VAT, to reflect the fact that the hospitals would not recover the VAT when the drug was administered in hospitals. On hospital business HH received […]p per unit including the hospital discount of […]p per unit.

14. In 1999 Genzyme joined the Pharmaceutical Price Regulation Scheme ("PPRS") which is a voluntary scheme which sets a limit on the overall return a company can earn on its sales of branded products to the NHS. The PPRS does not regulate the list price of individual products, only the overall profitability of the company as a whole.

15. In 1999, however, the Department of Health ("DoH") negotiated with companies belonging to the PPRS an across-the-board reduction in list prices for branded medicines sold to the NHS of 4.5 per cent.

16. At that time Genzyme apparently wrote to the DoH by letters of 7 September 1999 and 22 March 2000 (set out in paragraphs 95 to 103 of the Decision) stating that the NHS list price for the drug (then £3.09 per unit) covered two elements – first the cost of the drug, and secondly the cost of providing home care assistance for patients who have infusions in their home environment. Genzyme argued that the across-the-board reduction of 4.5 per cent sought by the DoH should apply only to the drug element in the list price, not the service element. Genzyme put forward the following figures in the letter of 22 March 2000 under the heading "the calculation".

> "The average healthcare cost for the first nine months of 1999 was […]p. This represents the average of service levels from […]p to £[…]. As the average is near the lower end of the scale, the Genzyme management has thought it appropriate to build in a contingency of […]p to cover a likely shift of increased service levels for new patients. This gives a reduction of […]p per unit and corresponds to a reduction of the price for the 200-unit vial from £618 to £595."

17. Genzyme thus contended that the average cost of home delivery and home care services was […]p per unit and that the cost of the drug was £[…] per unit, to give the list price of £3.09 per unit. The DoH agreed that the reduction of 4.5 per cent should apply only to the 'drug' element in the list price. The new list price for Cerezyme therefore became £2.975 per unit (£[…] plus […]p for home delivery and home care services).

18. In May 2001, Genzyme terminated its agreement with HH and launched its own delivery and home care services operation, Genzyme Homecare. At that time HH's average remuneration per unit was […]p according to paragraph 114 of the Decision.

19. HH has continued to receive supplies of Cerezyme, and currently has the care of some […] patients at home. Genzyme supplies about […] to […] patients in hospital, and Genzyme Homecare looks after some […] patients at home. However, HH's supplies of Cerezyme have been obtained via the Royal Free and Addenbrooke's hospitals, but only at the full NHS list price of £2.975. This is the price which HH subsequently charges to the NHS and at which HH is reimbursed by the NHS. The consequence is that HH is continuing to provide delivery and home care services to the patients under its care but is receiving no remuneration for doing so. The arrangement with the hospitals is apparently to enable HH to avoid Genzyme's requirement that any direct supplies by Genzyme to HH must be covered by a letter of credit (in effect cash up front) rather than on normal credit terms.

20. According to paragraph 120 of the Decision:

> "HH told the Director that, in order to remain a player in the provision of delivery of Cerezyme and provision of homecare services […] in the terms set out above. Should the current position continue, […]."

21. I add however in parenthesis that in relation to prescriptions written by GPs, apparently about […] per cent of the total, HH receives from the NHS an "expensive drug" prescribing allowance of 2 per cent, apparently to compensate for delays in reimbursement through the NHS system.

22. I add also that HH has in any event had to withdraw from supplying Cerezyme to hospitals: Genzyme's concessionary price to hospitals is £[…] per unit plus VAT, but Genzyme will supply to HH only at £2.975 plus VAT. On that basis, HH cannot afford to supply hospitals at the lower hospital price of £[…]. There is some evidence that Genzyme has withdrawn the concessionary price from the Royal Free Hospital, apparently fearing that the Royal Free would pass on a margin to HH, but since it has not been investigated I do not place any reliance on that point for the purposes of this judgment.

23. On 23 March 2001, shortly before the termination of its contract with Genzyme took effect, HH made a complaint to the Director under the 1998 Act, and applied for interim measures under section 35 of that Act. On 11 June 2001 the Director decided not to grant interim measures, but instead to investigate whether there was an infringement of the Chapter II prohibition. Following further investigation, the Director issued what is known as a "Rule 14 Notice" (equivalent to a Statement of Objections) against Genzyme on 31 July 2002, to which Genzyme responded extensively. As already indicated, the Decision which is the subject of these proceedings was adopted on 27 March 2003.

24. As I have said, since 2001 HH has purchased all its supplies of Cerezyme from Addenbrooke's and the Royal Free. HH collects the stock from the hospitals and transports it to its main distribution/planning centre which is located at Burton-on-Trent. HH notifies the hospitals of the stock it requires. The Royal Free and Addenbrooke's then order from Genzyme both the stock they require for themselves and the stock HH requires.

25. Once the stock is at Burton-on-Trent, the HH pharmacy then dispenses Cerezyme against a prescription which is either a hospital prescription ([…] per cent) or community prescription ([…] per cent). There are apparently some 30 prescribing centres in addition to the Royal Free and Addenbrooke's. The 'dispensed item' is then prepared and delivered by cold chain

vehicle to HH regional centres. From there the local HH driver delivers Cerezyme to the patient's home.

26. At the patient's home a variety of services may be required. Paragraph 162 of the Decision summarises the position in this way:

> "… NHS patients fall broadly into two categories.
>
> - Patients that receive infusions of Cerezyme in hospital. Cerezyme purchased for infusion in hospitals is delivered by the delivery/homecare services provider to the hospital against a pharmacy order. In this case, the service is limited to the delivery of Cerezyme to hospitals and sales support. No patient registrations are undertaken. HH does not currently have any patients in this category. The cost of delivering Cerezyme to a hospital is covered by Cerezyme's NHS list price (see paragraphs 68 to 83 above). In this Decision, delivery of Cerezyme to hospitals and sales support will be referred to as "Wholesale" or "Wholesaling", and "Wholesaler" should be construed accordingly.
> - Patients that receive infusions of Cerezyme in their home. 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 (see paragraphs 30 to 35 above). …"

27. Paragraph 34 of the Decision says:

> "Therefore, when Cerezyme is for administration in the community, the delivery/homecare services provider delivers the Cerezyme to the patient's home and provides the homecare services. Depending on the patient, home delivery/homecare services can range from dispensing, home delivery, supply of accessories (e.g. fridges) and emergency help line only to full nursing support. The level of support needed by patients may vary over time and even self-administering patients may occasionally require some nursing support or respite care. In most cases, the delivery/homecare services provider delivers the Cerezyme to the patient's home and provides the level of care required by the particular patient. This may range from a basic stock check and waste removal service (where the patient self-infuses) to a higher level of service where training on how to infuse the drug is provided, or to an even higher level of service where the patient relies completely on the delivery/homecare services provider whose nurse routinely administers the drug. In a small number of cases, the delivery/homecare services provider delivers the Cerezyme to a patient's home, but a community nurse administers the Cerezyme and any other service required."

28. Against that background I turn to the case against Genzyme made in the Decision.

The Director's findings in the Decision

— Relevant markets and dominance

29. At paragraphs 127 to 158, and paragraphs 202 to 286 of the Decision, the Director concludes that Genzyme is dominant in the market for the supply of drugs for the treatment of Gaucher disease in the United Kingdom. That market is what the Director refers to as 'the upstream' market. The Director rejects Genzyme's contention that the relevant upstream market is the market for the research, development and supply of drugs to treat LSDs. He also rejects Genzyme's contention that it is not dominant in the market for drugs for the treatment of Gaucher disease.

30. The Director in the Decision further identifies a separate market, which he identifies as the 'downstream market'. According to the Director, the downstream market has two separate segments: (a) 'home care services', which comprises the provision of home delivery and specialized care services in the home setting for patients suffering from Gaucher disease being treated with Cerezyme; and (b) a 'wholesaling segment' which comprises the wholesale activity of the delivery of Cerezyme to hospitals. For present purposes I am mainly concerned with the 'home care services' segment of the so-called downstream market.

31. On the issue of the downstream market, Genzyme argued before the Director, that in any event there was no separate downstream market for Gaucher patients being treated with Cerezyme at home. There are a number of specialized companies providing home care services for patients at home, so that, according to Genzyme, the relevant downstream market is the supply of home care services in the United Kingdom. The Director rejects this argument on the basis, essentially, that Genzyme is in a position to determine who will supply the home care services associated with Cerezyme. The Director's position is that by virtue of its pricing policy Genzyme can prevent anyone other than Genzyme or someone approved by Genzyme from supplying home care services to Gaucher patients being treated at home with Cerezyme. Indeed that is the essence of the abuse alleged by the Director to which I come in a moment (see paragraph 287 of the Decision).

32. In that downstream market, as identified by the Director, HH is currently continuing to provide home care services to around […] patients (i.e. some […] per cent of the total) while Genzyme Homecare is supplying the balance of about […] patients. Despite the fact that HH remains in the market only at a loss, and will, in the Director's view, be forced out of the market if the status quo remains, the Director does not currently consider that Genzyme Homecare is currently dominant in the downstream market. Rather, the Director's case is that

Genzyme is abusing its dominant position in the upstream market by adopting a pricing policy for Cerezyme which prevents any delivery/home care services provider other than one appointed or reimbursed by Genzyme from providing home care services to Gaucher patients, thus effectively reserving to itself, to the exclusion of other home care service providers, the home care services in question.

— *The alleged abuse*

33. The abuse alleged by the Director is identified at paragraph 293 of the Decision:

> "The Director 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."

— *Bundling*

34. The Director's case, in essence, is that the NHS list price for Cerezyme of £2.975 includes two elements, the cost of the drug and the cost of home care services. As already mentioned, in late 1999/early 2000 Genzyme persuaded the NHS that […] per cent of the list price represented the price of the drug, whereas […] per cent of the list price represented the cost of the services. However, says the Director, because the list price of £2.975 is a "bundled" price – i.e. no separate charge is made for the drug and the home care services respectively, when the NHS pays the list price it automatically pays for both the drug and the services, whether it uses the latter or not. Thus if the NHS wished to acquire the services from anyone other than Genzyme (or an undertaking acting under contract with Genzyme) it would have to pay for home care services twice over. That means, in practice, says the Director, that the NHS is unable to acquire such services from anyone other than Genzyme – e.g. from specialist home care providers such as HH. According to the Director, the fact that HH has continued in the market at a loss depending on the outcome of the proceedings does not alter the analysis because it would not be economic for HH to continue indefinitely. The Director puts the matter as follows at paragraphs 305 to 307 of the Decision:

> "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."

35. At paragraph 308 of the Decision the Director cites evidence that the NHS wishes to have a choice of home care provider. It may I think fairly be added that the arrangements which the Royal Free Hospital and Addenbrooke's have made, whereby they are themselves prepared to acquire Cerezyme from Genzyme for onward transmission to HH, is at first sight further evidence that those hospitals wish HH to remain in the market pending the outcome of these proceedings.

36. Genzyme's main response to the Director (see paragraphs 309 to 330 of the Decision) is that the delivery of Cerezyme to the patients' home is included in the list price of the drug, but that "the list price does not include any element for home care which is supplied free of charge by Genzyme. There is therefore no price for home care to be unbundled" (paragraph 309). Genzyme further argues that the Director has fundamentally confused two separate issues: the working of the PPRS, on the one hand, and the setting of the NHS list price on the other. It was relevant, says Genzyme, to draw to the attention of the DoH in 1999 that its operating assumptions were different from those normally assumed under the PPRS. That does not, according to Genzyme, mean that the NHS list price should be interpreted as

covering anything other than the cost of the drug plus home delivery, so that homecare services are "free".

37. According to paragraph 313 of the Decision,

> "313. Genzyme also stated that it supplies "homecare" services (but not home delivery) to the NHS free of charge. In order to support this allegation, Genzyme submitted that the following matters illustrate the fact that "homecare" services are not included in the price of Cerezyme:
>
> > "First, there are a number of patients, currently […], who receive treatment in hospital (where Genzyme Homecare delivers Cerezyme to the hospital). Second, relatively few patients actually require nursing services at home. Most patients ([…]) taking Cerezyme at home administer it themselves (or in the case of children have their parents do so) so there is no nursing cost. Third, NHS community nurses look after many of those patients ([…]) that do require homecare which is paid for by the NHS budget (see volume 5 section 3.5). Fourth, the NHS is entirely free to outsource that nursing by contract to a third party other than Genzyme. Genzyme is in no position to prevent that happening. Fifth, those patients who receive Genzyme homecare treatment do so at no cost to the NHS."

38. The Director's response to this approach is summarized at paragraphs 314 to 315 of the Decision as follows:

> "314 Genzyme sets out five arguments in support of its statement that "homecare" services (but not home delivery) are provided for free. The first three arguments aim to show that there are very few patients actually receiving "nursing services" (i.e. "homecare" services). The Director considers that this argument does not support Genzyme's positon, flatly contradicting Genzyme's statement to the DoH that "Healthcare at Home provide extensive nursing support to many patients…". Even if, as Genzyme now maintains, it provides "homecare" services to a few patients, the fact that few patients receive "homecare" services can only mean that the NHS is paying for a service which is not provided in the majority of cases, although the NHS pays for it every time it purchases Cerezyme.
>
> 315. In any case, Genzyme's estimate of the number of patients receiving "homecare" services is based on patients who receive "nursing services" only, i.e. it excludes home delivery services (taking the drug to the patient's home, assisting with unpacking the product and the ancillaries, checking the stock, rotating the stock, removing all packaging and waste). When home delivery services are included as part of Homecare Services (see paragraph 172 above), the number of patients receiving Homecare Services is estimated to be […]."

39. The Director also considers that only about 20 patients receive nursing by an NHS nurse: paragraph 316 of the Decision.

40. At paragraph 331 of the Decision onwards the Director further finds that Genzyme's policy in bundling homecare services with the price of the drug also makes it difficult for competitors in the upstream market to launch a product competitive to Genzyme. Genzyme's policy, argues the Director, means that any patient who wanted to try a new drug would have to switch not only to another drug but to another service provider, which many patients would be reluctant to do.

41. Genzyme argues that this point of view is unfounded, and furthermore that its distribution policy is objectively justified as "the most cost effective, and the best option for the NHS" (paragraph 360 of the Decision).

42. Genzyme also contends 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, or other third parties" (paragraph 330 of the Decision). The Director's response to this is:

> "This is an argument that Genzyme has made throughout its Response. However, this argument has no bearing on the abuse, as set out in the Rule 14 Notice and in this Decision. The abuse, as set out in those two documents, is 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. The abuse, as set out in the Rule 14 Notice and in the Decision, is not Genzyme's decision to supply Cerezyme directly and not through HH or any other third party. In view of this, there is no need for the Director to address Genzyme's representations in this respect." (paragraph 330)

— *Margin squeeze*

43. Turning from the issue of the "bundled price", the Director also alleges that Genzyme is guilty of a "margin squeeze" against HH by supplying HH only at a price which allows HH no profit margin. The Director's case is that, since the end of the distribution arrangements in 2001, HH is competing in the 'downstream' home care services segment against Genzyme Homecare. Genzyme Homecare apparently buys Cerezyme from elsewhere in the Genzyme group at the transfer price of £[…] per unit, and resells it to the NHS at £2.975 per unit when the product is supplied for use in the community. The difference between these two figures is […]p a unit. On the other hand, says the Director, HH has to buy from Genzyme (via the hospitals) at the full list price of £2.975 per unit and operate without a margin, forcing HH to provide home care services for free if it wishes to compete with Genzyme Homecare. The Director concludes at paragraphs 377 to 378 of the Decision:

> "377. The Director therefore considers that Genzyme's pricing policy prevents independent delivery/homecare services 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.

378. Genzyme is aware that the current conditions under which it is supplying Cerezyme to HH will have the effect of forcing HH out of the Homecare Services segment of the downstream market. Genzyme has sent letters to a number of doctors responsible for Gaucher patients advising them to switch their patients to Genzyme Homecare, as HH will not be able to provide the Homecare Services at a competitive price in the long term. According to Dr Norfolk, a consultant at the Leeds Teaching Hospital, in September 2001 Genzyme indicated to him that "if we [the hospital] stayed with Healthcare at Home, the Health Authorities would have to pick up a much bigger bill, as your organisation [HH] obviously couldn't continue to subsidise the service". This statement suggests that the price charged by Genzyme to HH is intended to force HH's exit from the Homecare Services segment of the downstream market, thus reserving it to its own operation, Genzyme Homecare."

44. At paragraph 387 the Director concludes:

"Genzyme is the dominant supplier in the UK of drugs for the treatment of Gaucher disease (the upstream market). The geographic dimension of the relevant markets is the UK. Genzyme's policy that is the subject of this Decision has the effect of completely foreclosing entry into the Homecare Services segment of the downstream market, as well as raising barriers to entry into the upstream market. Ultimately, this policy restricts or will restrict the UK customer's (NHS) and consumers' (patients') choice of Homecare Services provider and is liable to delay the introduction of new competing drugs for the treatment of Gaucher disease, requiring home delivery and homecare services, in the UK. Consequently, it affects or may affect trade within the UK."

The Direction

45. At paragraphs 390 to 396 of the Decision, under the heading "Directions", the Director states:

"390. Section 33(1) of the Act provides that if the Director has made a decision that conduct infringes the Chapter II prohibition, he may give to such person or persons as he considers appropriate such directions as he considers appropriate to bring the infringement to an end.

391. Genzyme is dominant in the market for the supply of drugs for the treatment of Gaucher disease and it has abused this position in the manner set out in paragraph 386 above. Genzyme has therefore infringed the Chapter II prohibition.

392. The Director proposed in the Rule 14 Notice, to make a direction that the price at which Genzyme supplies Cerezyme to the NHS shall be a stand-alone price for the drug only, that is, exclusive of any Homecare Services that may be provided, thereby giving the NHS the option to purchase the drug alone or as part of a package including Homecare Services.

393. In 1999, in the context of a price reduction imposed by the PPRS (for the PPRS period of 1999-2004), Genzyme submitted to the DoH that the NHS list price of Cerezyme covered two elements: the drug (representing […]% of the list price of Cerezyme) and the Homecare Services (representing […]% of the list price of Cerezyme). Accordingly, following the implementation of the PPRS price reduction, the implied stand-alone drug-only price charged by Genzyme to the NHS for Cerezyme was and remains £[…] per unit for the 1999-2004 PPRS.

394. The price of £[…] per unit of Cerezyme is a price agreed between the DoH and Genzyme. The Director acknowledges that any future alteration to this price is entirely a matter for negotiation between Genzyme and the DoH.

395. The Director also proposed to make a direction that the price at which Genzyme supplies Cerezyme to third parties should not be higher than the stand-alone drug-only price as agreed between Genzyme and DoH with respect to Cerezyme.

396. The Director accordingly gives to Genzyme Limited ("Genzyme") the following direction:

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 help line, respite care and full nursing support)."

The penalty

46. At paragraphs 399 to 444 the Director finds that Genzyme has infringed the Chapter II prohibition intentionally or negligently and imposes a penalty of £6,809,598. I am not concerned with the penalty at this stage, payment of which is automatically suspended, in the event of an appeal, under section 46(4) of the 1998 Act.

47. However, the Directions set out in paragraph 396 of the Decision are not automatically suspended in the event of an appeal to the Tribunal: hence the present application.

The Enterprise Act

48. On 1 April 2003 the functions of the Director became subsumed into a new corporate body, the Office of Fair Trading, by virtue of section 2 of the Enterprise Act 2003 under S.I. no. 2003/766. ("The Office of Fair Trading" which previously existed was not a corporate body). This has no effect on these proceedings except that the respondent is the Office of Fair Trading ("the OFT") not the Director. In accordance with this change I will refer to the respondent hereafter as the OFT. Also on 1 April 2003, this Tribunal, namely the Competition Appeal Tribunal, came into existence under section 12 of the Enterprise Act and S.I. no. 2003/766, replacing its predecessor body the Competition Commission Appeal Tribunal. Again nothing turns on that save that, for the time being, the Competition Appeal Tribunal continues to operate under the Competition Commission Appeal Tribunal Rules 2000 S.I. no. 2000/261, as amended by S.I. no. 2003/767 of 1 April 2003.

Genzyme's application

49. On 3 April 2003 Genzyme lodged an application with the Tribunal seeking the suspension, pending the hearing of Genzyme's substantive appeal under section 48 of the 1998 Act, of the Directions, pursuant to Rule 32 of the Tribunal's Rules. Rule 32 provides:

> "**32.**–(1) The tribunal may make an order granting on an interim basis any remedy which the tribunal would have the power to grant in its final decision.
>
> (2) Without prejudice to the generality of the foregoing, if the tribunal considers that it is necessary as a matter of urgency for the purposes of:–
>
> (a) preventing serious, irreparable damage to a particular person or category of person, or
>
> (b) protecting the public interest
>
> the tribunal may make an order giving such directions as it considers appropriate for that purpose.
>
> (3) The tribunal may make an order:–

(a) suspending the effect of the disputed decision in whole or part; or

(b) varying any or all of the conditions or obligations attached to an exemption.

(4) The tribunal shall exercise its power under this rule taking into account all the relevant circumstances, including:–

(a) the urgency of the matter;

(b) the effect on the party making the request if the interim order is not made; and

(c) the effect on competition if the interim order is made.

(5) Any order or direction under this rule is subject to the tribunal's further order or final decision.

(6) A person shall apply for an order under this rule by sending a request for interim relief in the form required by paragraph (7) below to the Registrar.

(7) The request for interim relief shall state:–

(a) the subject matter of the proceedings;

(b) in the case of a request for an order pursuant to paragraph (2) of this rule, the circumstances giving rise to the urgency;

(c) the factual and legal grounds establishing a prima facie case for the interim order being made by the tribunal;

(d) the relief sought;

(e) if no application has been made in accordance with rule 6, in respect of the decision which is the subject of the request for interim relief, the information required by rule 6(4) above.

...

(10) If the urgency of the case so requires, the tribunal may dispense with a written request for interim relief or grant the request for interim relief before the observations of the other parties have been submitted.

(11) Unless the context otherwise requires, these rules apply to requests for interim relief."

50. Genzyme has not yet lodged its main appeal for which the deadline is 27 May 2003, pursuant to Rule 6(1) of the Tribunal's Rules.

51. In its application for interim relief Genzyme emphasises first that only very few patients receive home care services. About […] patients are currently being treated at home, of whom about […] are self-administering. Of the remaining […] patients, HH supplies nursing services to […] patients, while Genzyme Homecare supplies such services to […] patients. The remainder are looked after by community nurses supplied by the NHS.

52. Genzyme challenges the Director's definition of the relevant markets, and denies dominance, essentially on the grounds advanced during the administrative procedure. Genzyme

emphasises that Cerezyme is a so-called "ultra orphan drug" – i.e. a drug developed for a rare disease which in ordinary circumstances would never have been developed at all; the potential market is so small that most companies would not have been able to justify the return on investment. Thus, argues Genzyme, the Director's whole approach is inimical to developing new orphan drugs and to growth in the industry of biotechnology.

53. As to "abuse", Genzyme argues that HH made substantial profits out of its contract but had no expectation that it would be used as a distributor by Genzyme beyond the initial three years. HH's adverse financial situation is the result of its own misjudged commercial strategy. More fundamentally, argues Genzyme, there is no element of the NHS list price which relates to home care for patients: the list price was the cost of the drug and delivery to the hospital or the patient's home as the case may be. At paragraph 58 of its application Genzyme says:

> "The Director accuses Genzyme of committing an abuse by squeezing margins for HH and others in the "downstream" market. In fact, there is no "downstream" market as alleged by the Director and, even if there were, no margin squeeze has taken place. Genzyme has simply decided, for reasons that are clear and represent normal competitive conduct, to carry out one of its activities in-house on the expiry of the agreement under which it outsourced that activity to HH. That is simply unobjectionable vertical integration. It would be absurd to characterise that as a margin squeeze constituting an abuse. It would, in effect, place an obligation on any dominant undertaking to supply and to subsidise indefinitely any business with whom it had chosen to contract on the expiry of that contract. It would mean that an undertaking such as Genzyme would be bound to supply its erstwhile contracting partners for ever more. That would be perverse."

54. Genzyme further argues that its approach is objectively justified in the context of Genzyme's research and development in orphan drugs (as a result of Genzyme being more closely concerned with the patients) and is more cost effective. Nutricia, another pharmaceutical company, has acted similarly as appears from a report by the Monopolies and Mergers Commission (*Fresenius AG and Caremark Limited* Cm 3925, April 1998, ("the *Fresenius/Caremark* report") at paragraph 2.60, as have other companies: see paragraph 2.40 of the same report. Moreover HH undertakes distribution for another company which is a rival to Genzyme in the treatment of another LSD, Fabry's disease. Patients can be perfectly adequately protected by the mechanisms available to the DoH (see again the *Fresenius/Caremark* report, and particularly the DoH letter EL (95) 5 annexed to that report).

55. As far as the Directions are concerned, Genzyme argues in its application:

(1) that the Director's apparent intention is to impose on Genzyme a price of £[…] per unit, a reduction of […] per cent.

(2) The existing list price of £2.975 per unit is already a "stand alone" price for the drug, since Genzyme does not sell or receive remuneration for home care services. Hence there is nothing to "unbundle". In terms of the *Fresenius/Caremark* report, the home care services are "prescribed" (where the supplier is reimbursed the price of the drug) rather than "contracted" (where any services are subject to a separate contract and not covered by the price of the drug).

(3) The NHS could contract out the provision of home care services if it wished to, as EL (95) 5 indicates.

(4) The Direction is unclear. If it is intended that Genzyme should give a wholesale discount, the standard discount is 12.5 per cent off list price, which would give a list price of £[…] (i.e. the wholesaler would buy at £[…] and resell to the pharmacy at £[…]). This would reduce the "expensive prescription allowance", already mentioned, which is an extra allowance of 2 per cent which is paid to the pharmacy by the NHS to meet financing costs, from 5.95p per unit (i.e. 2 per cent of £2.975) to […]p per unit (i.e. 2 per cent of £[…]).

(5) The Direction would serve no purpose. HH is currently remunerated through the "expensive prescription allowance" of 2 per cent just mentioned, and thereby has a margin of 2 per cent. To reduce the list price would simply give HH a lower revenue from the expensive drug allowance.

(6) Genzyme already complies with paragraph 2 of the Direction since £2.975 is a stand alone price. Any attempt to enforce the Direction pending the hearing of the appeal is simply impracticable: no court would make an order under section 34 of the Act while the appeal to the Tribunal was pending.

(7) To change its commercial conduct pending the appeal would cause Genzyme numerous commercial difficulties and serious and irreparable damage. The effect on Genzyme of reducing its NHS list price from £2.975 to £[…] would be an irrecoverable loss of revenue of some £[…] per quarter, according to the witness statement of Malcolm Johnson, Genzyme's United Kingdom General Manager.

56. Genzyme therefore submits:

> "90. …
>
> (a) Genzyme has a good prospect of succeeding on appeal in having the Decision (including the penalty) and/or the Direction set aside. Genzyme's appeal is plainly "not manifestly unfounded".
>
> (b) The operation of the Direction pending the outcome of the appeal would cause Genzyme serious and irreparable damage.

(c) The suspension of the Direction pending the outcome of the appeal would not cause any, or any material, damage to competition in the United Kingdom."

57. In its application Genzyme offered, if the Directions were suspended, to continue to supply HH under the present arrangements, and to put the NHS in the same position it would have been in if the Directions had not been suspended, in the event that Genzyme's appeal is ultimately unsuccessful.

OFT's observations of 11 April 2003

58. In its observations of 11 April 2003 the OFT strongly opposed Genzyme's request for a suspension. The OFT argues:

(i) the matters presented by Genzyme in its appeal do not show that it has an arguable case for success on the merits of the appeal: hence the threshold for interim relief as set out in *Napp v DGFT* [2001] CAT 1 [2001] CompAR 1 (hereafter "*Napp*") is not met. Genzyme, says the OFT, has merely recycled its argument from the administrative procedure without dealing with the Director's detailed rebuttal of those arguments in the Decision.

(ii) Genzyme's argument that there is already a "stand alone" price for Cerezyme at the price of £2.975 which includes no element for home care services is in flat contradiction with its correspondence with the DoH in 1999 and 2000.

(iii) The Directions cannot reasonably be interpreted as permitting Genzyme to maintain £2.975 per unit as the stand alone price exclusive of any home care services that may be provided: the implied stand alone price agreed with the DoH for the period 1999 to 2004 is £[…] per unit.

(iv) The claim that there is nothing stopping the NHS from contracting out home care services has already been dealt with in the Decision: to do so would mean the NHS paying twice over.

(v) The point made about pharmaceutical wholesalers sows confusion where none exists. Even if, as a result of the lower list price for the stand alone drug, HH were to receive a lower expensive drug dispensing fee, that would be compensated for by HH's ability to charge for the provision of Homecare Services, which it is unable to do at the moment.

(vi) If an interim order is not made, it is true that Genzyme will lose money, which may be irrecoverable, but that does not constitute "serious and irreparable damage": see the

remarks of President Vesterdorf in Case T-184/01 R II *IMS Health v Commission* [2002] 4 CMLR 2.

(vii) On the other hand, if an interim order is made suspending the Directions there would be a serious adverse effect on competition, because there is a serious risk that, in such an event, HH would exit the market, putting Genzyme Homecare in a monopoly position in the "downstream" market, and making it more difficult for suppliers of new drugs to enter the "upstream" market: see also Case C-481/01 P(R) *NDC Health Corporation v IMS Health and EC Commission* (President Rodriguez Iglesias at paragraph 84).

Genzyme's observation of 15 April 2003

59. In response to those observations, Genzyme submitted observations on 15 April 2003 to the effect that (i) its appeal was not manifestly unfounded; (ii) its loss of revenue constituted "serious and irreparable damage"; (iii) HH's position was not serious, as indicated by its Annual Report dated 22 August 2002 in which the directors stated:

> "The directors remain confident in the outlook for the business and that the continuing growth in new contracts will over time offset this loss of margin irrespective of the ultimate outcome of the OFT investigation." (emphasis added)"

The first hearing on 16 April 2003

60. The matter came before me for hearing on the afternoon of 16 April 2003. On that occasion I admitted HH as an intervener, notwithstanding some opposition from Genzyme. Redacted versions of the Decision and of the documents before the Tribunal were served on HH, excluding confidential material.

61. Following argument on 16 April 2003 Genzyme offered the following undertakings if the Directions were suspended: (i) to continue to supply HH with Cerezyme at the NHS list price; (ii) to grant HH a discount of 5 per cent off that list price if HH certified that the Cerezyme was supplied in conjunction with "nursing services" defined as the use of a qualified nurse employed by HH; (iii) if Genzyme were unsuccessful in the appeal (a) to reimburse HH by a further discount of 5 per cent in respect of supplies of Cerezyme combined with "nursing services" as aforesaid and (b) to put the NHS in the same position it would have been in had the Directions not been made.

62. In order to give time for further reflection and argument, I suspended the Directions temporarily at the close of the hearing of 16 April 2003, on the basis of Genzyme's

undertakings, the matter to be restored for argument on 1 May 2003 if a consent order could not in the meantime be agreed. All further observations and evidence were to be served by 1 pm on 30 April 2003. The Directions, which would otherwise have come into force in my view on 17 April 2003 were therefore suspended on those terms and have remained so suspended up to the date of this judgment.

The interchange after 16 April 2003

63. Following the hearing on 16 April 2003, a considerable but ultimately fruitless interchange took place between the parties.

— OFT's position

64. It appears that the OFT's position was:

(i) Any discount granted by Genzyme to HH should be on the basis of all deliveries of Cerezyme not just those linked to cases where an HH nurse attended.

(ii) According to a report prepared on behalf of Genzyme by Dixon Wilson, Accountants, in October 2002, the direct cost to Genzyme of supplying home delivery/nursing services was at least […]p per unit, and allocated overheads were at least […]p per unit (making […]p altogether). As a compromise, Genzyme should give HH an interim discount of 14.5p per unit, or approximately 5 per cent off the list price of £2.975.

(iii) Those terms should apply to other third parties.

(iv) That the supply to HH should be on normal credit terms.

(v) That Genzyme should undertake to take no steps to worsen the competitive position of HH or a third party pending the appeal.

(vi) That in agreeing to reimburse the NHS it should be accepted by Genzyme that the Direction requires the list price to be reduced to the implied price of £[…] per unit.

— Genzyme's position

65. None of these points were acceptable to Genzyme. Mr Perrott, who acts as Genzyme's solicitor in this matter, in a witness statement dated 30 April 2003 (and the only statement served on time in accordance with the Tribunal's order) protested vigorously against the OFT's approach, particularly as regards the interpretation and workability of the Directions. He submits that complex negotiations with a number of primary care trusts across the United

Kingdom would be necessary before the Directions could be implemented. Furthermore, Mr Perrott contends that Genzyme's undertaking should not extend to cases where HH merely delivers Cerezyme (as distinct from providing nursing services) and that HH's costs in any event can be fully met from the 2 per cent expensive drug allowance HH receives from the NHS. According to Mr Perrott, HH's financial situation is not nearly as bad as it is painted and is due, if anything, to HH's rapid expansion rather than to the loss of the Genzyme business. Mr Perrott states that he is informed that, when Genzyme pursued the Royal Free Hospital for payment of overdue accounts, the Royal Free stated that it was still awaiting payment from HH. Mr Perrott infers that HH has no financing costs to set against the 2 per cent expensive drug prescribing fee. According to Mr Perrott, HH has now over 5,000 patients in conditions ranging from rheumatoid arthritis, MS, Gaucher disease, Fabry's disease, Cystic Fibrosis, HIV/AIDS, chemotherapy and haemophilia.

66. As far as HH costs are concerned, Mr Perrott relies on a schedule prepared by Genzyme and sent to the OFT on 17 April 2003 purporting to show HH's nursing and delivery costs.

67. As regards the OFT's reliance on the Dixon Wilson report, Mr Perrott citing paragraphs 8.3 and 8.4 of that report, states that HH's position is not comparable to that of Genzyme:

> "80 However, the reliance by the OFT on paragraphs 8.4 to 8.7 of report by Mr Michael Jarvis of Dixon Wilson [Volume A, Tab 5] is flawed because Genzyme Homecare and HH are simply not in comparable positions. The OFT have also ignored paragraph 8.3 of the report which states:-
>
> > "It is Genzyme's policy to provide a substantial support service, not only for patients who are being treated with Cerezyme (and its other LSD drugs) but also for their familes, physicians, and other healthcare providers.
> >
> > Part of this overall support service was being fulfilled by Healthcare at Home under the distribution agreement up to May 2001 remunerated by Genzyme.
> >
> > Part of this service apparently continues to be fulfilled by Healthcare at Home but no longer remunerated by Genzyme."
>
> 81 Mr Moreland has prepared a cost categorisation of the 2002 homecare budget to differentiate between the infrastructure and other costs and the incremental costs. As can be seen from this schedule, of the total "homecare costs" identified at paragraph 8.4 of the Dixon Wilson report as £[…] these are allocated as follows:-
>
> | | |
> |---|---|
> | 81.1 The homecare infrastructure | £[…] |
> | 81.2 Distribution | £[…] |
> | 81.3 Ancillaries and intermates | £[…] |
> | 81.4 Education, registry, and clinical trials | £[…] |
> | 81.5 Irish operations | £[…] |

81.6 Homecare nursing £[…]"

68. According to Genzyme, the only incremental costs which HH will continue to bear are those for home deliveries and nursing services.

HH's position

69. HH drew attention, by reference to its published accounts for the year to 31 October 2001, to a significant deterioration of its financial position and in its net assets which, said HH, represented the impact on HH of the loss of the Cerezyme distribution agreement.

70. Mr Walsh, HH's Chairman, supplied a witness statement dated 30 April 2003. Since that statement contained a great deal of highly confidential information about HH's financial situation and costs, I ordered that it should be disclosed to Genzyme on the basis of external legal advisers only. After argument and opposition from HH, I extended that protection order to include Ms Elizabeth McMorrow, a senior in-house counsel with Genzyme Corporation. Ms McMorrow is a member of the Bars of New York, Massachusetts, Washington DC and Connecticut to whose disciplinary arrangements she is subject. She has been subject to similar protective orders made by the US Courts and gave the Tribunal her personal undertaking not to disclose confidential information about HH to her lay clients.

71. Mr Walsh gave information about HH losses in the year to 31 October 2002, following HH's loss before taxation of £533,000 in the year to 31 October 2001, and also as regards HH's current net asset position. Mr Walsh contends that Genzyme's offer of a 5 per cent discount as regards patients supplied with nursing services is entirely worthless to HH and would amount to only about £[…] per month on purchases of some […] units at £2.975 per unit. Interest charges would largely swallow that amount, and the administrative burden of certification would be heavy. Mr Walsh states at paragraph 16:

> "At present, HH carries out the entire range of homecare services (indirectly for the Applicant's benefit as the Applicant rather than HH is remunerated for them) for free. These comprise a range of services including pharmaceutical care (including specialised storage and dispensing operations); an audited and guaranteed cold chain delivery function for a valuable and sensitive product; telephone based customer services; and nursing services from a 24 hour on call service to patient infusion training to regular contact to attending in person to administer Cerezyme infusions."

72. Mr Walsh gave information about HH's costs on different bases. On the absorbed cost method (where operating costs are allocated according to activity, and overheads allocated on a turnover basis) and on an opportunity cost basis. He points out that HH was earlier

receiving from Genzyme a contribution of […]p per unit which has been lost by Genzyme's actions. He states that the OFT's proposal of a margin of […]p is, however, acceptable to HH on a compromise basis, but that such a margin would be less than the opportunity cost to HH of remaining in the Cerezyme business, and also less than HH's "absorbed" costs.

73. According to Mr Walsh, if interim relief is not granted HH's continued presence in the Cerezyme home care services market would be subject to a significant risk. HH obtains supplies from the Royal Free and Addenbrooke's on 30 days credit, terms considerably worse than those previously available from Genzyme. The working capital requirement is £[…] million which places a heavy strain on the company's cash flow. HH has so far supported this situation in order to remain in the Gaucher market, but […]. Similarly, the hospitals (the Royal Free in particular) have taken the highly unusual step of agreeing themselves to supply HH with Cerezyme because they do not wish HH to leave the market. That exposes the hospitals to the credit risk that HH might default. It is uncertain whether the hospitals would be prepared to continue with this arrangement if the Directions were suspended. According to Mr Walsh's figures at Schedule 1 to his first witness statement HH's monthly costs are:

	£	
Deliveries	[…]	
Nursing	[…]	
Central costs	[…]	(allocated on the basis of turnover […]% of HH's turnover)
Interest cost of working capital investment £[…] million cash investment at 5%	[…]	
	[…]	

Further statements

74. On the morning of 1 May 2003, the day of the second hearing, the OFT produced information emanating from Sue Patey, Deputy Pharmacist at Great Ormond Street Hospital, and John Farrell, Head of Pharmacy Services at the Royal Free Hospital. These documents suggest that it would be relatively easy to implement the Directions, and also to reverse the Directions if Genzyme's appeal succeeded. Genzyme, however, reserves its position on these matters which it has not considered in detail in the time available.

75. In reply to Mr Walsh's first witness statement, Genzyme suggested that HH's figures for nursing and delivery services were overstated, and that it was not appropriate to include anything for central costs at the interim relief stage. An allocation on the basis of turnover was inappropriate: since Cerezyme was very expensive, overheads allocated to Cerezyme would be disproportionately high. An allocation of overheads on the basis of, for example, the number of deliveries affecting Cerezyme as a proportion of HH's total deliveries would reduce HH's claimed overheads of £[…] a month to approximately £[…] a month.

76. In response to a request from the Tribunal Mr Walsh served a second witness statement of 2 May. That statement sets out details of the payments made to HH – by some 30 different hospitals and NHS trusts (where the prescription had been written by the hospital) and by the Prescription Pricing Authority ("PPA") where it is a community prescription. Mr Walsh also sets out the credit arrangements which HH has with hospitals and the PPA. According to Mr Walsh, the total working capital cost of creditors who have to be paid before HH is reimbursed, stockholding, and claims for repayment of VAT, comes to £[…] million, or £[…] a month.

77. Genzyme considers this evidence does not deal properly with whether or not HH incurs financing costs on its supplies from the Royal Free Hospital. In any event, the fact that HH deals with many more funding hospitals and trusts than the OFT intimated confirms the difficulty of implementing the Directions.

The Tribunal's analysis

78. It was pointed out in *Napp* that, unlike the position with regard to a penalty, directions are not automatically suspended in the event of an appeal. At paragraphs 37 to 44 of that judgment I came to the view that applications for interim relief to suspend Directions should be dealt with by analogy with the principles applied by the Court of First Instance of the European Communities when dealing with applications for interim relief against decisions of the European Commission:

> "37. In relation to an application to suspend a decision of the relevant Director, Rule 32(4), which is set out above, requires the Tribunal to take into account "all the relevant circumstances", including (a) the urgency of the matter; (b) the effect on the applicant if the Decision is not suspended; and (c) the effect on competition if the Decision is suspended. Since a decision giving directions under Sections 32 or 33 of the Act is not automatically suspended merely by virtue of lodging an appeal, it is difficult to avoid the conclusion that "the relevant circumstances" to be taken into account under Rule 32(4) must include the question of whether the applicant has any prospect of success in the main appeal. That raises the question of how far

a tribunal hearing an application to suspend a decision pending appeal should go into the merits of the applicant's case, rather than concentrate on the "balance of convenience" in the light, notably, of Rule 32(3)(b) (effect on the applicant) and Rule 32(4)(c) (effect on competition).

38. In that connection, it is important to emphasise that a principal purpose of interim relief is to preserve the integrity of the appeal, and in particular to ensure that so far as possible, taking into account the other interests involved, the applicant does not suffer serious and irreparable damage pending the hearing of an appeal which may yet succeed. It is undesirable, and may in most cases be anyway impracticable, for the tribunal hearing an application for interim relief to go into the merits of the case any further than is strictly necessary for dealing with the application for interim relief in a way that does not pre-judge the main appeal. There may, however, be other cases where, in order to weigh "all relevant circumstances" pursuant to Rule 32(4) it may be necessary to go more fully into the merits than would otherwise be the case.

39. As to the test to be applied, I have not heard argument on that point so the present remarks are indicative only. I am inclined to the view that the principles normally applied in applications for interim injunctions or similar relief in the civil courts in such well known cases as *American Cyanamid v Ethicon* [1975] AC 396, while providing many useful and relevant analogies, are not in themselves necessarily determinative of the issues likely to arise under Rule 32(4). This is not party and party litigation. The Director is not (or so I shall assume) obliged to offer any cross-undertaking in damages. The matters arise in a specific statutory framework in which the public interest figures prominently alongside the private interests of the applicant. As a further incidental point, the principles of *American Cyanamid* are not necessarily applied in an identical fashion throughout the United Kingdom, for example on a motion for an interim interdict in Scotland: see *NWL Ltd v Woods* [1979] 1WLR 1294 at 1309 to 1310. Whatever test is applied by this Tribunal it should, so far as possible, be the same throughout the United Kingdom.

40. In my judgment the nearest analogous situation to hand is that of an application to the Court of First Instance of the European Communities for interim relief, pending an appeal to that court against a decision taken by the European Commission under Articles 81 and 82 of the EC Treaty.

41. Although Rule 32 is not identical in all relevant respects, its provisions are similar to those governing the grant of interim relief to be found in the Rules of Procedure of the Court of First Instance and of the Court of Justice of the European Communities.

42. I also have regard to Section 60 of the Act, which provides 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."

43. In those circumstances it is, in my judgment, appropriate to have regard to the decisions of the Court of First Instance, and the Court of Justice, made

in analogous circumstances, when dealing with applications for interim relief under the Act.

44. As regards the threshold test to be applied, that has been the subject of a large number of decisions including notably the order of the President of the Court of Justice of 19th July 1995 in Case 149/95P (R) *Commission of the European Communities v Atlantic Container Line AB and Others* [1995] ECR I-2165. In that case, the President of the Court of Justice said at points 26 and 27:

> "26 In that regard, it must be noted that a number of different forms of wording have been used in the case-law to define the condition relating to the establishment of a prima facie case, depending on the individual circumstances. The wording of the order under appeal, referring to pleas in law which are not, prima facie, entirely ungrounded, is identical or similar to that used on a number of occasions by this Court or its President (see, *inter alia*, Case 56/89 R *Publishers Association v Commission* [1989] ECR 1693, paragraph 31; Case 246/89 R *Commission v United Kingdom* [1989] ECR 3125, paragraph 33; Case C-195/90 R *Commission v Germany* [1990] ECR I-2715, paragraph 19; Case C-272-91 R *Commission v Italy* [1992] ECR I-457, paragraph 24; and Case C-280/93 R *Germany v Council* [1993] ECR I-3667, paragraph 21). Such a form of wording shows that, in the opinion of the judge hearing the application, the arguments put forward by the applicant cannot be dismissed at that stage in the procedure without a more detailed examination.
>
> 27 It is clear from the case-law cited above that the judge hearing an application may consider that, in the light of the circumstances of the case, such pleas in law provide prima facie justification for ordering suspension of the application of an act under Article 185 or interim measures under Article 186."
>
> The President of the Court of Justice in the *Atlantic Container* case thus upheld the approach of the President of the Court of First Instance, who had asked himself the question whether the pleas in law raised by the appellant on an application for interim relief were prima facie "relevant and not entirely ungrounded", see [1995] ECR II-595, point 49."

79. In most cases the Tribunal's approach, combined with the specific provisions of Rule 32(4), involves asking five questions:

(i) Are the arguments raised by the applicant as to the merits of its substantive appeal, at least prima facie, not entirely ungrounded, in the sense that the applicant's arguments cannot be dismissed at the interim stage of the procedure without a more detailed examination? (see *Napp*, paragraphs 44 to 46).

(ii) Is urgency established?

(iii) Is the applicant likely to suffer serious and irreparable damage if interim relief is not granted? (see *Napp*, paragraph 38)

(iv) What is the likely effect on competition, or relevant third party interests, of the grant or refusal of interim relief?

(v) What is "the balance of interests" under heads (iii) and (iv)?

80. As to the merits, it may be necessary in some cases to go some way into the merits in order to properly appraise the situation before the Tribunal (*Napp*, paragraph 38). The Tribunal is entitled, if necessary, to make a prima facie assessment of the strength or weakness of the applicant's case on the merits. As to "serious and irreparable damage" the view of the President of the Court of First Instance is that financial loss which cannot be compensated in the event of a successful appeal does not constitute serious and irreparable damage unless the survival of the undertaking is in question: see Case T-184/01R *IMS Health v Commission* [2001] ECR II-3193. As regards the likely effect on competition and third parties, the Tribunal is entitled to take into account the protection of the interests of competing undertakings where such interests cannot be separated from the maintenance of an effective competitive structure: see Case T-13/99R *Pfizer Animal Health v Council* [1999] ECR II-1961; confirmed on appeal to the Court of Justice in Case C-329/99 (P) R [1999] ECR I-8343. The Tribunal said in *Napp*, at paragraph 48:

> "Even where urgency is established and a minimalist threshold test is passed as regards the merits, balancing all the other relevant factors under Rule 32(4) may be a complex exercise. Even if an applicant for interim relief can plainly demonstrate serious and irreparable damage, it is not to be assumed that the relief will necessarily be granted if the damage to competition or third party interests would be significant. All will be depend on the circumstances."

81. I stress that the principles outlined above do no more than provide a general framework for the exercise of the Tribunal's jurisdiction under Rule 32. In my view that jurisdiction must remain flexible, ready to be adapted to the particular circumstances of the case where the interests of justice so require. I deal briefly with each issue.

Do the applicant's arguments on the substance of the appeal appear to be entirely ungrounded, so that they may be dismissed at this stage without further examination?

82. I begin by pointing out that the approach of asking whether the applicant's arguments on the merits cannot be dismissed without further examination, set out in Case 149/95P(R) *Commission v Atlantic Container Line AB and Others* [1995] ECR I-2165, has now been confirmed by the Court of First Instance in *IMS Health* cited above.

83. On the view I have formed, it is unnecessary for me to say anything in this judgment about the issues of dominance and market definition. The Decision contains a detailed analysis of

these issues, and it will be for Genzyme to rebut that analysis in the course of the main appeal. For the purposes of the present case on interim relief all I need do is note what appears to be uncontested, namely that, as of today, Genzyme appears to be, in practice, the only supplier of what is currently the only effective drug for the treatment of Gaucher disease, or at the least, the drug of choice for the 180 or so patients currently receiving treatment.

84. On the issue of abuse, the main allegation, boiled down to its essentials, is that Genzyme, the only supplier of a drug for the treatment of Gaucher disease, has adopted a pricing policy which prevents anyone except Genzyme itself or a distributor appointed by Genzyme from providing home care services (as defined in the Direction) to patients. This is achieved, so it is said, by (a) "bundling" the list price of Cerezyme, so that the drug, and the home care services, are not separately priced, the price of homecare being 'wrapped up' in the price of the drug; and (b) supplying Cerezyme only at the full list price, with the effect that any third party supplier of home care services such as HH has no margin on which to operate. The OFT aims to resolve that problem by requiring Cerezyme to be "unbundled", to a price to be agreed between Genzyme and the DoH but which is implicitly, says the OFT, the list price of £[…] which formed the basis of Genzyme's negotiations with the DoH in 1999/2000. As I understand it, the intention is that, apart from the "stand alone" list price for the drug, separate prices will be charged for the supply of the "home care" element, whether by HH or Genzyme Homecare.

85. On the substantive issue of abuse, the OFT's case is also closely argued. Conduct by a dominant undertaking on a particular market "which 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 or separate market, with the possibility of eliminating all competition for such undertaking" is an established head of abuse: Case 311/84 *Télémarketing* [1985] ECR 3261, paragraph 27. The issue of "bundling" (I use the term neutrally, for shorthand, not in any perjorative sense) is well known in competition law generally, as is the idea of a "margin squeeze". On the other hand, there has been as yet no fully developed examination of these issues, nor of the relationship, if any, between these issues and refusal to supply, in the context of the pharmaceutical industry. Certain passages from the MMC's report in 1998 in *Fresenius/Caremark* indicate that at least some other pharmaceutical companies may have followed a similar policy, and the issue of whether or not Genzyme's conduct amounts to "an abuse" is likely to be of general importance across the pharmaceutical industry. It seems to me there are issues arising on the question of abuse that are likely to require more detailed examination in the context of this case.

86. Of further practical relevance at the stage of interim relief are the mechanics of implementing the Directions as they stand pending the appeal. The Directions envisage a price being "agreed" with the DoH, the OFT's case being that £[…] is already the agreed stand alone price. While the OFT's case no doubt calls for a convincing answer on the part of Genzyme in the main appeal, the issue of precisely how and at what level, if at all, the existing list price could or should be "unbundled" and the related issue of what, if any, margin could or should be available to a third party supplier of homecare, are not, so it seems to me, issues that can safely be dismissed at this stage without a more detailed examination.

87. It follows in my view that Genzyme has surmounted the somewhat low hurdle of showing that there are issues in the case which require a more detailed examination. I stress that that conclusion does not carry any implication, one way or the other, for Genzyme's prospects of success on the main appeal. Similarly the fact that I do not feel it necessary to discuss in this judgment the issues of dominance or abuse does not imply that I have formed a view about those, or indeed any other issue, in the case. I strongly caution against any attempts "to read between the lines". The merits are a matter for the full Tribunal, once the arguments have been more fully deployed than is possible on an application for interim relief.

(ii) Is serious and irreparable damage shown?

88. Since the Directions have to be implemented within 15 days, Genzyme had to make an urgent application to the Tribunal for suspension. Whether it is urgent to grant the relief claimed is, it seems to me, an aspect of the question whether the applicant will suffer serious and irreparable damage: see the decision of President Vesterdorf in Case T-184/01R *IMS Health Inc v Commission*, [2001] ECR II-3193, 26 October 2001, at paragraph 116.

89. On the issue of "serious and irreparable damage", Genzyme's loss is, first of all, financial. If implemented in the form proposed by the Director, the loss of revenue would be approximately £[…] a month. Implementing the Direction at a list price of £[…], such a price would, apparently, bring Genzyme's list price below the transfer price charged to Genzyme by Genzyme Corporation. In *IMS Health Inc v Commission*, cited above, President Vesterdorf considered that the possibility of an undertaking being unable to recover financial losses is not generally sufficient in Community law to constitute serious and irreparable damage unless the survival of the undertaking is threatened: see paragraphs 120 to 121 of that judgment. In this case, Genzyme's survival is not threatened.

90. However, in *IMS Health* President Vesterforf also found that, on the facts of that case, the market changes imposed by the decision in question (the licensing to rivals of formatted data protected by copyright under national law) would be very difficult, if not impossible to reverse if an appeal were successful (paragraphs 128 to 129). In particular, powerful buyers, once offered a choice between competing suppliers, would not "willingly accept a forced return to a single service offered at a higher price by a monopolistic service provider" (paragraph 128).

91. It does seem to me that the implementation of the Directions prior to the hearing of the main appeal would not merely involve Genzyme in financial loss but would require a major change in its business operations. On the OFT's case, Genzyme would have to introduce a new price at £[…], and establish a separate price for homecare and invoice separately the services provided by Genzyme Homecare, apparently on the basis of agreements negotiated with various hospital trusts or other authorities. Genzyme would, it appears, have to supply third parties such as HH with Cerezyme at the new price. These changes, it seems to me, would amount to a major upheaval in Genzyme's business, in addition to the loss of revenue. While it is true that such changes could perhaps be unscrambled in the event that Genzyme were successful in the appeal, it seems to me that, once the new trading arrangements required by the Directions were in place, the NHS and its constituent parts would be likely to resist any reversion to the previous position, irrespective of the outcome of the appeal. It seems to me that I cannot exclude the risk that Genzyme might find itself in practice unable to re-establish the previous arrangements, even if it were to win the appeal.

92. In addition, in *IMS Health* the President of the Court of First Instance took into account the fact that implementation of the contested decision would restrict the applicant's freedom to define its business policy (paragraph 130: see Case T-41/96R *Bayer v Commission* [1996] ECR II-381, at paragraph 54). That is the case here, where Genzyme strongly resists the suggestion that it should have imposed upon it an "unbundled price" or grant a reasonable margin to third parties, or indeed supply Cerezyme to third parties engaged in the supply of home care services, there being, according to Genzyme, no legal basis for any of those requirements. The fact that, pending the appeal, the applicant would have substantially to modify its business policy is in my judgment a relevant factor.

93. Taking all these matters into consideration, and notably possible difficulties in re-establishing the previous position even if the appeal is successful, in my view Genzyme has further surmounted the hurdle of "serious and irreparable damage" so as to give this Tribunal

jurisdiction to suspend the Directions. How the Tribunal should exercise that jurisdiction is quite another matter, to which I now come.

(iii), (iv), and (v) The balance of interests

94. Given that the Tribunal has, as I have found, jurisdiction to suspend the Directions, whether it should do so depends on a balancing of interests, taking into account all relevant circumstances including the effect on Genzyme if no suspension is ordered, and the effect on competition if a suspension is ordered: Rule 32(4).

95. As far as Genzyme is concerned, the effect of not suspending the Direction is probably an irrecoverable loss of revenue, a substantial risk that it would prove impossible to revert to the status quo ante even if Genzyme succeeds, and the need radically to change its business policy while its appeal is pending. As far as the effect on competition if a suspension is ordered, in my judgment by far the most important issues are the effect on HH, on the patients currently served by HH, and on the Royal Free Hospital and Addenbrooke's Hospital, if a suspension is granted.

96. As far as HH is concerned, that company has been prepared so far to remain in the market, pending the outcome of the OFT investigation, although it apparently receives no margin for doing so apart from, indirectly, the expensive drug prescribing fee of 2 per cent received on GP prescriptions (apparently some […] per cent of the total). Without the arrangements already described made for HH by the Royal Free Hospital (and, I assume Addenbrooke's) it seems doubtful whether HH could have acted as it did in remaining in the market. In so acting, HH has, I am satisfied, incurred serious losses. Notwithstanding a somewhat optimistic statement by HH's directors in the Report for the year ended 31 October 2001, I am satisfied on the evidence of Mr Walsh in his first witness statement that there is a serious risk of HH exiting the market if nothing is done to protect the position in the meantime pending the outcome of the appeal.

97. In that connection, although the Tribunal will do its best to determine the appeal within its normal six months time frame, the appeal is not yet lodged and is said by Genzyme to be very wide ranging. The six-month period cannot be guaranteed and after that there may be further appeals. HH has already remained in the market on a loss-making or no-profit basis for two years, and it seems to me that its bankers and investors may well not be prepared to continue to support the company further if the Tribunal takes no action to protect HH. I bear in mind that unforeseen events and changes in economic circumstances may occur. The risk that HH

might exit the market during the period of the appeal if nothing is done seems to me to be a real one.

98. If HH were to leave the market, the result intended to be achieved by the Decision would be largely defeated. Probably for the foreseeable future, or at least a prolonged period, Genzyme/Genzyme Homecare would be left as the sole supplier of home care services to sufferers from Gaucher disease, even if the appeal were unsuccessful. In my view the concept behind "preserving the integrity of the appeal", referred to in paragraph 38 of the *Napp* judgment, applies also to preserving the integrity of the OFT's decision. The Tribunal should be prepared to intervene if not to do so would run a real risk that the decision would be without practical utility even if the appeal were unsuccessful. Just as the procedure for interim relief is there to ensure that the applicant, if successful, does not enjoy a purely Phyrric victory, so too the Tribunal should ensure that the OFT, if successful, does not lose in the meantime the competitive outcome which, in the public interest, the Decision seeks to achieve.

99. As far as the patients currently being treated by HH are concerned (some […] sufferers, all being treated at home) it seems to me highly undesirable that they should be required to suffer the risk that they might lose HH as a supplier, a circumstance which in particular cases could be upsetting and detrimental to the patient's health, and the further risk that they would in future have no option than to be supplied by Genzyme, instead of enjoying a choice of supplier as they do at the moment.

100. As far as the Royal Free Hospital and Addenbrooke's is concerned, the evidence is that those hospitals have been prepared to support HH, at cost to themselves, namely assuming the credit risk in supplying HH which Genzyme apparently declined to assume. In the case of the Royal Free, HH alleges that, as a result of supporting HH, the Royal Free no longer enjoys from Genzyme the concessionary price charged to hospitals, but that is a matter that I have not gone into. The principal consideration here, it seems to me, is that the clinicians of the specialist hospitals concerned wish to see HH remain in business as a supplier of home care services to Gaucher patients. That is a desire which, it seems to me, the Tribunal should respect and give effect to so far as possible.

101. The issue here is not whether HH as a company might become insolvent, but whether during the appeal HH might be constrained by commercial pressure to withdraw from the market for home care services for Gaucher patients which it has already been serving on an

uncommercial basis for two years. The risk that HH might be constrained to withdraw from those activities is not a risk that the Tribunal is prepared to run.

102. Balancing as best I can the different interests set out above I have come to the conclusion that the Directions should be suspended, but only on terms adequate to protect HH (and through HH the competitive structure, the patients and the interests of the hospitals) in the interim pending the hearing of the appeal.

The terms of a suspension

103. On the second day of the hearing, much discussion took place on the question of what the terms of a suspension might be. The Directions as they stand envisage a reduction in the list price and separate arrangements being made for home care services. The Tribunal is still not wholly clear what the detailed mechanics of implementing the Directions would be, but the Tribunal would, if necessary, go further into the details and use its own powers to settle the mechanics if that were necessary in order to protect competition. There is, however, another route by which the same object may be achieved, namely by Genzyme granting a discount off the list price to HH to enable the latter to earn at least some margin pending the determination of the appeal. That is the option which the parties have explored.

104. As already related, Genzyme was prepared to offer HH a discount of 5 per cent (14.9p) where nursing services were supplied, whereas the OFT and HH were, broadly, prepared to accept a discount of 5 per cent, but on the whole of HH's turnover in Cerezyme. I expressed the view that it was unsatisfactory to isolate "nursing services", because of the difficulty of identifying particular situations, problems of certification and definition, changing circumstances and so on. I understand the parties to concur with this view.

105. As I understand it, Genzyme's offer of 5 per cent on nursing services only would be, in cash terms, equivalent to a discount of […]p on all HH's purchases. At the close of the hearing Genzyme was prepared, in the light of its own figures for nursing and distribution, to offer an across-the-board discount of […]p, which on a list price of £2.975 is equivalent to a discount of […] per cent. The OFT and HH still seek a discount of […]p, equivalent to a discount of […] per cent. That is the principal issue between the parties.

Subsidiary issues

106. Four other matters were raised, namely supplies to third parties, credit terms, the wording of any order and the reimbursement of the NHS or HH if the appeal is unsuccessful. I deal with these subsidiary issues first.

107. I am not prepared at this stage to make an order regarding supplies to third parties, which seems to me to go beyond the preservation of the status quo. I have no evidence which would justify extending an order to third parties, notwithstanding the resulting "duopoly".

108. As regards credit terms, it seems to me the way to resolve the matter is for any order/undertaking to be to the effect that Genzyme will continue to supply hospitals with Cerezyme for onward supply to HH, on terms that where the drug is ordered by the hospital for onward supply to HH a discount of x per cent will apply. A solution along those lines was suggested by the OFT and avoids Genzyme's problems as regards credit terms. I appreciate that a somewhat similar situation apparently caused problems when the Royal Free apparently sought to pass some element of the concessionary price to hospitals on to HH. The Royal Free apparently refused to comply with a request from Genzyme that apparently related to patient information and the concessionary price to hospitals was withdrawn. As I see it, no patient details need be involved in the arrangement now proposed: the Royal Free would simply pass to Genzyme the order the Royal Free had received from HH for so many units of Cerezyme. HH will settle their account with the hospitals on the same terms as it does at the present and the hospitals will similarly settle with Genzyme. If there are unforeseen problems with the OFT's suggestion, the parties will need to revert to the Tribunal for further directions.

109. As regards issues on the wording of the undertaking, I see no objection to a provision whereby Genzyme will not give any third party more favourable terms than it gives HH. However, I am not persuaded of the need to include point (5) of the draft undertaking sought by the OFT which purports to prevent Genzyme from taking "measures designed to restrict the terms or conditions upon which any NHS Trust may deal with HH". Apart from the generality of this wording, I doubt that Genzyme would be so foolish as to act irresponsibly while its appeal is pending. In the event of any concerns, the remedy is an immediate application to the Tribunal by the OFT or HH for a further order.

110. Finally as regards the possible reimbursement of the NHS, or for that matter HH, I have come to the conclusion that, in the absence of agreement, I should not at this interim measures stage

make any order about reimbursement in the event that the appeal is unsuccessful. Whether the Tribunal has power to make such an order at the stage of final judgment needs in my view further argument. If Genzyme is unsuccessful, both the NHS and HH have their civil remedies, either in proceedings before the Tribunal under section 18 of the Enterprise Act (which inserts a new section 47A in the 1998 Act), which comes into force next month, or in the High Court.

Calculation of the interim discount

111. That leaves, in effect, the main outstanding issue, whether the discount to HH should be […] per cent or […] per cent or somewhere in between. My approach is to minimise the revenue foregone by Genzyme consistently with ensuring, so far as possible, that HH does not exit the market during the appeal. In my view, in interim proceedings, the Tribunal's approach must necessarily be broad brush, exercising its own judgment.

112. I start by assembling what evidence there is before the Tribunal about the margins historically enjoyed or claimed in this case. That gives the following picture:

— On 20 March 2000 Genzyme told the DoH

> "The average healthcare cost for the first nine months of 1999 was […]p. This represents the average of service levels from […]p to £[…]." Genzyme, however, thought it appropriate "to build in a contingency of […]p" to cover a likely shift of increased service levels to new patients."

The average figure of […]p represents just over […] per cent of the list price of £2.975, while the figure of […]p gives a margin for home care services of about […] per cent.

— At the time HH's agreement was terminated in 2001, HH was receiving […]p. […]p gives a margin of just under […] per cent on the list price.

— A not dissimilar margin or service fee was previously received by Caremark, i.e. initially […]p rising to […]p from 1994 (paragraphs 106 to 109 of the Decision).

— Section 8 of the Dixon Wilson report of 18 October 2002 supplied by Genzyme indicates that the "homecare" costs to Genzyme of supplying Cerezyme were […]p per unit, while allocated overheads (general management, facilities and finance) were […]p per unit, giving a total of […]p per unit. This represents about […] per cent of the list price.

— Genzyme buys Cerezyme from Genzyme Corporation at a transfer price of £[…] and resells at £2.975, giving a margin of […] per cent. This is also the margin earned by Genzyme Homecare.

— The normal wholesale margin in the pharmaceutical industry is 12.5 per cent. (A wholesaler will normally collect from the manufacturer, hold stock, and deliver to retail pharmacies or hospitals. Although this is a different operation from that at issue in the present case, elements of those operations are present here.)

113. Bearing all those factors in mind, the position we have at the moment is that margins between, broadly speaking, […] per cent and […] per cent have been earned in recent times by the relevant suppliers of homecare services or similar providers, while Genzyme has, in effect, claimed that a reasonable margin would be around […] per cent.

114. In those circumstances, for the purposes of interim proceedings it seems to me that an interim margin of 14.5p (5 per cent) as contended for by the OFT is not unreasonable, representing as it does no more than half any previous margin earned in this sector, less than the margin apparently earned by Genzyme Homecare, and less than a third of the margin claimed by Genzyme as a reasonable margin in its negotiations with the DoH in 2000.

115. Against that background, I reject Genzyme's initial argument that any margin should be restricted to nursing services: in my view it should cover "Homecare services" as defined at paragraph 396 of the Decision. If there is to be a margin at all, which in my view there should be, it should be a margin earned on HH's homecare business as a whole. Genzyme, as I understand it, now accepts that any margin should cover distribution as well as nursing, but still contends that those costs would be adequately covered by a margin of […] per cent. Genzyme, however, resists the suggestion that a margin should contribute to HH's overheads.

116. I accept that, on an incremental cost basis, a margin of […] per cent or just over would appear to be sufficient to cover HH's nursing and distribution costs, which appear to be […] Genzyme's costs, although it is not clear whether HH's costs include certain items such as ancillaries.

117. However, taking a broad view, having regard to margins historically earned, or normal in this industry, I do not regard a minimal margin of […] per cent as in itself sufficient to ensure that HH, already in a relatively weakened state, would remain in the market during the appeal. Nor do I accept that HH's bankers or investors would regard as adequate a margin of about […] or less of what has been earned historically, also bearing in mind what could be earned by putting the funds in question to other uses.

118. In this context the real difference, however, between the parties relates to the treatment of overheads. Genzyme submits that no overheads should be allowed at the interim stage. The OFT submits that the direct costs attributed to homecare in the Dixon Wilson report should be included in the calculation. According to Mr Perrott's witness statement, paragraph 81.1, costs of some £[…] per annum, (i.e. in round figures about £[…] per month) are attributed to "the homecare infrastructure" of Genzyme. Those costs, says the OFT, should be included.

119. On HH's average sales of […] units a month at £2.975 (Mr Walsh's first witness statement at paragraph 11), HH's average revenue is about £[…] a month. If HH's costs of "the homecare infrastructure" were approximately the same as Genzyme's, a monthly cost of £[…] would represent, by my calculations, about […] per cent of revenue. Added to the sums for nursing and distribution, that would give a figure of […] per cent.

120. HH has estimated its overheads on Cerezyme at a higher figure, £[…] a month, on the basis of allocation of turnover, without giving further details. For the purposes of interim relief, it seems more realistic to take into account Genzyme's more specific directly allocated infrastructure costs at least as a starting point.

121. In my judgment, no business can survive for long unless it is in a position to make some contribution towards covering at least the overhead costs directly associated with that business. I emphasise "contribution" because we are not here considering any margin above total costs, i.e. "profit". I note that Genzyme's figure for "homecare infrastructure" relates to the overhead costs directly related to the Cerezyme business, and does not include any contribution to group overheads such as central services and finance charges.

122. In my judgment to remain in the market HH is bound to incur infrastructure costs relating to the supply of Cerezyme, including the cost of management, the cost of backup services and advice such as an emergency service, and other costs relating to warehousing, premises, specialist pharmacy staff and so on. In my judgment as a matter of business reality, any interim margin allowed to HH should include an element for such infrastructure costs, notwithstanding Genzyme's argument to the contrary.

123. Before coming to a specific figure for such infrastructure costs, I deal first with finance costs, which are a specific aspect of overheads. HH estimates its interest costs at £[…] per month on the basis of a working capital need for this business of £[…] million. On the evidence I have from Mr Walsh, and despite Genzyme's doubts as to whether HH really does have to pay the hospitals before it has been reimbursed by the NHS, and doing such cross checks as I

can, the figure for interest costs given by Mr Walsh (including the cost of stockholding etc) does not seem to me to be without foundation. The resulting cost of finance, expressed as a percentage of average monthly revenue, would be around […] per cent of revenue on my calculations.

124. However, one complicating factor is the 2 per cent expensive drug prescribing fee received by HH on prescriptions for Cerezyme written by GPs (see Mr Walsh's first statement at paragraph 14). On a crude calculation (£[…] x […]% = £[…]; £[…] x 2% = £[…]) these fees paid by the NHS would seem to give HH a revenue of some £[…] per month, or approximately […] per cent of revenue. Unless my understanding is incorrect, that source of revenue roughly equates to the finance cost to HH, on HH's figures.

125. I have considered whether, for the purposes of interim relief, I should take into account this source of revenue and I have decided that I should do so. I understand HH's argument that it used to receive this fee in addition to the […]p per unit it was being paid by Genzyme, at a time when Genzyme's credit terms were much less strict. It is also somewhat untidy to take this element into account, in that this revenue comes from the NHS whereas what I am considering is the reasonableness of an interim margin as between HH and Genzyme. Nonetheless, looking at the matter from the perspective of the minimum justifiable interim margin required by HH to ensure its survival, in my judgment the income from the expensive drug prescription fees falls to be taken into account. In the result, and not without some hesitation, I make no allowance for finance charges in the interim margin calculation as between Genzyme and HH.

126. I revert, therefore to the question of overhead allocation. HH's information on overheads is extremely scanty, and an allocation based on turnover may be overstated, as Genzyme submits because Cerezyme is apparently more expensive than other drugs. It may be that HH's costs of infrastructure are less than Genzyme's. In any event, in my view, I should be cautious about relying on detailed figures yet untested, at an interim stage of the proceedings: a broadly based approach is required.

127. In the circumstances it seems to me reasonable at this interim stage, and in the absence of firm information from HH, to reduce Genzyme's figures by approximately […] for infrastructure costs, which is equivalent to reducing HH's estimate of its overheads by about 45 per cent. The result is to allow about £[…] per month or about […] per cent of revenue for overheads and infrastructure costs relating to Cerezyme.

128. That, coupled with the cost of distribution and nursing, and making some allowance for other items such as ancillaries which may have been overlooked, gives an overall margin of approximately […] per cent, but allows nothing for finance charges for the reason I have given. The resulting interim margin for HH is approximately £[…] a month (in broad terms £[…] for nursing and distribution, £[…] for Cerezyme related overheads). That figure allows nothing for finance charges, nothing for Group overheads and nothing for profit or return on investment. It is not, in my view a generous margin, nor does it prejudge in any way the longer term outcome of these proceedings. It is simply a temporary holding operation.

129. In adopting what I regard as a minimalist approach I have been conscious of the fact that neither the Director nor the Tribunal has, in my view, any power to order a cross undertaking from HH. It is true that in one old case *NCB/National Smokeless Fuels/NCC* OJ 1976 L36/6, [1976] 1 CMLR D82 the European Commission did grant interim relief on the basis of a cross undertaking, but that approach has not been followed since, either by the Commission, the Court of First Instance or the Court of Justice. The 1998 Act does not seem to me to confer any statutory power to obtain a cross undertaking in these proceedings.

130. I would myself doubt whether any such obligation could arise as regards the OFT in the enforcement of its public duties in the context of an appeal to the Tribunal. This is not party and party litigation. The issue is a public one, the maintenance of competition. HH's interests are not being protected for their own sake, but only as part of a wider exercise to preserve competition, and safeguard the patients. There are many circumstances in which the actions of public authorities in enforcing the law may cause loss of one kind or another that turns out to be irrecoverable even if the applicant is successful in the end, but that is not a reason for refusing interim relief, as President Vesterdorf said in *IMS Health* already cited. In my view, however, the absence of financial redress on the part of Genzyme if its appeal were successful, is an important factor which makes it incumbent on the Tribunal to act in a way that strikes the balance on as minimal a basis as possible. That is what I have sought to do.

131. There remains finally the question of the date from which any such suspension shall take effect. The Directions are at present suspended on Genzyme's earlier undertaking given on 17 April. In my view the Directions should be suspended as from 17 April 2003 on the basis that all sales on or after that date of supplies of Cerezyme destined for HH will bear a discount of […] per cent of the list price.

132. Nothing in this judgment is intended to prejudge the application of the Chapter II prohibition as from 1 March 2000, nor to prevent the Directions, in their present, or any modified, form from ultimately taking effect from 17 April 2003 in the event that Genzyme's appeal is unsuccessful.

133. The Directions will therefore be suspended in the terms I have indicated.

134. The authorised version of this judgment will be circulated initially to the parties' legal advisers so that issues of confidentiality can be resolved. When that is done the judgment will be published in the normal way.

Christopher Bellamy

Charles Dhanowa
Registrar

May 2003