



Neutral citation [2005] CAT 32
(Short version)

IN THE COMPETITION
APPEAL TRIBUNAL

Case No: 1016/1/1/03

Victoria House
Bloomsbury Place
London WC1A 2EB

29 September 2005

Before:

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

Sitting as a Tribunal in England and Wales

BETWEEN:

GENZYME LIMITED

Appellant

-v-

THE OFFICE OF FAIR TRADING

Respondent

supported by

HEALTHCARE AT HOME LIMITED

Intervener

JUDGMENT: REMEDY
(SHORT VERSION – Non-Confidential)

Mr David Vaughan CBE QC, Mr Christopher Vajda QC and Mr Aidan Robertson (instructed by Taylor Vinters, Cambridge) appeared for the Applicants

Mr Rhodri Thompson QC and Mr Jon Turner (instructed by the Treasury Solicitor) appeared for the Respondent

Mr Euan Burrows (of Ashurst) appeared for the Intervener

Note: Excisions to this judgment marked “[...][C]” relate to commercial confidential information: paragraph 1 of Schedule 4 to the Enterprise Act 2002

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I INTRODUCTION

1. This is a short version of the Tribunal's judgment as to the remedy to be imposed following the appeal by Genzyme Limited ("Genzyme") against decision no. CA98/3/03, taken by the Office of Fair Trading ("OFT") on 27 March 2003¹. This short version is identical to the full version of the judgment, save for the omission of the background material which is set out in the full version at sections III to VIII.
2. The OFT found in its decision that Genzyme had abused a dominant position by bundling the price of its drug, Cerezyme, at a price to the NHS which included not only the supply of the drug but the supply of Homecare Services, as defined in the decision. The OFT also found that Genzyme had abused a dominant position by providing Cerezyme to third party providers of Homecare Services only at the NHS List Price, thereby denying a margin to any such third party provider.
3. The Tribunal gave its judgment on the merits of Genzyme's appeal on 11 March 2004 [2004] CAT 4. In our judgment we decided, inter alia, that Genzyme had abused a dominant position in the period from 7 May 2001 contrary to the Chapter II prohibition by, without objective justification, adopting a pricing policy which resulted in a margin squeeze, with the effect of foreclosing the supply of Homecare Services to Gaucher patients. The OFT's finding in the decision that Genzyme's practice of bundling Homecare Services in the NHS List Price for Cerezyme was a separate abuse, was set aside by the Tribunal. However, the Tribunal found that Genzyme's practice of bundling had facilitated the margin squeeze abuse. The Tribunal imposed a penalty of £3 million on Genzyme in substitution for the penalty of some £6.8 million imposed by the decision.
4. The background facts, including, inter alia, as to the relevant markets, Gaucher disease and arrangements for its treatment in the United Kingdom, the OFT's investigation of Genzyme's practices and the relevant regulatory regimes and NHS

¹ Although the Decision was in fact taken by the Director General of Fair Trading all his functions were assumed by the OFT from 1 April 2003 under the Enterprise Act 2002.

mechanisms applicable are set out in our judgment on the merits. Defined terms used in our earlier judgment have been adopted in this judgment.

5. The decision, at paragraphs 390 to 396, contained a direction to Genzyme intended to bring both of the abuses identified by the OFT to an end. Paragraph 396 of the decision set out the direction in these terms:

“1. Genzyme shall

- 1.1. within fifteen working days from the date of this Decision bring to an end the infringement referred to at paragraph 386 above;
 - 1.2. thereafter, refrain from repeating the infringement referred to at paragraph 386 above; and
 - 1.3. with effect from the date of this Decision, refrain from adopting any measures having an equivalent effect.
2. In particular, within fifteen working days from the date of this Decision
- 2.1. the price at which Genzyme supplies Cerezyme and Ceredase to the National Health Service shall be, in respect of each drug, a stand-alone price for the drug only that is exclusive of any Homecare Services that may be provided; and
 - 2.2. the price at which Genzyme supplies Cerezyme and Ceredase to third parties shall be, in respect of each drug, no higher than the stand-alone price for the drug only as agreed between Genzyme and the Department of Health.
3. The term ‘Homecare Services’ in paragraph 2.1 means, in respect of each of Cerezyme and Ceredase, the delivery of the drug to a patient’s home and the provision of homecare services (including, but not limited to, basic stock check, supply of and monitoring of the need for accessories such as fridges and syringes, waste removal, dispensing the drug, training on how to infuse the drug, infusing the drug, providing an emergency helpline, respite care and full nursing support).”

6. The direction is currently suspended following the President's judgment of 6 May 2003 on certain terms pending the determination of this appeal or until further order: see [2003] CAT 8.
7. As to the appropriate remedy in this case we decided in our judgment on the merits to adjourn the matter for six weeks to enable negotiations to take place: see paragraphs [654] to [679] of that judgment.

II PROCEDURE FOLLOWING THE TRIBUNAL'S JUDGMENT

8. Since the handing down of our judgment in March 2004 we have, however, been provided with extensive further submissions on remedy from all parties running to hundreds of pages. We express our regret that, notwithstanding indications on the part of Genzyme that it felt it would be possible to reach an agreed solution, for a prolonged period Genzyme adopted a position which, in our view, precluded any reasonable negotiated settlement. That approach involved the OFT in many hours of extra work.
9. While this judgment was being prepared, the Tribunal was informed by letter of 8 July 2005 that Genzyme Homecare (now renamed Careology) had been sold by Genzyme by means of a management buy-out. With effect from 1 July 2005, Cerezyme was to be supplied by Genzyme to all healthcare providers, including Healthcare at Home, at a discount of 6.5 per cent from the new NHS List Price of £2.767 per unit. In a letter to Healthcare at Home dated 4 July 2005 Genzyme said that:

“The discount of 6.5% on Cerezyme is a voluntary unbundling offer made in the interim until a final direction has been given by the CAT”.

10. The OFT was informed by Genzyme by letter of 8 July 2005 that:

“the former homecare division of Genzyme [Careology] will now be trading on an arms length basis and on the same discount/credit terms as its competitors in the homecare services markets”.

11. The more significant steps in the procedure since March 2004 are summarised below and, where necessary, considered in more detail later in this judgment. The recent developments mentioned above have reduced the scope of the matters the Tribunal has to decide. Nonetheless, it is important to set the matter in context.

Genzyme's instruction of experts

12. Following the Tribunal's judgment of 11 March 2004 Genzyme did not immediately begin to make arrangements for negotiations with the DoH and hospital purchasers as envisaged by the Tribunal but instead, as evidenced by a letter from Genzyme's solicitors to the Treasury Solicitor dated 31 March 2004, instructed Professor Appleyard, ICAEW Northern Society Professor of Accounting and Finance at the University of Newcastle Business School, to prepare a report for submission to the OFT. Genzyme envisaged that following completion of Professor Appleyard's report, discussions should take place between Professor Appleyard and Professor Yarrow on behalf of Genzyme and economists from the OFT. Professor Yarrow had previously been instructed by Genzyme and gave evidence before the Tribunal in the main proceedings: see paragraphs 179 et seq of our judgment on the merits.

13. In response to Genzyme's letter dated 31 March 2004 the Treasury Solicitor, on behalf of the OFT, wrote to Genzyme in the following terms:

"We are surprised by the approach which you have unilaterally adopted, and would point out:

- (1) It was clearly envisaged by the Tribunal that the parties should adopt a co-operative approach to this exercise; and
- (2) The Tribunal has stated that, based on the information already available, the average cost of homecare appears to lie within a relatively narrow range of between 8%-11% of the NHS list price (see paragraphs 673-678 of the judgment). It should be noted that the Tribunal did not consider that formulating a precise direction to terminate the margin squeeze would be a difficult exercise based on the amount of information already available (see paragraph 672 of the judgment)

(...)

In these circumstances and in view of the limited time available before the need arises to file reports with the Tribunal, please inform us by return of (a) the substance of the instructions; and (b) the full extent of the information which you have given to Professor Appleyard."

14. The Registrar of the Tribunal wrote to the parties on 19 April 2004 setting the date on which the parties were required to file and serve reports as to the result of negotiations no later than 5pm on 20 May 2004.
15. On 19 May 2004 the Treasury Solicitor wrote to the Tribunal referring to the Registrar's letter dated 19 April 2004 and stating that whereas, at that time, the parties had thought it possible that a negotiated settlement could be reached by 20 May 2004 it had since become clear that further work was required, including a study of Healthcare at Home's costs.
16. As a result the Tribunal decided to hold a directions hearing on 27 May 2004.

The directions hearing on 27 May 2004

17. The OFT explained that Genzyme had served Professor Appleyard's report by cover of a letter dated 8 April 2004 and that, with Genzyme's consent, the OFT had passed that report to Healthcare at Home and to Mr Farrell of the Royal Free Hospital for comment. On 20 April 2004 the OFT obtained proposals from Genzyme that the appropriate discount per unit to reflect normal competitive conditions in this case was 2.6p per unit or just under 1 per cent. The OFT did not agree with Genzyme's proposal and submitted that the most appropriate way forward was for the OFT to produce its own report. The OFT was concerned about the commercial reality of what had been proposed by Genzyme, given the history of the case and of Genzyme's market power.
18. Genzyme submitted that negotiations were then at an advanced stage and Genzyme was confident that a negotiated solution could be achieved which would obviate the need for the Tribunal to issue a direction in this case.
19. Genzyme reported that a meeting had taken place on 1 April 2004 with the Department of Health. Genzyme then had a meeting with the OFT on 6 April 2004. Genzyme then had four meetings with NHS pharmacists at the four specialist centres where Gaucher patients are treated, including with Mr John Farrell of the Royal Free

Hospital and Ms Sue Patey, Deputy Chief Pharmacist at Great Ormond Street Hospital. Those meetings had taken place between 7 April 2004 and 5 May 2004. Genzyme had had meetings with two of the consultants treating Gaucher patients, Dr Atul Mehta of the Royal Free Hospital and Professor Cox at Addenbrooke's Hospital. A meeting had also been held with the Gaucher Patients' Association on 27 March 2004.

20. The Tribunal noted that the resolution of issues concerning the direction had been taking rather more time than the Tribunal had anticipated. The Tribunal directed:

- (a) that the OFT submit to the Tribunal by 7 June 2004 a draft consent order concerning the establishment of a confidentiality ring of identified people to whom commercially sensitive information could be disclosed in relation to a possible direction in this case.
- (b) that the OFT submit a report by 14 July 2004 setting out the state of progress reached in relation to the negotiations regarding the price of Cerezyme and Homecare Services as required by the Tribunal's judgment of 11 March 2004; and
- (c) that a further hearing be listed for 29 July 2004.

21. A confidentiality ring was established by the Tribunal's order of 14 June 2004.

The Progress Report dated 14 July 2004

22. On 14 July 2004 the OFT submitted a "Report setting out the state of progress reached in relation to the negotiations regarding the pricing of Cerezyme and Homecare Services" (the "Progress Report"). According to the Progress Report, a submission had been received by the OFT from Healthcare at Home on 17 June 2004 and this had led to a further information request from the OFT on 23 June 2004, to which Healthcare at Home had responded on 1 July 2004. Further information had been requested by the OFT from Healthcare at Home by letter dated 7 July 2004 regarding the level of nursing, Healthcare at Home's allocation of delivery costs and

profit margins. The OFT had held a meeting with Central Homecare on 7 June 2004 which also provided cost information on 28 and 30 June 2004. Further information had been sought by the OFT from Clinovia, by email dated 16 June 2004 and a response was expected by 19 July 2004. The information sought from Central Homecare and Clinovia concerned the approach those companies would take to pricing the Cerezyme Homecare Services if they were to tender to supply, including what direct costs would be incurred, the contribution they would expect towards fixed overheads and the margin they would expect to earn on such business.

23. According to the Progress Report a meeting was to be held between the OFT and Mr Farrell of the Royal Free Hospital. The OFT hoped to have completed the drafting of its report by 26 July 2004. A meeting with Genzyme's experts had provisionally been planned for 28 and 29 July 2004 to discuss the report.

The OFT's Costs Report of 23 July 2004

24. On 23 July 2004 the OFT submitted a "Report on the Cost of Homecare Services for Gaucher Patients and the Discount Necessary for Genzyme to Bring the Margin Squeeze Abuse to an End" (the "OFT Costs Report"). The OFT Costs Report concluded that the appropriate discount from the NHS List Price required to remove the margin squeeze lay at the higher end of the range of 6.4 to 8 per cent of the then list price of £2.975 per unit.
25. In response to the OFT Costs Report, Genzyme submitted further written reports from Professor Yarrow (dated 6 August 2004 and 24 September 2004, respectively) and Professor Appleyard (24 September 2004). Healthcare at Home provided detailed submissions responding to the OFT Costs Report on 14 September 2004.

The OFT's Supplementary Report of 13 September 2004

26. On 13 September 2004 the OFT submitted a "Supplementary Report on the Cost of Homecare Services for Gaucher Patients and the Discount Necessary for Genzyme to Bring the Margin Squeeze Abuse to an End" (the "Supplementary Report"). In the Supplementary Report the OFT slightly revised its initial proposal made in the OFT

Costs Report to the effect that an appropriate margin lay towards the higher end of the range of 5.1 to 7.3 per cent of the then NHS list price of £2.975 per unit.

27. On 14 September 2004 Healthcare at Home applied to the Tribunal for permission to intervene in the proceedings. A case management conference was held on 17 September 2004 at which Healthcare at Home was granted permission to intervene.
28. On 6 October 2004 Genzyme's solicitors made an application for specific disclosure of various documents from the OFT and from Healthcare at Home.

The hearing on 13 October 2004

29. A hearing was held on 13 October 2004. At the start of the hearing Genzyme made further proposals to the Tribunal and in particular made an unconditional offer, for the future, to "unbundle" the price of Cerezyme from the price of Homecare Services. The other parties had not had prior notice of Genzyme's intention to make such a proposal.
30. During the hearing the Tribunal discussed with the experts present various aspects of the OFT Report and Supplementary Report.

Events following the hearing of 13 October 2004

31. Following the hearing of 13 October 2004, Genzyme informed the Tribunal that it had commenced further negotiations with representatives of the Department of Health and of pharmacists under the auspices of the OFT.
32. On 28 October 2004 the Department of Health issued an announcement to inter alia Chief Executives of Primary Care Trusts, NHS Trusts, Foundation Trusts and Strategic Health Authorities that for a period of two years from April 2005 to March 2007 six centres will be nationally designated and funded by the Department of Health under the auspices of the National Specialised Commissioning Advisory Group ("NSCAG") to provide a service for patients with lysosomal storage disorders including Gaucher's disease. The announcement explained that the cost of such drug

treatments would be funded on a national basis, although some funding responsibility for local patients would apparently remain with the PCTs. The six NHS Trusts concerned are: Great Ormond Street, Manchester Children's, the Royal Free, Addenbrooke's, University College and Hope Hospitals.

33. It appears that Genzyme wrote to the OFT on 19 November 2004 proposing a reduction of the NHS list price of 15 pence to give a new list price of £2.825 per unit. The OFT responded to Genzyme on 24 November 2004 and expressed the view that Genzyme's offer was insufficient as it did not fall within the range identified in the Supplementary Report (15 pence represented a discount of 5 per cent from the then NHS list price of £2.975 per unit).
34. The OFT met Healthcare at Home on 6 December 2004. The latter submitted a memorandum to the OFT on 21 December 2004.
35. It appears that representatives of Genzyme stated at a meeting with the OFT on 13 December 2004 that it was intended to close Genzyme Homecare. The stated reason for the closure of Genzyme Homecare was that Genzyme no longer considered that Genzyme Homecare would be able to obtain the minimum margin of 5 or 6 per cent it requires in order to be viable once the market is opened up to competition.
36. Following the meeting on 13 December 2004, Genzyme wrote to the OFT with a revised offer. At this stage a notable matter was that the NHS list price for Cerezyme was to be reduced by 7 per cent as a result of industry-wide negotiations regarding the 2005 PPRS. For the future that list price was to be £2.767 per unit instead of £2.975 per unit. Genzyme offered to reduce the new NHS list price by 18 pence per unit (or 6.5 per cent of the new NHS list price) to give a bulk pharmacy price of £2.587.
37. On 27 January 2005, following confirmation of Genzyme's intentions, the OFT notified relevant pharmacists and homecare providers of Genzyme's intention to close Genzyme Homecare and requested their observations on Genzyme's latest proposals. Notwithstanding Genzyme's decision to close Genzyme Homecare, the OFT considered it still necessary for the Tribunal to issue a ruling.

38. On 27 January 2005 the OFT also informed the Tribunal that the PPRS had required a 7 per cent reduction in the NHS list price for Cerezyme for 2005 onwards, thereby reducing the NHS list price for Cerezyme to £2.767 per unit.
39. On 27 January 2005 the Registrar invited all parties to submit written observations to the Tribunal by 8 February 2005 on the implications of Genzyme's decision to close Genzyme Homecare and on the PPRS reduction in the Cerezyme list price.
40. Genzyme then wrote to the OFT on 28 January 2005 stating that it was not, in fact, proposing to unbundle the NHS list price of Cerezyme. The NHS List price would, according to its proposal, remain at the new bundled price of £2.767 per unit but there would be a discounted "bulk pharmacy" price that would apply to providers of Homecare Services and hospitals.
41. On 8 February 2005 the OFT submitted a report on progress since the hearing on 13 October 2004 (the "February 2005 Progress Report"). The OFT maintained that nothing new had emerged to persuade it to alter the views set out in its Supplementary Report.
42. Healthcare at Home (on 4 February 2005 and 25 February 2005) and Genzyme (10 and 11 February 2005 and 25 February 2005) also provided further detailed submissions. Further correspondence between the parties, to which the Tribunal was copied, was sent during February and March 2005.
43. On 9 March 2005 Genzyme's solicitors informed the OFT that instead of closing Genzyme Homecare, work was then in progress on a management buy-out of Genzyme Homecare Division from Genzyme. It was envisaged that there would be no cross-subsidy by Genzyme of the new company created by the management buy-out. The new company would be financially independent. Genzyme's intention was that the process would be completed so that the handover of patients to the new company could take place by the end of May 2005.

44. On 18 May 2005 Genzyme informed the OFT that there had been a delay in the establishment of the management buy-out of Genzyme Homecare. Completion of the project had been delayed until 1 July 2005.
45. On 8 July 2005 Genzyme informed the OFT and the Tribunal that the management buyout of Genzyme Homecare (now renamed “Careology Limited”) was completed that day. Genzyme has stated that the consequence of the management buyout is that the former homecare division of Genzyme will now be trading on an arm’s length basis on the same terms as its competitors in the Homecare Services market.
46. We understand that with effect from 1 July 2005 Genzyme has made Cerezyme available to healthcare providers such as Healthcare at Home at a discount of 6.5 per cent from the list price of the drug.
47. On 14 September 2005, at the Tribunal’s request, Genzyme submitted further representations on the disclosure application it had previously made in October 2004.

[See the full version of the Tribunal’s judgment for sections III to VIII (paragraphs 48 to 211) for particulars of the OFT Costs Report of 23 July 2004, the OFT Supplementary Report of 10 September 2004, Genzyme’s application for disclosure, the hearing on 13 October 2004, and the February 2005 Progress Report].

IX THE TRIBUNAL’S ANALYSIS

Preliminary comments

212. The margin squeeze abuse in this case began in May 2001. Subsequently, when the OFT intervened, Genzyme contested every aspect of the case, both in the proceedings before the OFT which led to the decision of 27 March 2003, and in the proceedings before the Tribunal, which led to the Tribunal’s judgment on the merits of 11 March 2004. When, following that judgment, the Tribunal adjourned the issue of remedy for six weeks to enable sensible negotiations to take place, we did not expect the turn of events which in fact transpired.

213. Instead of negotiating, Genzyme continued, for a long period, the adversarial posture which it has maintained throughout this case by instructing experts, who arrived at the conclusion that the margin needed by a reasonably efficient provider of Homecare Services to Gaucher patients could be accommodated by a discount of some 1 to 2 per cent of the then NHS list price. That conclusion was contrary to the historical evidence then before the Tribunal.
214. As a result of lengthy interchanges and submissions, the OFT then prepared its Costs Report of 23 July 2004, followed by its Supplementary Report of 13 September 2004, which were extensively commented on by Genzyme and Healthcare at Home. The Tribunal held case management conferences on 27 May 2004, 21 July 2004 and 17 September 2004. The Tribunal finally fixed a remedies hearing for 13 October 2004 on the basis that no negotiated solution was in sight, contrary to earlier assurances by Genzyme that a settlement could be anticipated.
215. At the hearing of 13 October 2004 Genzyme, while pursuing an application for disclosure against the OFT and Healthcare at Home, announced without prior warning to the OFT that it proposed to “unbundle” the NHS list price so as to separate the Homecare Services element. Genzyme proposed that further negotiations should then take place with NHS representatives and hospital pharmacies as to the implementation of this proposal. At this stage Genzyme, through its experts, was strongly maintaining that an appropriate margin was some 1 to 2 per cent.
216. Negotiations and consultations on “unbundling” then took place up to the end of 2004. However, on 28 January 2005 Genzyme told the OFT that it did not, after all, propose to “unbundle”, but proposed instead to offer a discounted “bulk pharmacy” price. We share the OFT’s view that little, if anything, was achieved during the autumn of 2004 and early 2005, other than further delay.
217. Meanwhile, at a meeting with the OFT on 13 December 2004 Genzyme told the OFT that it proposed to close its homecare operations, on the basis that these operations needed a profit margin of at least some 5 to 6 per cent, which Genzyme did not think was achievable in competitive conditions.

218. That statement by Genzyme management to the effect that Genzyme needed a margin on Homecare Services of some 5 to 6 per cent is in our view inconsistent with Genzyme's expert evidence that a margin of 1 to 2 per cent would suffice. Indeed Genzyme's statement to the OFT in December 2004 was more consistent with other evidence that Genzyme had relied on earlier before the Tribunal, such as Genzyme's internal proposal at the end of 2000, the Dixon Wilson Report and Mr Williams' evidence, than with Genzyme's more recent expert evidence.
219. With effect from the beginning of 2005, the NHS list price for Cerezyme was itself reduced by 7 per cent in the context of the PPRS negotiations affecting the pharmaceutical industry as a whole. On 19 January 2005 Genzyme made an offer to the OFT to reduce the new NHS list price of £2.767 by 6.5 per cent (18p per unit). It later transpired that that was the level at which Genzyme proposed to set the new "bulk pharmacy" price. In the OFT's February 2005 Progress Report the OFT maintained that a discount was required off the new list price towards the top end of the range of 5.3 per cent to 7.7 per cent, as against Genzyme's offer of 6.5 per cent. Although the gap between the parties has thus narrowed, it is regrettable in our view that Genzyme was able to delay matters for so long after the Tribunal's judgment of 11 March 2004.
220. The OFT at that stage – February 2005 – was still under the impression that Genzyme proposed to close its Homecare Services operation. However, in March 2005 Genzyme informed the OFT that such was not the case, and that there was to be a management buy-out instead. This was originally to have been completed by the end of May 2005.
221. The Tribunal is informed that completion of the management buy-out took place on 8 July 2005, and that the former Homecare Services Division of Genzyme is now a new company, Careology Limited. We are told that, as from 1 July 2005, Genzyme has made supplies of Cerezyme available to Careology and Healthcare at Home at a discount of 6.5 per cent off the new NHS list price. It is said that Genzyme's dealings with Careology are at arm's length, and that that company will operate independently. Careology appears to be being run by the same operating management and from the same premises as it did when it was part of Genzyme.

222. Looking at the matter broadly, and despite some recent progress, this case has in general been characterised by determined opposition by Genzyme to the OFT's position. Genzyme's approach has, in our view, delayed the resolution of this case. Genzyme has also made a number of statements that turned out to be incorrect, e.g. to the effect that there were good prospects of a settlement in 2004, that the NHS list price was to be unbundled, and that Genzyme Homecare was to be closed, none of which transpired. We are also of the view that Genzyme's management must have known all along that, in commercial terms, Genzyme Homecare required a margin substantially above what its experts said was appropriate.
223. As we pointed out in our judgment on the merits, there is no doubt that both the patients represented through the Gaucher Association, and the hospital pharmacists, wished to see a choice of homecare providers and, in particular, the survival of Healthcare at Home. However, the whole thrust of Genzyme's position had the effect of making it as difficult as possible for Healthcare at Home to remain in the market, contrary to the wishes of many Gaucher sufferers and those who are responsible for their care. See paragraphs 108 to 119, 254 and 555 to 558 of our judgment on the merits.
224. From March 2001 until the President's interim order of 6 May 2003, Healthcare at Home received no margin at all out of which to fund Homecare Services and remained in the market only in the hope that these proceedings would be favourably resolved. The interim margin ordered by the President in May 2003 was well below the margin of 5 to 6 per cent which Genzyme indicated to the OFT in December 2004 was the minimum commercial margin which it required, and well below the margin of 6.5 per cent which is the basis of the "bulk pharmacy" price that has apparently been offered by Genzyme since 1 July 2005. In these circumstances the effects of a serious infringement of the Chapter II prohibition in fact continued for over 4 years, since March 2001.
225. In all these circumstances we are in no doubt that a direction under section 33 of the Act is called for.

Jurisdiction

226. Section 33 of the Act, as amended, provides:

“33. (1) If the OFT has made a decision that conduct infringes the Chapter II prohibition or that it infringes the prohibition in Article 82 it may give to such person or persons as it considers appropriate such directions as it considers appropriate to bring the infringement to an end.

...

(3) A direction under this section may, in particular, include provision-

(a) requiring the person concerned to modify the conduct in question; or

(b) requiring him to cease that conduct.

(4) A direction under this section must be given in writing.

227. Pursuant to paragraph 3(2) of Schedule 8 of the Act, the Tribunal has the same powers as the OFT. In particular under paragraphs (d) and (e) the Tribunal may “give such directions, or take such other steps, as the OFT could itself have given or taken” or “make any other decision which the OFT could itself have made”.

228. The OFT’s direction, which is currently suspended pursuant to the President’s order of 6 May 2003, is set out at paragraph 5 above. It is common ground that that direction now requires modification.

229. All parties invite the Tribunal to issue a ruling on an appropriate remedy in this case and no party has submitted that these proceedings have become devoid of purpose. Genzyme in particular accepts that that the Tribunal should determine: (a) whether there is any purpose served by the retention of a separate NHS list price for Cerezyme; and (b) the precise level of reduction now required from the price of Cerezyme to provide a margin to providers of Homecare Services.

230. In the present case, the margin squeeze abuse which we found in our judgment occurred in circumstances where Genzyme was both the supplier of the drug,

Cerezyme, and the supplier of Homecare Services, through Genzyme Homecare. The abuse consisted of charging independent suppliers of Homecare Services a margin insufficient to enable them to compete in the market. We are now, however, told that the management buy-out, of which as yet we have very limited details, has apparently created two separate entities, Genzyme and Careology Limited. What is said is that Genzyme itself is not now supplying Homecare Services but only the drug Cerezyme. We briefly consider whether these new circumstances affect our jurisdiction.

231. In that regard, in our judgment on the merits at paragraphs [358] to [364] we found, notably, that Genzyme is the only source of supplies of Cerezyme and that third parties are only able, in practice, to provide a homecare service to Gaucher patients if they can obtain supplies of Cerezyme at a price that enables the provision of such services to be economically viable. We found, at paragraphs [528] and [530] of that judgment, that there was no doubt in our minds that Genzyme's NHS list price for Cerezyme included the cost of Homecare Services, as defined in the decision, and that provision of Homecare Services is an independent economic activity which is separate from, albeit ancillary to, the supply of the drug Cerezyme (paragraphs [355] to [357] and [532]). At paragraph [533] of our judgment we accepted that the bundling together by a dominant undertaking of separate but ancillary products or services may constitute an abuse where the effect is to eliminate or substantially weaken competition in the supply of those ancillary products or services.
232. Although we accepted that an infringement based on Genzyme's bundling practice was not proved during the period March 2000 to May 2001 (paragraph [548]), we also found, at paragraph [641], that Genzyme's practice of bundling facilitated the margin squeeze abuse which we found to have been proved by the OFT.
233. In our judgment, the power to make a direction under section 33 of the Act includes the power to ensure that an infringement is not repeated, if the OFT in its discretion considers that such a direction is necessary. Moreover, in our view, the power "to bring the infringement to an end" covers conduct closely linked to, or to the like effect as, the infringement found, otherwise section 33 would be ineffective. Similarly, the Tribunal's powers to give such directions or make any decision the OFT could have given or made must, it seems to us, be construed as a power to give a direction that is

adapted to the developments that have taken place in the course of the proceedings, provided that the underlying problem to be addressed remains the same or similar. Otherwise, a kind of “catch as catch can” situation could arise in which a dominant undertaking could, by constantly changing its arrangements, keep the competition authorities at bay indefinitely.

234. In the present case it is not yet clear whether there are financial, managerial, physical or other links between Genzyme and Careology such that it would be inappropriate to treat the latter as an entirely independent entity.
235. However, even if we were satisfied that Careology was completely independent, it does not seem to us that the creation of Careology now creates a fundamentally different situation in this case. The underlying vice to which these proceedings are directed is that Genzyme, the dominant supplier of drugs for the treatment of Gaucher disease, has failed or refused to supply such drugs (i.e. Cerezyme) to independent Homecare Services providers at a price such as to enable the latter to operate competitively in the downstream market for Homecare Services, for which there is a separate demand. The remedy for that abuse is to establish a price for Cerezyme for supply to Homecare Services providers which will enable the latter viably to supply Homecare Services.
236. It is true that, strictly speaking, the expression “margin squeeze” commonly refers to a situation where the dominant undertaking is present in both the upstream and downstream markets. However, it seems to us that, even if Careology is now considered to be an independent provider, rather than part of Genzyme’s “in house” operation, in the circumstances of this case it would still be an abuse for Genzyme to squeeze the margin between the NHS and ex-manufacturer prices to the point at which an efficient Homecare Services provider is unable to compete in the market. Such a strategy on the part of Genzyme would foreseeably lead to the withdrawal of independent Homecare Services providers, thus disrupting the provision of Homecare Services to Gaucher patients and enabling Genzyme to re-enter, and monopolise, the market. This in turn would simply restore the *status quo ante*, in which the only homecare providers would be either those contracted to Genzyme, or Genzyme itself. That was precisely the situation addressed in the OFT’s decision.

237. In addition, as long as the conventional NHS list price for Cerezyme remains, an issue which we discuss below, there would appear to be nothing to prevent Genzyme in the future in fact offering to supply Cerezyme on a bundled basis, including Homecare Services. That would, in turn, again raise the possibility of a classic margin squeeze. Any agreement or understanding between Genzyme and Careology to the effect that Genzyme did not intend to re-enter the market for Homecare Services would not obviate the need for a direction. Private arrangements can be modified, and the future is not foreseeable. Similarly, any unilateral undertakings by Genzyme, even if made in good faith, would not remove the need for a direction: circumstances may change in the future in all kinds of unforeseeable ways.

238. We are therefore of the view that we have jurisdiction to make a direction with a view to ensuring that Genzyme's infringement of the Chapter II prohibition is terminated, and to prevent that infringement, or any similar infringement, from arising in the future. Indeed, all parties invite the Tribunal to rule on the outstanding issues between them.

Maintaining the existing NHS List Price

239. At various stages in these proceedings it has been suggested that the best solution would be if the existing NHS list price became a "drug only" price, and that the cost of Homecare Services was paid for separately, probably on the basis of tenders put out by the various hospital authorities.

240. We can see the attractions of this solution. In particular, one disadvantage of maintaining the existing NHS list price and introducing a "bulk pharmacy" drug-only price is that competition then has to take place within the parameters set by the NHS list price and the bulk pharmacy price. That could have the effect of constraining the free play of competitive forces in a way which would not occur if there were simply a drug only price, and the price of Homecare Services was left to find its own level in competitive conditions.

241. However, at this stage the administrative and funding complexities of requiring Genzyme's NHS list price to be a "drug-only" price seem to us to be too great for that to be done by way of a direction under the Act.
242. This aspect of the matter is complicated by the lack of any clear definition of what the "NHS list price" is intended to cover. As explained at length in our earlier judgment, under the NHS system the NHS list price is not an ex-manufacturer price, but the price at which the retail pharmacist is reimbursed, subject to "clawback", by the Prescription Pricing Authority (PPA) for the supply of the drug. The NHS list price therefore historically includes the wholesaler's margin. Although the function of the Homecare Services provider is not equivalent to the normal "wholesale" function, the cost of Homecare Services has traditionally been funded out of the NHS list price. In the case of Cerezyme, where Cerezyme has been supplied to the patient pursuant to a hospital prescription, the hospital has reimbursed Healthcare at Home or Genzyme Homecare with the cost of the drug at the NHS list price. When a prescription for Cerezyme is written on a Form FP10 (e.g. by a GP under shared care arrangements or in some cases by hospital consultants), the homecare provider is reimbursed by the PPA and receives the Expensive Prescription Fee. Again, it is assumed that the cost of Homecare Services will be funded out of the NHS list price for Cerezyme (paragraph [82] of our judgment on the merits).
243. If the NHS list price for Cerezyme were to become a simple ex-manufacturer price we are told that Cerezyme would be the only product to be so treated among the many thousands of products included in the Drug Tariff. We cannot, at present, exclude the possibility that that would cause administrative difficulties, particularly in relation to the funding arrangements for Homecare Services. The evidence before the Tribunal was that a substantial proportion of Healthcare at Home's business was done on FP10s which are reimbursed by the PPA at the NHS list price, which has up to now been treated as including Homecare Services.
244. Gaucher patients are scattered all over the country, from Cornwall to Scotland. Up to now, payment at the NHS list price has been regarded by PCT's as including the cost of Homecare Services. If that were no longer the case, it is not clear to us what the funding mechanisms for Homecare Services would be.

245. It is true that we have been told that funding arrangements for Cerezyme are to be taken over by NSCAG: see Mr Brownlee's email to the OFT of 15 November 2004. However, we have insufficient information about these arrangements to be sure that the present mechanism of funding through the NHS list price can be safely abandoned. In any event, the NSCAG arrangements are apparently only for two years. In addition, any systems of tenders for Homecare Services to Gaucher patients are as yet untried. It is not yet clear to us that any new tendering procedures introduced will automatically replace fully the old funding arrangements which currently involve a number of PCT's up and down the country. In addition, although we are told that the use of FP10s is in decline, we take the view that it is not for the Tribunal to seek to deprive hospitals and doctors of that facility. That is a matter for the NHS to sort out.

246. We are therefore of the view that, at present, Genzyme's existing NHS price, in the conventional sense, of £2.767 should remain, but that a discounted "bulk pharmacy" price should be introduced. Such a price would introduce transparency, while leaving the NHS free to develop purchasing procedures as it sees fit. There would, however, be nothing to prevent the OFT from modifying the direction at some later date if it were satisfied that changes in NHS funding arrangements and procedures were such as to obviate the need to maintain an NHS list price for Cerezyme in the sense traditionally understood.

247. We turn now to the substantive main issue that arises for consideration: the appropriate level of discount from the NHS list price to arrive at the bulk pharmacy price.

The appropriate level of discount: general considerations

248. Genzyme's latest proposal, of a discount of 6.5 per cent off the new list price of £2.767 per unit, although still contested by the OFT and by Healthcare at Home, is in our view much more realistic and constructive than its earlier proposals.

249. In assessing the margin that is required in this case the Tribunal has attempted, on the basis of the information now before it, to consider what ex-manufacturer price for Cerezyme would enable a reasonably efficient homecare services provider to supply its services to Gaucher patients and in so doing earn a competitive return.
250. In dealing with that question the Tribunal now has ample information from three different sources, namely: (a) historical information; (b) indicative estimates by other potential providers, Clinovia and Central Homecare; and (c) detailed information about Healthcare at Home's costs. We consider that this mass of detail is sufficient to enable the Tribunal to make a determination.
251. Genzyme has, however, urged us to obtain further information about allegedly comparable situations involving homecare treatment for other diseases such as haemophilia, thalassaemia, HIV, multiple sclerosis and other treatments. Genzyme seeks disclosure of tenders submitted in the past by Healthcare at Home in relation to these other treatments. Despite Genzyme's arguments, set out earlier in this judgment, and repeated in further submissions dated 14 September 2005, which we have carefully considered, we are not persuaded that that approach is either necessary or desirable. Moreover, a mass of information has already been disclosed to Genzyme who have had every opportunity to comment on the matters taken into account in this judgment.
252. In our opinion, the gap between the parties' position is now relatively slight, and the Tribunal in our view has sufficient material on which to resolve the remaining dispute. The detailed investigation of allegedly comparable situations was suggested at a time when Genzyme was contending for a margin of 1 to 2 per cent, but matters have since moved on. Genzyme has now acknowledged, de facto, that a margin of at least 6.5 per cent is appropriate.
253. Moreover, it seems to us that a detailed investigation of allegedly comparable situations is not likely to be productive in this case. First, the evidence before us is that there are differences between the various treatments concerned. There are substantial disputes between the parties as to whether a given treatment is or is not comparable with Cerezyme, the complexities of which are set out at paragraphs [325]

to [354] of our earlier judgment. There is, for example, already a substantial dispute as to whether homecare provision for haemophilia patients is comparable to homecare provision for Gaucher patients, and there is every indication that the comparability of the treatments for thalassaemia, HIV, multiple sclerosis, and so on would similarly be disputed. In our view, to go in detail into these matters would lead the Tribunal into lengthy collateral disputes on comparability, further adding to costs and delay. Secondly, even if it were established that different treatments were technically comparable, it would be very difficult to know whether the results of particular tenders were or were not comparable with what might be expected in the future for Cerezyme, since so much depends on the particular tender specifications in question, the strategy pursued by the tendering firms, and the characteristics of each of the different markets concerned, all of which may be very different from the factors affecting Homecare Services for Cerezyme. Investigating all these matters would, in our view, be disproportionate, given the narrow issues we now have to decide and the cost and delay involved.

254. We therefore propose to decide the remaining issue on the extensive material that is now before us.
255. We note that the determination of an appropriate margin is necessarily a question of judgment and appreciation. That is particularly so when the Tribunal, as here, is required to deal with markets affected by the intricate operation of the NHS arrangements and regulatory systems more fully described in our earlier judgment. Despite the highly technical nature of the submissions made to us, there are inevitably some areas of uncertainty on matters upon which experts may well take differing views. In those areas the Tribunal is required to exercise its own judgment.
256. In exercising our judgment we have had regard, in particular, to the interests of Gaucher patients and to the interests of the customer, the NHS. Those are the interests which the legislation is primarily designed to protect although, of course, the interests of Genzyme and of healthcare providers are also important. In our view, the NHS and Gaucher patients will be best served by a remedy that ensures effective competition in the supply of Homecare Services. It is, in our view, unrealistic to assume that the market for Homecare Services is already characterised by undistorted

competition. In our view, that market has been disrupted, and competition has been distorted, by the abusive actions of Genzyme which have yet to be remedied.

257. In our view, there is little point in devising the remedy on the basis of a margin which no homecare services provider would consider commercially acceptable, or which bears no relation whatsoever to the levels of margin that, for whatever reason, have traditionally come to exist. We bear particularly in mind the small number of sufferers from Gaucher disease and their wide distribution geographically, combined with the specialised nature of the services required. Providers are unlikely to remain in that market unless they have an appropriate incentive to do so. Contrary to Genzyme's submissions, we do not see this case as setting down any wider benchmark, because of the special nature of the facts we are dealing with.

258. We agree with the OFT that, in this case, the risks associated with a remedy that may under-compensate third party Homecare Services providers are greater than those associated with over-compensation. However, even if, contrary to our view, the remedy now imposed might lead to an element of over-compensation, that can be expected to encourage competing providers to tender for contracts to provide Homecare Services in future and to compete away, over time, any such over-compensation. On the other hand, if from the start our remedy were to under-compensate third party providers, it is likely that competition would be muted immediately and possibly irremediably, since existing providers would withdraw and new providers would not come forward. Alternatively, the level of service currently offered to sufferers of Gaucher disease would, in the future, be diminished. We have taken account of these risks.

The historical information

259. In our earlier judgment we noted the considerable historical information that had already been presented to us concerning the margins typically observed in this area in the past (see paragraphs [673] to [678]). Although some of that information is now of a certain age, it has the particular benefit of having been prepared during a period when none of the parties concerned were involved in proceedings. In particular we noted that: (i) Genzyme's correspondence with the DoH in 1999 suggested that the

costs of homecare would be 34p per unit or just over 11 per cent of the list price of £2.975 per unit; (ii) the margin agreed between Genzyme and Caremark in 1993 was in the order of 10 per cent of the then list price; (iii) when the contract with Healthcare at Home was terminated in 2001, having been re-negotiated in 2000, the average remuneration was approximately 28.4p per unit, or 9.5 per cent of the then list price; (iv) the figures in the Dixon Wilson Report produced for Genzyme and dated 18 October 2002 suggested that 10 per cent of the then list price would cover costs and overheads of Homecare Services; and (v) Genzyme's hospital price of £2.73 per unit represented a discount of 24p per unit or about 8 per cent of the then list price.

260. We were invited by Genzyme and its experts to disregard that historic information entirely. It was suggested that it is all either too old to be of assistance or that it reflects an imbalance of negotiating position between Genzyme and suppliers of Homecare Services. It was also suggested that that information, if relied on, would result in the Tribunal endorsing excessive and/or discriminatory prices for Homecare Services. The OFT, on the other hand, submits that the historic information before the Tribunal is of assistance in devising the remedy in this case, in particular it is a useful "cross-check" against the OFT's own cost calculations as to the realism of the margin suggested.

261. We agree with the OFT that the historic evidence to which we made reference in our earlier judgment is important evidence before the Tribunal. Although we accept that the earlier historical evidence is of less weight, we attach particular importance to:

- (a) The figure negotiated between Genzyme and Healthcare at Home in 2000 which gave Healthcare at Home a remuneration of some 28.2p per unit, or about 9.5 per cent of the then list price. That negotiation was at arm's-length, with bargaining power on both sides.
- (b) The figures relied on by Genzyme itself before the OFT and the Tribunal in the Dixon Wilson Report showing that a margin of some 10 per cent, or 29.7p per unit, would cover the costs and overheads of Homecare Services.

- (c) The hospital price of £2.73 per unit, which covers delivery to the hospital but no other aspect of Homecare Services, which represented a discount of some 24p per unit or 8 per cent off the then list price.

262. These figures continue to suggest to us that margins of 24p to 29p per unit (which would correspond to between 8.6 and 10.5 per cent of the new list price of £2.767 per unit) are within the range that an efficient Homecare Services provider might historically have sought to achieve in this small and highly specialised market.

Clinovia and Central Homecare

263. Contrary to Genzyme's submissions, we do not consider it appropriate to dismiss information submitted by Clinovia and Central Homecare in relation to hypothetical tenders for Homecare Services. Clearly, that information was prepared in a short timescale and it has not been possible for the OFT to ensure perfect consistency in the information submitted. In addition, those companies prepared their information on the basis of using agency nurses, whereas neither Healthcare at Home nor Genzyme Homecare use agency nurses for this service. According to the OFT, Mr Farrell, who is the Chief Pharmacist at the Royal Free, and whose evidence we entirely accepted in our judgment on the merits, is of the view that the use of agency nurses is inappropriate.

264. Central Homecare considered that a market entry price of around [...] per cent was required. Adjusting that figure according to various different assumptions as to the number of nurses required, the OFT considered that Central Homecare's figures suggested margins of between [...] per cent and [...] per cent of the then list price of £2.975 per unit. Clinovia's figures, as similarly adjusted by the OFT, suggested margins of between [...] per cent and [...] per cent of that price. We have taken account of the fact that Clinovia does not itself currently provide Homecare Services to any Gaucher patient and of the fact that the OFT had more confidence in the information of Central Homecare, not least because that company currently services at least one Gaucher patient. We note, however, that neither of these companies has extensive recent experience of the relative complexity of supplying services to Gaucher patients. Given that both companies rely on agency

nurses, which is not the regular practice of either Genzyme Homecare or Healthcare at Home, we think it possible that both companies may have underestimated the cost of providing trained nursing of the quality currently enjoyed by Gaucher patients.

265. Taking these factors into account, the indicative figures for Central Homecare do not seem to us to be significantly below the bottom of the range suggested by the historical evidence, although the Clinovia figure – which seems to us to be prepared on a less detailed and slightly different basis – is admittedly lower.

The costs figures

266. As outlined above, Professors Appleyard and Yarrow criticised the OFT Costs Report and the Supplementary Report. They submitted that the correct remedy in this case should be based on a margin of no more than 6p (or about 2 per cent). We note that the conclusions reached by Professors Appleyard and Yarrow are at variance with the historical evidence, with the evidence of Central Homecare and Clinovia, and with Genzyme's latest proposals. We note that Genzyme has now stated that Genzyme Homecare needs a margin of at least 5 to 6 per cent to viably maintain its level of service to patients. The margin currently offered by Genzyme to Homecare Services providers including Careology is 6.5 per cent. As a result, on a practical level, we consider that the evidence of Professors Appleyard and Yarrow, which is directed to supporting a margin of 1 to 2 per cent, has been cast into serious doubt. We do not, therefore, address that evidence in detail. Nonetheless we comment briefly on the principal issues.

267. The costs evidence is canvassed in detail in the OFT's Costs Report, Supplementary Report, and the February 2005 Progress Report, the various corresponding submissions of Genzyme and Healthcare at Home, and the reports of Professors Appleyard and Yarrow. There are four main areas to consider, namely the treatment of common costs and overheads, delivery, nursing and profit margins.

268. As regards the treatment of common costs and overheads, we agree with the OFT that the price arrived at should recover an appropriate share of the Homecare Services provider's fixed costs and central overheads – including directors' costs – for the

reasons given in paragraph 3.3 of the Costs Report and 2.4 of the Supplementary Report. We understand that this is not now disputed. As to how such costs should be allocated to the Cerezyme activity, we also agree with the OFT's rejection of Healthcare at Home's submission that certain costs should be allocated solely according to turnover: such an approach would allocate an unduly high proportion of overheads to Cerezyme, because of the high cost of the drug (Costs Report at 3.98). As to the various methods of allocation, the differences between the parties are summarised at paragraph 3.2 of the Supplementary Report. While the OFT agrees with Professor Yarrow that certain items such as finance, IT, retail costs and general overheads can be allocated on the basis of delivery numbers, there is a difference of view as to whether for certain items e.g. direct delivery costs and directors' time, an allocation should be made on the basis of delivery numbers alone. On that issue we agree with the OFT that in considering delivery costs account needs to be taken of the more complex nature of the delivery process for Cerezyme (Supplementary Report, 3.2 to 3.7). On the other hand, we share the OFT's reservations about accepting without qualification Healthcare at Home's "complexity quotient analysis". The OFT's conclusion that the figure for delivery costs is in a range between a figure based on delivery numbers alone and the figure produced by Healthcare at Home's complexity quotient seems to us to be a reasonable approach. As regards the costs of directors, the OFT did not accept Healthcare at Home's original figures. While we understand Genzyme's point that this item too should be allocated on the basis of deliveries, as a proxy for the amount of activity concerned, the allocation, on a time basis, carried out by the OFT seems to us to be within the bounds of reasonableness.

269. As to Genzyme's submission that the OFT's resulting figure for delivery costs is above market rates – by reference particularly to some evidence about a contract Healthcare at Home has with the Royal Free for haemophilia – the comparability of the haemophilia contract is strongly disputed. The figures produced by the OFT at page 9 of the Supplementary Report show a wide variation in rates, some below and some above the OFT's estimate for Cerezyme, and some varying with the value of the drug. The delivery figures for Clinovia and Central Homecare are either similar to or above the OFT's estimate (page 5 of the Supplementary Report). In these circumstances we do not accept that there are significant valid criticisms to be made to the OFT's approach to delivery costs.

270. With regard to nursing costs, the OFT estimated an upper and lower bound based on the information provided by Healthcare at Home, and the Royal Free Hospital as to the actual numbers of nursing visits provided. The OFT's upper limit in the Costs Report is 6.4 full time equivalent nurses, while the lower limit is 4.5. We note that the Dixon Wilson Report estimated that Genzyme Homecare would itself need to employ 9 nurses (including a Head Nurse) and that 8.4 full-time equivalent nurses would be involved in providing a service to Gaucher patients. Healthcare at Home's evidence is that, because of the geographic spread of patients, it would be impossible to operate at national level on less than [...] [C] full-time equivalent nurses.
271. A number of detailed points have been contested between the OFT and Genzyme, on such issues as nursing efficiency, the number of visits required and hourly charges. Given that the margin now under consideration is much higher than Genzyme was suggesting at the time the expert reports were prepared, we do not think it is necessary to consider these points in detail. For the reasons given in paragraphs 4.1 *et seq* of the Supplementary Report, we think the OFT's approach is reasonable. We also have in mind: (i) that Healthcare at Home employs [...] [C] Gaucher trained nurses; (ii) Genzyme's own estimate at the time of setting up Genzyme Homecare that some 8.4 full time nurse equivalents would be required; and (iii) Mr Farrell's evidence to the Tribunal (Day 2, p.51) that the Royal Free would require about 10 nurses if it were to look after its Gaucher patients itself. In these circumstances, in our view, the correct figure to take is the OFT's upper figure of 6.4 full-time nurse equivalents. Indeed, that figure may be well be on the conservative side. We also note that Genzyme Homecare did not and Healthcare at Home does not generally employ agency nurses to provide Homecare Services. We consider, in those circumstances, a calculation based on employed nurses to be reasonable.
272. The final issue between the parties was how to calculate the profit margin. This item accounted for the major difference between the parties' figures. Genzyme argued that return on capital (in this case, effectively, fixed assets) was the appropriate yardstick, but the OFT contended that in a service business, where fixed assets were low, that was inappropriate, and that return on sales was the correct approach. The approach of Genzyme's expert evidence would have given a profit margin of some 0.1 per cent of

the drug price whereas the OFT's figure is in the range of [...] per cent to [...] per cent (Supplementary Report, pages 18 to 25).

273. The discount of 6.5 per cent now offered by Genzyme, and Genzyme's earlier statement that Genzyme needed an overall margin of at least 5 to 6 per cent, imply to our mind that the profit margin assumed by Genzyme as necessary is well above the 0.1 per cent of the drug price suggested by Genzyme's expert evidence. Particularly in the light of that evidence, the figure of 0.1 per cent seems to us to be wholly unrealistic in practical terms. Despite the disadvantages of a return on sales yardstick – which links profit to the drug price, although costs are not necessarily linked to the drug price – a return on sales approach for the purposes of the present exercise does not seem to us unreasonable for the reasons given by the OFT in the Costs Report (paragraphs 3.1 to 3.27) and the Supplementary Report (paragraphs 4.23 to 4.47). The OFT's approach is supported by the study prepared for the OFT by Oxera in July 2003 entitled "*Assessing profitability in competition policy analysis*" (see OFT 657, paragraphs 1.24-1.25 and 4.49). That approach also appears to reflect how the industry actually works. As to the actual figure, the OFT's range of [...] per cent to [...] per cent, based on the evidence of Clinovia and Central Homecare, appears to us to be a reasonable range. Given that Healthcare at Home submits that it works on an overall margin of [...] per cent, in our view the figure is likely to be at the upper end of the OFT's range. The figure of [...] per cent used by the OFT is approximately the mid-point between Clinovia and Healthcare at Home, and seems to us to be reasonable.

274. Our overall conclusion is that the OFT's approach to cost analysis has been a reasonable one.

275. We accept also the OFT's submission that the 2005 reduction in the NHS list price of Cerezyme to £2.767 per unit as a result of the operation of the PPRS gives rise to a need for the OFT to adjust its original estimates in the Costs Report and Supplementary Report. The range now suggested by the OFT's analysis is 5.3 to 7.7 per cent of the new list price, or between 15p and 21.3p per unit.

276. The OFT notes that Genzyme's latest offer of 6.5 per cent of the new list price of Cerezyme is exactly in the middle of the OFT's range of between 5.3 per cent and 7.7 per cent. A margin of 6.5 per cent at the new list price of £2.767 is equivalent to 18p per unit.

Overall assessment

277. Although we consider that the OFT's detailed costs studies should play a substantial part in our assessment, we do not consider that those studies should be the sole determining factor. Estimates and allocations of costs will always have a degree of arbitrariness. In addition, a particular problem in the present case is what assumption to make about the scale of operation of the notional reasonably efficient homecare provider upon which the exercise is predicated. Healthcare at Home is well established and experienced in the market. Other homecare providers have substantial homecare businesses in other sectors, but little direct experience of Gaucher disease. Careology, as it now is, has hitherto been largely confined to Cerezyme and Fabryzyme.

278. Summarising:

- (a) the more recent historical information would suggest a range of 24p to 28p per unit, i.e. between about 8.5 and 10 per cent of the new list price;
- (b) the evidence from Clinovia and Central Homecare suggests a range of between [...]p and [...]p per unit, i.e. between [...] and [...] per cent of the new list price;
- (c) the OFT's Supplementary Report suggests a range of between 14.6p and 21.3p per unit, i.e. between 5.3 and 7.7 per cent of the new list price; and
- (d) Genzyme's recently offered margin of 6.5 per cent of the new list price represents 18p per unit.

279. The actual margin to be set is not a matter of precise mathematics. In our view we should set the initial margin at or near the top of the OFT's range for several reasons: (i) erring on the low side may affect the quality of service to Gaucher patients; (ii) we need to ensure that there is a sufficient margin to enable the envisaged new tendering system to work effectively; (iii) in our view the lower end of the OFT's range does not take sufficiently into account the special features of the delivery services for Cerezyme; (iv) the OFT's estimation of full-time equivalent nurses required is likely, on the evidence, to be too low at the lower end and possibly conservative at the upper end; (v) the OFT's lower range assumes a lower profit margin than we consider to be reasonable whereas in that regard, Central Homecare's figure, approximately at the mid-point between Clinovia and Healthcare at Home, seems to us the more appropriate to adopt; and (vi) a figure towards the top of the OFT's range is more consistent with the historical evidence.
280. Taking all these considerations into account we consider that the discount off the existing NHS list price at which a bulk pharmacy price should be offered by Genzyme to bona fide healthcare providers should be not less than 20 pence per unit. That is equivalent to 7.2 per cent of the current NHS list price and gives an ex-manufacturer bulk pharmacy price of £2.567 per unit. We propose to set that margin.
281. We note that the above level of margin is considerably less than the level of margin enjoyed by Healthcare at Home in 2001 (28.4 pence per unit). Nonetheless, the evidence is that the margin we propose to set should enable a reasonably efficient provider of Homecare Services to remain in the market. If Genzyme's submission, to the effect that such a margin would significantly over-compensate providers of Homecare Services, were correct, which we do not consider it to be, it can be expected that the tender process now envisaged will quickly result in the elimination of any such over-compensation. On the other hand, the margin we envisage leaves considerably more of the "value chain" associated with Cerezyme in the hands of Genzyme than was historically the case up to 2001.
282. The existing hospital price appears to us to be a separate matter outside the scope of the direction. However, if the hospital price and the new bulk pharmacy price were to differ, we cannot at present see any basis for imposing a restriction on the hospitals to

the effect that the hospital price is limited to circumstances where the patient is infused in the hospital, as is currently the case: see paragraph [256] of the judgment on the merits.

283. We do not accept Healthcare at Home's submission that it is appropriate that there be a transitional restriction setting minimum prices for Homecare Services. On the contrary, we consider it appropriate that competition now take place in the market as quickly as can be achieved. That is a matter for the relevant NHS authorities and hospitals to take forward.

Genzyme's disclosure application

284. For the reasons already given, we think that it is neither necessary nor proportionate to grant Genzyme's disclosure application, which mainly sought disclosure of information relating to tenders for the provision of homecare relating to other drugs or treatments. As already stated, in our view this application has largely been overtaken by events, since it was made in support of the margin of 1 to 2 per cent for which Genzyme was then contending. Moreover, in order to satisfy ourselves that the disclosure sought is relevant, it would have been necessary for us to consider to what extent, if any, the services provided in respect of those other treatments are comparable to Homecare Services for Gaucher patients. Even if we were so satisfied, we would nevertheless have then had to consider to what extent market-specific factors applicable to those services rendered such comparisons of limited relevance. The consideration of particular tenders would have had to have been gone into in detail. We note that, according to the evidence in the Supplementary Report, the delivery costs associated with different drug treatments appears to vary significantly. As already explained, we consider the disadvantages of embarking upon the costly and time consuming disclosure exercise which Genzyme suggests far outweigh any supposed advantages given, in particular, the narrowness of the issue we now have to resolve.

285. We do not consider it necessary to order disclosure of any of the other underlying documents which Genzyme also sought. Various documents underlying the OFT Costs Report and Supplementary Report were, in any event, disclosed to Genzyme by

the OFT. There is no reason to doubt the various other figures in the OFT report. We note that Genzyme itself presumably has considerable documentary information about its delivery and nursing costs, and the margin it requires, which it could have produced, but Genzyme chose not to do so.

286. Genzyme's further submissions of 14 September 2005 repeated, in effect, its submissions of October 2004 and thus did not, in our view, take account of the developments in this case since the disclosure application was first made. As already stated, we do not accept the suggestion that it would be impossible for the Tribunal fairly and properly to resolve the remaining issues without these documents, particularly since in our view the Tribunal already has ample evidence before it. In our view the matters relied on by the OFT have already been fully disclosed to Genzyme, who has had the fullest opportunity to comment on these matters in the course of proceedings.

The Tribunal's order

287. We attach a draft direction.

Christopher Bellamy

Peter Grinyer

Graham Mather

Charles Dhanowa

29 September 2005

DRAFT DIRECTION

1. Genzyme shall:
 - 1.1. forthwith bring to an end the infringement referred to at paragraph 640 of the Tribunal's judgment of 11 March 2004, namely setting a price for the supply of Cerezyme to providers of Homecare Services which results in a margin squeeze, with the effect of foreclosing the downstream supply of Homecare Services;
 - 1.2. hereafter, refrain from repeating that infringement; and
 - 1.3. refrain from adopting any measures having an equivalent effect.
2. In particular, within fifteen working days from the date of this direction Genzyme shall supply Cerezyme [and Ceredase] to any bona fide provider of Homecare Services at a drug-only price exclusive of any charge in respect of any element of Homecare Services, at a discount from the prevailing NHS List Price for such drugs from time to time of not less than 20 pence per unit.
3. The OFT may if it thinks fit, after consulting interested parties,
 - 3.1 modify any provision of this direction, with a view to ensuring that this direction remains appropriate and effective for its purpose; and
 - 3.2 revoke this direction or any provision of it, provided that this direction shall not be revoked until three years from the date hereof without the prior consent of the Tribunal.
4. Genzyme shall ensure that any trading as regards Cerezyme [or Ceredase] taking place between Genzyme and any company carrying on Genzyme's former homecare business is carried out strictly at arm's-length in all material respects, and on the same terms and conditions as trading with any other supplier of Homecare Services.
5. Genzyme shall supply to the OFT such information as the OFT may require in order to:
 - 5.1 monitor Genzyme's compliance with, and to assess the effectiveness of, this direction; and
 - 5.2 satisfy itself that any trading between Genzyme and any provider of Homecare Services is at arm's-length and on the same terms and conditions as aforesaid.

6. The term 'Homecare Services' in this direction means, in respect of each of Cerezyme [and Ceredase], the delivery of the drug to a patient's home and the provision of homecare services (including, but not limited to, basic stock check, supply of and monitoring of the need for accessories such as fridges and syringes, waste removal, dispensing the drug, training on how to infuse the drug, infusing the drug, providing an emergency helpline, respite care and full nursing support).