IN THE COMPETITION APPEAL TRIBUNAL

GENZYME LIMITED ("Genzyme")

Appellant

- and -

OFFICE OF FAIR TRADING ("OFT")

Respondent

SKELETON ARGUMENT OF THE OFT

INTRODUCTION[1]

The nature of this skeleton argument

1. The Decision and the Defence are detailed and fully reasoned. They set out the factual and legal basis for the Decision in a systematic way, reflecting the terms of section 18 of the Competition Act 1998 but also the relevant OFT Guidelines that have been issued in respect of the Chapter II prohibition. This skeleton argument draws together the central arguments in those two documents and provides suitable references. It does not however repeat them.

2. It also takes account of the additional materials that have now been produced by the parties, and in particular the skeleton argument served by Genzyme; the supplementary statement of Dr Jones; the Reply and the evidence accompanying the Reply; the OFT's note in relation to the questions raised by the Tribunal on 31 July 2003; and the further statements by Mr Brownlee and Mrs Stallibrass served by the OFT.

3. In this Introduction, we address the following issues:

   (1) The basis of the OFT's case;

   (2) The inconsistencies within Genzyme's appeal; and

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[1] In this skeleton argument, OFTCB/1/1 etc. refers to the OFT Core Bundle, whereas CB1/1/1 etc refers to the three core bundles produced by Genzyme.

(3) The economic significance of the case.

The basis of the OFT's case

4. This is a case about abusive pricing. However, the pleadings produced by Genzyme, including its skeleton argument served on Friday, 12 September 2003, insist that the OFT has three other concerns:

(1) "refusal to supply by Genzyme";[2]

(2) vertical integration by Genzyme by the creation of its own Homecare Services[3] provider, Genzyme Homecare ("GH");[4] and

(3) the market position of one competitor, the original complainant, HH ("HH").[5]

5. It is surprising that Genzyme persists in these arguments, which are clearly wrong:

(1) As the OFT has repeatedly noted, the Decision is not concerned with refusal to supply but the price abuses of bundling and margin squeezing, if only because Genzyme has *not* refused to supply third party purchasers, but has offered supplies only at a price equal to the bundled NHS list price since May 2001. The OFT is concerned with the adverse effect on the competitive structure of the market arising from Genzyme's pricing strategies.

(2) The OFT does not object to the creation of GH, which is in itself entirely consistent with a competitive market, provided that Genzyme does not use its control over pricing to exclude competition or to distort competition in favour of GH. The Decision finds that Genzyme's pricing strategy is abusive in that it serves to foreclose competition from all independent

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[2] E.g. paragraph 11 of the skeleton, though the point is repeated throughout. At paragraphs 26 and 27, it is used as a peg to hang a repetition of Genzyme's arguments based on the judgment of the ECJ in *Oscar Bronner*.

[3] "Homecare Services" is defined at paragraph 396 of the Decision to mean "the delivery of Cerezyme 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)".

[4] E.g. at paragraphs 84 to 86, 99 to 100 and 128.

[5] E.g. at paragraphs 9-11 and 14.

suppliers of Homecare Services, despite the fact that (i) there are a number of suppliers that are in principle capable of competing in that market; and (ii) clinicians and patients have a strong preference for choice.

(3) The OFT has made it clear throughout that it is not concerned with the protection of any individual competitor but with the protection of a competitive market structure. As the Tribunal accepted at the interim relief stage (e.g., at paragraphs 80 and 102 of its judgment), HH occupies a special position in this regard as currently the only independent supplier of Homecare Services. The Decision and the Direction make it clear that the OFT is seeking to remedy a structural defect arising out of Genzyme's pricing strategies, not to further the commercial interests of HH (or any other potential supplier of Homecare Services). The OFT is acting to protect the competitive process, and through it the interests of a vulnerable group of end-users and those responsible for their treatment, their doctors and the NHS bodies responsible for providing and paying for their care.

The inconsistencies within Genzyme's appeal

6. These are important errors, which undermine or render irrelevant much of the lengthy material that Genzyme has provided. However, there are three other features of the appeal that the OFT would note.

7. First, the evidence and arguments advanced by Genzyme on the central question of the nature of Homecare Services have become increasingly and strikingly incoherent:

(1) much of the evidence originally served by Genzyme during the administrative stage, including witness statements by Genzyme's employees and internal Genzyme documents, was to the effect that this is a highly specialised and sophisticated service which Genzyme is justified in taking in-house so as to ensure that the highest standards are achieved by GH's "peerless service";[6]

[6] See the specification for Royal Manchester Children's Hospital at OFTCB/2/90.

(2) however, its expert, Professor Yarrow, now advances a quite different view that is radically inconsistent with Genzyme's earlier evidence, likening the service to the delivery and collection of milk bottles, and boldly asserting that the "bespoke and flexible" service, advertised by Genzyme (and by competing suppliers of such services for a range of other conditions) and described in detail by Mr Farrell and Dr Jones,[7] is no more than good practice in the services sector.[8]

8. Secondly, and no less incoherently, Genzyme now seeks to disown the explanations of its pricing strategy that it gave to the DoH in 1999-2000 to avoid a full 4.5 per cent reduction in the Cerezyme list price.[9] Professor Yarrow describes these negotiations as "horse trading";[10] and it is now "accepted" by Genzyme "that the DoH ought not to have acceded to that argument as the NHS List Price was not in any sense higher as a result of the supply of the services".[11] This is not only inconsistent with the account given by Genzyme to the DoH in 1999/2000, confirmed by the direct evidence of Mr Brownlee, but also with Genzyme's own internal documents and correspondence about pricing (e.g. "*the way in which Caremark operate is by including the whole package under the heading of drug costs when they bill the health service*", internal memorandum dated 14 January 1997: OFTCB/1/61).

9. Thirdly, one of the leitmotifs of Genzyme's skeleton is to allege that the OFT has failed to carry out proper enquiries into the market.[12] This is not only quite untrue, as the detailed analysis in the Decision makes clear, but also rests on a false premise that there are major factual disputes between the parties that are relevant to the case. In fact:

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[7] See CB2/53 and 62.

[8] See CB1/22/194 and CB1/23/231. Professor Yarrow also compares Homecare Services to the delivery of Pizza and the driver of a school bus.

[9] The account given to the DoH is the same as the explanations given to Professor Cox and Mr Manuel of the Gaucher Association in 1996-1997 and is consistent with both the pricing history for Ceredase and Cerezyme and also the terms on which both Caremark and HH were engaged to provide Homecare Services between 1995 and 2001. This correspondence is at OFTCB/1-31.

[10] See CB1/22/198. Although Professor Yarrow maintains that he may be mistaken in his recollection, Mr Brownlee comprehensively rejects Professor Yarrow's theories in his first witness statement: CB1/32.

[11] In support of this new argument, Genzyme seeks to adduce a new analysis of the figures (including new data) produced by Mr Williams as part of the bundle of statements produced with Genzyme's Reply.

[12] See, e.g., paragraph 12 of the skeleton; indeed, section B of the skeleton is curiously entitled "The OFT's flawed investigation", although it is really a general restatement of Genzyme's case on all the issues in the appeal (though the issues on abuse are dealt with very briefly at paragraphs 84-88 and then also in Part C of the skeleton).

(1) much of the relevant background to the case was helpfully summarised by the MMC in its report on the proposed merger between Fresenius and Caremark,[13] which both parties accept as essentially correct; and Genzyme itself has provided evidence as to the nature of homecare services that the OFT has accepted and adopted in its Decision and Defence;[14]

(2) the central issues between the parties concern the proper characterisation of a limited number of essentially undisputed facts relating to (i) the research and development of treatments for lysomal storage disorders; (ii) the nature of competition for homecare services; and (iii) the pricing strategy adopted by Genzyme since 1995, analysed against the specific circumstances of supply of medicines to the NHS (which are also essentially undisputed);

(3) other issues (such as the meeting with NSCAG in February 2001, the nature of the business of Polar Speed - a third party supplier referred to for the first time at the interim relief stage - and TKT's hopes to introduce a competing enzyme replacement therapy in the next few years) are of marginal relevance to any issue that arises on this appeal; and finally

(4) some significant questions of opinion, such as the difference of emphasis that appears in the evidence of Professor Cox and Dr Mehta as against Dr Vellodi and Dr Waldek, or even between Mr Brownlee and Professor Yarrow, are essentially matters of evidence as to the state of mind of particular individuals - the principal individuals on whose evidence the OFT relied in its Decision have confirmed that their views have been correctly represented in the witness statements that have been prepared.

10. In relation to the first two points above, the OFT submits that this inconsistent approach is a relevant factor to be taken into account in assessing the arguments that are now advanced by Genzyme on this appeal. In addition, the consistent contemporary correspondence and internal record of Genzyme's conduct, confirmed by Genzyme's own witness statements served during the administrative

[13] CB2/39.
[14] Paragraph 54 of the Defence summarises this material.

procedure,[15] are a much surer guide to the reality of the situation than the hypothetical explanations and amendments to the historical record now proposed for the purposes of this appeal by Professor Yarrow and Mr Williams. Their suggestions are in any event to a large extent contradicted by Mr Brownlee, Mr Farrell, Dr Jones, Professor Cox and Dr Mehta on the basis of their direct knowledge and experience.

The economic significance of the case

11. Finally by way of introduction, Genzyme bluntly states that:

> "The issues in this case are of no or very limited public interest, the number of Gaucher patients involved who receive nursing and delivery are miniscule and the principles involved are of no obvious relevance to any other case."[16]

12. The OFT rejects this self-serving and rhetorical criticism as unfounded. Although the number of Gaucher patients receiving ERT is relatively small, most of them are treated with Cerezyme at home and these patients require Homecare Services, i.e. the specialist services:

(1) of the kind identified by the MMC in *Fresenius/Caremark*;

(2) repeatedly so described by Genzyme in correspondence between 1996 and 2001, and in the internal and bid documents that it produced when GH was created;[17] and

(3) recognised by Genzyme itself at paragraphs 66ff. of its skeleton argument.

The NHS doctors and pharmacists with overall responsibility for the provision of such treatment regard this as an important issue over which they have expressed their serious concerns at Genzyme's pricing strategy, especially since the creation of GH. In addition, the very high cost of Cerezyme substantially increases its economic implications for Genzyme's customers. As a matter of elementary

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[15] The relevant material in relation to the nature of Homecare Services is summarised at paragraphs 54 of the Defence.

[16] Paragraph 14 of the skeleton argument; as part of the Introduction to the argument, Genzyme has calculated the numbers of patients currently receiving nursing assistance, asserting that the significance of the case is limited to these individuals – that is quite false, as Mr Farrell's evidence makes plain. Genzyme also exhibits a short briefing note produced by RBB Economics in relation to this case, which suggests that the "underlying theory of competitive harm remains obscure" in the Decision.

[17] OFTCB/67-96.

arithmetic, 150 patients each costing the NHS £100,000 per year to treat are economically equivalent to 15,000 patients treated at a drug cost of £1,000 per year (cf. the MMC report into the *Fresenius/Caremark* merger at paragraph 4.15: "*Gaucher's disease, despite its small patient base, is the third-largest sector by value*"; and cf. Tables 4.2 and 4.3).

13. So far as the wider significance of the case is concerned, the setting by a dominant firm of a bundled price which includes additional services that are in principle available from a range of competing suppliers, is a form of abuse with potential application to a wide range of economic sectors. Likewise, the exclusion of downstream competition to a vertically integrated monopolist by application of a "margin squeeze" is an important form of market distortion, again with wide application. The system of price controls that form part of the factual background to this case do not alter those facts.

14. In his first report, Professor Yarrow suggests that there is no economic incentive for the abuses found in this case unless the OFT can demonstrate foreclosure effects on the upstream market: see CB1/22/216 ("in the absence of effects in other markets, it is difficult to see any anti-competitive rationale for Genzyme to seek to exclude other companies from distribution and homecare services provision"). The OFT maintains that such upstream effects are demonstrated here, but the theoretical point that Professor Yarrow makes is incorrect in any event. The facts of this case illustrate that a "bundled" price for the drug and Homecare Services creates a situation where any cost savings or efficiencies achieved in the supply of Homecare Services accrue to the upstream monopolist, Genzyme, rather than to end users – there has been no change in the Genzyme list price despite the reductions in the costs of homecare provision (such as when the HH contract was renegotiated in 2000). Indeed, since May 2001 Genzyme has continued to be paid its full bundled price even where HH is in fact providing the service at its own cost and without any remuneration from Genzyme. Genzyme does therefore have a commercial incentive to engage in bundling and to exclude other homecare providers from the downstream market via a margin squeeze, independently of any effects on the upstream market.

MARKET DEFINITION

Orphan drugs and LSDs

15. Before embarking on the issues in the appeal, Genzyme again stresses the context of the case, that it concerns an innovative medicine enjoying certain protections from competition not only as a matter of intellectual property law but also under the special regime for "orphan drugs": paragraphs 18 to 28 of the skeleton argument.

16. This issue has been exhaustively debated throughout the administrative stage and the OFT is well aware of the strong feelings that it naturally arouses in Genzyme. However, it remains the case that Genzyme's contentions have little relevance to the appeal.

17. That is so for two main reasons:

    (1) The issues of market definition, to which this issue has primary relevance in the arguments advanced in the NoA,[18] are not affected by the fact that this case concerns an "orphan drug". Indeed, the intervention of the legislator in respect of treatments for rare disorders is entirely consistent with the OFT's action in this case to protect the proper functioning of the competitive process, which ultimately affects the welfare of those suffering from such disorders: see paragraph 31 of the Defence.

    (2) Although Genzyme seeks to advance an argument that the Decision is to be criticised for failing to consider the issue of "orphan drugs" in relation to dominance and abuse, it does not go so far as to claim that there is any exemption from the competition rules for monopoly suppliers of such products. It is well established that the ownership of an intellectual property right, which Genzyme relies on by analogy at paragraphs 22 and 26 of its skeleton argument, confers no exemption on its owner to act in a way that goes beyond the specific subject matter of the right. In particular, it

[18] See, e.g., paragraph 16 of the NoA.

confers no licence to engage in pricing practices that have the effect of distorting competition on downstream markets.[19]

The OFT's market definitions

18. The OFT explained its approach to market definition at paragraphs 23-74 of the Defence. As stated at paragraph 24, the OFT identified an "upstream" market comprising "the supply of drugs for the treatment of Gaucher disease" and a "downstream" market comprising at most "delivery of Cerezyme to hospitals and sales support (i.e. Wholesaling) and home delivery of Cerezyme and provision of homecare services (i.e. Homecare Services)".

The upstream market

19. In summary, the upstream analysis applied by the OFT in the Decision was (i) a preliminary analysis by reference to EC merger decisions and the ATC classification for Cerezyme and Zavesca: paragraphs 134-9 of the Decision and paragraph 37 of the Defence; (ii) a standard demand-side analysis by reference to substitutability and consumer demand: paragraphs 140-9 of the Decision and paragraphs 38-41 of the Defence; and (iii) a standard supply-side analysis to identify those undertakings capable of meeting such demand: see paragraphs 151-3 and 158 of the Decision and paragraphs 42-44 of the Defence.

20. Genzyme offers no reason to doubt this analysis in its skeleton argument, paragraphs 33-43:

    (1) It repeats the erroneous claim that the OFT placed undue reliance on merger decisions and the fact that "Cerezyme is currently the most commonly prescribed treatment for Gaucher disease": paragraphs 35 and 37.

    (2) It re-asserts the need to consider the "dynamic conditions of the LSD market", without explaining how that can undermine the outcome of the OFT's standard supply-side analysis, given that Zavesca is the only product currently available or likely to be available within the short to medium term

[19] See paragraph 30 of the Defence; and, e.g., *Volvo v Veng* [1988] ECR 6211 at paragraphs 8-9, distinguishing between the refusal to grant a licence (which would interfere with the "substance" of the exclusive right) and extraneous anti-competitive conduct.

and that the OFT has assumed that Zavesca *is* on the relevant market for the purposes of the Decision: see paragraphs 36 and 39 of Genzyme's skeleton and paragraph 43 of the Defence.[20]

(3) It again criticises the OFT for finding a market that has few customers, something which cannot alter the correct market analysis and which is readily explicable by the nature of the product as an "orphan drug": paragraph 38 of the skeleton argument and paragraph 41 of the Defence.

(4) Paragraphs 40-44 make a variety of assertions about the views of interested parties. The OFT does not accept that they are correct, particularly in relation to the views of those prescribing, purchasing and using Cerezyme. Although the doctors responsible for treating Gaucher patients in general have a wider expertise in LSD's, there is no evidence that any of these parties regard Cerezyme as substitutable with any other product or that prescribing or purchasing decisions taken on behalf of patients proceed on such a basis.

The downstream market

21. The principal segment of the "downstream" market identified by the OFT relates to the supply of Homecare Services, i.e. "home delivery of Cerezyme and provision of homecare services" for Gaucher patients.[21] As in the NoA, Genzyme criticises the definition on two main grounds:

(1) There are "discrete markets for general home delivery and for nursing": paragraphs 47-49 (see also paragraphs 57-63, where Genzyme tries to segregate the elements of the services that are provided).

(2) Whether or not that is right, "neither of these services are further divided according to the therapy being delivered or for the treatment area for which nursing is supplied": paragraphs 50-53.

22. The first of these points was dealt with comprehensively at paragraphs 50-57 of the Defence, by reference to paragraphs 164-172 of the Decision. Genzyme repeats its

[20] Zavesca was only introduced to the UK market in March 2003.
[21] Essentially the same issues arise in relation to the other segment of the market, "Wholesaling": see paragraphs 162(ii), 175 and 181 of the Decision and paragraphs 72-4 of the Defence.

mistaken argument that homecare cannot be viewed as an integrated package of services, on the basis that only a minority of Gaucher patients receive (regular) nursing care as well as the home delivery service. In particular, Genzyme's criticisms do not meet the point that the homecare service provider supplies an integrated service that includes a nursing care component, that the needs of all individual patients vary, and that even patients who self-cannulate may require some nursing care or advice from time to time. As Mr. Johnson of Genzyme puts the matter at paragraph 7 of his latest witness statement, when explaining how he had described Genzyme Homecare's homecare service to NSCAG officials in 2001: "*I explained that Genzyme's commitment was open-ended, both financially and logistically, as the needs of the patients were to be managed on a case by case basis and the degree of individual nursing care could change or vary depending on their disease state or personal circumstances.*"

23. Genzyme offers no effective answer to this material. The only points that are made are:

    (1) HH has on occasion contracted out home delivery to Polar Speed; and

    (2) The tender document exhibited to Mr Farrell's statement shows that in at least one case, treatment for haemophilia, HH has successfully tendered for a contract with a purchaser who did not require nursing services.

24. Neither of these points are of any assistance to Genzyme: it is common ground that those who offer "homecare services" offer a range of different services to meet the demands of purchasers and patients. It is no answer to the OFT's case to point out that there are other undertakings (such as Polar Speed) who offer more limited services, that those undertakings have, occasionally and in exceptional circumstances, been used as sub-contractors by HH for the delivery of Cerezyme, or that in other treatment areas customers do not always require all of the services that are offered.

25. This final point applies equally to the argument that Genzyme advances in relation to the fact that only a proportion of patients requires regular nursing support in the administration of Cerezyme once they have been trained by GH or HH: as Genzyme's own internal documents emphasise, this is a "bespoke" and

"flexible" service comprising a number of interlocking elements that are available to meet the needs of patients in their home over time. Just as the guests at a hotel may not use the swimming pool, so a patient may not require regular specialist nursing, but in order to provide an effective service in this market, such service elements need to be made available to meet the varying and individual needs of patients – see, e.g., Clinovia's web-site at CB2/48/683 and HH's web-site at CB3/57; also paragraph 2.4 of the *Fresenius/Caremark* report at CB2/39/422.

26. The weakness of the appeal on this point is demonstrated by paragraphs 66-70 of the skeleton argument, which place emphasis on the same material as is relied on by the OFT at paragraph 55 of the Defence, showing that competitors such as Clinovia, Central Homecare and HH regard themselves as competitors on the homecare services market, not on markets for individual services such as home delivery, nursing, logistics, 24-hour phonelines or pharmacy services. HH's advertisements annexed to the skeleton tell the same story, HH describing itself as "the leading provider of complex homecare services".

27. Indeed, there are signs that Genzyme recognises that its first criticism is weak, in that paragraph 47 states that "*The evidence in relation to each of these factors makes it plain that there is a market for homecare services*, which in fact comprises discrete markets for general home delivery and for nursing", italics added. The OFT of course agrees with the italicised wording, the question that arises here being whether the provision of Homecare Services (for Gaucher patients) forms part of that wider market given the particular conditions of competition that prevail as a result of Genzyme's pricing policy.

28. It is of course a central part of the OFT's case on abuse that the effect of Genzyme's bundled pricing policy is to restrict competition on the downstream market by raising insuperable barriers to entry by the potentially competing homecare service providers identified by Genzyme at paragraphs 66 of its skeleton argument.[22] Further, no finding of dominance is, or needs to be made on the downstream market.[23]

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[22] See, for example, CB2/49/737, the note of a conversation between Mrs Pope and Mr Nabi of Clinovia: "Genzyme approached the hospital and informed it that Genzyme Homecare could provide the homecare service to the two patients concerned at no extra cost. This appears to have caused the hospital to think

29. The OFT's analysis of the downstream market is, in any event, orthodox and correct and is supported by the approach of the MMC in *Fresenius/Caremark*, contrary to Genzyme's arguments: see paragraphs 64 and 67-68 of the Defence and paragraphs 1.7 and 2.78 of the MMC report.[24]

30. In general terms, there is no demand substitutability between Homecare Services and "homecare services" for other conditions. The supply and administration of other products is not a substitute for supplies of Cerezyme by GH or HH for Gaucher patients, even if there is an overlap in the skills and facilities required: see paragraph 2.71 of the MMC report: "there is no substitutability on the demand side".

31. In relation to supply-side substitution, the problem is access to Cerezyme on competitive terms. As the MMC found at paragraphs 2.75, 2.78 and 4.128:

> "We believe it is necessary, in the light of this evidence, to draw a distinction between contracted and prescribed services. In prescribed services the possibility of entry by service providers depends on their ability to establish a relationship with the product supplier, which is the sole source of remuneration, and in effect to sell their services to them. *The product suppliers effectively, therefore, have the discretion, if they so choose, to foreclose the supply of homecare service*, either by providing the services in-house (vertical integration) or by establishing preferential relationships with individual service providers (vertical agreements), and in practice [...] have done so. Such foreclosure clearly limits the scope for supply-side substitution."
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> "In principle the five prescribed services could also be in the same market because of the similarities in the services supplied and the assets and skills required, but in practice this method of funding ensures that suppliers of drugs and feeds determine who will supply the services associated with each treatment. *Accordingly we believe it is necessary to examine supply for each of the prescribed services separately, while taking account of the possibilities for cross entry between them and from suppliers in the contracted service market.*"
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> "... the funding system for prescribed services implies that a homecare company generally gains business in these areas only if the relevant pharmaceutical supplier either offers it the product at a suitable discount or, alternatively, makes the homecare company a payment to cover its

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twice about using Clinovia. ... EN's view was that Clinovia are prevented from competing from Genzyme Homecare by Genzyme's pricing arrangements ... ".

[23] See paragraph 110 of the Defence, paragraphs 287-9 of the Decision. Contrary to Genzyme's assertion at paragraph 12 of the Reply, it would not be "fatal to the Decision" were the Tribunal to find that there was an error in the definition of the downstream market.

[24] CB2/39/418, 438.

> services. To the extent that pharmaceutical companies are unwilling to make such arrangements with different homecare providers, the potential for supply-side substitution between treatment areas will be reduced." (Emphasis added.)

32. Genzyme asserts that "there is no evidence upon which the OFT could conclude that there is such a market": paragraphs 45 and 50 of the skeleton argument. In fact, not only was the Decision supported by the findings of the MMC concerning this very issue, but also the events surrounding the withdrawal by Genzyme of remuneration to HH in May 2001 (including Genzyme's own assumption that this would lead to HH's exit from the market and that GH would take over all Homecare Services provision thereafter) clearly demonstrate the correctness of the MMC's analysis. A similar situation had been noted by the MMC in the case of Nutricia (paragraph 2.60 of the report), where Caremark had indicated that "it would no longer receive service payments from Nutricia and would not be able to buy the products at a price which allowed it to finance the homecare service".

33. The OFT therefore maintains that, *given the pricing policies currently adopted by Genzyme*, the downstream market is correctly defined in the Decision: see paragraphs 177 ff. The fact that competition on the Homecare Services segment of this market would in all probability be analysed as part of a wider homecare services market were Genzyme to offer Cerezyme at a stand alone price is a vivid illustration of the anti-competitive nature of its current practices, not a reason to doubt the correctness of the OFT's analysis. If Cerezyme was priced separately from Homecare Services, the position would be equivalent to that on the "contracted services" market segments identified by the MMC at, e.g., paragraphs 1.5 and 2.77, CB2/39/418, 437, where separate funding for homecare services enabled supply side considerations to be taken into account. As it is, as the MMC found in relation to "prescribed services", it is appropriate to look at Homecare Services in isolation.

34. Finally, at paragraph 55 Genzyme advances another theoretical point, which does not appear in the NoA but which is made by Professor Yarrow in his first report:

> "If Genzyme Homecare does not prove to be the success that Genzyme expects it will be or proves too costly and *Genzyme chooses* to contract out delivery and/or nursing to a third party, then HH and other homecare service providers would be able to take the opportunity to bid to offer delivery and/or nursing, just as Caremark did when homecare began to be supplied by Genzyme and HH did in 1997/98 when *Genzyme decided* to terminate its arrangements with Caremark.

> As the MMC observed, that demonstrates that viewed from the supply-side (the important side), there is complete substitutability and that therefore the market is not to be defined by treatment area." (Emphasis added.)

35. The reliance on the MMC report is wholly misplaced, as the MMC recognised that the funding arrangements for "prescribed services", including Gaucher disease, meant that there were significant supply-side constraints: see above. More importantly, the bundled price set by Genzyme has created a situation where Genzyme, the drug supplier, rather than the NHS, the Homecare Services customer, decides the terms and conditions on which Homecare Services are provided to the NHS. Thus, it is true that *Genzyme*, acting as an intermediate purchaser, could choose between various suppliers of homecare if contracting out the Gaucher service, as it did in 1998. However, the actual customer for the services is in fact the NHS which buys the drug and Homecare Services from Genzyme at a single price. As far as NHS purchasers are concerned, who wish to specify the services that they require in the same way as they do for other treatments, there is no demand-side substitutability and no prospect of supply-side substitution from other homecare companies: see paragraph 308 of the Decision and the witness statement of Mr Farrell.

DOMINANCE

36. As on other issues, the arguments advanced by Genzyme on dominance are not lacking in bravado, starting with the following comprehensive pleading at paragraph 74 of its skeleton:

> "The OFT has failed to understand or even investigate the question of dominance, whether in relation to the market itself (if the OFT had properly defined it) or in relation to competitive forces from outside that market."

37. Unfortunately, this boldness is not matched by legal reasoning, Genzyme apparently relying on the judgment of a court in relation to the supply of rum in Spain to demonstrate that Genzyme cannot be dominant on the market for the supply of Cerezyme in the United Kingdom: paragraph 75 of the skeleton argument.

38. The remainder of this part of Genzyme's skeleton argument comprises wild

assertions of perversity, irrationality and incompetence, including:

(1) failure to apply the OFT's own guidelines and warnings: paragraph 76;

(2) automatic findings of dominance based on the fact that "Cerezyme is the main available treatment": paragraph 77;

(3) overlooking the obvious fact that Genzyme "cannot be dominant" in the face of "competition from OGS's Zavesca and imminent competition from TKT's GCB, which TKT promises will be cheaper than Cerezyme": paragraph 78;

(4) failing to see that there are "low or non-existent barriers to entry, which is particularly impressive given the riskiness of research in this area and the low patient populations": paragraphs 79-81;

(5) crediting the evidence of TKT, Genzyme's rivals, rather than taking into account that "Far from facing a barrier to entry, TKT is able to "piggy-back" on the expertise and contacts that HH developed as Genzyme's distributor and on Cerezyme's success": paragraphs 82-3.

39. These extravagant criticisms have no relationship to the actual situation or the actual reasoning in the Decision, which is again entirely orthodox and represents a particularly meticulous and systematic application of the approach set out in the OFT's own Guidance, as the Defence explained at paragraphs 75 ff. under the headings "Actual competition and market shares"; "Barriers to entry and potential competition"; and "Buyer power and the PPRS".

40. In so far as the rambling case that Genzyme makes is intelligible at all, it fails to engage with that analysis or to provide any basis to find that it is incorrect. To take a conspicuous example, the first sentence of paragraph 81 states that it is "particularly impressive" that there are "low or non-existent barriers" to entry, while identifying, in that very sentence, two obvious indicators that barriers are very high – the high rates of failure and low patient populations, points on which Genzyme itself has provided extensive evidence (see paragraphs 242 and 243 of the Decision and paragraph 90(1) of the Defence).

41. Moreover, Genzyme offers no answer to the central point set out at paragraph 77 of the Defence, that "Genzyme has enjoyed a monopoly position in the supply of drugs for the treatment for Gaucher disease in the United Kingdom for over a decade and ... its pricing policy reflects its ability to act independently of competitors and customers. The very recent entry of Zavesca onto the market is at best a marginal challenge to Genzyme's dominant position".

42. In respect of the issue of "Buyer power and the PPRS", the further material that has been submitted to the Tribunal in response to the issues raised at the CMC hearing on 31st July 2003 (the Response of the OFT dated 8 September 2003 and the statement of Miss Stallibrass in respect of the involvement of NSCAG) confirm that the OFT's analysis of this issue is correct: see below.

43. In those circumstances, the OFT considers that no further response is called for, and it is content to rely on paragraphs 75 ff. of the Defence, summarising paragraphs 202-281 of the Decision.

ABUSE

44. In the following paragraphs, we address in turn what seem now to be the main points arising in relation to (a) the "bundling" abuse; and (b) the "margin squeeze" abuse.

45. So far as the issue of "objective justification" is concerned, we adopt the same approach as in the Defence. That is, any specific points on objective justification are addressed immediately after the analysis of the other arguments made in respect of each abuse.

46. Genzyme's general point of law about "objective justification", which still exists in a reduced form at paragraphs 92 – 98 of their skeleton, is then addressed by itself, together with Genzyme's insistence in its skeleton that the ECJ decision in the *Oscar Bronner* case governs the correct approach to assessing "abuse" in this case.

The "bundling" abuse

47. In summary, Genzyme now focuses on 3 main arguments:

    (1) By definition, the NHS list price for a drug does include an element representing payment for delivery to the patient, but the NHS list price does *not* include an element representing a payment for any other services (in particular, nursing care). Therefore, by definition, Genzyme does not "make the NHS pay" a price which includes Homecare Services if it wishes to purchase Cerezyme: see paragraphs 139 – 151 of Genzyme's skeleton;

    (2) Genzyme cannot "make the NHS pay" for anything against its will (i.e., through charging a bundled NHS list price for the supply of Cerezyme and Homecare Services). If the NHS wanted to procure home delivery or nursing services for patients using "different arrangements", then it could always exercise legal powers to achieve that result. Those are the same powers that the DoH exercised in 1995 when it issued its executive letter EL(95)5: see paragraphs 153 and 155 – 157 of Genzyme's skeleton;

    (3) In fact, far from imposing any additional financial burden on the NHS, the present arrangements for the provision of homecare enable the NHS to make a significant *cost saving*, because VAT is not paid on the price of the drug: see paragraph 154 of Genzyme' skeleton.

48. Within the section of its skeleton concerned with the "bundling" abuse, Genzyme makes one further point. Genzyme emphasises that, at a meeting with representatives of the DoH in February 2001, the DoH did not raise any objections to the proposed launch of its new in-house homecare provider, Genzyme Homecare: see paragraphs 158 – 161.

49. This claim is puzzling. It is somewhat difficult to see how the events at that meeting with DoH officials in 2001, even taking the account given by Genzyme's employees at its highest, could possibly relate to the "bundling" abuse. If Genzyme is saying that, at the meeting in 2001, representatives from the DoH expressed their satisfaction that the NHS list price for Cerezyme did *not* include an element representing Homecare Services, there seems to be no

foundation for such a claim. Similarly, if Genzyme is saying that, at the meeting in 2001, representatives from the DoH decided that the NHS list price for Cerezyme *did* include a (bundled) element representing Homecare Services, but that this state of affairs raised no problems from the perspective of the NHS, there seems to be no foundation for this claim either.[25]

50. The main possible significance of Genzyme's meeting with the DoH in February 2001 would seem to be that it might affect the level of the *penalty* if Genzyme were reasonably entitled to conclude (a) that the DoH had been made fully aware of their proposed pricing policy directed at HH (the "margin squeeze"), and (b) that the DoH had reached an informed view that this behaviour raised no problems from the perspective of the NHS and patients. However, Genzyme do not mention the point at all in connection with the appropriate level of the penalty. We further address the issue of the February 2001 meeting with the DoH under the heading of the "margin squeeze" abuse, where Genzyme also refers to it.

51. Each of the 3 main arguments outlined at paragraph 47 above is now addressed in turn.

Genzyme's argument that the NHS list price for Cerezyme includes an element to cover basic distribution of the drug to the patient, but does not include any element to cover the provision of (separate) homecare services

52. Genzyme's argument that the NHS list price for Cerezyme is not a "bundled" price was fully dealt with at paragraphs 112 – 134 of the Defence. In particular, that part of the Defence pointed out:

(1) the fundamental false premise, which is now repeated in paragraph 137 of Genzyme's skeleton, that there are (merely) two discrete elements to homecare: delivery and nursing, as opposed to an integrated package of services provided for Gaucher patients at home;[26]

[25] In a further proposed witness statement from Mr. Malcolm Johnson of Genzyme, served on 18 September 2003, he says that neither NSCAG nor the DoH's Medicines, Pharmacy and Industry Division have ever raised any question in relation to the funding of the homecare service. However, he does not go so far as to assert that the DoH/NSCAG have approved Genzyme's pricing practices.
[26] Paragraph 119 of the Defence.

(2) that, in any event, the home delivery element of the service for Gaucher patients is a specialist operation which cannot be equated to ordinary basic wholesaling of drugs to a community pharmacy;[27]

(3) that one cannot *prove* what the NHS list price for Cerezyme has been set to cover by appealing to any "governing principles" of an NHS list price;[28] and

(4) that the contemporaneous evidence in this case is overwhelming, and leaves no doubt but that - in the very words of Mr. Cortvriend of Genzyme himself (the person responsible for the UK marketing of Ceredase and Cerezyme from 1993 until recently):

> "The price paid by the NHS for Cerezyme... includes an element of cost which covers nursing care for home infusion, home delivery and the provision of ancillaries such as water for injection, infusion pumps and lines, needles, swabs etc, together with refrigerators for the storage of drug."[29]

Renewal by Genzyme of the argument that the NHS list prices for drugs normally include delivery to the patient

53. Now, in its skeleton, Genzyme renews its argument that, as a matter of principle, the NHS list prices for drugs are set to include an element covering delivery to patients at home "*when, as is the case for Cerezyme, that is an efficient delivery arrangement*": see paragraph 139. Genzyme argues that the evidence of Mr. Brownlee in his witness statements supports this claim, because, it says, Mr. Brownlee "*agrees with Genzyme that the basic delivery of the drug to the patient in the exceptional context of a delivery to a patient at home is to be equated with the normal wholesaling function, and that the cost of doing so is paid for by the NHS List Price*": see paragraphs 146 – 149, and paragraphs 5 – 9 of the Reply.

54. However, Genzyme's reliance upon Mr. Brownlee is simply odd. What Mr. Brownlee *in fact* has said is that: (a) the operating assumption of the PPRS in primary care is that the supply to medicines manufactured by Scheme members is

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[27] Paragraphs 120 – 122 of the Defence.
[28] Paragraphs 124 – 127 of the Defence.
[29] Paragraphs 128 – 134 of the Defence. The quotation is from Mr. Cortvriend's letter of 28 September 1999 to the DoH, OFTCB/1/34.

through wholesalers and community pharmacists that dispense the medicines to patients in the community; and (b) that if any Scheme member was to inform the DoH that the NHS list price for one of its drugs included an element relating to home delivery to patients, then, for the purposes of the PPRS, the DoH would be interested in whether this was simply a replacement for the basic wholesaling function and covered the basic delivery of the drug to the patient. He would *not* regard a complex home delivery service for the patient as a normal element of the NHS list price.[30]

55. Mr. Brownlee has *nowhere* agreed that the home delivery of Cerezyme can be viewed as "simply a replacement for the basic wholesaling function"; nor has he agreed that that service is only "the basic delivery of the drug to the patient". On the contrary, he pointed out both in paragraph 22 of his first statement and in his second statement that the information which had been supplied by Genzyme, about the nature of the home delivery service that the NHS list price for Cerezyme was set to remunerate, led the DoH to the conclusion that this service was *not* equivalent to a basic wholesaling function. Despite Genzyme's subsequent Houdini-esque efforts in this litigation to characterise the home delivery service for Gaucher patients as (a) discrete from the other elements of the homecare service for patients and (b) as essentially equivalent to a pizza delivery, the consistent evidence from those involved in the trade leaves no doubt that this is profoundly misconceived: see all the material listed at paragraph 122 of the Defence, as well as in paragraphs 165 – 172 of the Decision.

56. Notably, in his second report on behalf of Genzyme, Professor Yarrow himself says: "Paragraph 22 of Mr. Brownlee's witness statement is also of importance in that it indicates that *perhaps the most fundamental question in this case is one of evidence, not metaphysics. The question is: to what extent are the relevant 'homecare' activities a replacement for the normal wholesaling function, which is remunerated via the list price?*" [emphasis added]. As to this, the collective effect of the evidence referred to at paragraph 55 above is clear and compelling. In particular, the statement by Mr. Johnson of Genzyme at the oral hearing before the OFT makes the point vividly:

[30] Paragraphs 20 and 22 of Mr. Brownlee's first statement.

> "Anyone who has worked in the pharmaceutical industry will know what it means by dealing with wholesalers... wholesalers are basically box shifters... They work on very fixed terms. They are very difficult to negotiate with to determine any levels of service... "

57. Moreover, in considering whether home delivery is simply a replacement for the basic wholesaling function (i.e., for the *distribution to* a community pharmacy), it should be recalled that the home delivery operation occurs *after* the point at which Cerezyme has already been distributed to a community pharmacy, and has been dispensed. Both Genzyme and HH have community pharmacies that dispense the drug. Their pharmacists receive dispensing and other fees in accordance with the Drug Tariff. The home delivery to Gaucher patients that *subsequently* takes place (post-dispensing) is a sophisticated additional activity, which needs to be responsive to the habits and idiosyncrasies of the individual patients.

58. Dr. Jones of HH explains in his second witness statement how such home delivery differs from a typically more rigid business-business delivery operation. At paragraph 11 of his statement, Dr. Jones said in particular:

> "In delivering to homecare patients, the service expectations are quite different from, say, the expectations of wholesalers, hospital stores, GP surgeries or retail pharmacies. The focus is not on the number of drops that can be made efficiently per day, but on meeting the individual personal needs of the patient. For example, a patient might unexpectedly want to move the programmed delivery to an evening slot, or to a Saturday, or they might simply forget to be in when a delivery arrives, so that a next-day delivery is needed at short notice. A patient might want to talk to the driver about some aspect of the service, and ask for a chat. The driver needs to be able to spend time ensuring that stock is properly rotated. For all these reasons and more, the more rigid systems used in a primarily business-business operation do not generally fit with this kind of service. We seek to produce a managed product of care for each patient."

59. This fits with the evidence of Dr. Waldek on behalf of Genzyme, who, although not responsible for the treatment of Gaucher disease, confirms in his second statement that clinicians need to be assured that the home care services provided for patients at home are of a high enough standard to meet the demands of the patients: see paragraphs 5 and 9 of Dr. Waldek's second statement.

60. The same point emerges from the evidence of Mr. John Farrell (the Head of Pharmacy Services for each of the Royal Free Hospital NHS Trust, the UCL

Hospitals NHS Trust, the Whittington Hospital NHS Trust and the Camden and Islington Community Health Services Trust), who is an informed NHS purchaser of homecare services. In particular, Mr. Farrell sets out, at paragraph 41 of his statement, the painstaking care that is taken in checking the quality of the *overall* homecare / delivery service:

"The quality of service which a homecare/delivery service provider gives to our patients is crucial. If the service goes wrong, this can be a very grave matter for the patients concerned. A measure of the seriousness with which I treat this issue is that I, together with my technical services pharmacist and, where appropriate, my quality control pharmacist, personally carry out detailed inspections of HH's operations from time to time. I have been twice to their former premises in Brentford, and once to their base in Burton-on-Trent. On such visits, we inspect their storage and pharmacy dispensing facilities, their records, and their cold chain equipment, down to the temperature control in the delivery vans. I even make a point of listening to their customer care representatives dealing with patients on the telephone, because I consider this such a vital element of the service for them."

61. Nor is there any mileage in Genzyme's suggestion that one may discern the "basic" nature of home delivery for Gaucher patients from the alleged fact that Polar Speed, the pharmaceutical distributor, carries out "many" home deliveries on HH's behalf. In response to the Tribunal's specific request at the CMC on 31 July 2003 to know whether delivery of Cerezyme is undertaken for HH by Polar Speed and similar companies, and in what circumstances,[31] Dr. Jones' second statement records the *negligible* extent to which any use has been made of such "basic distribution" companies, and that this has taken place *only* in exceptional circumstances - see, in particular, paragraph 6(b) of his statement:

"In the period from June 2001 to the end of July 2003, there were a total of 25 deliveries of Cerezyme made by companies other than HH, out of a total of 2,918. The breakdown of this is as follows: DHL made 17 of the deliveries - all to this same patient in Guernsey. Polar Speed made 8 deliveries (that is, 0.27 per cent. of the total). Four of the 8 deliveries were made in the period May to June 2003, when our Scottish driver resigned at short notice and we needed emergency cover whilst we recruited and trained a new driver. Two deliveries were made in October 2002 when we had an unforeseen rise in the need for overall home deliveries in the Devon area, and needed additional short-term resources in that area. (In fact, although I say that there were two deliveries, these were a single delivery for two family members). The two remaining external deliveries were made in January and February this year. Mike was not able to establish the reason for using a sub-

[31] The Tribunal specifically requested a further statement from Dr. Jones on this point at the CMC on 31 July 2003: see paragraph 2 of the Order, and the terms of the President's request at page 18, lines 26-29; page 19, line 20 to page 20, line 10.

contractor in those cases, but again this would only have been as a result of some exceptional situation."

62. The difference in the level of the service offering as between, on the one hand, a homecare service provider such as HH, and, on the other hand, a basic pharmaceutical distributor such as Polar Speed, is also apparent from a simple comparison of the "terms and conditions of service" of Polar Speed[32] and the specification for homecare services published by the Birmingham Children's Hospital NHS Trust[33]: see the copies attached for convenience at Annex 1.

63. Finally, for completeness, it is noted that Professor Yarrow, at paragraph 16 of his second report [CB1/23/225], asserts that the OFT's case "*[fatally] relies on an (untested) assumption that home delivery is an 'extra', not a "replacement for the normal wholesaling function.*" However, this is no matter of mere assumption: all the evidence referred to above demonstrates the point conclusively.

Genzyme's argument that the NHS list price for Cerezyme necessarily could not have been set to remunerate the provision of other aspects of the homecare service, in particular nursing care

64. Turning from home delivery to the *other* elements of the integrated homecare service that Genzyme outlined in its correspondence with the DoH in 1999/2000 (in particular, nursing care), Genzyme continues to assert that - apparently *by definition* - the NHS list price for Cerezyme cannot have been set by it to cover these other elements: see paragraphs 140 – 141, and 144 – 145, of Genzyme's skeleton.

65. The steps in Genzyme's argument may be simply summarised as follows:

(1) The question is: what, *objectively*, is paid for by the NHS List Price for a drug (paragraph 144 of Genzyme's skeleton);

(2) The NHS List Price is concerned with reimbursement to pharmacists for their costs of acquiring a drug (paragraph 145 of Genzyme's skeleton);

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[32] The terms and conditions of service for Polar Speed (copy supplied by Taylor Vinters under cover of a letter dated 18 September 2003) are their general terms, but apply equally in relation to home deliveries that the company undertakes.

[33] See, in particular, section 5 of the document.

(3) Therefore, the NHS List for a drug cannot, by definition, be an inclusive price set to remunerate the provision of nursing care or other ancillary homecare services (paragraph 140 of Genzyme's skeleton).

66. However, this is chopped logic. The *mechanical arrangements* under the Drug Tariff for reimbursing pharmacists through the PPA for the acquisition of a drug are, certainly, carried out by reference to the NHS List Price which has been set by the drug manufacturer, but this does not tell one anything about the *components* that make up the NHS list price for a particular drug, and in particular whether it is a bundled price. In any event, Cerezyme is generally paid for by means of *hospital prescriptions*: in such cases, the price is arrived at as a matter of negotiation, with the NHS List Price simply as a ceiling.

67. In fact, there is *no* regulatory control by the DoH over any specific elements in the price that is initially set by the drug manufacturer, and which becomes the NHS List Price. Mr. Brownlee has specifically explained the limited role of the PPRS (in constraining overall profitability and individual price increases), and the reserve powers deriving from ss.34-38 of the Health Act 1999: see paragraphs 37 – 38 of his first statement.

68. Moreover, in their *Fresenius / Caremark* report, the MMC had no difficulty in concluding that, in some cases, the NHS list price for a drug was set by the manufacturer to cover homecare services. At paragraph 4.51 of the report, they stated:

> "Although the FP10 [prescription] referred only to the drug required, it was usually intended that the supplier of the pharmaceutical product supplied the product together with the additional services and equipment necessary for the home service. *Thus, although the pharmacist's reimbursement for the prescription was based on the NHS list price for the product, this price was set to recognize not only the product cost but also the additional services and equipment associated with the home use of the product.*" [emphasis added]

69. Once Genzyme's "objective meaning" argument is dismissed, that leads on to the true factual inquiry about the particular circumstances of the NHS list price for Cerezyme. At paragraph 143 of its skeleton, Genzyme attempts to confront the clear meaning of its correspondence with the DoH in 1999/2000 about what

elements the current NHS list price for Cerezyme is set to cover, in the following way:

> "Genzyme did negotiate an amelioration of the 4.5% cut on NHS List Prices imposed by the DoH under the 1999 PPRS by advancing an argument that when the NHS pays the List Price it also receives value added services, but it is accepted that the DoH ought not to have acceded to that argument as the NHS List Price was not in any sense higher as a result of the supply of the services (see second witness statement of Mr Williams, paragraphs 5 - 41)."

70. Accordingly, Genzyme's case seems now to be that, although the company *did* represent to the DoH in 1999/2000 that the NHS list price for Cerezyme was set to remunerate the provision of homecare services as well as the supply of Cerezyme, the DoH "*ought not to have acceded to that argument as the NHS List Price was not in any sense higher as a result of the supply of the services.*" This is difficult to understand. Both Genzyme and the DoH proceeded on the common footing that the NHS list price was higher than it would otherwise be as a result of being set to remunerate the provision by HH of a package of (additional) homecare services for Gaucher patients, including home delivery. That is expressly why the price cut mandated by the DoH under the 1999 PPRS was applied only to a *proportion* of the NHS list price.

71. Nor does Mr. Williams give any cogent reason for supposing, in his second statement, that the NHS list price for Cerezyme somehow did *not* include elements to cover homecare costs (and so was not higher than it would otherwise be). So far as the OFT can see, the closest that Mr. Williams comes to making any kind of comment on the point is at paragraph 15(c) of his report, where he says weakly that Genzyme's costs "*were equivalent in nature [to a traditional pharmaceutical company] in that they related to getting the product from the manufacturer to the patient.*" That is, with respect, an unsatisfying and obviously incomplete description of Homecare Services.[34]

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[34] Mr. Williams' statement is essentially dedicated to making an attack on the *level* of the element of the NHS list price that was accepted by the DoH to relate to remunerating the provision of homecare services by Caremark, as opposed to the underlying *principle*. This attack is not in the nature of Reply evidence. While the OFT would generally not be inclined to take a point about such a development, the imminence of the final hearing, coupled with the difficulty that Mr. Williams has failed to supply unseen management accounts that he has used in his calculations, or to clarify the basis for his estimates and calculations, places the OFT in an invidious position.

72. In any event, the exertions of Professor Yarrow and Mr. Williams to explain away the 1999/2000 correspondence with the DoH are in vain, as the position is also confirmed by the internal Genzyme pricing documents and pricing correspondence on the file. See, for example:

(1) The letter dated 26 March 1993 from Mr. Cortvriend of Genzyme to Mr. Dibblee of Unicare/Caremark: "*With regard to the community pharmacy supply of Ceredase via FP10 prescriptions, we intend that the price be £2.97 per unit to the customer and that you be charged £2.67 per unit. This difference will encompass your total distribution costs, together with the supply of ancillary items used in the non hospital environment, the provision of nursing support by Caremark where deemed to be appropriate and other elements of service as discussed.*"[35]

(2) The memorandum dated 14 January 1997 from Mr. Van Heek to Mr. Cortvriend: "... *The way in which Caremark operate is by including the whole package under the heading of drug costs when they bill the health service.*"[36]

(3) The business proposal for Genzyme Homecare dated November 2000 stated: "*Genzyme pays an entirety of the cost of homecare provision: it is included in the cost of Cerezyme to the NHS at the agreed price.*"[37]

Conclusion

73. Genzyme's arguments that the NHS list price for Cerezyme is not a bundled price are insubstantial and contradicted by all the evidence.

Genzyme's argument that there cannot be an abuse because the NHS has chosen not to exercise its "powers" to change the basis upon which homecare services for Gaucher patients are funded, and so the NHS can be assumed to endorse Genzyme's current pricing policy

74. At paragraphs 153 and 155 – 157 of Genzyme's skeleton, Genzyme argues that there cannot be any "bundling" abuse because the NHS, as the customer, has

[35] OFTCB/1/1.
[36] OFTCB/2/61.
[37] OFTCB/2/78.

chosen not to exercise its powers to change the basis upon which homecare services for Gaucher patients are funded. The NHS can, implies Genzyme, therefore be assumed to endorse Genzyme's current pricing practices.

75. There are a number of flaws with this argument, which have been pointed out in paragraphs 170 – 173 of the Defence, and which, regrettably, Genzyme's skeleton does not attempt to grapple with or even acknowledge. In short, these are:

(1) The NHS is *not* a single trading entity: it is a collection of different parts which exercise different functions, and which cannot be relied upon to act as an effective counterweight to anti-competitive behaviour by drug companies;

(2) So far as the *PPRS Branch* of the DoH is concerned, their remit does not include addressing competition concerns arising from Genzyme's system of bundled pricing;

(3) So far as the *hospital Trusts* which purchase Cerezyme and Homecare Services for Gaucher patients are concerned, it is impossible to argue that they have endorsed Genzyme's inclusive pricing arrangements as in the interests of the NHS or of patients. On the contrary, see –

(a) the evidence that they want to have a realistic choice of homecare provider, listed at paragraph 308 of the Decision;

(b) paragraphs 356 – 360 of the Decision, referring to the questions raised about Genzyme's pricing policy by Professor Cox and by the Gaucher Association; and

(c) the witness statement of Mr. Farrell (responsible for purchasing at one of the four specialist Gaucher centres), pointing out his frustration at Genzyme's inclusive pricing policy.

(4) There is no basis for thinking that the DoH could have exercised powers to require Genzyme to "unbundle" the NHS list price for Cerezyme.

76. As to this latter point, at the CMC on 31 July 2003, the Tribunal required the OFT to answer, in particular, the question whether the Secretary of State could decide

that the price of a *drug* (such as Cerezyme) would be met on prescription, but that the price of *services* (such as homecare services) would not be met on prescription, but would be the subject of a separate contract: see paragraph 4 of the Order. The Tribunal's essential concern was indicated by the question from the President, at page 25 lines 36-38 of the transcript of the hearing:

> "Why can't you, through the mechanism of controlling the prescriptions, effectively unbundle the price?"

77. Having investigated the position with the DoH, the OFT's answer to the questions raised by the Tribunal were set out in its Response of 8 September 2003. The main points, for present purposes, are:

(1) EL(95)5 was administrative guidance intended to achieve the result that GPs should cease prescribing "packages of care" services (essentially, homecare services) on FP10 prescription forms. The practice had developed of supplying and reimbursing a range of services through GP prescribing as part of the overall cost of the treatment itself. Ministers had decided that providing these "packages of care" through *GP prescribing* was inappropriate. The reason why EL(95)5 did not mention Gaucher patients was probably because, in 1995, Ceredase (Cerezyme was not supplied at that time in the United Kingdom) was being prescribed for very few Gaucher patients *via* GP prescriptions (as opposed to *via* hospital prescriptions).

(2) Apart from the PPRS mechanism, there is no power to control the NHS list price charged by manufacturers (or wholesalers) to pharmacists and reimbursed by the PPA under the Drug Tariff. A drug such as Cerezyme, which is treated as a "zero discount" drug, is reimbursed by the PPA at the manufacturer's chosen list price.

(3) The Secretary of State does have statutory powers to determine the level of reimbursement by the Prescription Pricing Authority ("PPA") to pharmacists for the provision of pharmaceutical services. Those powers could in theory be used to limit *reimbursement by the PPA to pharmacists*, so as to exclude remuneration for the services element included by a manufacturer in a

bundled drug price.

(4) However: (a) that would be administratively very difficult if not impossible; and (b) in any event, simply limiting *reimbursement to pharmacists* would not compel a manufacturer such as Genzyme to unbundle its prices to the NHS, and might well lead to a successful legal challenge, on the basis that the Secretary of State was acting unlawfully by failing to meet the actual costs being incurred by pharmacists in acquiring drugs that had been prescribed for patients under the NHS;

(5) Cerezyme is not in general prescribed by GPs. The majority of prescriptions that are issued by hospital doctors are paid for directly by the hospitals, rather than being reimbursed by the PPA. These are purchases made on the basis of commercial negotiation between hospitals and suppliers of the relevant drug, in this case Genzyme. Therefore, even if the Secretary of State could direct NHS authorities such as hospital Trusts to contract separately for the provision of homecare services, this would fail to address the abusive pricing issue that arises in this case. It would simply result in those authorities incurring *additional* costs (because they would pay twice over for homecare services – once through Genzyme's price for the drug, and once again through a separate contract for homecare services), unless they could achieve an unbundled price by means of commercial negotiation. That is the position that effectively prevails already, as it is Genzyme's pricing policy, rather than any contractual restraint, which deters NHS purchasers from contracting for Homecare Services.

78. At paragraphs 155 and 156 of its skeleton, Genzyme suggests that, through the use of (unspecified) powers such as those which led to EL(95)5, the DoH could itself take action to require Genzyme to unbundle its NHS list price if this was wanted. For the reasons set out above at paragraph 77, that is wrong.

79. The inescapable reality of this case is that Genzyme's pricing practices *are* a matter of concern to individuals within the NHS who are responsible for purchasing treatment for Gaucher patients, and to the two specialists who have ultimate responsibility for the clinical treatment of all adult Gaucher patients in the country.

Moreover, two out of the four specialist Gaucher centres in the country are, pending the outcome of this appeal, themselves supporting HH by making purchases of Cerezyme on their behalf and thereby choosing to shoulder an additional commercial credit risk in order to keep HH in the market: see the points made by the President in the judgment on interim relief, at paragraphs 19, 35 and 100.

80. In those circumstances, it does not lie in Genzyme's mouth to say that the NHS is content with its pricing practices, and that the NHS can be assumed to have consciously chosen not to exercise "powers" to alter those pricing practices. On the contrary, only this Tribunal has the power to direct Genzyme to cease its abusive pricing practices.

Genzyme's argument that the present arrangements for the provision of homecare actually enable the NHS to make a significant cost saving, because VAT is not paid on the price of the drug

81. At paragraph 154 of its skeleton, Genzyme emphasises that the treatment of patients under homecare arrangements enables hospitals to make a significant cost saving on the price of the drug, as compared with the situation where patients are treated in the hospital setting. That is so because, when Cerezyme is dispensed in the community for the treatment of a patient at home, VAT is not paid on the price of the drug.

82. This is perfectly true, but it has no relevance whatsoever to the OFT's finding in the Decision, which is concerned with the impact of Genzyme's inclusive pricing policy on the possibilities for competition *between* homecare providers. Whatever the savings made on VAT, the purchaser is still faced with a bundled price and no incentive to obtain Homecare Services from anyone other than Genzyme. As stated in paragraph 302 of the Decision:

> "... when the NHS purchases Cerezyme (for use in the community or in hospitals), it automatically pays for the Homecare Services. Therefore, if the NHS wished to purchase Homecare Services from anyone other than Genzyme (or an undertaking acting under contract for Genzyme) it would have to pay for the Homecare Services twice: first to Genzyme, as part of the inclusive price of the drug and

Homecare Services, and then to the independent delivery/homecare services provider, as reimbursement for the Homecare Services. It is, therefore, of no interest to the NHS to purchase the Homecare Services from anyone other than Genzyme."

Genzyme's remaining arguments that its inclusive pricing policy is objectively justified

83. Genzyme's arguments relating to the issue of "objective justification" of its inclusive pricing policy have already been disposed of in the Defence, at paragraphs 163 – 176. At paragraphs 106 – 108 of its skeleton, Genzyme advances a small number of additional points, which are now addressed.

84. First, Genzyme suggests that the OFT's view that responsible individuals within the NHS want to be able to have a choice of Homecare Services provider boils down to a single individual – Mr. John Farrell, the Chief Pharmacist responsible for drug procurement at, in particular, the Royal Free Hospital. That is simply to ignore the evidence: in particular, see, in addition to the material listed in paragraph 308 of the Decision, the statements from Professor Cox and Dr. Mehta, and the account given by Clinovia of the difficulty faced by them as a result of Genzyme's pricing policies in relation to competing to provide homecare services for Gaucher patients on behalf of a hospital in Berkshire (exhibit CHM3 to Mr. Munro's witness statement). See also the views expressed by the patients' association in the Gauchers Association position paper dated 21 March 2001: [OFTCB/3/130].

85. Secondly, Genzyme asserts that Mr. Farrell is not at liberty to require Genzyme to "fund" him so that he can select his own homecare provider. That is a most puzzling assertion, and, with respect, appears to betray a misunderstanding of the case. The OFT's case is *not* that Genzyme should be required to pay the NHS in order that it can select a competing Homecare Services provider. The point is that Genzyme should desist from forcing the NHS to pay an inclusive price for Cerezyme, so that the relevant NHS Trusts have a realistic choice about which provider to use.

86. Nor is this a matter of mere "preference" on the part of an ordinary customer. It falls to be emphasized that the NHS Trusts have a responsibility to provide the

most appropriate clinical care for their patients, including homecare provision. Genzyme's pricing practices impede them from being able to achieve that important end.

87. Thirdly, in relation to the OFT's point that Homecare Services should be contracted for outside the NHS list price for the drug, Genzyme asserts (at paragraph 107 of its skeleton) that the OFT "appears to believe that it would be justifiable for Genzyme to deliver to community pharmacies, so that the patient would have to go with a cool-bag and collect the Cerezyme... ". This, again, seems to betray a troubling misunderstanding on Genzyme's part. The OFT's case is, of course, not that patients should have to go with cool-bags to their community pharmacies. It is that Genzyme should "unbundle" the NHS list price for Cerezyme so that the NHS may have a choice of Homecare Services providers for Gaucher patients (who would deliver to the patients at home).

88. Fourthly, at paragraph 108 of its skeleton, Genzyme claims that the OFT is seeking to impose a 18.3% price cut on Cerezyme retrospective to 1999, and that this cannot but prejudice the ability of Genzyme and other similar companies to attract investment in research and development. The reference to a price cut "retrospective to 1999" is obscure. But again, there is a fundamental misunderstanding. The OFT's case is *not* that the price for the drug itself is excessive; it is that the NHS list price for the drug currently includes an element intended to remunerate a quite separate economic activity (i.e. the provision of Homecare Services), and that this practice of "bundling" should be brought to an end.

THE "MARGIN SQUEEZE" ABUSE

The two additional points taken in Genzyme's skeleton

89. Most of Genzyme's arguments in its skeleton on the "margin squeeze" abuse have already been sufficiently addressed in the Defence. There are only two new points, which are now addressed. Moreover, one of these is simply by way of incorporating the contents of a polemical case note by RBB, the economic consultancy formerly retained by Genzyme.

90. First, at paragraph 166 of its skeleton, Genzyme asks rhetorically why it should be required by competition law to pay a third party to provide a service which it can offer itself? However, once again, this fundamentally misunderstands the nature of the "margin squeeze" case. There is no question of requiring Genzyme to *pay* any independent provider to supply services to the NHS. The point at issue is that Genzyme is prepared to supply Cerezyme to independent homecare providers only at the same price at which Genzyme (through Genzyme Homecare) sells *both* Cerezyme *and* Homecare Services to the NHS. That state of affairs means that no independent provider, no matter how efficient it may be, can compete sustainably against Genzyme in respect of the supply of Homecare Services.[38]

91. Moreover, Genzyme's attitude appears to betray another vital misconception. The provision of Homecare Services is *not* merely an aspect of the efficient distribution by Genzyme of its product to final consumers. It is *not* in the nature of an internal service for Genzyme, like a marketing or a legal department. It is a separate and complex service, for which the *NHS* is the distinct customer in a downstream market, and where there are a number of specialised competing providers.

92. That point also illuminates the fallacy in the RBB case note. RBB states: "*Since almost any product process involves the supplier combining a series of attributes, almost any product sold can be characterised as a bundle of some kind. A formalistic approach to the investigation of bundling concerns that is not disciplined by the need to identify a substantive competition concern raises the prospect of an epidemic of margin squeeze cases.*" However, as the OFT Decision took care to spell out, there *is* a substantive competition concern in this case. The provision of Homecare Services is clearly a separate activity from the supply of the drug, and it is a service which in other treatment areas is provided separately. It is also an activity over which clinicians value choice, and where the identity of the Homecare Services provider matters both to them and to the patients for whose care they are responsible.

93. RBB goes on to say: "*Consider the dominant firm that chooses to manufacture its product in-house. Does that decision represent a 'margin squeeze' against contract manufacturers who have thereby been denied the opportunity to enter this 'market' for contract manufacture? Are the issues any different for logistic services? Or advertising? Does the dominant firm's decision to employ in-*

[38] See paragraphs 375 - 376 of the OFT Decision.

house lawyers result in a margin squeeze against independent law firms? These scenarios are (to us at least) ridiculous, but it is hard to see any basis to differentiate them from Genzyme's decision to offer its product in a form that happens to embody homecare services."

94. Certainly, RBB's examples are very odd, but it is not hard to differentiate them from the present case. In-house lawyers, advertising executives and so on provide a service for the company in relation to the marketing of its product, and not directly to customers in a separate market. So, when RBB refers to "*Genzyme's decision to offer its product in a form that happens to embody homecare services*", this fails to recognise that Homecare Services are not a part of a single product called Cerezyme – they are a distinct service provided on a different market.

Genzyme's arguments on "objective justification" for the margin squeeze abuse

95. At paragraphs 109 – 118 of its skeleton, Genzyme makes a series of arguments in relation to the issue of an objective justification for its "margin squeeze" pricing practice. A number of the arguments made are, once again, sufficiently addressed in the Defence. However, the following 5 points need to be dealt with.

96. First, at paragraph 111 of the skeleton, Genzyme argues that it is *inconsistent* for the OFT to claim, on the one hand, that the identity of a homecare services provider can influence the choice of treatment for a patient, and yet, on the other hand, to reject Genzyme's view that there is a real risk that HH might favour a competing product to Cerezyme.

97. However, this is an elementary error. The OFT's case, which was set out clearly in the Decision[39] and in the Defence[40], is *not* that a homecare services provider will or may seek to exercise a direct influence over the choice of treatment for a patient. The OFT's case is, rather, that the *identity* of a Homecare Services provider can influence the prescribing clinician in relation to making the choice whether to switch a patient from one drug treatment to another, if it is also necessary to switch the Homecare Services provider. The strong view of Professor Cox in particular, who is one of only two leading specialists for the treatment of Gaucher

[39] See paragraphs 334 – 339.
[40] See, in particular, paragraphs 140 – 149.

disease in adult patients in the UK, is that there would be significant added difficulties in switching patients over to a new drug requiring homecare if this meant also changing the service provider. As a clinician, Professor Cox would take into account, when making his decision, the disturbance that this could cause to the patients concerned, given that they can form an *attachment* to their existing homecare services provider.

98. Secondly, at paragraph 112 of its skeleton, Genzyme complains that it should not be "*forced to deal with HH rather than the distributor of its choice or to distribute itself.*" Here as elsewhere, Genzyme continues to approach this case as though the provision of homecare services were merely a distribution function for its product, rather than an aspect of the treatment of Gaucher patients, and upon which it is for the clinicians responsible for the patients' care to exercise choice. More particularly, this case is not concerned with a refusal by Genzyme to deal with HH. Genzyme has chosen to deal with HH, and the margin squeeze issues in the case relate to the terms as to price upon which Genzyme is doing so.

99. Thirdly, at paragraph 116 of its skeleton, Genzyme asserts briskly that there is no evidential basis for the OFT's point, made in paragraph 210 of the Defence, that there is a tension between the commercial interests of the drug manufacturer and the clinical care interests of patients.

100. This is distinctly puzzling, since in the very same paragraph of the Defence, the OFT proceeded to set out a list of particular matters providing evidence of just such a tension, and Genzyme has not attempted to grapple with any one of them. For ease of reference, those matters are as follows:

(1) In his memorandum of 28 July 1999 to Mr. Cortvriend, Mr. Foster of Genzyme discussed the potential business strategies for mitigating the impact on the company of the 4.5 per cent. price cut to the NHS list price for Cerezyme that would be required under the 1999 PPRS, Mr. Foster said:

> "... restricting HH's nursing activities and in house healthcare provision would reduce the price reduction impact in the UK ... *Look to increase dosages to fill budget surplus created by lower pricing* ..." (emphasis added).[41]

[41] 3/465.

(2) In Genzyme's November 2000 business proposal for the launch of an in-house Homecare Services operation, Genzyme referred specifically to the advantage that this would:

> "enable the management of appropriate dosing, and protect our current business from potential competition."[42]

(3) In a series of internal memoranda from 1996, Mr. Cortvriend of Genzyme referred to the difficulties with low dosage prescribing of Cerezyme, particularly by Professor Cox, in the UK.[43]

(4) In a note dated 2 February 2000 from Julie Kelly of Genzyme to Rachel Mackintosh of HH,[44] Ms Kelly made clear that Genzyme has its *own* firm attitude to the extent of nursing care that should be offered to Gaucher patients as part of Homecare Services, in the place of nursing care in the hospital setting:

> "Very senior colleagues at Genzyme are now looking closely at the UK home care service, and if we carry on recruiting more patients into this Category E, we may find that painful and difficult decisions have to be made. It is the responsibility of the local Hospital to undertake infusions if the patient is unsuitable/unwilling to self-infuse (or carer), not Genzyme or HH. For the very last time of writing - PLEASE INSTRUCT THE NURSES ACCORDINGLY."

101. Fourthly, at paragraph 117 of its skeleton, Genzyme claims that a *third party* Homecare Services provider such as HH has an equivalent conflict to Genzyme between commercial interests and the clinical interests of patients. This point is based on the argument that, when HH was paid by Genzyme for carrying out Homecare Services, the remuneration was calculated as a discount per unit. Therefore, Genzyme argues, at least under the terms of its contract with its principal (Genzyme), HH would also have had an interest in trying to increase dosages for the patients.

102. There are two short answers to this: (a) if Genzyme's bundled pricing is ended, there is no reason to think that NHS Trusts will pay homecare service providers

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[42] 9/1911.
[43] Documents attached to the Defence, pages 1-8.
[44] Documents attached to the Defence, page 10.

for their services on a "discount per unit of drug" basis: cf. Mr. Farrell's witness statement, at paragraph 13 and page 4 of JF1; (b) in any event, the issues arising are matters for the NHS to decide upon, not Genzyme.

103. Fifthly and finally, Genzyme appears to claim that, as the result of a meeting with officials from the National Specialist Commissioning Advisory Group ("NSCAG") in February 2001, the DoH approved of the conduct now complained of in these proceedings, and that it is therefore objectively justified.

104. The OFT refers to the statement from Ms Stallibrass of NSCAG. The claim that, at the meeting in February 2001, Genzyme received the prior approval of the DoH for its subsequent conduct directed against HH is groundless. Genzyme's emphasis on the significance of the meeting is entirely overblown:

(1) NSCAG has only limited functions in relation to Gaucher disease, and these do *not* include granting prior approval for developments in the area of homecare service provision, nor funding for such services;

(2) Nor was the meeting of officials with Genzyme anything other than an information exchange: it lasted only one hour, and could not reasonably have been regarded by Genzyme's representatives as the occasion for a grant of informed regulatory approval to their proposed actions;

(3) At paragraphs 158 – 159 of its skeleton, Genzyme places reliance upon a letter dated 4 January 2001 from Dr. Carroll of NSCAG to Ms Kelly of Genzyme. That letter stated: "... *it would be helpful to have a briefing on proposed changes in home care service provision, but, in addition, to hear about the clinical trial with Fabrazyme. We have developed an approach to the introduction of new services and developments in the NHS which essentially requires individual regions to assess the evidence and, where necessary, to then refer the proposed service development to a national group on new services which will shortly be commencing work*". In fact, the OFT understands that the reference in that letter to "new services and developments in the NHS" was a reference to the "clinical trial with Fabrazyme" – not to homecare services for Gaucher Disease, which was not a potential new NSCAG service.

(4) In the present case, once Genzyme had taken action in April / May 2001 to replace HH completely in the provision of Homecare Services for all those Gaucher patients being treated at home, the feedback to NSCAG from individual regions was that this was a matter of some concern: see Stallibrass w/s, paragraph 15: "... *There was speculation among some of the clinicians that this was a transparent attempt to corner the market, through control of the clinical group, in the face of imminent competition... A letter was sent in May, by Genzyme to a wide range of people, including clinicians, responding to a letter that HH had sent out to clinicians... The letter raises concerns that undue pressure is being applied by Genzyme to use their homecare service, the incentive offered being a lower drug cost.*"

THE EFFECT OF GENZYME'S PRICING PRACTICES ON COMPETITION

105. At paragraphs 172 – 192 of its skeleton, Genzyme sets out its case on the effect on competition of its pricing practices for the supply of Cerezyme. The issues raised in relation to foreclosure of competition in the downstream market simply repeat old arguments, and they have already been fully addressed elsewhere.

106. However, there are a small number of additional points now raised by Genzyme in relation to the question of raising barriers to entry *upstream*. These are considered below.

107. First, at paragraph 178, Genzyme refers to the OFT's conclusion that "Genzyme would not be prepared to allow its own delivery/homecare service provider ... to provide delivery/homecare services for drugs which compete with its own". Genzyme says that this allegation does not appear in the Decision, and that it is "bizarre".

108. The first charge appears to be a careless slip on the part of Genzyme: the allegation was clearly presented at paragraph 335 of the Decision, together with the supporting reasoning and the evidence.

109. Nor is it at all "bizarre" for the OFT to claim that, if Genzyme Homecare did provide Homecare Services to the group of Gaucher patients receiving treatment at home, this would make it more difficult for a new drug to replace

Cerezyme. The OFT's reason is *not*, as Genzyme now says, because "other drug companies would regard it as necessary to use Genzyme Homecare [or its appointed distributor] to distribute their new drugs". As was set out clearly in paragraphs 334 – 339 of the Decision, the difficulty that would arise is that, from the point of view of the prescribing clinician, patients would be required not only to switch to the new drug, but also to a new Homecare Services provider, and that this would create a significant additional complication.

110. There are, moreover, some significant indications within the evidence that suggest that Genzyme was well aware of this additional complication, and of the resulting strategic value of being the provider of Homecare Services for all those Gaucher patients being treated at home with Cerezyme:

(1) In the letter dated 21 June 1996 from Mr. Cortvriend of Genzyme to Professor Cox, which is quoted at paragraph 357 of the Decision, Mr. Cortvriend responded to Professor Cox's query about whether it might be possible for hospital pharmacies to import the drug independently of Genzyme's chosen Homecare Services provider (at that time, Caremark). He cautioned Professor Cox that: "*... the price to the patients during the learning curve if new suppliers are involved, could be considerable*" [OFTCB/1/14];

(2) The extract from the business proposal for Genzyme Homecare, cited at [OFTCB/2/78-79] above, refers directly to the expected benefit of "*protect[ing] our current business from potential competition*". As already pointed out in the Defence, it is difficult to see what this statement might mean, if not demonstrating a full awareness of the strategic importance of controlling provision of Homecare Services in reinforcing the virtual monopoly position of Genzyme in the supply of drugs for the treatment of Gaucher disease.[45]

111. Secondly, at paragraphs 182 – 187 of its skeleton, Genzyme assaults the proposition that the clinicians who are responsible for the care of Gaucher patients would be affected in their choice whether to switch to a new drug by the consideration that this would also mean switching the Homecare Services provider.

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[45] Presumably, in this litigation Genzyme subscribes to Wittgenstein's maxim: "What we cannot speak about we must consign to silence": *Tractatus Logico-Philosophicus* (1921) (tr. D. Pears and B. McGuinness; Routledge; 1961).

112. However, it seems difficult for Genzyme to dispute this, given that (a) *both* of the two consultants in the UK principally responsible for the treatment of adults with Gaucher disease (Professor Cox and Dr. Mehta) have confirmed that this is a significant issue so far as their own prescribing attitudes are concerned; and (b) between them, Professor Cox and Dr. Mehta account for the great majority of *all* Gaucher patients in the country.

113. Genzyme has declined the opportunity in this appeal to test the basis of the view held by either man, through cross-examination on his witness statement. Yet, on this *particular* issue, cross-examination would appear inescapable if the point is going to be seriously contested by Genzyme. Instead, Genzyme adopts an alternative approach of attempting to adduce evidence from certain other physicians about their own personal attitudes. But, even if one ignores the fact that none of those other physicians directly grapples with the point at issue, such material can hardly affect the firm evidence from Professor Cox and Dr. Mehta about how *they* would act.

114. Turning to that other evidence, at paragraph 182 of its skeleton, Genzyme claims that the OFT ignores the views of the two remaining leading specialists, Dr. Vellodi and Dr. Wraith, "because their patients are children rather than adults". The OFT does no such thing: the point at issue is sufficiently established by the clear evidence from Professor Cox and Dr. Mehta, who account for the treatment of the great majority of Gaucher patients in the country.

115. In any event:

    (1) So far as *Dr. Wraith* is concerned, the position has not changed since the time of the Defence (see paragraph 148(3)): Dr. Wraith was *not* asked to address the question whether the need to switch the patient's Homecare Services provider as well as the drug could affect the specialist's choice of treatment for the patient;

    (2) So far as *Dr. Vellodi* is concerned, Genzyme have now submitted a witness statement from him, together with the Reply. One might reasonably have expected Genzyme to have asked Dr. Vellodi to address in his statement the question at hand, namely whether the need to switch the

patient's Homecare Services provider as well as the drug could affect the specialist's choice of treatment.[46] In fact, Dr. Vellodi does not address that question *anywhere* in his statement, which is essentially devoted to explaining that he has, to date, been satisfied with the quality of service provided for patients of his by Genzyme Homecare.

116. Genzyme has also submitted, together with its Reply, a second witness statement from Dr. Waldek, who has responsibility at the Salford Royal Hospitals Trust for patients suffering from *Fabry Disease*. Although this is intended to be Reply evidence, Dr. Waldek was not actually shown by Genzyme the witness statements of either Professor Cox or Dr. Mehta for the purposes of making his own statement.[47] That departure from ordinary practice is particularly unfortunate, since at paragraph 9 of his statement Dr. Waldek expresses clear views about how the Gaucher specialists would react if an alternative product to the established treatment, Cerezyme, were to become available. Dr. Waldek says:

> "I am quite clear that if an alternative product for Cerezyme were to become available, the clinicians prescribing enzyme replacement therapy for patients with Gaucher disease would look at the product first and foremost, and having made the choice of drug, would then ensure that the home delivery/home care services were of a standard which met their requirements and those of their patients. I do not think that it would be the other way round in that clinicians would look first to the home care service provision and use that as the primary basis for selecting a preparation."

117. It is plain that, in the absence of having been shown the written statements from Professor Cox and Dr. Mehta, Dr. Waldek has also not appreciated the essential point that they are making. They are, of course, *not* claiming in their evidence that, if a new drug were to appear on the market, they "would look first to the home care service provision and use that as the primary basis for selecting a preparation". They are pointing out that, if it were necessary to change the Homecare Services provider for a patient as well as the drug, this would be an additional significant factor to take into account in deciding where the best interests of the patient lay.

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[46] Genzyme did so in relation to the evidence which they sought at the same time from Dr. Waldek.
[47] Letter from Taylor Vinters dated 11 September 2003.

118. In conclusion, there is no basis for questioning the OFT's conclusion from the evidence that Genzyme's practices are likely to make it more difficult for new drugs to be administered to the clinical group of Gaucher patients.

119. As to the OFT's point that Genzyme's practices are also likely to impede doctors' ability to try various available treatments on a particular patient before being able to determine which one is best suited (see paragraph 340 of the Decision), Genzyme complains at paragraph 188 of its skeleton that there is no evidence for this. However, the point is merely an extension of the main finding that Genzyme's control of Homecare Services provision is likely to make it more difficult for new drugs to be administered to Gaucher patients, and it follows naturally from that finding.

120. Finally, two further points of clarification require to be made in relation to Genzyme's skeleton, where it seems that "the wrong end of the stick" has been grasped by Genzyme, and it is sensible to try to avoid wastage of time at the oral hearing:

(1) At paragraph 190 of its skeleton, Genzyme says that the OFT is advancing a case on abuse that "homecare will impede the development of new drugs", and Genzyme refers to paragraph 116 of the Defence. Genzyme then triumphantly attacks that proposition. But the OFT has not advanced any such case in relation to the abuse issue. In paragraph 116 of the Defence, the point made was the one discussed above, namely that Genzyme's "control over the identity of a Homecare Services provider would influence the *introduction and use* of new drugs for Gaucher disease, which would compete with Genzyme's established drug" (emphasis added). The only context in which the OFT has referred to trials of new drugs is in relation to the issue of *dominance*, and barriers to entry: see paragraphs 230 *et seq.* of the Decision.

(2) At paragraph 191 of its skeleton, Genzyme says that the OFT's case is that "in-house homecare is intended to drive up dosing levels". It is not, and the Defence was quite carefully specific about the point being made. The OFT's case, which only articulates the concerns that have been expressed by the

two leading clinicians, Professor Cox and Dr. Mehta. Those concerns are that, despite no doubt the best intentions of Genzyme, there is a *conflict of interest* in Genzyme's dual role as a drug manufacturer and as a direct (or indirect) supplier of Homecare Services to Gaucher patients in their homes: see paragraphs 208 – 210 of the Defence. In part for this reason, those specialists want to be able to have a choice of Homecare Services provider. This *adds* to the point that it is not objectively justifiable for Genzyme, through its pricing practices, effectively to force its own preferred provider upon the NHS.

GENZYME'S LEGAL ARGUMENTS ON ABUSE AND OBJECTIVE JUSTIFICATION

Abuse: the Bronner case

121. Genzyme repeats at least 7 times in its skeleton that the correct approach to assessing abuse in this case is governed by the ECJ judgment in *Bronner*.

122. At first sight, this is puzzling, since the complaint in *Bronner* was almost, but not quite, the exact opposite to the complaint in the present case:

(1) In *Bronner*, a newspaper publisher in Austria wanted access to the newspaper distribution system which had been developed at considerable expense by a major competing publisher for the purposes of its own business.

(2) In the present case, by contrast, the NHS wants the freedom to be able to use *independent* providers of Homecare Services (and such other providers correspondingly want to have the ability to supply services to the NHS on economic terms), but the difficulty is that the dominant supplier of drugs for the treatment of Gaucher disease is *forcing* its own service upon the NHS.

(3) In other words, far from this being a case in which a competing drug supplier is seeking to gain access to Genzyme Homecare's "distribution" facilities (the closest analogy), this is a case in which Genzyme is trying to force those facilities upon unwilling customers, and foreclose competition,

by means of the dominance that it enjoys in an upstream market.

123. Despite the repeated references to the "*Bronner* principles" in Genzyme's skeleton, the only specific parts of that case that are referred to anywhere by Genzyme are in paragraph 27 of the skeleton, and these are drawn from the Advocate General's opinion rather than the ECJ judgment.

124. In those parts of his opinion (paragraphs 56 – 69), the Advocate General discusses the circumstances in which a dominant firm might be required to grant a competitor access to its business facilities. His language has, however, been modified by Genzyme. So, for example, the Advocate General stated at paragraph 57 of his Opinion:

> "... In the long term, it is generally pro-competitive and in the interest of consumers to allow a company to retain for its own use *facilities* which it has developed for the purpose of its business. *For example, if access to a production, purchasing or distribution facility were allowed too easily there would be no incentive for a competitor to develop competing facilities.* Thus while competition was increased in the short term it would be reduced in the long term. Moreover, the incentive for a dominant undertaking to invest in *efficient facilities* would be reduced if its competitors were, upon request, able to share the benefits. Thus the mere fact that by retaining a facility for its own use a dominant undertaking retains an advantage over a competitor cannot justify requiring access to it." [emphasis added]

In Genzyme's skeleton, at paragraph 27(i), this is translated as follows:

> "In the long-term it is generally pro-competitive to allow a company to retain for its own use *matters* which it has developed for the use of its own business. The incentive for competitors to develop *competing products* will be reduced if access to a product were allowed too easily. Similarly the incentive for competitors to develop *competing products* will be reduced if access to a *product* were allowed too easily. Similarly the incentive for a dominant undertaking to invest in such *products* would be reduced if its competitors were able to share the benefits." [emphasis added].

Accordingly, Genzyme seeks to suggest that the abusive practices in this case relate to a simple refusal to supply valuable property (presumably Cerezyme) to another party. In fact, they concern anti-competitive *pricing practices* designed to extend Genzyme's market power into a separate but related downstream activity (Homecare Services), and thereby to reinforce its virtual monopoly position in

the upstream market.[48]

125. At paragraph 26 of its skeleton, Genzyme also seems to place reliance upon the ECJ judgment in *Volvo v Veng*[49], apparently for the proposition that there are only very restricted areas in which abuse can occur in the field of intellectual property rights. That case concerned the infringement of a registered design for body parts of a car, and the issue was whether the proprietor of the design right should have to licence third parties for the supply of products incorporating the design. It is difficult to see how this bears on the abusive pricing practices that are the subject-matter of the present case.

Objective justification: the remaining legal case

126. Genzyme's legal arguments on "objective justification" appear to have largely collapsed. In particular, Genzyme now *seems* to have clarified that its only point is that where a party has placed material before the OFT in support of a claim of "objective justification", then the OFT will need to be satisfied that the claim is unfounded before reaching an infringement decision: see paragraphs 97 and 98 of Genzyme's skeleton.

127. On that footing, there is very little to argue about on the facts of the present case, since, at paragraphs 355 to 363 of the Decision, the OFT addressed systematically the only points on objective justification that had been raised by Genzyme in its written and oral representations, and explained why they had no merit.

128. Nor does it much matter whether Genzyme formally accepts that its legal position involves the assumption by it of an evidential burden (see paragraph 97 of its skeleton), provided that the substance of its argument is reasonably clear.

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[48] See, in particular, paragraphs 150 – 160 of the Defence. Furthermore, even if this case were concerned with a refusal by Genzyme to supply Cerezyme to independent Homecare Services providers such as HH, *Bronner* would not assist them: see, in particular, paragraph 61 of the Advocate General's Opinion (to which Genzyme has not referred), stating: "*It is on the other hand clear that refusal of access may in some cases entail elimination or substantial reduction of competition to the detriment of consumers in both the short and the long term. That will be so where access to a facility is a precondition for competition on a related market for goods or services for which there is a limited degree of interchangeability*". In this case, access to Cerezyme obviously is a necessary precondition for competition on a related market, namely the supply of Homecare Services.

[49] Case 238/87, *Volvo v Veng* [1988] ECR 6211.

129. Nevertheless, some residual arguments are still to be found in Genzyme's skeleton in paragraphs 92 – 98, and, since it is still not altogether plain what Genzyme is now arguing, these are addressed for good order.

130. First, as to the incidence of the burden of proof where objective justification is in issue, the OFT pointed out in paragraph 224(3) of the Defence that there is clear jurisprudence of the European Courts on the matter, which establishes that it is the task of the dominant undertaking, whose behaviour is apparently abusive, to show that there is some objective justification for its behaviour.

131. In response, at paragraph 98 of its skeleton, Genzyme does not engage with any one of the authorities cited by the OFT. It resorts instead to the generalisation that: "*None of the case law referred to by the OFT [Defence 224] states or infers that the burden of proof is on the undertaking to prove objective justification. The passages cited by the OFT only demonstrate the Court weighing the evidence, not reversing the burden of proof*".

132. However, this is a poor response in terms of legal reasoning. For one thing, in the *Aeroports de Paris* case, the Court was explicitly addressing a contention that the EC Commission had reversed the burden of proof, so that there can be no doubt on the point (see paragraphs 200 – 203 of the judgment). Moreover, a reading of each of the extracts from *Irish Sugar*, *Tournier*, and *Aeroports de Paris* quoted in paragraph 224(3) of the Defence shows that the Court took the view that it was for the dominant undertaking to justify its apparently abusive behaviour.

133. Secondly, it appears that Genzyme may be asserting that *Bronner* provides authority for the strong proposition that, in order for behaviour to be characterised as abusive, it is necessary to show that it is "irrational" from the perspective of a respectable and fair-minded businessman, *in addition to* being illegitimate business conduct that is prima facie abusive: see paragraphs 92 and 94 of Genzyme's skeleton. Although Genzyme is not specific in its skeleton (merely referring to "the most recent guidance to the correct approach given by the Court of Justice in *Bronner*"), it appears to be referring to paragraph 41 of that judgment for the proposition concerned.

134. Yet, in that paragraph, the Court merely said that in order to establish an abuse in the circumstances of that particular case, on the basis of certain case-law

relating to the exercise of an intellectual property right (the *Magill* judgment), it would still be necessary to show in particular both that the refusal to grant access to facilities was likely to eliminate all competition on the part of the person requesting the service, and that such refusal was "incapable of being objectively justified". This certainly does not purport to lay down some important new general rule that it is necessary to show that apparently abusive conduct is also "irrational" when judged by the lights of fair-minded and respectable businessmen.

135. Thirdly and finally, Genzyme persists in the strange argument that, whatever the position in EC law, this Tribunal is bound to follow two interlocutory decisions of Laddie J. in the High Court as a matter of the doctrine of precedent. Even leaving aside the status of these decisions as interlocutory judgments (when no final decision on the issues of law involved was reached), Genzyme has puzzlingly failed to engage with the particular points made in the Defence: (a) that the Tribunal plainly has a co-ordinate jurisdiction to the High Court, in particular in the light of the fact that appeals on points of law from the Tribunal lie directly to the Court of Appeal; and (b) that in any event the Tribunal is required by s.60 of the Competition Act 1998 to secure that there is no inconsistency with the clear jurisprudence of the Community Courts.

THE DIRECTION

136. The only point made by Genzyme in relation to the OFT's Direction that falls to be addressed here is the claim at paragraph 126 of its skeleton. Genzyme argues that the Direction would be unworkable because there is "no mechanism whereby any reduction in price could be used to fund the provision of homecare by third parties". According to Genzyme, the Direction "contains no mechanism for requiring the DoH to fund PCTs to procure homecare services from independent providers."

137. This is misconceived. The OFT (or the Tribunal) do not need to give directions to the Department of Health to fund PCTs to procure homecare services, and the Direction is certainly not flawed on that account. PCTs are readily capable of contracting to procure such services, as they already do in other treatment areas: cf. Farrell w/s, paragraphs 7 – 19 and 54 – 56. The fact that such contracting does

not currently take place in relation to homecare for Gaucher patients is a result of the abusive pricing practices which the OFT seeks to bring to an end.

THE PENALTY

138. There are no additional points in relation to Genzyme's submissions on the penalty that require to be addressed. The points in relation to NSCAG and the alleged lack of economic significance of the case have been addressed above.

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Gray's Inn.

JON TURNER

Monckton Chambers,
4 Raymond Buildings,
Gray's Inn.

19 September 2003