IN THE COMPETITION APPEAL TRIBUNAL **Case Number: 1016/1/1/03**

BETWEEN:

GENZYME LIMITED **Applicant**

and

THE OFFICE OF FAIR TRADING **Respondent**

SKELETON ARGUMENT ON BEHALF OF GENZYME IN REPLY TO THE OFT'S SKELETON

INTRODUCTION

1. This skeleton argument in reply is served pursuant to the permission granted by paragraph 5 of the Tribunal's Order of 31 July 2003. Save where otherwise indicated, Genzyme will respond separately in relation to the questions raised by the Tribunal at the interim hearing earlier today. Genzyme expects to see the OFT's answer to those questions in advance of the hearing.

2. Genzyme does not intend to respond in the same tendentious (and at times downright abusive) way in which the OFT seeks to present its case in its skeleton. However, Genzyme does wish to place on record that it regards the OFT's continuing insinuation that Genzyme is seeking to exploit patients ("a vulnerable group of end-users" [OFT skeleton, para 5(3)]) as a deeply offensive allegation in which the OFT still persists without any evidence in support [Genzyme skeleton, para 24].

3. Genzyme's ground-breaking research and development in the LSD field has enabled many sufferers from LSDs to live normal lives instead of suffering debilitating and often life-threatening illnesses, and has given great hope to those

suffering from previously untreatable conditions, as well as to their families. The home delivery of Cerezyme and the provision of nursing assistance where need was introduced by Genzyme to reduce disruption to patients' lives, as well as freeing up NHS resources for other patients and to enable the NHS better to manage the funding for treatment (and incidentally also enabling the NHS to make a VAT saving as the OFT accepts at para 82). This is now also the case in relation to the treatment of Fabry disease where both Genzyme and TKT offer homecare (TKT through HH).

4. Much of the OFT's arguments depends on its bundling of the services of delivery and nursing in its definition of "Homecare Services". As Professor Yarrow explained in his report, "surprisingly given the nature of the case, the Decision nowhere contains a definition of the homecare services market" and the term used by the OFT "Homecare Services" is a misleading use of language as it refers to a bundle of activities including activities which "are not homecare services on any sensible definition of the latter (e.g. wholesaling to hospitals)" [CB1/22/205]. The OFT produces no evidence to support its bundled definition, save for the fact that some (not all) supplies of nursing services also provide delivery services, and disregards the fact that some providers of delivery services (e.g. Polar Speed, Healthcare Logistics) never provide nursing services.

5. At the same time, the OFT in its definition of Homecare Services restricts it to services relating only to Gaucher patients, again without any justification. It now appears to concede that is not justifiable unless it were appropriate to treat Gaucher solely because of Genzyme's conduct (see paras 15-25 below).

6. The OFT then criticises Genzyme for dealing with those services separately and not using its artificial bundled definition. A particularly egregious example is the OFT's unwarranted criticism of Mr Williams at para 71 for his "unsatisfying and obviously incomplete description of Homecare Services" when Mr Williams was carefully and precisely describing the service of home delivery "getting the product from the manufacturer to the patient".

7. The OFT criticises evidence which proceeds on the basis that home delivery and nursing are separate services (e.g. OFT skeleton, paras 7 & 12). Instead, the

OFT proceeds on the basis of this artificial bundled definition, for which it has no support.

8. This skeleton thus addresses particular points arising out of the OFT's skeleton argument upon which Genzyme wishes to reply. Of course, if issues are not covered in this skeleton, that should not be treated as an acceptance of any argument advanced by the OFT. This skeleton also addresses the three further statements which the OFT has adduced or called for and upon which Genzyme has not previously had the opportunity to advance its submissions:

   (i) Mr Aliski's email served on 11th September 2003;

   (ii) Miss Stallibrass' statement served on the evening of 11th September;

   (iii) Mr Evans' letter of 17th September 2003 in reply to questions raised by the Treasury Solicitor in relation to his two witness statements served with Genzyme's Reply.

9. The skeleton is divided as follows:

   (A) refusal to supply;

   (B) "downstream" market;

   (C) "upstream" market;

   (D) home delivery;

   (E) the NHS List Price;

   (F) the DoH's powers;

   (G) **Bronner**; and

   (H) the Direction.

A. REFUSAL TO SUPPLY

10. The OFT continues to insist that its case is not one of refusal to supply [OFT skeleton, para 5(1)]. That is incorrect. The Direction places an obligation on Genzyme to supply any third party with Cerezyme at what the OFT describes as the stand-alone drug only price, a discount of some 18.3% from the NHS List Price.

11. The OFT's position in the Decision is that Genzyme has been committing an abuse ever since it commenced exclusive distribution arrangements with first Caremark and then HH. Of course, there was never any complaint from any source about Genzyme's conduct while it had those exclusive distribution arrangements in place; it was Genzyme's decision to provide services in-house which it had previously contracted out on an exclusive basis that caused HH to complain to the OFT.

12. The OFT's position is now that Genzyme by reason of its alleged dominance cannot enter into exclusive distribution arrangements, such as it had before with Caremark and then HH, and is not permitted to bring distribution and/or nursing services exclusively in-house as many other pharmaceutical companies have done (see the *Fresenius/Caremark* report). It thus follows that the OFT contends that Genzyme is under an obligation to supply all third parties with their requirements.

13. Further, the OFT's skeleton in part makes it clear that the OFT insists upon Genzyme supplying HH. The OFT argues that "it is not concerned with the protection of any individual competitor but with the protection of a competitive market structure" but then proceeds to contend that in its view "the only independent supplier of Homecare Services" with whom Genzyme must deal is HH [OFT skeleton, para 5(3)]. Yet at para 98 of the skeleton, it makes the completely contrary contention that its case is based on the fact that "Genzyme has chosen to deal with HH".

14. The inescapable conclusion, despite the OFT's protestations to the contrary, is that the substance of the OFT's case against Genzyme is of an abuse of refusal to supply to HH. That is, of course, the allegation that the OFT made at the

interim measures stage in 2001 and which it then accepted as a matter of law was unsustainable.

(B) "DOWNSTREAM" MARKET

15. The OFT now concedes at para 33 of its skeleton that its definition of the downstream market would in the ordinary case be incorrect. The OFT accepts that:

> "The OFT therefore maintains that, *given the pricing policies currently adopted by Genzyme*, the downstream market is correctly defined in the Decision: see paragraphs 177ff. 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 ..."

16. Thus the only justification advanced by the OFT for restricting its downstream market definition to homecare for Gaucher patients is its case that Genzyme is committing an abuse of bundling and margin squeeze in the pricing of Cerezyme and Ceredase. That is a fundamental error of law.

17. The correct approach to market definition is set out at paras 54-55 of Genzyme's skeleton, was explained by the MMC at §2.71 the *Fresenius/Caremark* report and by Professor Yarrow in his report [CB1/22/209-212].

18. In particular, as Professor Yarrow emphasises:

> "when assessing substitutability, *the relevant tests should be conducted at competitive prices*, or, more practically, at prices that are not obviously the result of monopolistic conduct; but that is exactly what has not been done at [paragraph 177 of the Decision]". [CB1/22/209]

19. On the OFT's view, every time a supplier signs an exclusive agreement with a group of buyers (e.g. retailers) a new and separate market would be created because other suppliers cannot sell to that group of buyers while the agreement remains in force. Similarly, as RBB point out any vertical integration, however partial, would exclude competitors from a "market" (see passage quoted in Genzyme Skeleton, para 169).

20. Since it is wrong to define the market by reference to Genzyme's current pricing policies, the OFT must now accept that "in all probability" the correct market is the "wider homecare services market".

21. Accordingly, as Genzyme explained at NoA 532-545, there is no question that Genzyme's conduct could have any significant foreclosing effect on that market (as HH's growth from providing homecare to 2,000 patients when its contract with Genzyme came to an end to 5,000 patients today amply demonstrates).

22. That is fatal to the Decision[1], because having thus conceded lack of effect on the downstream market, the OFT's case on infringement hangs by the thread of its far-fetched case on the effect of homecare on entry in the upstream market, as to which see section C below.

23. Although the OFT has sought to castigate Genzyme's contention that the number of patients who receive both nursing and delivery services as being miniscule as "self-serving and rhetorical criticism" (OFT skeleton, para 12), it does not dispute this as a matter of fact and does not challenge the categorisation of patients set out at Annex 2 of Genzyme's skeleton.

24. Finally, in relation to the downstream market, the OFT also now accepts that the *Fresenius/Caremark* report is "essentially correct" (OFT Skeleton, para 9(1)). As the Tribunal observed at today's interim hearing, §2.40 of the Report sets out a list of drug suppliers which supply drugs and homecare services. None of these undertakings were contacted by the OFT during the administrative procedure (just as the OFT did not contact any of the service providers listed at §2.41, other than the complainant HH), despite Genzyme's written and oral representations that the OFT should do so [see NoA 141-161; written representations File 4/822-829 and oral hearing File 18/4657, lines 15-34].

25. Had the OFT contacted those undertakings for their views, doubtless the OFT would have been told that Genzyme's homecare service provision for its

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[1] The OFT argues at footnote 23 to para 28 that it would not be fatal because its case is that it does not have to prove that Genzyme is dominant on a downstream market. That misses the point entirely. Dominance is irrelevant in this context. The OFT's case depends on significant foreclosing effect on the downstream market. There is no question of Genzyme foreclosing a significant part of the market for homecare service provision generally.

treatment was a common practice, did not depart from standards of "normal competition" and was objectively justifiable. It would have found out that homecare service provision through an exclusive distributor is also a common practice, as is well illustrated by the fact that TKT distributes Replagal for Fabry Disease through HH as an exclusive distributor, and it appears that TKT plans to use HH as an exclusive distributor for its new Gaucher treatment, GCB.

(C) "UPSTREAM" MARKET

26. As is explained at paras 175-192 of Genzyme's Skeleton, it is inconceivable that homecare in the UK could restrict the research and development of new LSD treatments. TKT's principal problem in developing its GCB treatment, which it regards as a manageable one, is in identifying treatment-naïve patients for trials. Treatment-naïve patients, by definition, are those who have not previously received any treatment, whether in hospital or at home. Genzyme's conduct to which the OFT takes exception has no effect on entry upstream by TKT or anyone else.

27. This is further emphasised by the latest email obtained by the OFT from TKT and served on Genzyme on 11th September 2003.

28. Mr Munro asked Mr Aliski of TKT to comment on Dr Smith's witness statement served with the Reply [CB1/8/34-42]. Mr Aliski replied in an email. Mr Munro seeks to serve the email in a redacted form, not on any ground of confidentiality, but allegedly on the ground of relevance. The tone of the full unredacted email makes it clear that there is no love lost between TKT and Genzyme, confirming Genzyme's submission [NoA 28(iii), 127-132, 278-279 & 311] that it is inappropriate for the OFT to rely uncritically on TKT for evidence in relation to its alleged upstream market (see further NoA File 11/2427 to 2697 for details of disputes between TKT and Genzyme).

29. Genzyme has three points to make in relation to Mr Aliski's email.

30. First, the problems TKT identifies in carrying out trials on its ERT for Gaucher, GCB, relate to identifying treatment-naïve patients (although apparently the trials do not require as many treatment-naïve patients as the successful Zavesca trials

did). They have nothing to do with homecare in the UK, which by definition is not supplied to treatment-naïve patients. It is clear that TKT, as Mr Aliski and his CEO Mr Astrue have said in discussions with investors, regard finding such patients as a problem but a manageable one. This is a problem which will always arise where there are orphan drugs or the equivalent.

31. The OFT now argues that once GCB is developed by TKT, the identity of the homecare service provider will somehow impede its introduction into the UK (Genzyme's skeleton, para 120(1)). But there is no evidence from TKT to that effect and it appears to be content to use HH as its homecare service provider as it does for Replagal.

32. Second, Mr Aliski's response to paragraph 20 of Dr Smith's statement is revealing. Dr Smith had explained at paras 18-19 that TKT had already carried out successful trials on its ERT for Hunter disease (MPS II), and is about to embark on a 90 patient 12 month endpoint Phase III trial either this or next month. Dr Smith commented at para 20:

> "Of course, if the OFT is correct in its approach, then TKT is already in a dominant position in relation to this drug [to treat Hunter disease], which is already being used in trials to treat patients, and therefore subject to all the strictures that entails. That seems to me both as a scientist and as a businessman to be an absurd result, and one that runs directly contrary to the policy of both the European Commission and the UK government to seek to create incentives for biotech research, not destroy them."

33. Mr Aliski's response was:

> "I simply do not understand his point. The drug is not available in Europe outside of the trial we are about to initiate. There is Orphan legislation to development treatments for rare diseases, Hunter fits into that category and that is what we are doing."

34. Mr Aliski is, of course, in fact in complete agreement with Genzyme. What neither he nor Genzyme can understand is the OFT's point. It is incomprehensible that TKT should be held to be in a dominant position on the ground that it produces the only treatment available for Hunter disease. In the light of Genzyme's submissions on orphan drug legislation, it is particularly relevant that he is also at pains to stress the importance of orphan drug legislation in this area.

35. Finally, the tone of the unredacted version of Mr Aliski's email reveals how inappropriate it would be for Genzyme to be forced to be dependent upon distribution by HH, which is TKT's distributor for Replagal and is thought by Genzyme likely to be TKT's distributor for GCB [NoA 613-614; see also Reply 31-32]. This has not been disputed by TKT, HH or the OFT. In such circumstances, should it wish to do so, it would clearly be objectively justified for Genzyme to choose not to deal with HH.

36. If the OFT were right, and assuming TKT's 60% share of the Fabry disease treatment were sufficient to confer dominance as the OFT appears to believe, then TKT would be under a duty to supply Genzyme Homecare with Replagal at an "unbundled" discounted price, but Genzyme, with Fabrazyme only having a 40% market share, would be under no duty to supply TKT. That is an absurd result, which demonstrates the incoherence of the OFT's case.

37. The OFT has also markedly changed its case in relation to the possible effect of homecare service provision on prescribing decisions by clinicians and hence on the alleged effect on the upstream market. At para 97, the OFT now states that its case "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 has clearly appreciated that its case on that issue was entirely self-contradictory (see Genzyme's skeleton, para 111). Having accepted this, it is difficult to see why the OFT continues to allege (despite its assertion that it is not: OFT skeleton, para 120(1)) that Genzyme will seek to influence dosage levels (OFT skeleton, para 100). If a homecare services provider cannot seek direct influence over the choice of treatment, still less would it be able to influence dosage level and in any event as explained in detail in Genzyme's Reply there is not a shred of evidence to support that accusation (Reply 49-53).

38. Now the OFT seeks to argue at para 97 that its case is that "the *identity* of a Homecare Services [sic] provider can influence the prescribing clinician", because patients "can form an *attachment* to their existing homecare services provider", citing the views of Professor Cox to this effect. Thus it is said that changing the provider would add to difficulties if it meant changing the service provider. This must mean the nurses, not the delivery drivers: Genzyme does not

take the OFT to be asserting that patients form "an *attachment*" to the driver making home deliveries of Cerezyme every 4-6 weeks. Thus the alleged effect concerns only those 42 patients receiving nursing visits from either HH or Genzyme Homecare nurses.

39. As to the importance of this alleged effect, when Professor Cox was first interviewed by the OFT on 4th July 2001, his view was that the identity of homecare service providers might be changed every two to three years as the result of putting homecare service provision out to tender [NoA File 21/5680]. He expressed no concern whatsoever about patients' "*attachment*" to their homecare service provider (nor did he do so in his letter of 29th March 2001 to the MPI Division of the DoH in which he raised his concerns about Genzyme moving to in-house service provision [NoA File 21/5672-5673]. Similarly, the issue was not raised by Dr Mehta when he was first interviewed by the OFT on 10th July 2001 [NoA File 21/5699-5700]. If patients' "*attachment*" to homecare service providers was an issue of any real significance, it is inconceivable that both Professor Cox and Dr Mehta would have omitted to tell the OFT about it when they were first interviewed. The fact that it is not an issue of any real significance is illustrated the fact that Professor Cox contemplated changing the identity of a homecare service provider every two to three years.

40. In any event, whatever the views of Professor Cox and Dr Mehta, those views are not supported by the two consultants responsible for paediatric care for Gaucher patients, nor by the two consultants treating Fabry disease sufferers where – in contrast to the current Gaucher position – there are indeed two drugs and two suppliers of homecare. If the OFT's concerns had any substance, one would expect direct evidence of that problem in the treatment of Fabry disease. But there is none.

41. The OFT cannot base a case on speculation by two consultants (as the OFT accepts at para 97, particularly by Professor Cox), when four other consultants working in this area are clearly not of the same view, and where there is no evidence to support that theory. Genzyme does not doubt that either Professor Cox or Dr Mehta hold their views sincerely, and so there is no need to cross-examine as suggested by the OFT at para 113.

42. The OFT has chosen not to obtain the views of Drs Vellodi, Waldek or Lee because they contradict the case the OFT is seeking to make. The OFT did interview Dr Wraith, but subsequently quoted him entirely of context, distorting his views and ignoring the substance of what he had told them (see paras 3, 7, 8 and 11 of his statement).

43. The OFT now suggests that Genzyme has not put the substance of the OFT's allegations to those consultants and that therefore their evidence should be discounted. That cannot be accepted. Each of those consultants was well aware of the issues when making the statements. Indeed, the OFT criticises Genzyme for asking Dr Waldek the wrong question to which he replied in his witness statement served with the Reply [CB3/75/1059-1063], yet the question to which his witness statement responds is the very question the OFT criticised Genzyme in both the Decision [§349] and the Defence [para 147] for not having asked Dr Waldek. The OFT also criticises Genzyme for not having shown Dr Waldek the statements from Professor Cox and Dr Mehta, but that objection is also unwarranted; Dr Waldek was asked for his independent views. If the OFT wished to alleged they were misled, and that their statements are not correct expressions of their views, or if it wished to put Professor Cox's and Dr Mehta's statements to any of them, it was open to the OFT to apply to cross-examine them, but it has chosen not to do so.

44. The decision which drug to prescribe is for the clinician alone and if the OFT's investigation has demonstrated nothing else it is that the consultants in the UK are extremely independently minded. If any of the OFT's allegations were actually to happen, there can be no doubt that they would take action immediately with the appropriate authorities (as is demonstrated by the unfortunately precipitate action taken by Professor Cox in relation to Miss Kelly of Genzyme in relation to what he subsequently accepted to have been "completely unfounded" allegations: "For her to have committed some impropriety in her dealings with patients would have been entirely out of character" – see Reply 45-48).

45. Finally, it is to be noted that in any case, "the *attachment*" between patient and nurse will be disrupted by many other events during the course of what is a

lifetime of treatment for the patient, as individual nurses join, leave or retire from a homecare service provider, take holidays, or go on sick leave. The OFT's allegation is speculative and simply does not withstand scrutiny.

(D) HOME DELIVERY

46. The OFT continues to advance the "integrated" service argument first advanced in the Defence (see Genzyme's skeleton, paras 57-63), while ignoring Mr Evans' evidence – which it had asked for – that Polar Speed operates a cold chain drug home delivery service (see Part C below).

47. The OFT now seeks for the first time to place reliance at para 57 of its skeleton on the point at which dispensing of the drugs takes place. For home delivery, Cerezyme is dispensed at Genzyme Homecare's or HH's pharmacy before being delivered, whereas without home delivery Cerezyme would be dispensed when the patients visited their local NHS pharmacy to collect their drugs in a cool-bag. The OFT's reliance on this point confirms Professor Yarrow's opinion that "Part of the confusion in the case might have been caused by the location of the pharmacy in the vertical chain" [CB1/22/192-193, para 7.2]

48. Professor Yarrow explained Cerezyme differed from the standard case because "dispensing is embedded in the wholesaling/distribution activity", and that:

> "This fact could, potentially, provide an account of how delivery came to be classified as a homecare service in that this part of the distribution activity occurs subsequent to dispensing. ... [H]owever, the changed location of the dispensing function does not change the fundamentals of the reimbursement regime. ... [T]he reimbursement price (for ZDDs) is paid on behalf of patients, for products made available at a convenient location. the location of an "embedded pharmacy" is not, however, convenient for most patients: it is neither a community pharmacy (except for one or two patients) nor a hospital where patient receive treatment. Pharmacists cannot therefore expect to be paid the reimbursement price for products made available at an embedded location (in the case of Genzyme Homecare, at Oxford, where the dispensing takes place)." [CB1/22/192]

49. The OFT's argument that the fact that dispensing takes place centrally rather than on the high street means that home delivery is a "sophisticated additional activity" and thus is inseparable from an "integrated" service is contrary to the evidence of Polar Speed's home delivery service as explained by Mr Evans. The

OFT's suggestion that home delivery is integrated and thus an inseparable service is entirely contradicted by Mr Evans evidence in his two statements [CB3/64-65] and in his letter of 17th September 2003 (see below) produced at the request of the Treasury Solicitor.

50. As is explained at paras 19-22 of the Reply, the OFT has ignored evidence given to it by Polar Speed that cold-chain home delivery of drugs is a separate service from nursing. Genzyme served two witness statements in support from Mr Evans, the Director of Pharmaceutical Services at Polar Speed. The OFT requested that a series of further questions be put to Mr Evans, these were forwarded to him and Mr Evans wrote on 17th September setting out his response.

51. Mr Evans' letter of 17th September confirms and adds further detail to his two witness statements. It is clearer than ever that home delivery for pharmaceuticals is a separate service to nursing, which is why HH is able to sub-contracting delivery to Polar Speed. It is not necessary for a home delivery service provider to have an in-house NHS pharmacy; it can make appropriate arrangements with a nearby independent NHS pharmacy, as Polar Speed currently does and as HH did at the time when it was appointed as the distributor for Cerezyme in 1998.

52. The OFT's only response is that Mr Evans' evidence is "no answer to the OFT's case" (OFT Skeleton, para 24) and to imply that it is unimportant because Polar Speed was "referred to the first time at the interim relief stage" (OFT Skeleton, para 9(3)). Had the OFT carried out a proper investigation, it would have asked HH for details of any sub-contracting arrangements and thus have contacted Polar Speed for its views during the administrative procedure. Now that Polar Speed has been given the opportunity to explain the nature of its business and its role in carrying out home deliveries of cold chain drugs, including sub-contracted deliveries on behalf of HH, it is clearer than ever that the OFT's case is fundamentally misconceived.

53. The OFT seeks to minimise Polar Speed's involvement as a sub-contractor for HH by pointing to its limited involvement in delivering Cerezyme (OFT skeleton, para 61). However, Dr Jones of HH explained that HH has in fact made

significant use of Polar Speed to deliver a range of drugs to patients at home (rising to some 4.4% of all HH's home deliveries by this year [Reply 20]). There is no evidence to suggest that deliveries of Cerezyme require anything different from deliveries of other drugs to patients at home. Polar Speed's role as a sub-contractor for HH demonstrates that HH regarded home delivery of drugs as a service that could be separated and entrusted to another service provider.

54. It is not in dispute that a home delivery service must be properly and efficiently carried out. Indeed, one of the reasons why Genzyme stopped using Caremark was because of problems with its delivery drivers leaving packages of Ceredase in inappropriate locations.

55. The OFT does not dispute that the home delivery of Cerezyme is a more efficient alternative to delivery of Cerezyme to Community pharmacies (OFT skeleton, para 87). It therefore follows that as the NHS List Price pays for delivery to Community pharmacies, as Mr Brownlee accepts, then the NHS List Price must also pay for the more efficient alternative of delivery to patients' homes. There thus is no question of Genzyme "making the NHS pay" extra for home delivery.

(E) THE NHS LIST PRICE

56. The OFT accepts at para 66 that, for a ZDD drug such as Cerezyme, the NHS List Price is the price at which the pharmacist is reimbursed (the "simple fact" which, as Professor Yarrow explains, if "borne in mind, much confusion can be avoided" [CB1/22/176]). However, the OFT now seek to argue it is necessary to look at the "the *components* that make up the NHS list price for a particular drug, and in particular whether it is a bundled price". What the OFT is seeking to do is to allocate the NHS List Price for a drug to the drug supplier's component costs. It is not made clear why the cost of providing nursing, for example, should be included as an element of this bundled price but not other costs incurred by the drug supplier? As RBB[2] observed (Genzyme's skeleton, para 169):

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[2] Contrary to what is implied at para 89 of the OFT skeleton, RBB produced its briefing paper on the Genzyme decision entirely independently of Genzyme and its advisers (save for the factual accuracy check carried out by Genzyme's junior counsel). It cannot be dismissed as a polemic: it is a considered expression expert opinion by a respected team of consultants, who are instructed from time to time by the OFT.

> "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."

57. The OFT attempts to justify this approach to the NHS List Price at para 68 by reference to §4.51 of the *Fresenius/Caremark* report. The passage quoted there is, however, taken by the OFT out of context. As is clear from the next paragraph of the MMC Report, §4.51 was describing the background to the decision by the DoH to issue EL(95)5 [CB2/39/486].

58. As is explained in detail at paras 4-21 of Genzyme's Reply to the Response of the OFT to the Questions of the Tribunal at the 2nd CMC, EL(95)5 drew a crucial distinction between cases where "the NHS pays the list price of the drug" – such as Cerezyme – where EL(95)5 did not apply and those cases where the NHS "pays a special price reflecting the other items that are supplied". Genzyme notes that the OFT has not disputed in its skeleton Genzyme's Reply to the Response.

59. There is no question of the price for Cerezyme or Ceredase being "a special price reflecting the other items that are supplied". If it were, EL(95)5 would have applied. But the price for Cerezyme and Ceredase has only ever been the NHS List Price, the price for the delivered drug.

(F) THE POWERS OF THE DEPARTMENT OF HEALTH

60. The OFT seeks to argue that the Department of Health did not approve Genzyme's homecare arrangements, and seeks to bolster its case with a further witness statement from Miss Stallibrass of NSCAG. It also seeks to argue that individual component parts of the NHS were powerless to resist Genzyme (OFT Skeleton, paras 74-80).

61. The OFT also misrepresents Genzyme's arguments in relation to the significance of the meeting with the DoH on 13th February 2001 (OFT Skeleton, para 49: "If Genzyme is saying that ..."). Genzyme's case is clearly set out in Genzyme's skeleton, paras 158-160. The OFT's case appears now to be that the DoH did not in that meeting express approval for "bundling" and "margin squeeze". That is unsurprising, because – until the OFT came on the scene – no one had ever described Genzyme's generous provision of homecare in those terms. The DoH

knew that Genzyme had provided home delivery and nursing through a third party and was now being informed of Genzyme's decision to cease contracting-out those services and to provide them in-house.

62. The OFT also incorrectly asserts that Genzyme does not rely upon the DoH meeting it relation to its appeal against the penalty. Genzyme does: see NoA 660. The Tribunal has full jurisdiction over the level of penalty, should it find against Genzyme on infringement.

63. As has been explained in Genzyme's Reply of Genzyme's Reply to the Response of the OFT to the Questions of the Tribunal at the 2nd CMC, the DoH has ample statutory and other powers to take the action advocated by the OFT, were it to consider it necessary to do so, as EL(95)5 well illustrates.

64. As to lack of objection by the DoH, the DoH have always been kept informed. Had NSCAG objected to Genzyme switching from contracted-out to in-house homecare service provision in 2001, then Genzyme would not have proceeded without meeting those concerns.

65. The OFT has not obtained a witness statement from any DoH attendee at the meeting of 13th February 2001 although they were obviously available, but instead served a witness statement from Miss Stallibrass of NSCAG. This was served in draft on Taylor Vinters and Genzyme's counsel also on Thursday 11th September 2003, after 7pm. It is in response to the 2nd witness statement of Mr Johnson which was served with Genzyme's Reply on 22nd August 2003. A brief 3rd witness statement from Mr Johnson in response was served on 18th September 2003 together with Genzyme's written observations for the interim hearing on 22nd September 2003. No other relevant documents have yet been provided in response to Genzyme's requests (see para 16 of Genzyme's written observations for the interim hearing on 22nd September 2003).

66. Miss Stallibrass' statement does not contradict Genzyme's account of the meeting with the DoH of 13th February 2001. She did not attend; those she has spoken to who did attend have no clear recollection of what was said at the meeting and they are unable to produce any detailed note of the meeting. However, Mr Johnson made a detailed note of the meeting two months later

[CB1/36/352], and there is no reason to doubt Mr Johnson's and Miss Kelly's clear recollection of what was obviously an important meeting for Genzyme.

67. Miss Stallibrass asserts at para 20, without any supporting evidence, that homecare for Gaucher patients falls "outside any possible remit of NSCAG" and that therefore the DoH was in no position to approve Genzyme's decision to commence providing homecare through Genzyme Homecare at the meeting on 13th February 2001.

68. Genzyme makes five points in reply to Miss Stallibrass' statement.

69. First, when the meeting was arranged to inform the DoH about the setting up of Genzyme Homecare, Dr Carroll of NSCAG wrote to Genzyme on 4 January 2001 stating that:

> "Given your previous contact with Dr Doyle related to treatment for Gauchers Disease, 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." [CB1/36/349, emphasis added]

70. This letter made it clear that NSCAG wished to assess the introduction of this new service from Genzyme Homecare, as it was specifically requesting "a briefing on proposed changes in home care service provision". There was no question of NSCAG asserting that this fell outside their remit: quite the opposite. Genzyme was entitled to rely on the clear view expressed in this letter that "the proposed service development" did fall within NSCAG's remit. Miss Stallibrass offers no explanation of this.

71. The OFT asserts at para 104(3) of its skeleton omits the reference to the Genzyme's previous contacts with Dr Doyle in relation to treatment for Gaucher Disease and asserts that the reference in the letter to "new services and developments in the NHS" referred to Fabrazyme, but that is obviously incorrect in the light of the invitation in the letter for "a briefing on proposed changes in home care service provision" and nowhere does Miss Stallibrass suggest to the

contrary in her statement. It is clear from the letter that NSCAG agreed that Genzyme had previously been in contact with its head, Dr Doyle, and that NSCAG had been fully briefed about Genzyme's provision of homecare for Gaucher Disease.

72. Second, that matters that were discussed at the meeting and the concerns expressed (patient confidentiality and cost – which were allayed by Genzyme) demonstrate that those participating in the meeting on behalf of NSCAG regarded the matters as falling within their remit.

73. Third, the published statement of NSCAG's remit published on its website and quoted by Mr Johnson at para 4 of his 3rd statement is clearly wide enough to encompass homecare:

> "NSCAG aims to help patients by improving access to uncommon services, whilst at the same time seeking to sustain high levels of expertise by preventing proliferation of too many centres. It aims to help local commissioners by smoothing out risk, and removing from them the responsibility to plan for the unplannable. And it aims to help provide us by assuring a cash flow to support rare and expensive treatments, and by providing a focus for discussion about service development".

74. The matters which were discussed between Genzyme and NSCAG on 13th February 2001 fall within that description of NSCAG's role. This is not adverted to by Miss Stallibrass.

75. Fourth, Mr Johnson explains at para 6 of his 3rd statement that it has been his experience that whenever matters relating to Gaucher Disease are discussed within the DoH it is in NSCAG. It is NSCAG which is perceived to have responsibility for the treatment of Gaucher Disease within the DoH. This role certainly appears to be supported by the limited information given in the record of agenda item 7 at the NSCAG meeting of 27 June 2001 exhibited to Miss Stallibrass' statement. Mr Johnson also explains at para 9 that the previous head of the NHS department for metabolic diseases, Dr Peter Doyle, had never to his knowledge raised any questions with Genzyme about the provision of homecare.

76. Finally, as far as Genzyme is aware no question has ever been raised with Genzyme by any other part of the DoH (such as the Medicines, Pharmacy and

Industry Division, in which Mr Brownlee works) as to funding of homecare (Johnson, 3rd witness statement, para 9).

77. Miss Stallibrass also exhibits notes of two other meetings not previously disclosed.

78. The first note [exhibit JS2/13-14] is of a meeting on 18th June 2001 between the OFT and DoH officials including Mr Brownlee – despite the OFT's undertaking to Genzyme on 28th April 2003 that "We confirm that we have disclosed the totality of the documentary evidence from Mr Brownlee." No explanation has been given why this record of a meeting was not provided before.

79. This note confirms at the 10th bullet point that there is an NHS List Price for Cerezyme, contrary to the OFT's theory of an "implied" list price. The 7th bullet point is wrong: Genzyme did inform the DoH when first setting an NHS List Price for Cerezyme as it had done for Ceredase [CB1/28/2910292]

80. The second note [exhibit JS2/7] is of an agenda item for a meeting of NSCAG on 27th June 2001. This notes the OFT's investigation. It concludes that:

> "The issue is under investigation by the Office of Fair Trading (OFT), who are in the process of information gathering to help make a decision on the issue ... Our involvement is relevant on the implications for commissioning: equally, there are important policy issues for the Medicines, Pharmacy and Industry (MPI) Division of the Department of Health. the OFT plan to meet MPI and Specialist Services.
>
> The Committee will be updated on any further developments."

81. In fact, no action has been taken by NSCAG or the MPI Division to raise any concerns with Genzyme concerning the issues referred to. There is no record on the OFT's file of any objection being raised by the MPI Division. The OFT's only meetings with the MPI Division were those on 18th June 2001 referred to above, which had already taken place, and the unminuted meeting of 17th December 2002. Had any concerns been raised, the OFT would undoubtedly have recorded them and put them to Genzyme during the administrative procedure. The planned meetings referred to in the note obviously did not take place, which suggests that the DoH did not in fact have any policy objections to what Genzyme was doing, for it cannot have been delayed until 17th December 2002

(which was after the Rule 14 Notice, Genzyme's written response and the oral hearing before the OFT).

82. The suggestion at para 104(4) of the OFT's skeleton that there was feedback from regions is incorrect; the only "feedback" referred to in the note of the meeting on 27th June 2001 relates to "speculation among some of the clinicians", as which see Genzyme's submissions in relation to the OFT's reliance on the views of Professor Cox and Dr Mehta.

83. The conclusion to be drawn from Miss Stallibrass' statement is that the DoH is content with Genzyme's homecare arrangements, and specifically with the decision to switch from contracted-out homecare provision to in-house provision in 2001.

(G) BRONNER

84. Although, as in all cases, there is unlikely to be any exact factual precedent, the importance of the Advocate General's Opinion in **Bronner** (in general terms accepted by the Court) is that it sets out general principles as to the application of objective justifications and abuse, as was accepted by Laddie J in **Getmapping** and **Suretrack**.

85. The OFT criticises Genzyme for setting out the principles which it contends can be derived from the Opinion, and for not quoting exactly from the Opinion. the whole point is that Genzyme is relying on the principles which can be derived from that Opinion, not on the application of those principles in the factual situation of **Bronner**. In any event, if Genzyme had quoted all the relevant passages verbatim, paragraph 27 of Genzyme's skeleton would have run to several pages.

86. All the said principles are very much in issue in the present case, as they were in **Bronner**, **Getmapping** and **Suretrack**, as are the principles to be derived from **Volvo v Veng**.

87. **Bronner** is highly relevant both as a matter of principle and because the OFT's case, as stated above, is in reality one of refusal to supply. Genzyme's case on **Bronner** is set out at NoA 479-483. In summary, Genzyme's decision to supply

homecare first through an exclusive distributor and then by itself (both of which are common practices in the industry) is perfectly legitimate, is not an abuse and is clearly justifiable:

(i) Any incursion on Genzyme's right to choose its trading partners and freely to dispose of one's property would require careful justification: none is forthcoming here.

(ii) Cerezyme is the fruit of very substantial investment by Genzyme, and so particular care is required.

(iii) The strong need for an incentive for orphan drugs to be produced, as recognised by US and EU legislation in this field, dictates that Genzyme be free to choose its own method of distribution and not be subject to requirements to sell at a lower price, which could only reduce the incentive in this area.

(iv) The mere fact that Genzyme controls access to Cerezyme is insufficient as a ground for intervention by the OFT.

(v) HH and other homecare service providers are not the consumer, which here is the NHS on behalf of the patient.

(vi) Intervention under the Competition Act as here sought by the OFT and HH is unworkable. Drug pricing is a matter for the DoH. If there is to be regulation in the field of drug distribution or drug pricing it is a matter for the DoH not for the OFT.

88. As the *Fresenius/Caremark* report shows, this homecare service provision by drug suppliers, both through exclusive distributors and through in-house provision, is a common practice and was never the subject of any criticism by the experienced MMC panel in that report.

(H) THE DIRECTION

89. The OFT continues to assert, with no evidence in support, that the Direction is workable (OFT Skeleton, paras 136-137). The OFT states that "PCTs are readily

capable of contracting to procure such services", which entirely misses the point. There is no mechanism in the Direction for the DoH to fund the myriad of bodies which arrange for treatment (as the Tribunal pointed out at today's hearing, the evidence of Mr Walsh of HH at the interim hearing indicated that there were some 30 different bodies involved) whatever the reduction in the NHS List Price of Cerezyme. See further Genzyme's Reply to the Response of the OFT to the Questions of the Tribunal at the 2nd CMC, served on 19th September 2003.

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22 September 2003