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

A. INTRODUCTION

1. This skeleton argument is served pursuant to paragraph 5 of the Tribunal's Order of 31 July 2003 made at the second Case Management Conference ("CMC"). Cross-references unless otherwise stated are to Genzyme's Notice of Appeal ("NoA"), Reply and revised Core Bundle ("CB" – the page references are to the top right hand corner) and to the OFT's Decision and Defence. An updated chronology is at Annex 1.

2. This skeleton does not contain Genzyme's Reply to the OFT's latest Response on the EL(95)5 issue, which was only received late on 8 September 2003, although due on 14 August 2003 (paragraph 4 of the Tribunal's Order of 31 July 2003). Genzyme will deliver its Reply within the same time scale that the OFT has to reply to this skeleton, namely by 4pm on Friday 19 September 2003, giving the OFT until 4pm on Monday 22 September 2003 to make such response as it sees fit.

3. Annex 2 of this skeleton sets out an analysis of UK Gaucher patient being treated with Cerezyme and Ceredase broken down by location of treatment and nursing provider. They do not include patients being treated with Zavesca alone or not receiving treatment. These figures are Genzyme's best estimate. Unfortunately, it is not possible to state categorically that these figures are correct because the OFT, for some reason it

has never explained, did not contact any of the 4 Gaucher centres in order to take the steps to obtain accurate figures. HH's figures were only supplied after the Decision and NoA in Dr Jones' witness statement [CB3/62/951-952, paragraphs 17-22] served with the Defence. Genzyme believes that its estimate may understate the true level of NHS support, as it is probable that his figures for NHS nursing do not include those patients who have home delivery, no nursing at home, but who visit their GP to have the cannula inserted in the back of the hand and then return home to carry out the infusion by themselves [CB1/26/273-277, paragraphs 31-37]. It is known that two out of Genzyme Homecare's eight delivery-only patients do so.

4. These figures show:

(a) the miniscule size of the so-called market that the OFT is alleging (42 patients out of a total of 193 patients receiving Cerezyme and Ceredase);

(b) the hopelessness of the OFT's contention that delivery and nursing are inextricably linked, even if the market were restricted to Gaucher patients.

5. It can be seen from Annex 2 that the total number of Gaucher disease patients receiving homecare treatment in the UK is 171.

(i) The only patients who receive combined delivery and nursing services are:

(a) 37 from HH (22%);

(b) 5 from Genzyme Homecare (3%).

(ii) The vast majority (68%) either require no nursing support:

(a) 107 receive deliveries only from HH (or its sub-contractors) (63%);

(b) 8 receive deliveries only from Genzyme Homecare (4.5%);

(c) 1 receives deliveries from Central Homecare (0.5%);

or obtain nursing support from the NHS (8%), of whom:

(a) 10 receive deliveries from HH (or its subcontractors) (6%);

(b) 3 receive deliveries from Genzyme Homecare (2%).

It can also be seen that there are 22 patients who receive their treatment at hospitals. All deliveries to hospitals are made by Genzyme Homecare. So again delivery is separate from treatment.

6. It is not intended to respond in this skeleton to every argument raised in the Defence. Genzyme's case has been set out in its NoA and Reply. The purpose of this skeleton argument is to provide a synopsis of Genzyme's proposed oral presentation to the Tribunal at the hearing listed for 25-30 September 2003, though the content of that presentation will be adapted to take account of the OFT's skeleton in response.

7. In view of the fact that Genzyme's oral presentation is restricted to one day, Genzyme considers that it is a much more helpful use of time to provide an extended synopsis of its case and its answer to the OFT's Defence for in that way:

(i) the Tribunal can be aware of Genzyme's contentions in the light of the OFT's Defence;

(ii) the Tribunal can be aware of Genzyme's answers to the matters raised in the OFT's Defence;

(iii) the Tribunal can indicate to Genzyme (should it chose to do so) those areas in which it would require a more extended oral development of the matters set out herein, and those areas where Genzyme could be more brief (at least in opening).

8. Genzyme intends to present its oral submissions in the following order. Genzyme will first show that the OFT arrived at a Decision which is completely wrong mostly because of the manner in which the OFT conducted its investigation (see Part B below). Genzyme will then turn to consider the issues identified by the OFT as the basis for its conclusion on infringement [Decision §386], and where in particular the OFT has sought to bolster its case by submitting further evidence not adduced during the administrative procedure and hence not relied upon by the OFT in the Decision (see Part C below).

B. THE OFT'S FLAWED INVESTIGATION

(i) Introduction [CB3/849-1008]

9. This whole case started with a complaint by HH which the OFT surprisingly took up, and did not tell HH to seek its remedies in the Court (as many other undertakings in a similar situation have done, particularly where interim relief is sought). The OFT came to the conclusion at a very early stage of its investigation into that complaint that Genzyme's conduct constituted an abuse, and then proceeded only to obtain such evidence as it considered necessary to prove that case. The OFT started out on the basis that it was alleging that Genzyme was committing an abusive refusal to supply and issued a section 35 Notice on that basis. It sought a remedy then (continued exclusive supply to HH) which is now one of the very matters of which the OFT has complained.

10. Following Genzyme's Defence and an oral hearing in the section 35 proceedings, the OFT accepted that Genzyme's conduct in refusing to supply HH was justifiable. However, instead of closing the investigation by taking a decision to reject HH's complaint (as it should have done) leaving HH to pursue such remedies as it considered it was entitled to by litigation if it thought fit, the OFT then recycled the facts and made it into a case of bundling and apparently added the allegation of margin squeeze at a very late stage before issuing the Rule Notice [NoA 255].

11. The reality is, however, that this case is indeed about HH's complaint of a refusal to supply by Genzyme, which the OFT has already accepted was justifiable. However, in the Defence the OFT now even appears to be hinting that it may subsequently allege an abuse of refusal to supply after all [Defence 189-190]. Having pursued its investigation for over two years and having insisted at the oral hearing [NoA File 18/4732, lines 35-36, OFT case officer to leading counsel for Genzyme: "Where in the Rule 14 do we say that refusal to supply was at stake here?"] and in the Decision [§§380-381] that its case is not one of the abuse of refusal to supply, it is not now open to the OFT to change tack again because its case on bundling and margin squeeze is doomed to failure and the Decision is bound to be annulled. It would be a flagrant abuse of process for the OFT to seek to do that. It would have to be the subject of a completely fresh Rule 14 Notice and all appropriate rights of defence, and in any event such an allegation is also doomed to fail

in the light of **Bronner** (as to which see further below), and the OFT's correct position that the refusal to supply was justified.

12. As a consequence of its preconceived approach, the OFT (as will be made clear) failed to carry out a full or proper investigation contrary to its obligations in law (NoA 232 – 238). Its investigation has been characterised by:

    (i) no fact-finding at all into many highly relevant matters;

    (ii) extraordinarily limited fact-finding into other highly relevant matters;

    (iii) taking at face value assertions by the complainant HH and by TKT, with whom Genzyme has been involved in protracted litigation, without requiring documentary evidence to be produced or any corroborative evidence; and

    (iv) an almost complete failure to take any steps to consider or investigate Genzyme's written and oral representations and supporting evidence.

13. In particular, the OFT placed considerable and uncritical reliance on statements by the complainant HH (without any documentary support) during the administrative procedure [CB3/55/849-867].

14. The need for detailed examination of a complaint (in particular by requiring allegations to be supported by contemporary internal documentation and by corroborative evidence) is particularly important where the OFT acts in a dispute between competitors (as here) which would normally be the subject of litigation (as has been the case in the majority of cases concerning the Competition Act and/or Article 81, since the coming into force of the Competition Act), with all the appropriate procedures of litigation (discovery, evidence on oath and cross-examination) which do not apply in an administrative procedure. No reason has ever been advanced as to why the OFT devoted scarce resources to further the interests of a particular competitor in a matter which could (and should) have been litigated (after all HH had very experienced competition law specialist solicitors acting for them) and which would inevitably have had to be litigated if the complaint had been to the EU Commission. 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.

15. The OFT's narrowness of investigation is in very marked contrast to the extensive and wide-ranging enquiries made by the MMC in its investigation into the proposed *Fresenius/Caremark* merger [CB2/39/548-549]. Doubtless the OFT will explain in its skeleton argument why it considered it was not necessary to carry out the extensive enquiries, such as were carried out by the MMC in preparing the *Fresenius/Caremark* report, in particular into those manufacturers who it knew well were also providing homecare nursing treatment, and those who it should have known were providing separate delivery services (if nothing else a detailed examination of HH's internal documentation would have told them that).

16. Because the OFT did not carry out a full or proper factual investigation, the Decision gives an inaccurate and highly distorted picture of the matters relevant to an understanding of the operation of the relevant market and of Genzyme's conduct. It has thus been necessary for Genzyme to explain the operation of those markets and to adduce extensive evidence in support in its NoA.

17. The OFT objects to the amount of detail and evidence set out in the NoA (and makes empty threats on costs) [Defence 18] but Genzyme had to provide this to the Tribunal precisely because the OFT had not done so, having failed to carry out a full and proper investigation.

(ii) Orphan drugs [NoA 49-80; CB1/13-21/73-170]

18. The starting point to any proper understanding of the competitive structure of the field in which Genzyme operates is the producer and consumer interest in the research, development and production of orphan drugs. The OFT has failed to appreciate the significance of orphan drug legislation, the Biotechnology Directive and the EU's Sixth Framework Programme on research, and the fact that that legislation provides every possible encouragement for such development, including the grant of monopoly rights going in many cases far wider than patent rights. This is extensively set out in [CB 7.3 – 8.1]. The relevant legislation is at NoA File 7. See in particular Regulation 141/2000 [NoA File 7 tab 3.1.1] and recitals (1), (2), (3), (8), (9), (10), (11), Article 6, Article 7(1), Article 8(1), (2), (3) and Article 9.

19. The legislation recognises the importance of benefits to patients and potential patients. The legislation in particular granted exclusive market rights for the treatment of the

orphan diseases (subject to important exceptions as set out in the Regulation, in particular in the case of inability to supply sufficient quantities, or if the new product is proved to be safer, more effective or clinically superior), and other incentives such as reduced registration fees and allowed Member States to introduce tax incentives. There is no exception for a cheaper product. Insofar as the OFT might have relied on the contents of a telephone conversation with EMEA [CB.170], Genzyme relies on NoA paragraphs 65-67 and Genzyme's Third Supplementary Written Representations [CB3/79/1088-1092, section 3] and the second Witness Statement of Dr Tambuyzer [NoA File 19/5148-5152], which have not been challenged.

20. Cerezyme is not in fact technically an orphan drug in Europe (although it would in fact have qualified for such a designation) for at the time of its introduction the EU, unlike the USA, had not adopted the appropriate legislation but Cerezyme is treated as if it had such rights for all purposes other than the grant of monopoly rights.

21. The OFT appears to regard these matters as relevant only to market definition [NoA 65-74; Defence 31]. It seems to take the view that competition law consists simply of rules to be applied with "full rigour" [Defence 30] irrespective of economic context and impact upon economic and social incentives and the interests of consumers. But that is wrong. The orphan drug issue affects not only market definition, but also dominance, abuse, objective justification, direction and penalty. It is a fundamental error for the OFT to restrict its consideration of orphan drugs simply to market definition, and that by itself is a reason to annul the Decision.

22. EU and UK competition law serve to promote the interests of consumers. The consumer interest here lies in promoting the research, development and production of orphan drugs, which would not happen without such legislation. Fast track approvals and/or review are in the process of being introduced [NoA paragraph 56], a common position having been agreed earlier this year and the legislation providing for such a fast track procedure is due to be adopted in November [CB1/8/39, paragraph 23]. That interest requires incentives to carry out research and development, and this is particularly important in the field of biotechnology where Europe lags behind the US and Japan. Competition law has to be applied in the context of other legislation and policies, including orphan drug legislation and intellectual property laws (which include the orphan drug monopoly rights given by the legislation).

23. Yet the OFT in relation to all matters other than market definition in the Decision and in particular the Direction and penalty wrongfully excluded any consideration of the special position of such orphan drugs. If allowed to stand, the Decision would seriously undermine incentives for research and development of new orphan drugs and these highly important EU and national objectives by fettering each and every company which makes an orphan breakthrough with the obligations of a dominant undertaking and the possibility of an equivalent Direction and penalty and thus undermines the legislative objectives. Each breakthrough, if the OFT were right on its market definition, would entail Article 82 obligations by virtue of the marketing exclusivity rights conferred by Regulation 141/2000. What the EU gave by this Regulation, the OFT would take away or severely limit. That can only prejudice orphan drug development in the EU, to the great harm of the ultimate consumer, namely patients suffering from these often life-threatening and certainly debilitating conditions, as well as to the biotechnology industry itself.

24. In this regard, it is particularly offensive (and deeply resented by Genzyme) for the OFT to allege that Genzyme is seeking to exploit patients and the NHS [Defence 4]. Were it not for Genzyme's pioneering work in the LSD field, patients suffering from these conditions would not have the range of treatments already on the market and in development for what are often life-threatening illnesses, and which treatments enable patients in many cases to go on to live normal lives instead of suffering from and being handicapped by these debilitating conditions. The NHS (and the patients concerned and their relatives) would not benefit from home treatment for Gaucher disease (introduced by Genzyme) and the free provision of nursing (in the minority of cases where this is necessary) for patients receiving home treatment, thus freeing up NHS facilities, NHS community nurses and financial resources.

25. The true position (disregarded by the OFT) is described by the director of the Genetic Interest Group, Alistair Kent:

> "Without the incentives provided by [orphan drug legislation] there can be little doubt that industrial and commercial interest in developing products for these conditions would disappear like water in the desert. [Orphan drug legislation has] proved to be a valuable spur to development because they give companies the confidence to invest in the knowledge that should the research pay off and a new product that benefits patients emerge as a result, there is the prospect of a commercial return on their investment. ... This encouragement has given hope to many families who otherwise would have continued to suffer from potentially treatable conditions, but for whom, without [orphan drug legislation], good

science would not have been translatable into safe and effective products available for their use." [CB1/18/157-160, paragraphs 7 & 9; see also Henri Termeer, Genzyme's CEO at CB1/13/76, paragraph 11]

26. The OFT's failure to have regard to the need for incentives for investment (specifically referred to in the orphan drug legislation), as well as for entrepreneurial activity and the importance of a free market economy, disregards the guidance of the European Court of Justice in **Bronner** as to the approach to be taken to allegations of abuse. [NoA 480-483]. That case makes clear that in the ordinary event, even when dominant, undertakings have the right to conduct their own business in a way they consider most appropriate, save in very exceptional conditions which do not apply here, precisely because of the importance of ensuring incentives to invest. It is no answer for the OFT to argue that **Bronner** is concerned with a refusal to supply (as it was). As already stated, this case is in reality an attempt by the OFT to force Genzyme to supply third parties including HH and to do so at a discounted price. In any event the principles of **Bronner** are of general application and are not restricted to refusal to supply cases. See also the very restricted areas in which abuse can occur in the field of intellectual property rights (with which orphan drug rights are analogous) as in **Volvo v Veng**[1]: none of the limited category of abuses referred to there (arbitrary refusal to supply, unfair price or discontinuance of production) is here alleged in the Decision.

27. The Advocate General's guidance in **Bronner** (which was in general terms followed by the Court) lays down the following relevant principles.

(i) The right to choose one's trading partners and freely to dispose of one's property are generally recognised principles in the laws of the Member States, in some cases with constitutional status. Incursions on those rights require careful justification [56]. There is no justification advanced in the Decision.

(ii) 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

[1] Case 238/87 **Volvo v Veng** [1988] ECR 6211, paragraph 9.

products would be reduced if its competitors were able to share the benefits [57]. That is the case here.

(iii) The primary purpose of Article 82 is to prevent distortion of competition – and in particular to safeguard the interests of consumers – rather than to protect the position of particular competitors [58]. Consumer interests here are those of the patients and potential patients suffering from LSDs, not the interests of middle-men distributors such as HH.

(iv) Particular care is required where the goods to which access is demanded represent the fruit of substantial investment [62], as is the case for Genzyme and other bio-tech firms here.

(v) Intervention (in the way sought by the complainant HH and the OFT) would lead to detailed regulation of markets, entailing the fixing of prices and conditions for supply in large sectors of the economy. Such intervention is not only unworkable but would also be anti-competitive in the longer term and is scarcely compatible with a free market economy [69]. This is recognised by the DoH in the PPRS, which allows drug manufacturers to make reasonable profits and there is no question (or allegation) of Genzyme making excessive profits. There is no justification for the OFT to intervene in relation to Genzyme's trading in the detailed way it seeks to do in the Direction.

(vi) In short, it is not sufficient that an undertaking's control over a facility should give it a competitive advantage [65]; the mere fact that by retaining a product for its own use a dominant undertaking enjoys an advantage over a competitor cannot justify requiring access to it [57]. Here Genzyme's competitive advantage with Cerezyme is entirely down to the merits of Cerezyme as a "spectacularly efficacious" treatment. That is the product of competition on the merits, not evidence of dominance or anti-competitive behaviour.

28. These principles have been completely disregarded here by the OFT. The OFT is seeking to impose a one-fifth price cut on Cerezyme (and Ceredase, even though the only patient still being treated with it receives treatment at the Royal Free, not at home) and forcing it to trade with others. The risk of that sort of intervention is not only trespassing upon Genzyme's **Bronner** rights, but amounts to a massive disincentive to

investment, contrary to the fundamental principles of competition law, as well as all the EU and UK initiatives to promote orphan drugs and biotechnology. It will be difficult to encourage development in the UK in these fields if the OFT's attitude as set out in the Decision is not rejected by the Tribunal.

(iii) Market definition [NoA 81-103; Reply 54-56]

29. OFT has fundamentally misunderstood the market or markets, both in relation to the product and in relation to the provision of homecare services. This is unsurprising when one considers the extraordinary way in which the OFT carried out its investigation at both its supposed "upstream" and "downstream" levels.

30. It is worth recalling at this point the factors which the Tribunal ruled in **Aberdeen Journals** at [96] must be taken into account in defining a market. These are:

(i) the objective characteristics of the products;

(ii) the degree of substitutability or interchangeability between the products, having regard to their relative prices and intended use;

(iii) the competitive conditions;

(iv) the structure of the supply and demand; and

(v) the attitudes of consumers and users.

31. In fact, the OFT took no steps to obtain any evidence upon which it could base its case in accordance with these factors. There is little or no evidence and certainly no cogent evidence to support the OFT's case on market, on dominance or on abuse or lack of objective justification.

32. The OFT has approached the whole question with preconceived views of the market, both upstream and downstream. The OFT's attitude to evidence seems to be that the only evidence of any relevance is that which supports its case and it wholly fails to mention any evidence which does not support its case.

(iv) The alleged "upstream" market [NoA 296-343; CB1/1-72 & 161-169]

33. The OFT has wrongly defined an upstream market as being for the supply of drugs for the treatment of Gaucher disease, when the OFT ought to have found that there is only one relevant product market which extends to research, development, supply and distribution/delivery to patients at hospital and in the home, and which relates to the drugs for the treatment of LSDs. There is extensive evidence which supports that view, not only from Genzyme, but from all those involved in the development for LSDs (including OGS and TKT), and those involved in the prescribing of treatments for those diseases.

34. Genzyme is not dominant on that market; in fact, its success with Ceredase and then Cerezyme has attracted several other entrants who now have a range of treatments for LSDs either in production or in the advanced stages of research and development.

35. What has gone wrong on market definition is that the OFT has simply relied upon merger cases to define the alleged "upstream" market as a matter of law, and left it at that; and has not attempted to investigate the full factual situation whether or not the market is defined as it says and has not taken any account of evidence advanced by Genzyme in exercise of its rights of defence. Equally the OFT has assumed that because Cerezyme is currently the most commonly prescribed treatment for Gaucher disease, that is an end of the matter.

36. The OFT has not considered anything else, which is extraordinary in the light of the extreme dynamic conditions of the LSD market.

37. The OFT starts from the misconception that the definition of markets in merger cases is the same as in Chapter II enquiries. This is a fundamental error and has led it to wholly disregard highly important matters of fact and indeed not to conduct any proper enquiry at all.

38. The OFT has made the basic error of assuming that simply because a very small class of persons needs a particular product, then by definition that is the relevant market. What the OFT admits is a "particularly rigid" approach to defining the market only by reference to that demand side consideration [Defence 41] would lead to the creation of myriads of different markets with smaller and smaller populations. It would lead to the

creation of some 40 different markets for the various treatments for LSDs as and when they are developed and some 5,000 – 8,000 different markets for all orphan drugs (which will include treatments/cures for various cancers, infectious diseases, metabolic disorders and tropical diseases), some of which will have miniscule populations (for example Sly's disease, with 7 reported cases worldwide but where there is nevertheless research taking place [CB1/15/100 lines 11-21]). Such an approach would lead to markets becoming smaller and smaller as patients/consumers become dependent upon a particular formulation or version of a product. Zavesca (which does not require infusion) could also be a separate market on the OFT's approach. The logic of the OFT's case is that the one Royal Free patient receiving Ceredase because of an intolerance to Cerezyme constitutes a market in his or her own right.

39. It is also wrong to look only at the current situation and to look no further. In a dynamic market such as with, as here, biotechnological products and orphan drugs it is nonsensical to look merely at individual requirements of patients and at the current situation and to disregard what will happen in the future. With the arrival on the market of Zavesca and with the commencement of human clinical trials for TKT's enzyme replacement therapy GCB in the first half of next year, (which TKT claims will undercut Cerezyme in price) and with the arrival of other products for the treatment of other LSDs, the market clearly is much wider than simply products for the treatment of Gaucher disease.

40. The Tribunal held in **Aberdeen Journals** that the contemporary views of participants in the market are probably the most decisive single factor in defining the market. No participant in this business sees the market as being anything other than LSDs or as being restricted to Gaucher. None of the uncontested documentary evidence suggests it is restricted to Gaucher [eg CB1/1-12/1-72]. One disease is simply too small to be a market. Gaucher is probably the most common of the LSDs, but its prevalence is minute: 190 or so patients out of 58 million in the UK: about 1 in 320,000. This is the equivalent of one person in the whole of a city such as Leicester. Others (eg, Sly) are far less prevalent – 1 in 1.3 million. It is also true that all of the consultants regard the area as relating to LSDs, not the individual diseases.

41. There are no cures at present for LSDs - only treatments (although Genzyme and others are making exciting advances in gene therapy which could in time lead to cures

[CB1/15/100 lines 11-21] if the investment necessary to fund that research can be raised). Until ten years ago in the UK there was no treatment for any of these LSDs. Gaucher disease was where Genzyme made the initial breakthrough. It might just as well have been in another LSD. This meant that for the first time – thanks to Genzyme's work after Dr Roscoe Brady's initial breakthrough – it was possible for most of those with Gaucher disease to live something of a normal life. Even here the OFT has sought to belittle the massive contribution by Genzyme in bringing Ceredase/Cerezyme and other LSD treatments to market [Decision 232] which gives a fair indication of the OFT's attitude to entrepreneurial and scientific endeavour.

42. Now there are also treatments for Fabry disease and MPS-I. Treatments for Pompe, Niemann-Pick and Hunter (by TKT) are under development [CB1/8/34-39]. For those suffering from these diseases and their families the introduction of these treatments has been, and will be, nothing short of a miracle. As Dr Smith told the OFT at the oral hearing, there are babies alive today as a result of the trials taking place at the moment for Genzyme's ERT for Pompe disease, Myozyme [CB1/8/38, paragraph 16]. And the same will be true of TKT's treatment for Hunter disease, where as TKT's CEO Mr Astrue said, "It's a generally fatal disease that hits young boys usually between the age of two and four. The most severe patients die a pretty wretched death at about the age of 12, although some of the patients, a small percentage, live into their 20s and 30s. We have had a successful Phase I/II test of this product." [Reply, tab 8, annex 1].

43. Yet the OFT seeks to burden companies such as Genzyme and TKT, who have the possibility of performing these miraculous developments in biotechnological science, with the extra burden of dominance and all that involves, and having to supply that product to all third parties (including competitors) under the same terms as in the Decision.

(v) The alleged "downstream" market [NoA 141-161 & 344-389; Reply 10-32]

44. With regard to the "downstream" market, the OFT has concentrated on HH's complaint, has not investigated the market from the point of view of any other participant in that market, and refused to accept (or even understand) the MMC's findings in *Fresenius/Caremark*, which clearly show – as does the evidence adduced by Genzyme – that the downstream market it claims to have found is wholly artificial and non-existent.

45. However, the OFT alleges that there is a "downstream" market for the provision of services for the treatment of Gaucher disease. This is a market where, if the OFT were right, there are no more than 171 consumers in the whole of the UK, of whom less than a quarter (42) receive nursing as well as home delivery from the same company (5 of them from Genzyme Homecare). It is, of course, an absurdly narrow and wrong approach. There is no such market, and there is no evidence upon which the OFT could conclude that there is such a market. It is inconsistent with the approach to market definition advocated by the MMC in *Fresenius/Caremark*.

46. The OFT's case rests on the fact that, at present, Cerezyme is prescribed for most patients with Gaucher disease and that most patients take their treatment at home. That does not justify treating homecare for Gaucher disease as a separate market. The substantial majority (68%) of the patients who have their treatment at home receive no nursing services and some 8% receive nursing at home from the NHS. Gaucher disease is simply one of many conditions that a homecare service provider can offer to treat.

47. The evidence in relation to each of these factors makes it plain that there is a market for general homecare services, which in fact comprises discrete markets for general home delivery and for nursing. The OFT argues that home delivery and nursing are in one and the same market because Genzyme has always supplied both home delivery and nursing together [Defence 54-55] but that shows no more than Genzyme wanting to supply both services together. Only a relatively small proportion of patients to whom HH delivers Cerezyme, receive nursing treatment from HH: 37 out of 154 (24%).

48. Home delivery is available and often supplied as a separate service. HH, for example, has on occasion contracted out delivery of Cerezyme to Polar Speed and had until very recently sub-contracted cold-chain home delivery to Polar Speed of other drugs on an increasing scale. HH also provides delivery only services itself, as the Royal Free Factor VIII invitation to tender for which HH successfully bid exhibited to Mr Farrell's statement demonstrates [CB2/54/770-848 – note HH's tender at 783-848 is confidential and has been removed from the Core Bundle supplied to Genzyme]. The actual facts show that the combination of home delivery and nursing is very much the exception to the rule.

49. The OFT did not know about this during the administrative procedure because of its failure to make the relevant enquiries during the administrative procedure. The first the

OFT appears to have been aware that there are undertakings offering cold chain home delivery services as a separate service not involving nursing was when Genzyme referred to firms such as Polar Speed and Healthcare Logistics at the interim relief hearing before the Tribunal. The OFT then contacted Polar Speed, but despite being informed about the nature of Polar Speed's business, took no steps to put that evidence before the Tribunal. The Tribunal now has two witness statements from Mr Evans of Polar Speed which explain that home delivery is a separate service and can be supplied without nursing [CB3/64-65/959-972].

50. But whether home delivery and nursing are one or two downstream markets is not the crucial premise that the OFT alleges it to be [Defence 119]; it does not so much matter whether these discrete services form two separate markets (as Genzyme contends they do) or are discrete services supplied in one and the same market. The key point is that neither of these services are further divided according to the therapy being delivered or for the treatment area for which nursing is supplied. There is nothing specific to Cerezyme about home delivery or nursing [Reply 26-32]. There is no evidence whatsoever to support such an allegation, and all the evidence is to the contrary.

51. HH told the MMC in the *Fresenius/Caremark* inquiry that "winning contracts in one or two treatment areas facilitated entry into others because some of the capabilities required were similar" and that "it would be very difficult for a pure service provider to build a profitable business in only one treatment" (MMC, §5.115 [CB2/39/524). HH was clearly then of the view that there were no disease specific markets. The MMC did not find that there were disease specific markets: it in fact adopted HH's terminology of "treatment areas" (MMC, §4.92 [CB2/39/496], quoted by the OFT in the Defence 14). Nothing has changed since the MMC Report to justify the OFT now taking a different view and the OFT has not obtained any evidence upon which it could now take a different view.

52. The only homecare service provider with which the OFT was in contact during the administrative procedure is HH, which was partisan in its views and whose allegations could only be relied upon if consistent with internal documentation (as to which the OFT made no enquiries) and consistent with the experience of others in the same field (as to which the OFT also made no enquiries). The OFT will need to explain to the Tribunal why it did not contact the major homecare service providers Clinovia (formerly Caremark – HH's predecessor in relation to Ceredase/Cerezyme), Central Homecare, Baxter or

Fresenius for their views as to whether HH's assertions were correct. The OFT will also need to explain to the Tribunal why it did not question HH as to why its submissions to the OFT were so completely at odds with its submissions to the MMC, and why it did not carry out any investigation of HH's internal documentation or of third parties to see if there was corroboration for HH's contentions.

53. The only explanation advanced thus far by the OFT for its almost total reliance on HH – that only GH and HH are involved in supplying Cerezyme [Defence 61] – self-evidently misses the point. The question is whether those not supplying Cerezyme regard themselves in the same market as those that do. It also begs the question why OFT did not contact Clinovia, Genzyme's previous distributor for Ceredase and Cerezyme? Did it regard itself as having completely exited a market when its distributorship came to an end, or was the position instead that it had lost a contract for a particular "treatment area" within the homecare market?

54. The OFT relies upon lack of demand side substitutability in its argument that the market is defined by treatment area [Defence 62]. However, as observed by the MMC at §2.71 of the *Fresenius/Caremark* report, quoted but not applied by the OFT at §187 of the Decision, that is not the way in which the market is to be defined here. The MMC stated:

> "The issue of market definition, therefore depends principally on the extent of supply-side substitution, that is the ease and speed with which a producer of one product or service is able to offer another in response to a price rise or the opportunity to offer the service at a lower cost." [CB2/39/437, emphasis added]

55. 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.

56. It is also demonstrated by the move to block contracting, which demonstrates that a single homecare service provider may be engaged to provide services across a range of treatment areas both in relation to delivery and nursing services (together or separately):

it is a supply-side substitutability point, and not the demand side point that the OFT misrepresents it to be [Defence 67].

57. The OFT seeks to remedy this fundamental defect in its market analysis by advancing a new argument in the Defence that home delivery of Cerezyme is an "integrated" service involving a pharmacy, distribution, customer care and nursing service which somehow uniquely marks it out from homecare generally [Defence 63-64] and so marks out HH from all other homecare service providers. This is pure invention entirely unsupported by any evidence.

58. As regards the distribution element of the supposed integrated service, the delivery service involves the delivery of Cerezyme to patients' homes and collection of waste packaging and disposables (sharps bins and the like). This service differs little according to the treatment, and most certainly does not have any features unique to Cerezyme. The OFT seeks to emphasise its specialist features [Defence 120-122 & 135-136] and it is true that each company providing the service prides itself on its quality of service. But there is nothing to suggest that cold-chain delivery to community pharmacies is of such a significantly different character that it is not to be equated with basic cold-chain delivery of drugs to the patient.

59. Home deliveries of Cerezyme are carried out by different individuals and do not coincide with nursing visits at all. Of HH's 154 patients, 107 (69.5%) have deliveries only. Of the remaining 47, 10 (6.5%) have nursing visits from NHS community nurses [Reply 15]. So only 37 out of HH's 154 patients, less than a quarter (24%), receive the so-called integrated service. If overall UK patient numbers are taken into account by including the patients served by Genzyme Homecare, the position is the same. Only 42 out of 171 patients, again less than a quarter, receive a so-called integrated service.

60. Indeed, on occasion, HH sub-contracted deliveries to Polar Speed which has no involvement in nursing [Reply 20]. There is no question of the delivery service being inherently integrated with nursing as alleged by the OFT. It is a separate activity which can be and is carried out independently of the nursing.

61. As for the pharmacy element of the supposed integrated service, that too can be contracted out, which was precisely what HH did when it was first appointed by Genzyme as its distributor. It is also what Polar Speed does in relation to NHS

prescriptions. Polar Speed does have its own pharmacy and so is able to dispense against private prescriptions.

62. As for customer care, that is something almost any reputable service will offer, irrespective of the service provided.

63. Finally as regards nursing, this service involves administering Cerezyme to those patients in their own homes who are not able to self-cannulate whether by themselves or by their parents. This involves, in essence, the nurse making up a solution of Cerezyme and administering it through intravenous infusion by cannulation, a standard medical procedure of inserting a needle into a vein which two thirds of patients (or their parents) are trained to carry out for themselves.

64. Taking the first two of the **Aberdeen** factors, there is nothing objectively to distinguish those nursing services provided in such cases with Cerezyme as from other treatments which require cannulation or indeed many other similar services (eg, oncology etc). Obviously, it is important that the nurses are well-trained in cannulation and have experience with the problems related to Gaucher disease and LSDs generally, but there is nothing to prevent any suitably qualified nurse from being so trained. There is nothing disease specific about nursing for Gaucher patients. And, of course, two thirds of Gaucher patients receiving treatment at home in the UK do not require nursing assistance to administer Cerezyme, once they have been trained to administer it themselves or in the case of children their parents have been so trained (see Annex 1), which illustrates that with the appropriate training it is a routine procedure for most people.

65. The fact that nursing is available for those two-thirds of Gaucher patients who are self-infusing should they wish to resume having nursing assistance adds nothing to the OFT's integrated service theory [Defence 137-139]. All that means is that the nursing service is available to all who wish to use it, and further there is no evidence to support such a contention.

66. As to the other three **Aberdeen** factors, it is plain that homecare service providers are in competition and regard themselves as being in competition in the supply of homecare services. Print-outs from the websites of the major homecare service providers Clinovia (formerly Caremark), Central Homecare, Baxter, Fresenius and, of course, HH, contain

not the slightest suggestion that the market is anything other than homecare [CB2/48/682-727 & CB3/57/886-907; see also press articles at CB3/58/908-934].

67. Thus Clinovia advertises itself thus "In essence, our service supplies care packages to pharmaceutical companies to support the effective administration of their products in the home". Central states that it has a "well established home care service" and its "expertise covers many therapy areas" listing some 13 areas, one of which is enzyme replacement therapy. Baxter's Unicare provides renal dialysis homecare, which is its core area of operation, but it states that "Unicare is actively involved in the provision of homecare support in several areas and interested in exploring alternative areas of homecare provision with a range of partners". Baxter plainly does not regard homecare as being limited to the particular treatment in which it has specialised. Similarly, Fresenius, a renal dialysis specialist, states that it is "adding other extracorporeal therapies, outside dialysis, to its range of services".

68. HH states that the foundation of its success "is our home oncology service. However, having a rapidly expanding and expert nursing team across the country allows us to embrace many other, often complex, home therapies including blood transfusions, IV antibiotics and many others." HH says that it has over 100 full-time nurses working from 15 regional centres around the UK. It states that "typical treatment areas include chemotherapy for cancer including supporting therapies ..., blood transfusions, IV antibiotics and antivirals, stem cell transplantation support and many others". HH states that it "is continuing to work with many pharmaceutical companies to develop bespoke programmes of homecare to support bespoke therapies" and that it "continues to explore innovative homecare initiatives with the NHS". The nursing attention required by HH's Gaucher patients could not possibly be described as "often complex" [CB3/57/886-907].

69. Further, even this summer HH has been advertising to recruit nurses to "care for a caseload of patients with acute and chronic conditions receiving a wide range of IV, IM and S/C therapies ... We are particularly looking for nurses who have a wide variety of experience in oncology, haematology, acute medicine, rheumatology, neurology and care of intravenous devices but would be interested to hear from other specialities" (advertisements at Annex 3 of this skeleton). There is nothing to indicate that the nursing services to be provided by those nurses will be treatment specific; on the contrary, HH is

looking for nurses "who have a wide variety of experience" so that they can cover the wide variety of treatment areas encountered in HH's business.

70. These are views of the market participants which the Tribunal said in **Aberdeen Journals** were potentially decisive and which are highly relevant to supply-side substitutability applying the MMC's market definition test. Yet the OFT has made no enquiries of those market participants. The OFT has completely ignored them, flying in the face of all common sense.

71. It can be seen that there is nothing to support the OFT's view, based – as it is – upon HH's allegations in its complaint that there are separate markets for homecare based upon the treatment area concerned. Those allegations are entirely inconsistent with its own published statements and the evidence it provided with the Defence, and subsequently, of Dr Jones, HH's Medical Services Director [CB3/62-63/947-458]. HH is competing with a number of other service providers, some independent and some part of pharmaceutical companies, to provide a homecare service to support a range of therapies. Sometimes that service will be both delivery and nursing; sometimes, as with the Royal Free Factor VIII contract awarded to HH (and indeed for the vast majority of Gaucher patients undergoing home treatment), delivery only, where HH may also find itself in competition with delivery service providers such as Polar Speed and Healthcare Logistics.

72. When it comes to the Gaucher treatment area, HH is in competition with Genzyme Homecare and other service providers. It was successful in winning the distribution contract to replace Caremark (now Clinovia) in 1998 and lost the chance of a new contract in 2001 when Genzyme concluded it could carry out the service more efficiently and effectively itself. That is no more and no less than competition on the merits in homecare service provision.

73. Finally on market definition, mention should be made of the OFT's invented concept of third party wholesaling for Cerezyme, by which the OFT explains it means delivery of Cerezyme to hospitals. The OFT says that this has been "uneconomic" for any company other than Caremark from 1993-1998 and HH from 1998-2001 [Defence 73-74]. This highlights the absurdity of the OFT's position. By uneconomic, what the OFT means is that during those periods Genzyme contracted out delivery to those third parties and

paid them to do it. The OFT seems to believe that a dominant firm is under an obligation to pay third party contractors to carry out activities (including distribution) it could undertake more efficiently itself. That is an absurd proposition. Competition law is intended to promote economic efficiency, not to impose inefficiencies.

(vi) Dominance [NoA 390-466]

74. 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.

75. The OFT's approach to dominance in the so-called "upstream" market is simplistic, misconceived and not borne out by any or any adequate factual investigation. The OFT wrongly defined the market and then went on to assume dominance on the basis that Cerezyme is currently the main treatment for Gaucher disease. Even on the OFT's incorrect "upstream" market definition, the evidence makes it clear that Genzyme is not dominant (see also the judgment of the Spanish Restrictive Practices Court in **Bacardi**: NoA 396).

76. The OFT's approach in this case is all the more perverse and irrational because it flies in the face of the OFT's guidelines and its own warnings about the dangers of over-reliance on market definition. The OFT guidelines on the Chapter II prohibition state that "Market share is an important factor but does not, on its own, determine" dominance (OFT 402, §3.13). The OFT therefore has to consider whether an undertaking is likely to face competition from new entrants (OFT 402, §3.14) and to take account of the "the rate of innovation" so that "competition policy does not undermine the incentives for such innovation" (OFT 402, §3.16). The OFT guidelines also say that buyer power is highly relevant to determining dominance, particularly where a customer is large relative to the undertaking (OFT 402, §3.17). The OFT has completely disregarded all of that very sensible guidance.

77. By contrast, in this case, the OFT's so-called investigation has been cursory. What seems to have happened is that the OFT has fallen for the "zero-one fallacy" against which the Chairman of the OFT has counselled.[2] The OFT has assumed, without any

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2 Vickers [2003] ECLR 95 *Competition Economics and Policy*.

proper basis for doing so, that the correct market is that for the treatment of Gaucher disease and that because Cerezyme is the main available treatment, Genzyme is automatically dominant. Had the OFT applied its guidelines correctly, heeded its Chairman's warnings and made the proper factual and evidential enquiries, it could not possibly have come to that conclusion.

78. On the supply side, markets for orphan drugs, including those for the treatment of LSDs, are by their very nature highly dynamic. There are, by definition, a miniscule number of patients (even by orphan drug standards). Even if Cerezyme was actually an orphan drug for monopoly purposes, if a safer or more effective treatment is put on the market, those patients can switch to the new treatment almost overnight, and the fact that original orphan drug had monopoly rights would not protect it in such circumstances. There is, after all, only one consultant at each of the four designated centres in the UK, each of whom is intimately acquainted with all LSDs and not only patients with Gaucher disease. That happened when Cerezyme became available to replace Ceredase. It is also illustrated by TKT's success with Replagal. At this moment, Cerezyme faces competition from OGS's Zavesca and imminent competition from TKT's GCB, which TKT promises will be cheaper than Cerezyme. Some of these consultants at these centres will have conducted trials upon these new products and therefore have prior knowledge of experience in these products. It is obvious that Genzyme cannot be dominant in those circumstances, and the OFT adduces no evidence to support its case on dominance, only assertion based on percentages.

79. As for barriers to entry, the factors relied upon by the OFT [Defence 90] are simply matters than any pharmaceutical company has to take into account. There is nothing special or unique about Cerezyme or treatments or LSDs, save for the greater incentives to enter the market based upon Genzyme's financial success. The fact that Cerezyme does not enjoy an orphan drug monopoly right means that any new entrant would not even have to establish that its product was superior. This is why orphan drugs are, according to EMEA, the silver lining at present when it comes to drug research and development [NoA 54].

80. It is nonsensical in this market to talk about Genzyme enjoying a "first mover advantage" as a barrier to entry [Defence 91-94]. It is not a self-evident truth and requires evidence to justify it. There is none relied upon by the OFT. The evidence shows that the opposite

is true. It was Genzyme which took massive financial risks, against its own internal advice, and demonstrated that it was possible for an ultra-orphan treatment for Gaucher disease and other LSDs to be a commercially viable proposition [CB1/13-14/73-91 & CB1/19/161-165]. Genzyme showed the small size of the patient population was not the high barrier to entry that it had been perceived to be, and orphan drug legislation has now further increased the incentives for entry. Others such as TKT and OGS have a "second mover" advantage of being able to capitalise on Genzyme's experience and have obtained investment and developed their products in the slipstream of Genzyme's success. Already, in treatments for Fabry disease, TKT claims that Replagal is outselling Genzyme's Fabrazyme by 60:40 in Europe. Other products for the treatment of other LSDs are in the pipeline and will, in all likelihood, soon be available.

81. All of that indicates low or non-existent barriers to entry, which is particularly impressive given the riskiness of research in this area and the low patient populations. The only barrier to entry that could be raised would be if the economic incentive to bring new drugs to the market to treat LSDs were reduced – which is precisely what the Decision and the Direction threaten to do if left to stand (ignoring the warning in **Bronner**).

82. This evidence is completely at odds with the statements TKT made to the OFT about alleged barriers to entry. TKT has been involved in a series of disputes with Genzyme in relation to the marketing of Replagal. TKT is also intimately involved with HH, which it intends to use as a distributor for its generic competitor to Cerezyme and with which it already has an exclusive distribution agreement with Replagal. 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.

83. However, the OFT has chosen to take TKT at its word, rather than judging it by its actions, because its actions do not support the view of the case that the OFT wants to take. The OFT will have to explain its skeleton why TKT's statements rather than its conduct were considered to be evidence upon which it could base a finding of infringement having regard to the high standard of proof required of it.

(vii) Abuse [NoA 467-571]

84. The OFT's case runs entirely contrary to the principles accepted by the European Court of Justice that normal competitive conduct cannot be abusive (see **Hoffmann-La Roche**[3], **Bronner** and **Volvo v Veng**).

85. Taking homecare treatment in-house is a perfectly normal and unobjectionable course of conduct.

86. The DoH, through the National Specialist Commissioning Advisory Group ("NSCAG") which is part of the NHS Executive, was fully informed of Genzyme's plans to do so at a meeting in February 2001 and did not to raise any objection. If the DoH had raised objections, Genzyme (which at that point was still in negotiation with HH) would not have implemented any plan without first satisfying those concerns.

87. The OFT has made no enquiries of other drug companies which also have in-house homecare service providers with no explanation. It did not contact Nutricia, despite the fact that the MMC observed without the slightest hint of criticism in the *Fresenius/Caremark* report that Nutricia was terminating its arrangement with Caremark and taking homecare in-house (MMC, §2.60 [CB2/39/434]).

88. Genzyme's submissions as to the specific allegations of abuse – bundling and margin squeeze – are outlined at Part C below.

(viii) Objective justification [NoA 572-617]

89. Genzyme put forward in its response to the Rule 14 Notice its case on objective justification.

90. The OFT's case on lack of objective justification in the Decision was exiguous in the extreme. In relation to bundling [NoA 592-599], the OFT relied upon correspondence from 1996 and 1997 relating to Caremark and correspondence with Taylor Vinters referring back to events in 1993. None of this could have the slightest conceivable relevance to Genzyme's decision in 2001 to move to in-house provision of homecare. It

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[3] Case 85/76 **Hoffmann-La Roche** [1979] ECR 461 at §19.

also alleges that "it is not for Genzyme to determine what is in the best interest of the NHS" [Decision §361, NoA 598] but that wholly ignores the fact that the DoH raised no objection to the decision to take distribution in-house, provided that it did not invoke any increase in cost. It is the DoH which speaks for the NHS on such matters, not individual consultants. As for the allegations of margin squeeze and unreasonable term of supply, the OFT [NoA 600-604] just asserted lack of objective justification and did not even attempt to provide any evidence in support. The OFT apparently failed to understand that the burden is on it to prove its case.

91. No doubt because of the fundamental weakness of the Decision in this respect, the OFT has now sought in the Defence for the first time to advance a new case of lack of objective justification [Defence 163-174 & 196-210]. It is denied that it is entitled to do so, and the arguments advanced are misconceived as can be seen hereafter. Genzyme's response is set out below.

92. In order to make good any allegation of abuse against Genzyme, not only does the OFT have to prove in the light of full and objective examination of all relevant facts the relevant market and Genzyme's dominance in that market but also in order to establish abuse the OFT has to accept in the Rule 14 Notice and to prove by cogent evidence to a high degree of probability [NoA 224-238] that the conduct:

(a) does not amount to legitimate business conduct;

(b) is prima facie abusive; and

(c) is irrational and cannot be objectively justified.

The OFT never so alleged and has not so proved.

93. The OFT disputes that it has the burden of proving to the requisite high standard of proof that Genzyme's conduct cannot be objectively justified [Defence 211-232]. As Laddie J held in **Getmapping** and **Suretrack** this means that the OFT would have to show that Genzyme's conduct constitutes an abuse "which no rational and fair person could justify". This is, as the learned judge observed, "a high hurdle to cross". The OFT does not even come close to getting off the ground, letting alone clearing this hurdle.

94. The OFT disputes the authority of **Getmapping** and **Suretrack**, the latter judgment being based (at [25]-[26] upon the learned judge's reserved and carefully reasoned judgment in the former case, in which he held at [52] "to demonstrate that OS' choice of ortho-rectification is incapable of being objectively justified demands more than showing that a rational trader in OS' position could have made a different choice. In substance it means that OS' choice has to be clearly unjustified." This is entirely in line with relevant EC jurisprudence. No authorities are cited by the OFT to the contrary save for a reference to **Hoffmann-La Roche** [Defence 231]. That repeats a submission made by the OFT's junior counsel in this case in **Suretrack** which was rightly rejected by Laddie J at [27] in the light of the most recent guidance to the correct approach given by the Court of Justice in **Bronner**.

95. As to precedent, the Tribunal is not a court of co-ordinate jurisdiction to the High Court [Defence 228] and therefore is bound by the High Court as set out in Genzyme's Further Submissions of 23 June 2003 [NoA addition (paragraph 3, CAT Order 31 July 2003)]. It is not, as the OFT suggests, in an analogous position to the Employment Appeal Tribunal [Defence 228 note 184]. That Tribunal was specifically constituted under the Employment Protection Act 1975 as a Superior Court of Record, which this Tribunal is not, and was created to hear appeals previously heard by the High Court.

96. The OFT argues that it does not have the burden of proof during the administrative procedure, describing it as an "odd" proposition [Defence 214]. In fact, the Tribunal ruled in **Napp** that the burden of proof is on the OFT throughout [NoA 228], and it is impossible to understand what justification could be advanced for not imposing the burden of proof on the OFT during the administrative procedure. The Rule 14 procedure places the burden on the OFT to prove its case (which is why the Tribunal remitted in **Argos & Littlewoods** [2003] CAT 16).

97. The OFT is not being required to prove a negative [Defence 216]. Genzyme having placed the facts before the OFT in support of its case that its conduct is objectively justified, the burden is on the OFT to prove that on those facts there is no objective justification. The burden does not shift to Genzyme at any time, and the distinction the OFT seeks to draw between legal and evidential burden of proof [Defence 222] is

contrary to the normal approach, as set out by Moses J in **Marks and Spencer plc v Customs & Excise** [1999] EuLR 450 at 482B-E:

> "I am not sure that it assists to speak of an evidential 'burden of proof'. It is no more than, possibly, a convenient shorthand designed to indicate that unless the trader asserts that it has been damaged and provides some material for the tribunal of fact to consider, the Commissioners will succeed merely by proving that the tax was passed on. There is, perhaps, a danger in referring in shifts in the burden of proof. A reference to that shift may obscure the proposition the proposition that it is for the Commissioners to prove unjust enrichment if it can and that burden never shifts. In raising the issue of damage in consequence of having passed on the burden of a wrongly charged tax and producing material to support that assertion, in my judgment, the trader does not take upon itself any burden of proving that it was not unjustly enriched. The reason why such a trader must assert damage and provide some material on which to base the assertion is because, absent any such material, there would be no evidence to rebut the defence of unjust enrichment established, *prima facie*, by the evidence of the Commissioners that the tax was passed on."

98. The case law set out in Genzyme's Further Submissions entirely supports that approach. In each case the undertaking under investigation put facts before the Commission. The burden was then on the Commission to prove that those facts did not disclose an objective justification for the conduct in question. 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.

99. As to the facts in relation to objective justification, Mr Johnson of Genzyme summarised the fundamental reason for bringing homecare in-house succinctly to the OFT at the oral hearing:

> "Why did we bring homecare in[-house]? ... How many times have you said to yourself 'if I want the job done properly I will do it myself'?" [CB2/49/591, lines 7-11]

100. Genzyme Homecare enables homecare to be provided by Genzyme under its direct control, which:

(i) improves quality [NoA 118-119] It is more satisfactory for nursing to be under Genzyme's direct control, instead of being farmed out to a third party. The problem with using third parties is well-illustrated by the statement by HH's

Director of Nursing to Genzyme, when problems were identified with HH's service provision:

> "With so many nurses in the field how can I be expected to control what they get up to day to day. They are given instructions but don't always follow them." [CB2/42/592, lines 3-6]

(ii) enables Genzyme Homecare nurses to build up expertise in treatment across the range of LSDs, which is particularly important as new treatments (such as Fabrazyme, Aldurazyme and Myozyme) become available [NoA 120, Reply 54-56 and Annex 8 (Dr Smith)]

(iii) improves standard of care for patients [NoA 122];

(iv) reduces Genzyme's costs [NoA 121];

(v) removes Genzyme's dependence for distribution on a distributor who distributes for a competing drug supplier [NoA 614].

101. In taking homecare in-house, Genzyme was following the example of Nutricia, which had decided not to continue to use Caremark, a development noted by the distinguished MMC panel in *Fresenius/Caremark* without any adverse comment (as the OFT acknowledges [Defence 194]) and the precedent of other drug companies which had always provided homecare in-house.

102. Genzyme informed the DoH of its plans; no objection was raised and the OFT did not challenge this in the Decision [Defence 170-173]. See further in Part C below.

103. In those circumstances, it is impossible for the OFT to prove to the requisite high standard that Genzyme's decision to bring homecare in-house was "clearly unjustified". On the contrary, as Dr Wraith observed based upon his experience with homecare for Fabry disease [NoA 282], it was "logical for Genzyme to take the homecare service in-house". [CB3/78/1075]

The OFT's case in the Defence on objective justification

The bundling allegation [Defence 163-176]

104. The OFT suggests that Genzyme has advanced an argument on objective justification that a "system of inclusive pricing" enables it to keep costs down [Defence 165]. That entirely misrepresents Genzyme's argument at NoA 595. Genzyme has never adopted any such system.

105. The correspondence to which to the OFT referred in the Decision dated from 1996-1997, prior to the appointment of HH. In it, Genzyme explained to the Gaucher Association that it bore the cost of using a homecare service provider to get the drugs to the patient because that avoided a problem that had been encountered when Ceredase was distributed via community pharmacies, namely that those pharmacies were charging an extra 10% for dispensing Ceredase and that might lead some health authorities not to fund treatment. So Genzyme decided to bear the cost of distributing directly to patients in order to ensure they received treatment, and charged no extra price for doing so. How can Genzyme's decision to bear costs in order to ensure treatment for patients who might otherwise have it withdrawn be castigated by the OFT as "clearly unjustified"?

106. The OFT then suggests that the NHS is not content with the way in which Genzyme provides homecare for Cerezyme [Defence 169-173], an assertion which appears to be based almost entirely on the evidence of Mr Farrell's preference for selecting his own homecare provider. To equate an individual pharmacist's view with that view of the NHS shows a total ignorance of the NHS system. Mr Farrell is of course perfectly at liberty to hold his view, but he is not at liberty to require Genzyme to fund him to do that, as the Direction would require: that would be contrary to the **Bronner** principles. More fundamentally, the DoH (who would speak for the NHS) has never objected to Genzyme's provision of homecare; NSCAG did not object to Genzyme's decision to bring homecare in-house when informed on 13 February 2001.

107. The OFT argues that the NHS List Price does not include delivery of the drug to the patient and so such delivery cannot afford an objective justification for Genzyme's practice in doing so [Defence 174]. That, as will be seen in Part C, is not even supported by its own witnesses. Mr Brownlee accepts at paragraph 4 of his second witness statement (served with the Treasury Solicitor's letter of 5 September 2003) that basic

delivery of the drug to the patient is paid for by the NHS List Price even in the exceptional case of delivery to the patient's home. 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 (as indeed a few used to do), but that it is not justifiable for Genzyme instead to take the drug directly to the patient's home and to collect waste at the same time so that the patient does not have to dispose of it himself. How can the OFT justify such a view?

108. Finally, in relation to bundling, the OFT suggests that Genzyme has argued that it should be entitled to bundle in order to engage in research and development in LSDs [Defence 175-176]. Again, this misrepresents Genzyme's argument; it is not arguing that it is entitled to raise funds for research and development through abusive pricing practices. The simple point is that Genzyme does not engage in bundling or abusive pricing practices. The Direction is intended by the OFT to impose a 18.3% price cut on Cerezyme retrospective to 1999. That level of financial risk cannot but prejudice the ability of Genzyme and others in this biotechnology field to persuade investors to invest in what is already very risky research.

The margin squeeze allegation [Defence 196-210]

109. The OFT's first argument is simply a reiteration of its view that Genzyme is bundling [Defence 198-199], which it is not. The documents referred to simply state that Genzyme would be ceasing to pay HH to provide homecare at the end of its contract and would be providing homecare itself.

110. The OFT tries to side-step the fact that in-house homecare service provision is a normal business practice by relying upon Mr Farrell's clear preference for using HH as a homecare service provider [Defence 200-201]. The OFT never contacted any of the companies to which it refers (Aventis, Baxter and Wyeth), in stark contrast to the MMC which took evidence from them in the *Fresenius/Caremark* inquiry, and concluded that in-house service provision was a normal feature of the marketplace, and not one that was "clearly unjustified".

111. The OFT then purports to reject Genzyme's argument that it would not wish to be reliant for distribution on a homecare service provider which was entrusted with distribution by its major competitor [Defence 202-205]. As already explained in the Reply at paragraph

32, this is entirely inconsistent with the OFT's case which rests upon the assertion that the identity of homecare service provider can influence choice of treatment. If it were more commercially advantageous for HH to distribute GCB than Cerezyme (because TKT were paying HH more than Genzyme), then on the OFT's case HH would seek to promote GCB rather than Cerezyme through its homecare provision, to the disadvantage of Cerezyme. In those circumstances, it would clearly be justified for Genzyme not to distribute through HH. The OFT's case must therefore be that HH would not be able to promote GCB over Cerezyme through its provision of homecare. But that is directly contrary to the OFT's case that Genzyme can influence the choice of treatment through its provision of homecare services.

112. Genzyme does not suggest that HH nurses would seek to influence the choice of treatment. But that is no reason why it should be forced to deal with HH rather than the distributor of its choice or to distribute itself. It is a common business practice for suppliers not to use their competitors' distributors and not one that can be said to be clearly unjustified. The OFT refers [Defence 204] to an article from Haemophilia Quarterly in support of its contention that pharmaceutical companies are content for their competitors' in-house homecare service divisions to deliver their products, but the article commences by observing that "some pharmaceutical companies only deliver their own products". As Laddie J observed in **Getmapping** at [52] proving lack of objective justification requires more than showing that rational traders may make different choices.

113. The OFT seeks to dispute Genzyme's view that it can ensure higher quality standards [Defence 206-210], but Genzyme's view is not clearly unjustified. In fact, it is justified in the face of comments such as that from HH's Director of Nursing when it was using HH's services:

> "With so many nurses in the field how can I be expected to control what they get up to day to day. They are given instructions but don't always follow them." [CB2/42/592, lines 3-6]

114. It is also consistent with the DoH's lack of any objection to Genzyme taking homecare in-house.

115. The OFT suggests that NHS will be denied HH's services [207-208], but that is nonsense and would require detailed evidence (which has never been produced) to make such a suggestion credible. HH continues to grow (from 2,000 patients in 2001 to

5,000 now) [CB3/57/886-907] and continues to recruit new nurses (see Annex 3). Should Genzyme Homecare not be the success that is hoped, doubtless HH (and others) will be available to bid should Genzyme seek to return to third party service provision.

116. Finally, the OFT seeks to make play of what it describes as "the inherent tension between the commercial interests of the drug manufacturer and the clinical care interests of patients" [Defence 210]. As is explained in detail in Part C below, there is in fact no evidence to support that allegation; in particular, dosing is a matter for clinicians only.

117. But even on the OFT's misguided thesis, there is an equivalent tension between the commercial interests of a third party service provider such as HH and the clinical interests of patients, because HH's remuneration was calculated as a discount per unit and so would have had the same interest as the OFT alleges Genzyme has in increasing dosages. Indeed, Genzyme had to renegotiate the agreement initially entered into with HH to remove the remuneration for carrying out visits, irrespective of whether any infusion was carried out, because it considered that HH were carrying out unnecessary visits to patients in order to increase revenue [CB2/41/580, paragraph 14]. It is precisely that sort of problem which is removed through in-house service provision.

118. In conclusion, it is unsurprising that the OFT's case on lack of objective justification is so remarkably exiguous, even by the standards of the remainder of the Defence. The OFT thought it could ignore the issue in the Decision, and now it comes to advance a case before the Tribunal in its Defence, it is obvious that it cannot demonstrate to the requisite high standard of proof that Genzyme's provision of homecare services is "clearly unjustified". There is not only no evidence to support such a contention, but also all the evidence points to it being a great benefit to all concerned and very obviously justified.

(ix) Direction [NoA 618-656]

119. The Direction in essence appears intended by the OFT to force Genzyme to sell Cerezyme to third parties at what is referred to as a "stand-alone price for the drug only". That is fundamentally misconceived and flawed.

120. The Direction to supply on a "stand-alone price" would have no effect because the NHS List Price of Cerezyme is already "stand-alone" price in the sense of being a price for the delivered drug. Genzyme does not sell homecare services to or receive remuneration for homecare services from the NHS. There is therefore no homecare service price to "un-bundle" from the price of Cerezyme. We return to this in more detail in Part C below.

121. The OFT alleges that there is, however, another "implied" stand-alone drug only price. It argues that "prior to any renegotiation that may occur between Genzyme and the PPRS Branch of the DoH, the stand-alone price for Cerezyme will be the figure deduced from Genzyme's own submissions to the DoH at the time of joining the PPRS, and which the DoH accepted". This price is said by the OFT to be £2.43 per unit. It would equate to a 18.3% cut in the price of Cerezyme additional to that required under the 1999 PPRS.

122. As is explained in detail by Professor Yarrow and Mr Williams [CB1/22/198-203; CB1/23/226230; CB1/24/248 & CB1/25/250-259], the negotiations between Genzyme and the DoH had nothing to do with agreeing a stand-alone drug only price. Genzyme sought exceptional treatment to reduce the impact of the 4.5% reduction on NHS List Prices being imposed under the 1999 PPRS and was granted it. Its NHS List Price was thus reduced by 3.7% rather than 4.5% from £3.09 to £2.975 per unit. That was the explicitly agreed price. As a matter of fact, there was no other stand-alone price, agreed or otherwise to be implied, for Cerezyme, and it is trite law that a term cannot be implied into any agreement which is contrary to an explicitly agreed term.

123. The Direction is unclear because it leaves the price to be negotiated with the DoH, without specifying which part of the DoH the negotiations are to take place. The OFT now argues for the first time that the relevant part of the DoH is the PPRS branch [Defence 235], although this does not appear in the Decision. This element of the OFT's Defence appears to have been advanced in response to a question raised by the President of the Tribunal at the interim measures hearing on 16 April 2003 (Transcript, page 5, line 1 "what does one mean exactly by the Department of Health"?). The OFT does not admit to having discussed the Direction with anyone in the DoH other than Mr Brownlee and his colleague in the PPRS branch Mr Kullman and such discussions were unminuted.

124. As Mr Williams explains in his expert report [CB1/24/240-243, paragraphs 15-41], the PPRS involves assessing drug companies' overall profitability. Drug suppliers are free to set the price of their drugs, subject to a cap on overall profitability, though once the NHS List Price has been set it cannot be increased, save in the circumstances expressly permitted under the PPRS (essentially, where the company's profit has fallen below a specified level of return on capital [CB2/38/366, paragraph 2.6]). Therefore it is misleading for the OFT to suggest that if a "stand-alone" price had been agreed, it would be open to Genzyme to renegotiate the price with the DoH [Defence 235]. In fact, Genzyme would be bound by the implied stand-alone price, unless permitted to raise it under the terms of the PPRS.

125. Moreover, homecare service provision is normally procured by PCTs, not the DoH or its PPRS branch – a fact which was known to the OFT but ignored in the Decision [NoA 635].

126. Even if negotiations could take place, the Direction would be unworkable to achieve the result the OFT seeks because there is no mechanism whereby any reduction in price could be used to fund the provision of homecare by third parties [NoA 634]. As the President of the Tribunal observed at the interim measures hearing on 16 April 2003, the Direction contains no mechanism for requiring the DoH to fund PCTs to procure homecare services from independent providers (Transcript, page 5, lines 7-19), and the OFT has suggested none in its Defence.

127. The Direction would serve no purpose other than to destroy incentives for competition in the research and development of new treatments for LSDs. Moreover, had Genzyme not co-operated in the development of shared care, and thus developed homecare, it would not now find itself in this position and no one could have challenged its Drug Tariff price for Cerezyme. The Direction will have a chilling effect on similar co-operation in the future. The Direction can only be to the prejudice of the ultimate consumers, namely patients suffering from LSDs.

(x) Penalty [NoA 657-723]

128. There is no justification for imposing any penalty on Genzyme, even if the Tribunal were to find an infringement. It is impossible to find that Genzyme negligently or intentionally infringed the Act in circumstances where the DoH was informed about the launch of

Genzyme Homecare, could have raised objections to the launch and did not do so [NoA 664-688].

129. The size of the penalty is exorbitant. HH only supplies nursing and delivery of Cerezyme for 37 Gaucher patients. A fine of £6.8 million – nearly £200,000 per patient affected – is out of all proportion to the scale of the alleged infringement.

130. As set out in the NoA [689-722], the steps that the OFT went through to calculate the fine are demonstrably incorrect at every stage and reflect a total misunderstanding of orphan drugs, of the importance of the product to patients and the actions of Genzyme in doing what it did.

131. Even if the Tribunal were against Genzyme on all other points, if a fine were appropriate, it would have to be one that reflected the minimal economic significance of what in fact has happened.

C. THE ISSUES IDENTIFIED BY THE OFT AT §386 OF THE DECISION AS THE BASIS FOR ITS CONCLUSION ON INFRINGEMENT

Introduction

132. The OFT's conclusion on infringement is at §386 of the Decision:

> "The OFT concludes that Genzyme has abused its dominant position in the upstream market by, without objective justification
>
> (i) making the NHS pay a price which includes Homecare Services if it wishes to purchase Cerezyme, thereby reserving to itself (or to an undertaking acting under contract for Genzyme) the ancillary but separate activity of providing Homecare Services; and
>
> (ii) adopting a pricing policy following the launch of Genzyme Homecare which results in a margin squeeze;
>
> with the effect of
>
> (i) foreclosing the Homecare Services segment of the downstream market;
>
> and
>
> (ii) raising barriers to entry to the upstream market."

133. The OFT has sought to bolster each element of that alleged finding of infringement in its Defence by adducing evidence that was never put to Genzyme during the administrative procedure. Given the inadequate investigation that was carried out, it is unsurprising that the OFT should feel compelled to seek to do so, but as is explained in Genzyme's Reply and witness statements in response none of the evidence, properly understood, assists its case.

134. In this section, Genzyme addresses its submissions in response to each of the four elements relied upon at §386. Of course, the OFT's failure to make its case in relation to any of the key elements of infringement (market definition, dominance, abuse, objective justification) is fatal to the Decision, not just the elements specifically relied upon at §386.

135. Genzyme's submissions in this Part are set out under the following headings:

(i) Genzyme does not "make the NHS pay" for homecare and there is no bundling;

(ii) the launch of Genzyme Homecare does not involve a margin squeeze;

(iii) there is no foreclosure in any correctly defined downstream market;

(iv) homecare does not raise barriers to entry to the upstream market.

(i) Genzyme does not "make the NHS pay" for homecare: no bundling [CB1/22/171-CB2/54/848]

136. The OFT's case against Genzyme is based on the fundamentally mistaken premise that there is "a stand-alone price for the drug only" (Decision, §396) which is lower the NHS List Price for Cerezyme, that Genzyme somehow "makes the NHS pay" for homecare, and Genzyme is committing an abuse of "bundling".

137. There are two discrete elements to homecare: delivery and nursing. Genzyme does not "make the NHS pay" for either of them.

138. Contrary to what is alleged by the OFT [Defence 119], it does not matter whether these discrete elements form part of one market or are two separate markets. What matters is whether each service is paid for and by whom.

139. Delivery to patients is paid for by the NHS as part of the NHS List Price. The NHS List Price pays for drugs to be delivered to the patient, at hospital, community pharmacy and home. This is because the DoH has chosen to make the NHS List Price a reimbursement price paid to pharmacists when pharmacists deliver (i.e. supply/dispense) the product to the patient, and not before. Thus NHS List Price for Cerezyme includes payment for delivery to patients at home when, as is the case for Cerezyme, that is an efficient delivery arrangement.

140. The NHS List Price is not a payment for other services. Nursing is supplied by Genzyme, where required for patients at home for whom community nursing is not supplied by the NHS, free of charge. Currently 24.5% of Gaucher homecare patients have GH/HH nursing and 8% have NHS nursing. The remaining 68% do not receive nursing visits.

141. Accordingly, other than the NHS List Price, there is no such thing as "a stand-alone price for the drug only". There is one price and one price only, the NHS List Price, for the

delivered drug. There is no such thing as a stand-alone price for any drug on the NHS Drug Tariff without delivery. There is no ex-factory price to the NHS.

142. The OFT has ignored the extensive evidence supplied by Genzyme both during the administrative procedure and in the NoA to demonstrate that the NHS list price is the price for the delivered drug and thus covers home delivery [NoA 162-223; Reply 5-9]. The OFT's case in the Decision rests on the OFT's misinterpretation of Genzyme's correspondence with the DoH in 1999-2000 regarding the 4.5% cut on NHS List Prices imposed by the DoH, and of a one and a quarter page emailed note from Mr Brownlee's evidence as to the operating principles of the PPRS [Decision §90] (which, properly understood, supports Genzyme's case).

143. Contrary to the OFT's allegations [Defence 128-134], the NHS List Price does not include any element for the supply of nursing. 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 [CB1/25/249-262, paragraphs 5-41]).

144. The fact that the DoH agreed to reduce the price cut required of Genzyme apparently because of the nursing provided by Genzyme (according to Mr Brownlee's second witness statement of 5 September 2003, as to which see further below) does not alter the fact that the NHS List Price does not pay for nursing. The question is what, objectively, is paid for by the NHS List Price.

145. The expert evidence from Professor Yarrow [CB1/22-23/171-237], Mr Williams [CB1/24-25/238-262] and the authors of the Translucency report [CB2/38/356-410], all of whom have extensive experience and detailed factual knowledge in this area, all gives the same answer: the NHS List Price is not a payment for the supply of nursing services. The OFT must accept this, because none of that evidence is being challenged under cross-examination. Indeed, the "Response of the OFT to the questions of the Tribunal at the Case Management Conference on 31 July 2003" confirms Genzyme's analysis, because it emphasises that the NHS List Price is concerned with reimbursement to

pharmacists (see paragraph 6 of that Response), which, as Professor Yarrow explained in his expert report is precisely the simple fact to be borne in mind to avoid the confusion into which the OFT has fallen [CB/22/176, paragraph 3.1].

146. The OFT has sought to bolster its contentions in the Defence with a witness statement from Mr Brownlee and has subsequently applied to serve a second witness statement from Mr Brownlee of 5 September 2003. None of this evidence is sufficient to support a finding to the requisite standard of proof that there is "a stand-alone price for the drug only". In fact, properly understood Mr Brownlee's evidence supports Genzyme's case that the NHS List Price covers "the basic delivery of the drug to the patient" [CB/32/331, paragraph 22; Reply 5-9] and Mr Brownlee's second witness statement confirms this.

147. At paragraph 2 of Mr Brownlee's second statement, he reiterates paragraph 22 of his first statement in which he explains that "the basic delivery of the drug to the patient" is paid for by the NHS List Price. He then goes on to explain at paragraph 4 that the "basic delivery of the drug to the patient" was to be equated with "the normal wholesaling function" and explains that remains the case "in the exceptional context of a delivery to a patient at home rather than collection from a pharmacy". Thus, 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. The OFT's assertion that the NHS List Price does not cover home delivery of Cerezyme to patients [Defence 123-127] is thus unsupported by and indeed inconsistent with the evidence of its own witness.

148. Mr Brownlee states at paragraph 5 of his second statement that the DoH acceded to Genzyme's request for special treatment in the 1999/2000 negotiations because HH provided extensive nursing support as well as home delivery, and that the extensive nursing support was not a replacement for the normal wholesaling function. But it does not then follow that the NHS List Price is a price for that nursing. It is not; as Mr Brownlee's evidence makes clear, it is a price for the drug delivered to the patient including in the exceptional context of a delivery to a patient at home.

149. What the DoH should have done, according to the 'test' advanced in Mr Brownlee's witness statement, is to have distinguished those elements of homecare that were a replacement for the normal wholesaling function (which includes delivery to the point

where the drug is acquired by the patient) from those elements that were incremental to that function (nursing). According to his test, only expenditures on the latter should have been subtracted from the list price before applying the 4.5% reduction. This should have been apparent to the DoH at the time as there is nothing misleading in the Genzyme correspondence.

150. Thus the NHS List Price for Cerezyme is a price for the drug delivered to the patient at home and that is what Genzyme provides when it delivers Cerezyme to patients every 4-6 weeks. The NHS is not being made to pay for home delivery; on the contrary the NHS List Price requires delivery. It is immaterial to the NHS whether in fact delivery is to a community pharmacy or patient's home, for the price is the same.

151. The additional elements of the home delivery service by which the OFT places such great store [Defence 120-122 & 135-136] are irrelevant to defining what the NHS List Price is a payment for. If they were to be an extra cost over and above delivery to a community pharmacy, they would simply be another cost that Genzyme incurs without remuneration. But all the evidence is that home delivery is the more efficient and appropriate option for all concerned, and it would be nonsensical to regard delivery to a community pharmacy and to require patients to travel there (with a cool-bag) to obtain their supplies (and return their waste materials).

152. Genzyme is in no position to dictate to the NHS in relation either to delivery or to nursing [NoA 456-461]. Genzyme cannot require the NHS to use Genzyme nursing and about a quarter (23.5%) of home nursing for Gaucher patients is in fact carried out by NHS community nurses [Annex 1].

153. None of the OFT's evidence is sufficient to support a finding to the requisite standard of proof that Genzyme "makes the NHS pay" for homecare. If the NHS wanted different arrangements for delivery or nursing, it could exercise its powers to do so. Indeed, about a quarter of the home nursing for Gaucher patients is supplied by the NHS. The OFT adduced no evidence in the Decision that the NHS does not have such powers. It has sought to bolster its case by adducing a witness statement from Mr Farrell, but he is not responsible for NHS procurement policy.

154. Mr Farrell's evidence also demonstrated that far from imposing an additional financial burden on the NHS as the OFT contends, homecare enables hospitals to make what he

describes in his statement as "a significant cost saving" through VAT zero-rating, a benefit which in the case of the Royal Free and Cerezyme is passed back to the PCT funding the treatment. In a note of his earlier meeting with the OFT on 17 December 2001 exhibited to his statement, Mr Farrell is recorded as stating that homecare services "are now generally funded by the VAT saving made by dispensing the drug in the community rather than in hospital" [CB2/52/747; see also the confidential HH tender exhibited at JF2/23]. There is no need to fund homecare services for Gaucher disease, because these are provided free of charge by Genzyme. This is not a "new" point, as contended in the Treasury Solicitor's letter of 10 September 2003, but Genzyme's answer to the OFT's allegation of "making the NHS pay" arising out of evidence first served upon Genzyme with the Defence.

155. The NHS did change its purchasing policy for a range of treatments in 1995 – EL(95)5 – and has chosen thus far not to do so for Cerezyme. The MMC, when it considered homecare in the *Fresenius/Caremark* report raised no objection. It stated at §2.48 of the report that the matter was one for the DoH [CB2/39/432].

156. The DoH has not relinquished the powers it had exercised in 1995. The only person the OFT has contacted within the DoH in relation to EL(95)5 is Mr Pearson. The OFT contacted him in 2001 and he states [CB1/34/342, paragraph 5] that "I was unable to provide [the case officer] with any information that would help to explain why Ceredase was not included in EL(95)5". The OFT appears at this point simply to have stopped pursuing enquiries into EL(95)5, and has only made further enquiries after adopting the Decision, following Genzyme's NoA. A witness statement was only obtained from Mr Pearson after the adoption of the Decision, and it is apparent that he has very limited knowledge or experience in this area [CB1/33-34/339-342]. However, his evidence is that the policy behind EL(95)5 remains in force [CB1/33/340].

157. The fact that the OFT carried out no detailed investigation into the DoH's powers is illustrated by the fact that it only did so when requested by the Tribunal at the second CMC, was unable to provide its concluded answer within the deadline set by the Tribunal and only finally served its submissions some time later on the evening of 8 September 2003. That is too late for a detailed reply in this skeleton argument, and as stated at

paragraph 2 above a reply will be served separately, but it can be observed at this stage that:

(a) whatever the legal basis for EL(95)5, there is no doubt that it was implemented, and that the MMC reported that as a result there was a distinction to be drawn between prescribed services such as treatment for Gaucher disease where the DoH had not sought to implement any change, and contracted services, where services were separately contracted for as a direct result of EL(95)5;

(b) unsurprisingly, given its role as the monopoly purchaser the DoH continues to enjoy extensive powers to dictate the terms on which drugs and services are supplied to the NHS as is illustrated by its implementation of a 4.5% cut in NHS List Prices as a condition of membership of the 1999 PPRS[4];

(c) it is up to the DoH to decide whether it is cost-effective to continue to fund treatment with Cerezyme for Gaucher disease given the small patient numbers and high cost of treatment per patient (cost-effectiveness of drugs is an area upon which the DoH is advised by NICE[5] as explained in the NoA 457); and

(d) the DoH could have objected to the launch of Genzyme Homecare but did not.

158. The launch of Genzyme Homecare was not the subject of any objection by the DoH. When a 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 [CB1/36/349] stating that:

> "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."

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4 As illustrated by the two papers published by the DoH on 1st September 2003, a Discussion Paper on the PPRS, which considers what should follow the current scheme, and Consultation Document on Arrangements for the Future Supply and Reimbursement of Generic Medicines for the NHS.

5 The National Institute for Clinical Excellence. Its remit is to "give advice on the clinical and cost effectiveness of both new and existing technologies, including pharmaceuticals, diagnostic tests, surgical procedures and other treatments" (speech by the Secretary of State on the launch of NICE, 31 March 1999; more information available on www.nice.org.uk).

159. This letter made it clear that NSCAG wished to assess the introduction of this new service from Genzyme Homecare. It was in the light of this that Genzyme and the DoH met on 13 February 2001 so that Genzyme could fully inform the DoH (and specifically NSCAG) about the setting up of Genzyme Homecare to take over from HH. The DoH raised questions as to patient confidentiality and cost. These concerns being met by Genzyme, the DoH did not raise any objection to this proposed service development. [CB1/35-37/343-355].

160. Had the DoH raised any objection, Genzyme would not have proceeded to launch Genzyme Homecare without meeting their concerns. It was still at this point in negotiations with HH [CB1/35/345, paragraph 10].

161. The OFT has adduced no evidence from the DoH in support of its allegation that Genzyme "makes the NHS pay" for homecare, although it had contacted Dr Sheena Parker, the Medical Secretary to NSCAG, in late 2001 [CB/35/345, paragraph 12].

162. In summary, there is no such thing as "a stand-alone price for the drug only" which is lower the NHS List Price for Cerezyme, Genzyme does not "makes the NHS pay" for homecare, and accordingly there is no "bundling".

(ii) The launch of Genzyme Homecare does not involve a margin squeeze

163. The OFT's allegation that foreclosure of the homecare market through a margin squeeze can take place (Decision, §§370-381) is in the circumstances perverse.

164. First, Cerezyme could not possibly be described as being necessary or an essential facility to enable HH to enter the homecare market. It is obvious that HH had entered the market and had established itself as a homecare provider several years before it secured what turned out to be a very lucrative three year contract to distribute Cerezyme.

165. Second, the OFT's reliance on principles developed in relation to ensuring competitive service provision over a telecommunication network (see §§375-376) is inappropriate in relation to the orphan drug field, where the competitive structure, as explained above, is entirely different. The OFT's defence of its reliance on obviously inappropriate case law shows the weakness of its position. Nowhere does the OFT explain why it is thought that principles applicable to completely different competitive context of the

telecommunication industry should be appropriate to the biotechnology or orphan drug sector, where conditions of competition are entirely different [Defence 184-187].

166. Further, the OFT seeks to equate Genzyme Homecare with HH but the two are in entirely different positions. As regards Genzyme Homecare, it is a separate division of Genzyme for patient confidentiality reasons. Contrary to what is stated at §371 of the Decision, Cerezyme is not sold to Genzyme Homecare but to Genzyme. Genzyme Homecare is simply the division, separately organised within Genzyme for patient confidentiality reasons, through which Genzyme chooses to offer a homecare service. Why on earth should Genzyme be required by competition law to pay a third party to provide a service which it can offer itself? If Genzyme chooses to do so itself that is its own decision, as **Bronner** makes clear. The OFT, at the interim measures stage, accepted that Genzyme was properly entitled to terminate HH's exclusive distribution agreement, yet it seeks to obtain by a different route essentially the same position (although it contends that such a solution would have to be open on a non-exclusive basis to all-comers).

167. Genzyme has never been in any position to foreclose HH's access to the homecare market by a margin squeeze or otherwise, and, as HH's expanding position in that market demonstrates, has never done so.

168. Finally in relation to margin squeeze, and indeed generally, the absurdity of the OFT's case has already attracted the attention of independent expert economists. The economic consultancy RBB[6] published a commentary on the Decision in July 2003 *The Genzyme Case and the OFT's Margin Squeeze Muddle* (RBB Brief 10, Annex 4 to this skeleton). Mr Ridyard, then with NERA, had been instructed by Genzyme at the interim measures stage in 2001, but has not had any further involvement since then and the views set out in the note were arrived at entirely independently of any involvement by Genzyme (the first Genzyme knew of this paper was when Mr Ridyard requested junior counsel for Genzyme to check a draft of the note for factual errors only in the week before its publication).

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6 Derek Ridyard, Simon Bishop and Simon Baker. The latter two expert economists were commissioned by the OFT to write the OFT's July 2001 Economic Discussion Paper on *The Role of Market Definition in Monopoly and Dominance Inquiries*.

169. RBB's views on the margin squeeze element of the abuse are as follows (it should be noted that these views proceed on the assumption that there is a bundled price, which as explained above, there is not):

> "The second abuse cited in the OFT decision is that of a 'margin squeeze' by Genzyme against HH. A margin squeeze occurs when an integrated firm adopts a pricing structure whereby independent downstream firms who rely on the integrated firm for the upstream input find it impossible to compete with the price charged by the integrated firm for the bundled downstream product. Since Genzyme only made Cerezyme available at the bundled price, the formal margin squeeze conditions were satisfied automatically. HH would find it impossible to compete with Genzyme Homecare, since HH's buying price would be the same as the selling price of Genzyme in the downstream market.
>
> This, however, highlights a more profound problem with the definition of bundling and margin squeeze. 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.
>
> 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-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."

170. RBB conclude generally as follows:

> "But what exactly is the deterrence message that flows from the Genzyme case? If it is that dominant firms are obliged to un-bundle every aspect of their products and offer competing suppliers fair terms to supply them with everything from contract manufacture to legal services, then the compliance message is madness. But if there is some more reasoned economic basis for the OFT's intervention in this case, it is not evident from the decision.
>
> The Genzyme case encapsulates a number of disturbing features in the enforcement of abuse of dominance laws, both in the UK and elsewhere. It appears that an increasingly aggressive enforcement stance is being taken that relies on formal case law precedents rather than substantive analysis of economic effects. This approach consistently fails to draw a decipherable line between normal competitive behaviour and abuse.
>
> As more cases are decided and fines to punish and deter such behaviour grow, an impact on business behaviour is inevitable. But as long as the underlying

theory of competitive harm remains obscure, it will remain impossible to provide reliable competition advice, and the risk that perceived competition law obligations will chill efficient and pro-competitive conduct will increase."

171. This strong criticism for an independent economic consultancy requires an answer in the OFT's skeleton.

(iii) There is no foreclosure in any correctly defined downstream market

172. Genzyme's case on the downstream market has been set out in Part B.

173. The reality is that homecare for patients receiving Cerezyme is a miniscule part (less than 1%) of the markets for home delivery and for home nursing. HH now supplies homecare services to over 5,000 patients [NoA 368]. By contrast, there are only 170 patients being treated with Cerezyme at home, 113 of whom receive deliveries only and no nursing [Reply 17].

174. That being the case, the Decision is wrong and no appreciable restriction through foreclosure in the homecare market could possibly take place.

(iv) Homecare does not raise barriers to entry in any upstream market

175. Genzyme submits that the OFT has wrongly defined an upstream market and that the OFT has wrongly assessed Genzyme has being dominant on that market: see part B above.

176. However, even on the OFT's narrow market definition, homecare does not raise barriers to entry upstream [NoA 445 & Reply 33-39].

177. The OFT identifies at paragraph 16 of the Defence three ways in which Genzyme Homecare is said to have the potential to prevent new drugs coming to the market.

178. The first is said to be that "Genzyme would not be prepared to allow its own delivery/homecare services provider ... to provide delivery/homecare services for drugs which compete with its own" [Defence 16(1)]. This allegation, which does not appear in the Decision, is bizarre. It suggests that other drug companies would regard it as necessary to use Genzyme Homecare to distribute their new drugs. There is no evidence to support that contention. There are several homecare providers and a number of delivery service providers available for drug companies which choose not to

supply homecare in-house. There is nothing in the Decision at all to suggest that the existence of Genzyme Homecare would impede them from distributing a rival drug and providing homecare. Indeed, TKT already uses HH for Replagal [CB2/43/618, paragraphs 62-64, and NoA9/2086] and appears likely to use HH for GCB.

179. The second is said to be that "Clinicians will be more reluctant to switch treatment for their patients if this means also switching the delivery/homecare service provider with whom the patients are content" [Defence 16(2); see also Defence 142-145]. Obviously that could not be the case when delivery only is involved and that is the position in the vast majority of cases. And with regard to nursing, there is no evidence that nursing (whether by HH or NHS) is product specific. An NHS nurse could just as well provide cannulation services for a new Gaucher treatment as for Cerezyme. That can be graphically seen in the case of Fabry disease.

180. Once a new drug commences trials in humans and is brought to the market, prescribing is a matter for the physician alone and there is no evidence that physicians are or would be constrained in the UK by the identity of homecare provider [Reply 37-39].

181. The OFT continues to base its allegations on reservations expressed by two of the four consultants responsible for the treatment of Gaucher disease in the UK, Professor Cox and Dr Mehta [Defence 145; the witness statements and documents recording interviews with doctors are at CB3/69-79/1009-1092].

182. There are, however, two other consultants also responsible for the treatment of Gaucher disease in the UK, Dr Vellodi and Dr Wraith. The OFT appears to believe that their views can be ignored because their patients are children rather than adults. That is irrelevant, and their views are just as relevant as those of Professor Cox and Dr Mehta. Indeed, children are a particularly important segment of Gaucher disease sufferers. Dr Roscoe Brady's first breakthrough in treatment was with a child, as Dr Smith explained at the oral hearing [CB1/15/94, lines 23-34]. Homecare for Gaucher patients first started when a mother, reluctant that visits to hospital for Ceredase infusions for her two sons should interrupt their schooling, took it upon herself to obtain the necessary equipment for carrying out infusions at home from the Royal Free and started to give them their infusions in their home. It was her initiative which led Genzyme and the Royal Free to realise that this approach to treatment could be extended to other patients. In other

LSDs, the disease normally first manifests itself in childhood and with Pompe, for example, most sufferers die before adulthood.

183. Neither Dr Vellodi nor Dr Wraith believes that the identity of homecare provider will affect their decision as to what drug to prescribe.

184. As important, if not more so, are the views of other consultants who are involved in the treatment of the other LSDs for which ERTs have been or are being developed. Dr Lee and Dr Waldek are consultants specialising in the treatment of Fabry disease. Their views are particularly important because there are already two competing ERTs available for patients in Europe: Genzyme's Fabrazyme and TKT's Replagal (uniquely, these drugs were given dual orphan drug authorisation in Europe – in the US, only Fabrazyme has orphan drug authorisation). Homecare for Fabry patients is supplied in the UK by both Genzyme and TKT, Genzyme through Genzyme Homecare and TKT through HH. There is no doubt that there is very keen competition between Fabrazyme and Replagal in the UK and across Europe, TKT claiming a 60/40 split in sales in its favour.

185. Dr Lee and Dr Waldek are therefore already in a position to give evidence of what actually does happen in a treatment area where there is more than one ERT available to prescribe and where there are different suppliers of homecare. If there were any substance in the OFT's allegation that the identity of the homecare provider could affect prescribing decisions, then one would expect to find these consultants expressing concern that Genzyme/Genzyme Homecare and TKT/HH were seeking to do so.

186. Neither Dr Lee nor Dr Waldek have expressed any such concern about the impact of homecare service provision. On the contrary. Dr Lee stated, based on his experience with Fabrazyme and Replagal, that "he did not see that the in-house delivery of Cerezyme would have any effect on the physician's decision". Dr Waldek's opinion is that "it is extremely valuable for both the patient and the physician in whose care that patient is to have a dedicated home care service for a particular product of the nature of Cerezyme, Fabrazyme or Replagal."

187. Particularly seriously, as regards the consultants, the OFT selectively quotes from the statements made by Drs Lee, Waldek and Wraith [Defence 147], thus misrepresenting their views. In fact, the views of these 3 consultants and Dr Vellodi directly contradict the

conclusions the OFT seeks to draw [Reply 34 & 37]. Where there are such differences of view, the OFT cannot possibly establish its case to the required standard of proof.

188. The third of the arguments advanced by the OFT in its Defence is that "it will impede doctors' ability to try various available treatments on a particular patient before being able to determine which one is the most effective and best suited in the individual case if this involves changing the service provider every time a different drug is tested" [Defence 16(3)]. This argument has not been advanced on the basis of any evidence [Decision §340] and there is no evidence to support it. None of the consultants have identified this as an issue.

189. Moreover, it would be a highly serious breach of ethical standards for all concerned if anyone else sought to influence the decision which drug to prescribe, about which the consultants concerned would have no hesitation in taking action with the appropriate authorities [Reply 40-53].

190. To the extent that the OFT still maintains a case that homecare will impede the development of new drugs [Defence 116] (no doubt the OFT will clarify its position in its skeleton), that is quite simply implausible. Trials on drugs take place outside the UK on a potentially worldwide basis, whereas according to the OFT homecare for Gaucher disease is unique to the UK [Decision §30, note 46 & Reply 36]. Furthermore, trials on drugs take place on treatment-naïve patients, who by definition are those not receiving any form of treatment whether at home or otherwise. Homecare could not have any effect on trials of new drugs.

191. It is unclear whether the OFT still maintains a case on the so-called clinical and ethical issues [Defence 17], in which it implies that in-house homecare is intended to drive up dosing levels. The highly serious allegation that Genzyme Homecare would seek to influence dosing levels is completely without foundation [Reply 40-53]. The OFT will no doubt make clear its position and the evidence upon which it relies on this matter in its skeleton.

192. In those circumstances, there is no substance in the OFT's case on the alleged "upstream" effect of homecare.

D. RELIEF SOUGHT [NoA 724-725].

193. Genzyme submits that the OFT has failed to discharge the burden of proof placed upon it in relation to any of the matters in the Decision and Defence, still less to the high standard of proof required in order to establish infringement.

194. Genzyme requests that the Tribunal quash the Decision, and make a declaration that Genzyme's conduct does not infringe the Act.

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12 September 2003