



COMPETITION APPEAL TRIBUNAL

NOTICE OF APPLICATION UNDER SECTION 46 OF THE COMPETITION ACT 1998

CASE NO 1016/1/03

Pursuant to Rule 13 of the Competition Commission Appeal Tribunal Rules 2000 (“the Rules”), the Registrar gives notice of the receipt of an application, dated 20 May 2003, under section 46 of the Competition Act 1998 (“the Act”) by Genzyme Limited of 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford, OX4 2SU (“the Applicant”) in respect of a decision (CA98/3/03) taken by the Director General of Fair Trading (“the Director”) and notified to the Applicant on 27 March 2003, (“the Decision”).

In the Decision the Director concludes that the Applicant has abused its dominant position for the market for the supply of drugs for the treatment of Gaucher disease in the United Kingdom in breach of section 18 (“the Chapter II prohibition”) of the Act. The Applicant supplies the NHS with Cerezyme, a drug for the treatment of Gaucher disease, a rare form of inherited enzyme deficiency disorder. According to the Decision, the Applicant has abused its dominant position and thereby infringed the Chapter II prohibition by making the NHS pay a price which includes home delivery of Cerezyme and provision of homecare services if the NHS wishes to purchase Cerezyme, and by adopting a pricing policy for Cerezyme which results in a margin squeeze. The Decision indicates that the first practice began in the early 1990s (and it has constituted an infringement of the Act since the coming into force of the Chapter II prohibition on 1 March 2000). The Decision further indicates that the second practice began in May 2001 when the Applicant launched its own delivery and homecare services operation and continued until the date of the Decision. The Director imposed a fine of £6,809,598 in respect of the infringement found as a result of both practices. In addition, the Decision contained a direction (“the Direction”) which the Director issued pursuant to section 33 of the Act. The Direction provides that the Applicant shall, within fifteen working days of the Decision, bring the infringement to an end and ensure that the price at which it supplies Cerezyme to the NHS and to third parties shall be a stand-alone price for the drug that is exclusive of any homecare services.

By a separate application lodged at the Competition Appeal Tribunal (“the Tribunal”) on 3 April 2003, the Applicant submitted a request for interim relief pursuant to Rule 32 to suspend the effect of the Direction pending the determination of the appeal (“the Appeal”) of the Decision, which the Applicant submitted to undertake with all due expedition. Following a hearing held partly in public and partly in camera for reasons of confidentiality on 16 April 2003, the Direction was provisionally suspended on the basis of various undertakings offered by the Applicant, the matter to be restored for argument on 1 May 2003 if a consent order could not in the meantime be agreed. In the event, no such agreement could be reached and, following a further hearing held in camera on 1 May 2003, the Tribunal (consisting of the President sitting alone in accordance with his powers under Rule 33(1)) ruled on the matter by judgment handed down on 6 May 2003. Pursuant to that judgment, the Direction is suspended until the determination of the Appeal or the Tribunal’s further order. A non-confidential version of the judgment and the order giving effect to it, are available on the Tribunal’s website (see the address below).

In its application the Applicant now seeks the following relief:

- (1) that the Decision and the Direction be set aside in whole or in part;
- (2) that the penalty imposed by the Decision be revoked or in the alternative reduced;
- (3) that the Tribunal make a declaration that the Applicant's conduct which is alleged by the Director to infringe the Act does not infringe the Act; and
- (4) such other or further relief as the Tribunal may consider appropriate.

The principal grounds of appeal upon which the Applicant relies are as follows:

- Market definition: The Director has erred in law and in fact by finding there to be two distinct relevant product markets, namely an "upstream" market for the "supply" of drugs for the treatment of Gaucher disease and a "downstream" market for the delivery of Cerezyme to hospitals and sales support, described by the Director as the wholesaling segment, and for the "home delivery" of Cerezyme and provision of Homecare Services for the treatment of Gaucher disease, described by the Director as the homecare services segment.

According to the Applicant, the Director ought to have found that there is only one relevant product market which extends to research, development, supply and distribution/delivery to hospitals and patients at home and which relates to the drugs for the treatment of lysosomal storage disorders, drugs which can qualify for orphan drug protection under EU legislation. As regards the alleged downstream market, the Director erred in narrowly defining it in relation to Gaucher disease. Any downstream market extends to nursing homecare generally. The nursing for Gaucher disease is only a miniscule segment (certainly no more than 1%) of the well-recognised wider market for the provision of nursing homecare which extends to many conditions. It does not include delivery.

- Dominance: The Director has erred in law and in fact by finding that the Applicant is dominant in the alleged upstream market and that there are barriers to entry to that alleged upstream market attributable to the Applicant's conduct. Even on this wrong upstream market definition, the Director ought to have found that the Applicant faces many actual and potential competitors on the LSD market, the entry barriers to that market are low or non-existent, and that Genzyme's conduct does not raise barriers to entry into that upstream market.
- Abuse: Even if the Applicant does enjoy a dominant position on a relevant market (however defined) the Director has erred in law and in fact in concluding that the Applicant has abused that dominant position by bundling or implementing a margin squeeze. The Director has already accepted that there is no question here of a refusal to supply, and the alleged bundling and margin squeeze abuses are in substance no different to an allegation of refusal to supply.
- Objective justification: Even if any conduct of the Applicant were prima facie capable of constituting an abuse of a dominant position, the Director has failed to establish that the Applicant's conduct was not objectively justified, and has approached that issue using the wrong burden of proof, the wrong standard for evaluation and has failed to take account of all relevant factors.
- The Director's inappropriate conduct of the investigation: The Director, even if it were not appropriate to leave Healthcare at Home Limited (the original complainant to the Director) to pursue its remedies by way of litigation, carried out inappropriate

and inadequate procedures in conducting the investigation and reaching the Decision, and has not applied the appropriate burden or standard of proof.

- The Direction is unlawful: the Direction, even were a Direction to be appropriate (which is denied), goes beyond what the OFT is empowered to adopt under section 33 of the Act and/or is inappropriate to bring the alleged infringement to an end, is unworkable and impracticable, is unclear and would serve no purpose.
- The penalty is unlawful: In any event, the Applicant did not commit any alleged infringement intentionally or negligently and the Director therefore had no power to impose any penalty under section 36 of the Act, or in any event should not have done. Alternatively, the penalty has not been properly calculated, and includes impermissible elements and in any event is grossly excessive in all the circumstances of the case and should be revoked or reduced.

Any person who considers that he has sufficient interest in the outcome of the proceedings may make a request for permission to intervene in the proceedings, in accordance with Rule 14.

A request for permission to intervene should be sent to the Registrar, The Competition Appeal Tribunal, New Court, 48 Carey Street, London WC2A 3BZ, so that it is received within **one month** of the publication of this notice.

Further details concerning the procedures of the Competition Appeal Tribunal can be found on its website at www.catribunal.org.uk. Alternatively the Tribunal Registry can be contacted by post at the above address or by telephone (020 7271 0395) or fax (020 7271 0281). Please quote the case number mentioned above in all communications.

Charles Dhanowa
Registrar

6 June 2003