ORDER OF THE COURT OF FIRST INSTANCE (Fourth Chamber)

2 June 2004 *

In Case T-123/03,

Pfizer Ltd, established in Sandwich, Kent (United Kingdom), represented by D. Anderson QC, K. Bacon, Barrister, I. Dodds-Smith and T. Fox, Solicitors,

applicant,

v

Commission of the European Communities, represented by H. Støvlbaek and X. Lewis, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATION for the annulment of the Commission Decision of 6 January 2003 initiating a referral to the European Agency for the Evaluation of Medicinal Products (EMEA) in relation to Lopid under Article 30 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67),

* Language of the case: English.

THE COURT OF FIRST INSTANCE OF THE EUROPEAN COMMUNITIES
(Fourth Chamber),

composed of: H. Legal, President, V. Tilli and M. Vilaras, Judges,

Registrar: H. Jung,

makes the following

Order

Legal framework

1 The European Agency for the Evaluation of Medicinal Products (EMEA), established by Article 49 of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1), is responsible for coordinating the existing scientific resources put at its disposal by the competent authorities of the Member States for the evaluation and supervision of medicinal products. Article 51 of the regulation provides that the objectives of the Agency are to provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, the safety, and the efficacy of medicinal products for human or veterinary use, which is referred to it in accordance with the provisions of Community legislation relating to

medicinal products. Under Article 50(1) of the regulation, the EMEA comprises several committees and departments, including the Committee for Proprietary Medicinal Products (hereinafter 'the CPMP'), which is responsible for preparing the opinion of the Agency on any question relating to the evaluation of medicinal products for human use.

2 The Second Council Directive (75/319/EEC) of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13), as amended by Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22) (hereinafter 'Directive 75/319, as amended') was codified by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) (hereinafter 'the MPHU Code').

3 Article 30 of the MPHU Code states:

'If several applications submitted in accordance with Articles 8, 10(1) and 11 have been made for marketing authorisation for a particular medicinal product, and Member States have adopted divergent decisions concerning the authorisation of the medicinal product or its suspension or withdrawal, a Member State, or the Commission, or the marketing authorisation holder may refer the matter to the [CPMP] for application of the procedure laid down in Article 32.

The Member State concerned, the marketing authorisation holder or the Commission shall clearly identify the question which is referred to the [CPMP] for consideration and, where appropriate, shall inform the holder.

The Member State and the marketing authorisation holder shall forward to the [CPMP] all available information relating to the matter in question.'

4 Under the procedure laid down in Article 32 of the MPHU Code, the CPMP is to issue a reasoned opinion on the matter in question. In the course of that procedure, the holder of the marketing authorisation (hereinafter 'the MA') may be asked to present explanations. He may bring an appeal against the reasoned opinion of the CPMP before that committee. The EMEA, after the CPMP has, if necessary, revised its opinion, forwards the final opinion to the Member States, the Commission and the holder of the MA.

5 Article 33 of the MPHU Code provides that the Commission is to prepare a draft of the decision to be taken, taking into account Community law, within 30 days of the receipt of the opinion. Where the draft decision is not in accordance with the opinion of the CPMP, the Commission is to provide a detailed explanation of the reasons for the differences.

6 According to Article 34 of the MPHU Code, a final decision is to be taken by the Commission, or, where appropriate, the Council in accordance with the procedure referred to in Article 121(2) of the MPHU Code. That decision is to be addressed to the Member States concerned and reported to the holder of the MA. In the 30 days following that notification, the Member States are to grant or withdraw the MA or to vary the MA as necessary.

7 In its judgment in Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others* v *Commission* [2002] ECR II-4945) (hereinafter 'the *Artegodan* judgment'), the Court held that while the procedures set out in Articles 13 and 14 of Directive 75/319, as amended, (now Articles 32 to 34 of

the MPHU Code) are in principle intended to be automatically linked and to culminate in a Community decision, that is not the case when the consultative procedure under Article 13 of Directive 75/319, as amended, is initiated under Articles 11 and 12 of that directive (now Articles 30 and 31 of the MPHU Code). Those articles establish a purely consultative procedure, which is also optional. Accordingly, they cannot be interpreted as meaning that they empower the Commission to adopt a binding decision under the procedure set out in Article 14 of Directive 75/319, as amended (now Article 34 of the MPHU Code) (see paragraphs 134, 146, 147 and 150 of the *Artegodan* judgment). The Commission appealed against the *Artegodan* judgment; the appeal was dismissed by judgment of the Court of Justice of 24 July 2003 (Case C-39/03 P *Commission* v *Artegodan and Others* [2003] ECR I-7885).

8 In its judgment in Case T-147/00 *Laboratoires Servier* v *Commission* [2003] ECR II-85, paragraph 59, the Court, referring to the *Artegodan* judgment, stated again that as regards the powers of the Member States Article 12 of Directive 75/319, as amended, establishes a purely consultative procedure, which is also optional. An appeal was brought by the Commission against the judgment in *Laboratoires Servier* v *Commission*, which was dismissed by order of the Court of 1 April 2004 (Case C-156/03 P, not published in European Case Reports).

9 Lastly, the first indent of Article 4 of Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the EMEA (OJ 1995 L 35 p. 1), as amended by Council Regulation (EC) No 2743/98 of 14 December 1998 (OJ 1998 L 345, p. 3) (hereinafter 'Regulation No 297/95, as amended') states that 'a fee of [EUR] 10 000 shall be payable where the procedures laid down in Articles 10(2), 11, 12 and 15 of Directive 75/319/EEC are initiated'. Those articles are now Articles 29(2), 30, 31 and 35 of the MPHU Code.

The facts

10 The applicant is a subsidiary of the Pfizer group, which comprises companies which are holders of national MAs for medicines sold under the Lopid name and other associated names (hereinafter 'Lopid').

11 Between December 2000 and April 2002, contact was established and letters were exchanged between various organisations relating to the possibility of harmonising the summaries of product characteristics (hereinafter 'SPCs') for Lopid. The participants in those exchanges were an informal group comprising directors of the agencies of the Member States responsible for medicinal products, an informal group set up to facilitate mutual recognition, European associations in the medicinal products sector, officials of the EMEA, and representatives of the Pfizer group.

12 By letter of 6 January 2003 (hereinafter 'the contested measure'), the Commission initiated a referral under Article 30 of the MPHU Code to the CPMP, which forms part of the EMEA, for the application of the procedure laid down in Article 32 of the Code by reason, according to the Commission, of divergences between the Lopid SPCs in the Member States and Iceland.

13 On 27 January 2003, the EMEA sent to Pfizer ApS, a member of the Pfizer group, a letter informing it of the referral and requesting the members of the Pfizer group that were holders of Lopid MAs (hereinafter 'the Pfizer Companies') to provide information and to pay the fee of EUR 10 000 provided for under Regulation No 297/95, as amended. The EMEA stated in the letter that the consultative opinion of the CPMP would be sent to the Commission, which was responsible for adopting the final decision following consultation with the Member States under Article 33 of the MPHU Code. That decision would apply to all holders of Lopid MAs, independently of whether those holders had provided answers to questions raised by the CPMP during the consultation procedure.

Procedure and forms of order sought

14 By application lodged at the Court Registry on 10 April 2003, the applicant brought the present action.

15 By a separate document lodged at the Court Registry on 25 May 2003, the Commission raised a preliminary objection as to admissibility under Article 114(1) of the Rules of Procedure of the Court of First Instance. On the same day, it applied for the present case to be joined with Cases T-19/02 and T-41/03. The applicant lodged its observations on that preliminary objection and on the application for joinder on 14 July 2003. After hearing the parties in Cases T-19/02 and T-41/03, the Court dismissed the application for joinder.

16 The Court put a question to the parties under the measures of organisation of procedure laid down in Article 64 of the Rules of Procedure. The parties responded in writing within the time allowed.

17 The applicant claims that the Court should:

— annul the contested decision;

— order the Commission to pay the costs.

18 In its preliminary objection as to admissibility, the Commission claims that the Court should:

— dismiss the application as inadmissible;

— alternatively, decline to rule on the application until an action to annul a definitive act of the Commission has been commenced;

— order the applicant to pay the costs.

19 In its observations on the preliminary objection as to admissibility, the applicant claims that the Court should:

— declare the application admissible;

— order the Commission to pay the costs.

Law

20 Pursuant to Article 114(1) of the Rules of Procedure, the Court may, if a party so requests, rule on the question of admissibility without considering the merits of the

case. Under Article 114(3), unless the Court otherwise decides, the remainder of the proceedings is to be oral. In the present case, the Court considers that the information in the documents before it is sufficient for there to be no need to proceed to the oral stage of the proceedings.

21 It is settled case-law that only measures which produce binding legal effects capable of affecting an applicant's interests by bringing about a significant change in his legal position are acts or decisions against which an action for annulment may be brought under Article 230 EC. To ascertain whether an act or decision has effects of that kind, it is necessary to examine its substance (Case 60/81 *IBM* v *Commission* [1981] ECR 2639, paragraph 9; Case C-308/95 *Netherlands* v *Commission* [1999] ECR I-6513, paragraph 26; Case T-562/93 *Obst* v *Commission* [1995] ECR-SC I-A-247 and II-737, paragraph 23; Case T-81/87 *Regione Toscana* v *Commission* [1998] ECR II-2889, paragraph 21; and Case T-160/98 *Van Parys and Pacific Fruit Company* v *Commission* [2002] ECR II-233, paragraph 60).

22 Furthermore, it is also settled case-law that, in the case of acts or decisions adopted by a procedure involving several stages, and particularly where they are the culmination of an internal procedure, it is in principle only those measures which definitively determine the position of the institution upon the conclusion of that procedure which are open to challenge, and not intermediate measures whose purpose is to prepare for the final decision (*IBM* v *Commission*, paragraph 10; Case C-147/96 *Netherlands* v *Commission* [2000] ECR I-4723, paragraph 26; Case T-326/99 *Olivieri* v *Commission and EMEA*, judgment of 18 December 2003, ECR II-6053, paragraphs 51 to 53).

23 It would be otherwise only if the acts or decisions adopted in the course of the preparatory proceedings not only bore all the legal characteristics referred to above, but in addition were themselves the culmination of a special procedure distinct from

that intended to permit the institution to take a decision on the substance of the case (Joined Cases 8/66 to 11/66 *Cimenteries CBR and Others* v *Commission* [1967] ECR 75, 92, and *IBM* v *Commission*, paragraph 11).

24 Lastly, whilst measures of a purely preparatory nature may not themselves be the subject of an application for annulment, any legal defects therein may be relied upon in an action directed against the definitive act for which they represent a preparatory step (*IBM* v *Commission*, paragraph 12; Case 346/87 *Bossi* v *Commission* [1989] ECR 303, 333; Case T-108/92 *Caló* v *Commission* [1994] ECR-SC I-A-59 and II-213, paragraph 13).

25 By the contested measure in the present case, the Commission initiated a referral to the CPMP under Article 30 of the MPHU Code for the application of the procedure under Article 32 of the Code in respect of various medicinal products for which the Pfizer Companies are the holders of MAs. By letter of 27 January 2003, the EMEA informed the Pfizer Companies of that referral and asked them, for the purposes of the procedure, to provide information and to pay the fee provided for under Regulation No 297/95, as amended.

26 The Court finds that the contested measure does not definitively determine the position of the Commission on the question of the harmonisation of the Lopid SPCs, any more than it represents the culmination of a special procedure distinct from that intended to result in a decision on that harmonisation. The measure does no more than set in motion the consultative procedure described in paragraphs 3 and 4 above, and merely represents a preliminary stage in that procedure.

27 The contested measure thus does not affect the legal position of the Pfizer Companies and is accordingly not a measure which is open to challenge under the case-law cited above. That conclusion is not affected by the applicant's claims that

the contested measure requires the Pfizer Companies to pay a fee of EUR 10 000 and to provide information to the EMEA, places them in a position of uncertainty similar to that arising in cases of State aid when proceedings are initiated under Article 88(2) EC, and involves a transfer of powers in relation to Lopid from the Member States to the Commission.

28 As regards, first, the obligation to pay a fee of EUR 10 000 as a contribution to the funding of the EMEA, it should be noted that the present application does not call into question the validity of the first indent of Article 4 of Regulation No 297/95, as amended, inasmuch as it requires payment of a fee to the EMEA when the procedure under Article 30 of the MPHU Code is initiated.

29 Nevertheless, the applicant claims that the obligation to pay a fee requires that the procedure be valid, a condition which is not met in the present case. It is clear in that regard that as the consultative procedure represents only an intermediate stage which is intended to result in the adoption of a final decision, its validity may be considered at the time of any challenge directed at the final decision. The applicant argues that there may never be a final decision; in that event, should the Pfizer Companies consider that they had suffered a loss by reason of an act for which the Commission was liable non-contractually, they could bring proceedings to recover that loss.

30 With respect, secondly, to the alleged obligation, on whose existence the applicant relies, to provide information to the EMEA as part of the consultative procedure, it is clear that that is an inevitable result of the consultative procedure and is necessary for its efficient conduct. It does not bring about a distinct change in the legal position of the Pfizer Companies.

31 Thirdly, contrary to what the applicant claims, the situation of the Pfizer Companies cannot be compared to that of undertakings faced with the initiation of proceedings under Article 88(2) EC. While the initiation of the formal examination procedure in State aid cases may entail independent legal effects in certain circumstances (Case C-312/90 *Spain* v *Commission* [1992] ECR I-4117, paragraphs 17 to 20; Case C-47/91 *Italy* v *Commission* [1992] ECR I-4145, paragraphs 25 to 30; Joined Cases T-269/99, T-271/99 and T-272/99 *Diputación Foral de Guipúzcoa and Others* v *Commission* [2002] ECR II-4217, paragraph 37), the initiation of a referral to the CPMP under Article 30 of the MPHU Code has no legal effect on the MAs concerned, which may be freely exploited pending the adoption of any decision that may ensue.

32 Fourthly, with respect to the applicant's claim that the initiation of a referral to the CPMP under Article 30 of the MPHU Code would have irreversible legal consequences given that, according to the Commission, it is tantamount to the harmonisation of the MAs in question and that there will be a transfer of powers from the Member States to the Community once that harmonisation is complete, it is clear that the initiation of a referral to the CPMP under Article 30 of the MPHU Code merely sets a consultative procedure in motion and does not in itself entail any harmonisation of the Lopid SPCs.

33 Lastly, the applicant is wrong to claim that if this action were to be dismissed as inadmissible, the Pfizer Companies would be deprived of judicial protection. As was pointed out at paragraph 29 above, it will be open to them to contest the validity of the consultative procedure should they bring proceedings against a final decision which is contrary to their interests and is based on the opinion of the CPMP and, if appropriate, to bring proceedings to recover any loss they may suffer.

34 In light of all the foregoing considerations, the application must be dismissed as inadmissible, and it is not necessary to consider the Commission's alternative claim.

Costs

35 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the defendant has applied for costs and the applicant has been unsuccessful, the latter must be ordered to pay the costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Fourth Chamber)

hereby orders:

1. **The application is dismissed as inadmissible.**

2. **The applicant shall pay the costs.**

Luxembourg, 2 June 2004.

H. Jung

Registrar

H. Legal

President