JUDGMENT OF THE COURT OF FIRST INSTANCE (Fourth Chamber)
3 July 2002 *

In Case T-179/00,

A. Menarini — Industrie Farmaceutiche Riunite Srl, established in Florence (Italy), represented by D. Waelbroeck and D. Brinckman, lawyers, with an address for service in Luxembourg,

applicant,

supported by

European Federation of Pharmaceutical Industries and Associations, established in Brussels (Belgium), represented by D. Anderson QC, J. Stratford, Barrister, I. Dodds-Smith and A. Wearing, Solicitors, with an address for service in Luxembourg,

intervener,

* Language of the case: English.

Commission of the European Communities, represented by R. Wainwright and H. Støvlbæk, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATION for annulment of the Commission's decision of 17 April 2000 rejecting the request by the applicant to include its logo in the blue box of the packaging of OPTRUMA, a pharmaceutical product registered under the centralised authorisation procedure,

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

composed of: M. Vilaras, President, V. Tiili and P. Mengozzi, Judges,

Registrar: B. Pastor, Principal Administrator,

having regard to the written procedure and further to the hearing on 6 March 2002,

gives the following

Judgment

Legal background

1 The marketing of medicinal products within the European Union is subject to the grant of a marketing authorisation. 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) provides for a 'centralised' procedure for the authorisation of medicinal products. In accordance with Article 9(1), third indent, of Regulation No 2309/93, the centralised procedure is to include an examination of whether the labelling and the package leaflet of the product are in compliance with Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (OJ 1992 L 113, p. 8)

2 In accordance with Article 6(5) of Regulation No 2309/93, the Commission has drawn up, in consultation with the European Agency for the Evaluation of Medicinal Products ('the EMEA'), the Member States and interested parties, detailed guidance on the form in which applications for authorisation are to be presented. The Guideline on the packaging information of medicinal products for

human use authorised by the Community (hereinafter 'the packaging guideline') has been included as a Notice to Applicants, Volume 2C, Regulatory Guidelines, in *The Rules governing Medicinal Products in the European Union.*

3 Article 2(1) of Directive 92/27 lists the particulars which must appear on the outer packaging or, where there is no outer packaging, on the immediate packaging of any medicinal product. They include the name and address of the holder of the authorisation for placing the medicinal product on the market.

4 In addition, Article 2(2) provides that:

'The outer packaging may include symbols or pictograms designed to clarify certain information mentioned in paragraph 1 and other information compatible with the summary of the product characteristics which is useful for health education, to the exclusion of any element of a promotional nature.'

5 Under Article 5(2) of Directive 92/27, Member States may, notwithstanding Article 5(1), require the use of certain forms of labelling making it possible to indicate information specific to a Member State. For the presentation of such specific information, the Commission created the concept of the 'blue box' which

is intended to contain that information on one side of the outer packaging of a medicinal product authorised under the centralised procedure. In the packaging guideline, the Commission states:

'The information specific to a Member State should be accommodated on the label in a boxed area (the so-called "blue box"), to appear on one side of the pack. Each "blue box" should only be presented in the official language or languages of the Member State concerned... The location of the "blue box" on the package should be the same for all language versions. When one pack is intended for marketing in several Member States, it is preferable to have only one "blue box" on the pack. This box will contain different information in each Member State. This could be achieved in practice for instance by printing a blank "blue box" on this pack onto which a sticker with the appropriate Member State information can be securely affixed. When in exceptional circumstances, this cannot be achieved, each "blue box" should have the same dimensions and appear on the same side of the pack.'

6 One of the items of information which may appear in the blue box is the name of the 'local representative'. In this connection, the packaging guideline states as follows:

'Some holders of Community marketing authorisations have requested that there be a contact point identified in the package leaflet and on the label. This would normally be the holder of the Community marketing authorisation. However, where the marketing authorisation holder wishes to add the name of another (local) contact point, the "local representative" may be indicated:

— in the leaflet by name, address and telephone number and

— by name in the "blue box" on the label (referred to in Section A).

...

The address and/or telephone number can be added if desired and if space permits (should not interfere with the legibility of the EU text on the outer packaging).

"Local representative" shall be taken to mean: any private or legal person established in the Community charged, through a civil contract with the marketing authorisation holder, with representing him in a defined (geographical) area; this contract excluding any transfer of any responsibility imposed on the marketing authorisation holder by Community law and by national law, regulation and administrative action implementing such Community law.

...'

7 In addition, it is stated that '[f]or practical and linguistic reasons holders of Community marketing authorisations are likely to present the medicinal product packaging in several linguistic and/or "national" versions (i.e. with the relevant boxed areas). In such cases, the logo, format, layout, style, colour scheme and pack dimensions must be identical for all the versions of packs of that medicinal product throughout the Community'.

Facts

8 The applicant is a company incorporated under Italian law engaged in pharmaceutical research, medicinal product development and marketing.

9 On 5 August 1998, the Commission issued a marketing authorisation under the centralised procedure to Eli Lilly Nederland BV (hereinafter 'Eli Lilly'), a Dutch pharmaceutical company, for the medicinal product 'OPTRUMA', a proprietary medicinal product containing the pharmacologically active substance 'raloxifene', which is indicated for the treatment and prevention of osteoporosis in post-menopausal women.

10 On 3 September 1999, Eli Lilly entered into an agreement with Menarini International Operations Luxembourg SA, a company incorporated under Luxembourg law, for the licensing of its rights in the trade mark OPTRUMA and the promotion and distribution of that product in Italy. Under that agreement, Menarini International Operations Luxembourg is itself entitled to sublicense those rights exclusively to the applicant, which it has done by agreement of 18 October 1999.

11 Eli Lilly, as the marketing authorisation holder, submitted to the EMEA several mock-ups of the outer packaging of the product, which included, at least in the blue box of the Italian packaging, the name of the applicant in the form of a stylised 'M' together with the word 'Menarini'.

12 In February 1999, the EMEA expressed the opinion that the proposed packaging was unacceptable on the ground that the applicant's logo should not appear in the blue box and it referred the applicant to the Commission for further discussions.

13 On 24 May 1999, the applicant sent a letter to the head of the Pharmaceuticals and Cosmetics Unit of the Commission's Industrial Affairs III Directorate: Consumer goods industries (the former Directorate-General Industry (DG III)) in which it requested permission to include its logo in the blue box of the OPTRUMA packaging. It enclosed a letter from Eli Lilly, dated 17 May 1999, which was headed: 'Request to include the logo in the blue box'.

14 By letter dated 9 June 1999, the deputy head of the Pharmaceuticals and Cosmetics Unit replied as follows:

'...

I confirm that, in principle, we see no reason to object to such an inclusion. However, we will raise this point at the occasion of the next Pharmaceutical Committee in September 1999 with a view to obtaining the agreement of Member States to an amendment of the respective Guideline.'

15 The 48th meeting of the Pharmaceutical Committee on 27 and 28 September 1999 discussed the issue of the use of a logo on the outer packaging of a product authorised under the centralised procedure. The members of the committee

unanimously agreed that the inclusion of the marketing authorisation holder's company logo on the outer packaging should be acceptable for identification purposes.

16 After that meeting of the Pharmaceutical Committee, the applicant wrote to the Commission by letter dated 9 November 1999 and submitted various arguments in favour of the inclusion of the distributor's logo or that of the licence holder in the blue box of medicinal products authorised under the centralised procedure.

17 The head of the Pharmaceuticals and Cosmetics unit replied by letter of 22 November 1999 and stated that he saw 'no reason to object to such an inclusion [that of the logo of the local representative] for identification purposes'. He also stated:

'However — as this issue has not been discussed with Member States before — I consider it necessary to raise this point at the occasion of the next Pharmaceutical Committee in March 2000 with a view to obtaining the agreement of Member States to an amendment of the respective Guideline.'

18 At the 49th meeting of the Pharmaceutical Committee, held on 22 and 23 March 2000, a discussion took place concerning the applicant's request for authorisation to include the local representative's logo on the labelling of products authorised under the centralised procedure. A large majority of the Member States' representatives declared that they considered the inclusion of the local representative's logo on the packaging of products authorised under the centralised procedure to be unacceptable. The main supporting argument put forward was that the indication of the name of a 'local representative' has to serve as a

national contact point for patients and that it is not necessary for health purposes to add a company logo to this information. Moreover, certain delegations raised the point that such an inclusion would create confusion for the patient between the marketing authorisation holder (who bears all the responsibility for the product) and the local representative who — by definition — has none.

19 By letter of 17 April 2000, received by the applicant on 26 April 2000 (hereinafter 'the contested decision'), the defendant informed the applicant that the request for the inclusion of the applicant's logo in the blue box had been definitively rejected.

20 In the contested decision the Commission states that:

'Although certain Member States' representatives supported the proposal, the large majority of them was against the inclusion of the "local representative" logo on the packaging of pharmaceutical products authorised according to the centralised procedure.

This position was principally motivated by the fact that the company logo would not add anything to the information which is necessary for health instructions, as the sole indication of the name and address of the "local representative" would in itself be sufficient to guarantee a national contact for the patients. Moreover, certain delegations have stressed that such an inclusion might create confusion between the owner of the marketing authorisation (who is responsible for the product) and the local representative who — by definition — is not responsible for the product.

The Commission services feel bound by the clear position expressed within the context of the Pharmaceutical Committee, not only in view of the large majority of opponents but also because of the fact that any modification to the "blue box Guideline", which would allow inclusion of the "local representative" logo, would require the support of the Committee itself. Therefore, on the basis of the abovementioned considerations, the proposal to include the "local representative" logo on the packaging of pharmaceutical products authorised according to the centralised procedure is not accepted.'

Procedure and forms of order sought

21 By application lodged at the Registry of the Court on 3 July 2000 the applicant brought the present action.

22 By document lodged at the Registry of the Court of First Instance on 4 January 2001 the European Federation of Pharmaceutical Industries and Associations (hereinafter 'the EFPIA') applied to the Court for leave to intervene in the present proceedings in support of the applicant. By order of the President of the Fourth Chamber of the Court of First Instance of 23 January 2001 the EFPIA was granted leave to intervene in support of the applicant.

23 Upon hearing the report of the Judge-Rapporteur, the Court (Fourth Chamber) decide to open the oral procedure. As a measure of organisation of procedure, it asked the applicant and the defendant to reply to certain questions.

24 The parties presented oral argument and replied to the Court's questions at the hearing on 6 March 2002. At the end of the hearing the Court adjourned the oral procedure. The oral procedure was closed on 18 March 2002.

25 The applicant claims that the Court should:

— annul the contested decision;

— in the alternative, declare illegal under Article 241 EC the European Commission's Guideline on the packaging information of medicinal products, in that it could be interpreted as containing a prohibition on the use of the logo by the local representative or a licensee;

— order the defendant to pay the costs.

26 At the hearing the applicant withdrew the second head of the form of order sought and the Court noted this in the minutes of the hearing.

27 The defendant contends that the Court should:

— dismiss the application;

— order the applicant to pay the costs.

28 The intervener claims that the Court should:

— uphold the application;

— order the defendant to pay the intervener's costs.

Law

29 In support of its action, the applicant relies on seven pleas in law: first, lack of any legal basis in the Community legislation allowing the Commission to prohibit the applicant from including its logo on the outer packaging of the medicinal product OPTRUMA; second, breach of the applicant's right to property; third, breach of the principle of non-discrimination; fourth, breach of the principle of protection

of legitimate expectations; fifth, breach of the obligation to state reasons; sixth, breach of the principle of proportionality and of the right freely to pursue economic activities; seventh, that the Commission was time-barred from adopting the decision.

Arguments of the parties

30 In its first plea, alleging lack of any legal basis for prohibiting the applicant from including its logo on the outer packaging of OPTRUMA, the applicant submits, first, that the essential aim of the Community provisions on the labelling and packaging of medicinal products, laid down in Directive 92/27, is to provide a high degree of consumer protection. The name and address of the person responsible for placing the medicinal product on the market constitute in this respect essential information for the user and health professionals and thus contribute to achieving that high degree of consumer protection.

31 The person responsible for placing the product on the market has various obligations in particular, with respect to the provision of scientific information and pharmacovigilance.

32 It is therefore important that the person responsible for placing the product on the market can be easily and correctly identified as such by both the user and the health professionals using the medicinal products in question, where necessary by means of the company's logo, which cannot be separated from its name and business identity.

33 Second, the applicant points out that the Italian legislation implementing Directive 92/27 provides that, where the marketing authorisation holder does not himself market the medicinal product, the name and address of the licensee or concessionaire (the local representative) must be mentioned on the outer packaging.

34 Third, the applicant submits that the contested decision cannot be based on any provision of Directive 92/27.

35 Fourth, the applicant maintains that the logo may highlight information necessary for health education purposes, such as information ensuring that patients have a national contact point.

36 The intervener supports the applicant's arguments and states that, under the centralised procedure, there is one marketing authorisation holder with responsibility for the whole of the Community market. The marketing authorisation holder is often not based in the country where the product is being sold. Consequently, the local representatives are often the only practical and effective point of contact for medical practitioners and patients, who might otherwise experience difficulties in notifying adverse reactions to the product or obtaining information about it. Users of the product are thus able to seek advice in their own language locally.

37 The defendant contends that neither the name nor the logo of the applicant, which holds an exclusive licence for the promotion and sale of OPTRUMA in Italy, is one of the compulsory particulars which are to appear on the packaging under Article 2(1) of Directive 92/27. The question is whether, under Article 2(2) of the directive, the applicant's name and/or logo may be included on the

packaging as 'other information which is useful for health education'. The Commission's practice in that regard is to accept that the holder of a marketing authorisation may indicate as a contact point the name of the local representative in the 'blue box' on the label. The justification for this practice is that, in the context of a Community marketing authorisation, there may be circumstances in which the name of a local representative as a point of contact for professionals or for consumers could be useful for health education in the broad sense of the term.

38 It submits that all patients or health professionals need to know in practice is a contact name or a telephone number in order to identify the local representative 'easily, rapidly and unequivocally'. It further argues that inclusion of the logo in the blue box would if anything reduce the possibility for those contact details to appear clearly and with sufficient prominence. Since space is often at a premium, in particular on small or multi-lingual packs, a prominent logo with contact details given in a restricted area in very small font does not help a user to work out whom to contact quickly and easily.

39 It adds that in the regulated area of medicinal product information there is a need to define and restrict the information presented and to require it to be presented in certain ways which are compatible with the goal of providing clear, accurate and complete information about the product to users and thus help to ensure protection of public health. Thus, a restriction of the information given on the label is in fact justified on public health grounds as it promotes protection of consumers.

40 The defendant considers that the two reasons put forward in the contested decision amount to a reasonable interpretation of Article 2(2) of Directive 92/27. Article 2(2) provides for an optional exception to the general rule established by Article 2(1) as regards the particulars which must appear on the packaging of medicinal products. Exceptions to general rules must be interpreted narrowly. Given the nature of the expression 'information which is useful for health education', the Commission's interpretation involves a degree of assessment of what is useful, and judicial review of it should be limited to an examination of manifest error or misuse of powers. In the present case there can be no question of a manifest error in the Commission's conclusion that the logo of the local representative is not information which is useful for health education.

41 The defendant contends that the use of the name without the logo does not compromise the company's identity. In the case in point, the logo is in fact merely a stylised version of the name. Moreover, for the purposes of the Commission's objective, which is to ensure that it is possible to contact a person for health education purposes, it is the name and address of the local representative which are useful, not his logo.

42 Finally, the defendant contends that, whatever the situation in Italy or any other Member State, the legal situation is that, for pharmacovigilance purposes, a person cannot be the person responsible for placing the product on the market without at the same time being the marketing authorisation holder. To the Commission's knowledge, inclusion of the logo of the local representative is not a policy common to all Member States. According to the minutes of the March 2000 Pharmaceutical Committee meeting, a large majority of Member States were opposed to the inclusion of such a logo for centrally authorised products and thus it might be assumed that the position agreed at the Pharmaceutical Committee is also applied by Member States to products authorised at the national level.

Findings of the Court

43 It must first be observed that Article 2(1) of Directive 92/27 sets out the particulars which must appear on the outer packaging of medicinal products for human use, whereas Article 2(2) indicates what may be included on the external packaging in addition to the compulsory particulars provided for in Article 2(1). In the contested decision the Commission in essence made a finding on whether a local representative may place its logo on the outer packaging of a medicinal product in light of Article 2(2) of Directive 92/27.

44 According to the case-law of the Court of Justice, where an administrative decision is the result of complex assessments in the medico-pharmacological field, such assessments are subject to a limited judicial review (see Case C-120/97 *Upjohn* [1992] ECR I-223, paragraph 33 and 34, and order of the President of the Court of 11 April 2001 in Case C-459/00 P(R) *Commission* v *Trenker* [2001] ECR I-2823, paragraphs 82 and 83).

45 In the present case, the decision which the Commission was called on to take did not involve complex assessments in the medico-pharmacological field, such as, for example, assessments of the efficacy, safety and quality of a medicinal product (order in *Commission* v *Trenker*, paragraph 82). The question whether it is possible, under Article 2(2) of Directive 92/27, to place the logo of a local representative on the outer packaging of a medicinal product depends in particular on whether or not such information is useful for health education. However, assessment of the usefulness of that logo for health education is not of such complexity as to justify a restriction on the scope of judicial review, since, in particular, it does not call for any particular expertise or technical knowledge.

46 As is apparent from the contested decision, the Commission took the view, first, that the logo of the local representative does not add anything to the information necessary for health education purposes; second, that the inclusion of the logo might create confusion between the holder of the marketing authorisation, who is responsible for the medicinal product, and the local representative, who is not; and, third, that it had to follow the opinion of the Pharmaceutical Committee.

47 As regards the first ground, it must be observed that the aim of Directive 92/27 is to ensure that the provisions governing the information supplied to users provide a high degree of consumer protection in order that medicinal products may be used correctly on the basis of full and comprehensible information (fifth recital).

48 In the light of that aim, it is necessary to examine whether the refusal to authorise the inclusion of the logo of the local representative in the blue box is justified. It should be observed, first of all, that in the present case the logo accompanied by the word 'Menarini' is a registered trade mark and represents the name and business identity of the applicant. Moreover, the packaging guideline provides that the name, address and telephone number of the local representative may be included in the information contained in the blue box (section C, point 5). Likewise, at its 48th meeting the Pharmaceutical Committee took the view that the inclusion on the outer packaging of the logo of the company holding the marketing authorisation should be accepted for identification reasons. If it is acceptable to include the logo of the holder of the marketing authorisation on the outer packaging for the purposes of identification, the same holds for the logo of the local representative.

49 The logo plays an important role in identifying a company operating on the market. Its function is to constitute a unit in combination with the name of the company in order to facilitate identification of that company. Since the aim of Directive 92/27 is, according to its fifth recital, in particular to ensure a high degree of consumer protection, inclusion of the logo in the blue box, which

facilitates identification of the local representative, helps to increase consumer protection. Given that consumers may contact the local representative more easily in the event of problems with the medicinal product and ask questions of him in their mother tongue and that, as regards questions of responsibility, the local representative can suggest to consumers that they contact the holder of the marketing authorisation, the inclusion of the logo of the local representative in the blue box is useful for health education within the meaning of Article 2(2) of Directive 92/27.

50 As regards the second ground underlying the contested decision, the Commission points to the risk of confusion between the responsibilities of the holder of the marketing authorisation and those of the local representative. According to the Commission, the inclusion of two logos in the blue box might create confusion in the mind of the consumer between the holder of the marketing authorisation, who is responsible for the medicinal product, and the local representative, who, by definition, is not.

51 Even though the Commission has rightly pointed to that difference, it is not conclusive for the outcome of the dispute. In assessing whether the inclusion of the logo of the local representative may create confusion between the holder of the marketing authorisation and the local representative, it is necessary to distinguish between the general and common information appearing on the outer packaging and the information specific to a Member State which appears in the blue box. According to Article 2(1) of Directive 92/27, the name and address of the holder of the marketing authorisation must be mentioned on the outer packaging of the medicinal product. The holder of the marketing authorisation may also display his logo on the packaging. In the packaging guideline it is stated that the name and address of the local representative may be included in the blue box (Section C, point 5). That being the case, a logo which constitutes a unit in combination with the name of the local representative cannot create a risk of additional confusion for the consumer, since the name and address of the local representative are already included in the blue box.

52 It follows that the Commission erred in law in prohibiting the inclusion of the applicant's logo in the blue box of the outer packaging of the medicinal product OPTRUMA by virtue of Article 2(2) of Directive 92/27.

53 Moreover, the contested decision cannot be justified by the fact that the Commission took the view that it had to follow the Pharmaceutical Committee's view regarding inclusion of the applicant's logo in the blue box. The Pharmaceutical Committee merely issues an opinion which is not binding on the Commission.

54 It follows from the foregoing that the first plea must be upheld and it is not necessary to examine the other pleas and arguments on which the applicant relies.

Costs

55 Under Article 87(2) of the Rules of Procedure of the Court of First Instance, 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 been unsuccessful, it must be ordered to bear its own costs and to pay those of the applicant and of the intervener, in accordance with the forms of order sought by them.

On those grounds,

THE COURT OF FIRST INSTANCE (Fourth Chamber),

hereby:

1. Annuls the Commission Decision of 17 April 2000 rejecting the applicant's request to include its logo in the blue box of the packaging of OPTRUMA, a pharmaceutical product registered under the centralised authorisation procedure;

2. Orders the defendant to bear its own costs and to pay those of the applicant and of the intervener.

Vilaras Tiili Mengozzi

Delivered in open court in Luxembourg on 3 July 2002.

H. Jung
Registrar

M. Vilaras
President