JUDGMENT OF THE COURT OF FIRST INSTANCE (Fifth Chamber)
10 December 2002 *

In Case T-123/00,

Dr Karl Thomae GmbH, established in Biberach an der Riß (Germany), 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 (EFPIA), established in Brussels (Belgium), represented by D. Perkins, Solicitor, and M. Van Kerckhove, Lawyer, 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,

supported by

Council of the European Union, represented by M.-C. Giorgi and G. Houttuin, acting as Agents,

intervener,

APPLICATION for annulment of the decision of 1 March 2000 of the European Agency for the Evaluation of Medicinal Products, rejecting an application for variation of certain terms of the marketing authorisation for the medicinal product, 'Daquiran',

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

composed of: J.D. Cooke, President, R. García-Valdecasas and P. Lindh, Judges,

Registrar: J. Plingers, Administrator,

having regard to the written procedure and further to the hearing on 29 January 2002,

gives the following

Judgment

Legal framework

1 Medicinal products are regulated by complex harmonising legislation, the aim of which is to bring about the free movement of those products within the Community, whilst ensuring that public health is protected. There are two distinct procedures under Community law for placing a medicinal product for human use on the market. The first of those procedures is based on the mutual recognition of a marketing authorisation issued in a Member State ('national MA'). The second involves the issue of a marketing authorisation which is valid throughout the Community and which confers the same rights and obligations in each Member State as a marketing authorisation issued by the Member State concerned ('Community MA'). Under that centralised procedure, applications for Community MAs are processed by the European Agency for the Evaluation of Medicinal Products ('the EMEA').

2 Under 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), the EMEA 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'. That responsibility is defined in general terms in Article 51 of the regulation, which states that 'the objectives of the [EMEA] shall be 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'.

3 The foundation for the relevant legislation was laid on 26 January 1965 with the adoption of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 24), which has been amended on various occasions, in particular by Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11) and Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) (hereinafter, as amended, 'Directive 65/65').

4 Under Article 3 of Directive 65/65, no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with that directive or an authorisation has been granted in accordance with Regulation No 2309/93. Use of the centralised procedure set up by Regulation No 2309/93 is (i) compulsory for medicinal products developed by certain biotechnological processes and (ii) optional for medicinal products which are innovative or of significant interest, those two categories being described, respectively, in Part A and Part B of the Annex to that regulation (Article 3(1) and (2) of Regulation No 2309/93).

5 Article 4 of Directive 65/65 states *inter alia* that, in order to obtain an MA of the kind provided for in Article 3, the person responsible for placing the product on the market is to make application to the competent authority of the Member State concerned. The application must be accompanied by certain information, including the 'name of the proprietary product (brand name, or common name together with a trade mark or name of the manufacturer, or scientific name together with a trade mark or name of the manufacturer)'.

6 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) makes clear in the first indent of Article 1(2) that '[the] name... may be either an invented name or a common or scientific name, together with a trade mark or the name of the manufacturer; the invented name shall not be liable to confusion with the common name'. Furthermore, under Article 2(1)(a) and Article 7(1)(a) of Directive 92/27 the packaging and the package leaflet are to include 'the name of the medicinal product, followed by the common name where the product contains only one active ingredient and if its name is an invented name'.

7 Under Article 5 of Directive 65/65, the marketing authorisation provided for in Article 3 is to be refused 'if, after verification of the particulars and documents listed in Article 4, it proves that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared... [or] if the particulars and documents submitted in support of the application do not comply with Article 4'.

8 Under Article 21 of Directive 65/65, the marketing authorisation cannot be refused, suspended or revoked except on the grounds set out in that directive.

9 As regards the centralised procedure, Article 11 of Regulation No 2309/93 states:

'Without prejudice to other provisions of Community law, the authorisation provided for in Article 3 shall be refused if, after verification of the information and particulars submitted in accordance with Article 6, it appears that the quality, the safety or the efficacy of the medicinal product have not been adequately or sufficiently demonstrated by the applicant.

Authorisation shall likewise be refused if the particulars and documents provided by the applicant in accordance with Article 6 are incorrect or if the labelling and package leaflets proposed by the applicant are not in accordance with Directive 92/27/EEC.'

10 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 Directive 93/39, (hereinafter 'Directive 75/319') sets up a Committee for Proprietary Medicinal Products (hereinafter 'the CPMP'), which is attached to the EMEA.

11 In the context of the mutual recognition procedure, the CPMP is responsible for issuing opinions concerning the granting, withdrawal, variation or suspension of a marketing authorisation (Articles 8 to 15 of Directive 75/319). As to the centralised procedure, Article 5 of Regulation No 2309/93 states that the CPMP is to be 'responsible for formulating the opinion of the [EMEA] on any question concerning the admissibility of the files submitted... the granting, variation, suspension or withdrawal of an authorisation to place a medicinal product for human use on the market...'.

12 Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93 (OJ 1995 L 55, p. 15) states, at Article 2:

'For the purposes of this Regulation the following definitions shall apply:

1. "variation to the terms of a marketing authorisation": an amendment to the contents of the documents referred to in Article 6(1) and (2)... of [Regulation

No 2309/93] such as they existed at the moment the decision on the marketing authorisation has been adopted in accordance with Article 10... of that Regulation or after approval of any previous variations, except where a new application for a marketing authorisation must be presented pursuant to Annex II to this Regulation...'.

13 Annex II to Regulation No 542/95 deals with major ('Type II') variations, i.e. those involving fundamental changes in the terms of the MA and thus giving rise to a need for a new application for an MA.

14 Annex I to Regulation No 542/95 concerns minor ('Type I') variations, such as a change in the name or address of the holder of the authorisation, the deletion of a colorant or the replacement of one colorant with another. Article 4(1) of Regulation No 542/95 provides:

'To obtain a Type I variation, the holder of the marketing authorisation shall submit to the [EMEA] an application, accompanied by documents demonstrating that the conditions laid down in Annex I to this Regulation for the requested variation are met, and all documents amended as a result of the application.'

15 Under Article 6(5) of Regulation No 2309/93, '[t]he Commission shall, in consultation with the [EMEA], the Member States and interested parties, draw up detailed guidance on the form in which applications for authorisation are to be presented'. In accordance with that provision, the Commission drew up *The*

Rules Governing Medicinal Products in the European Community. Volume 2 of those rules, 'The Notice to Applicants', contains several guidelines intended to explain the applicable legislation to applicants for Community MAs.

16 The Commission made the following statement in the introduction to the Notice to Applicants:

'This Notice has no legal force and does not necessarily represent the final views of the Commission. In case of doubt, therefore, reference should be made to the appropriate Community Directives and Regulations. The Notice to Applicants is prepared by the Commission in accordance with Article 6 of Regulation (EEC) No 2309/93 and the Annex [to] Directive 75/318/EEC as amended. It is important when reading this text to appreciate that the legal requirements of the Directives and the Regulations must be met and that this Notice presents the harmonised views of the Member States and the European Agency for the Evaluation of Medicinal Products on how those requirements may be met.'

17 In the present case two of those guidelines are at issue between the parties:

— the Guideline on Dossier Requirements for Type I Variations (November 1999) in the Notice to Applicants, Volume 2 C;

— the Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Community (April 1999) in the Notice to Applicants, Volume 2 C.

Background

18 The applicant is a company in the Boehringer Ingelheim pharmaceutical group. It produces a medicinal product whose active substance is pramipexole. That product is used for the treatment of Parkinson's disease when the effect of another active substance, levodopa, wears off or becomes inconsistent.

19 On 31 May 1996, the applicant made application to the EMEA for a Community MA for that product under the name 'Daquiran'.

20 By letter of 2 October 1996, the applicant informed the German pharmaceutical company Byk Gulden Lomberg Chemische Fabrik GmbH ('Byk Gulden') that it intended to market the medicinal product in question under the trade mark DAQUIRAN and asked it not to object.

21 On 5 November 1996, Byk Gulden refused to accede to that request, on the ground that there was a risk of Daquiran being confused with a neuroleptic medicine which it markets under the trade mark TAXILAN.

22 By letter of 2 October 1997, the applicant repeated its request to Byk Gulden. On 21 October 1997, the latter again refused to grant the request and asked the applicant to stop using the DAQUIRAN trade mark for the medicinal product in question.

23 On 27 October 1997, the Commission issued a Community MA for that medicinal product (OJ 1997 C 362, p. 2) under the name 'Daquiran'.

24 By letter of 17 February 2000, the applicant asked the EMEA to vary certain terms of that MA, in particular the name and package layout of the product at issue, stating in that regard:

'Because of an objection by a third company trademark DAQUIRAN is not available in Germany. In Denmark, Sweden and Finland trademark DAQUIRAN has not been registered and, therefore, it is intended to use trademark SIPNOK instead; SIPNOK is registered and available in these countries.

Along with the change to FIROL in Germany a new trade dress is intended to be used which is different from the package layout used in all other Member States.'

25 By letter of 1 March 2000, the EMEA rejected the application (hereinafter 'the contested decision') in the following terms:

'Please be informed that on 23 February 2000, the EMEA has received your application for a Type I variation for Daquiran concerning a change in the name of the medicinal product.

According to Commission Regulation (EC) No 542/95, as amended, the name of the medicinal product may be changed after authorisation through a Type I variation, Change No 2. In order to validate such a variation application the EMEA checks whether all conditions and requirements laid down in the Annex I to the abovementioned Regulation and in the "Guideline on dossier requirements for Type I variations (November 1999)" are fulfilled.

As the Community Marketing Authorisation is valid throughout the European Union, the tradename, an integral part of the authorisation, has to be valid in all EU Member States. The granting of a single Community Marketing Authorisation under the Centralised Procedure requires one single name for the Medicinal Product being authorised. This principle is derived from Community legislation, namely, point 2 of the third paragraph of Article 4 of Council Directive 65/65/EEC, as amended, and provisions in Council Directive 92/27/EEC, as amended (Article 1(2), first indent; Article 2(1)(a); Article 7(1)(a)), defining the name of the medicinal product in the chapters on "Scope and Definition", "Labelling of Medicinal Products" and "User Package Leaflet".

The new tradename proposed through a Type I variation must equally apply for all EU Member States. Taking into account the above, your variation application

proposing several tradenames within one marketing authorisation cannot be positively validated.

According to the ["Guideline on the Packaging Information of Medicinal Products for Human Use authorised by the Community (April 1999)"], the presentations of a medicinal product (logo, format, layout, style, colour scheme and pack dimensions) must be identical throughout the Community. The proposed specific package layout for the German market only, is therefore also not acceptable.'

26 The applicant thus applied, in particular, for the names 'Firol' and 'Sipnok' to be added to 'Daquiran'.

Procedure

27 The applicant brought the present action by application lodged at the Court Registry on 9 May 2000.

28 By a document lodged at the Court Registry on 21 July 2000, the Council applied for leave to intervene in the case in support of the form of order sought by the Commission. By order of 6 September 2000, the President of the Fifth Chamber of the Court granted such leave.

29 On 12 September 2000, the Council submitted its statement in intervention.

30 By document lodged on 5 October 2000, the European Federation of Pharmaceutical Industries and Associations ('the EFPIA') applied to intervene in support of the form of order sought by the applicant. Leave to intervene was granted by order of the President of the Fifth Chamber of the Court of 21 November 2000.

31 By letter lodged on 7 November 2000, the Commission waived its right to submit a rejoinder.

32 The EFPIA submitted its statement in intervention on 11 January 2001.

33 On 30 January 2001, the applicant informed the Registry that it did not intend to submit any observations on the EFPIA's statement in intervention.

34 On 27 February 2001, the Commission lodged observations on the EFPIA's statement in intervention.

35 Upon hearing the report of the Judge-Rapporteur, the Court of First Instance (Fifth Chamber) decided to open the oral procedure and, by way of measures of organisation of procedure, put various questions in writing to the Commission and the Council, which replied to them within the period allowed.

36 The parties presented oral argument and replied to the Court's questions at the hearing on 29 January 2002.

Forms of order sought

37 The applicant claims that the Court should:

— annul the contested decision;

— in the alternative, declare unlawful point 2 of the third paragraph of Article 4 of Directive 65/65 and Article 1(2) (first indent), Article 2(1)(a) and Article 7(1)(a) of Directive 92/27, in so far as any of those provisions could be read as containing a requirement to use a single trade mark and a single package layout for medicinal products authorised under the centralised marketing authorisation procedure; and

— order the Commission to pay the costs.

38 The Commission contends that the Court should:

— dismiss the application;

— order the applicant to pay the costs.

39 The EFPIA, intervener, claims that the Court should:

— annul the contested decision;

— order the Commission to pay the costs.

40 The Council, intervener, contends that the Court should dismiss the plea of illegality raised in respect of certain provisions of Directive 65/65 and Directive 92/27.

Law

Preliminary observations

41 The applicant claims that the contested decision is based on the false premiss that the grant and retention of a Community MA is subject to the condition that a single trade mark and a single package layout must be used. It submits, first, that such a requirement is not based on the relevant legislation; second, that it cannot be justified on grounds relating to the free movement of medicinal products; third, that it infringes the principle of proportionality and the right to pursue an economic activity; fourth, that it is in breach of the right to property; fifth, that it conflicts with the provisions of the Agreement on Trade-related Aspects of

Intellectual Property Rights in Annex 1 C to the Agreement establishing the World Trade Organisation, concluded on behalf of the European Community, as regards matters within its competence, by Council Decision 94/800/EC of 22 December 1994 (OJ 1994 L 336, p. 214); sixth, that the contested decision is vitiated by lack of a proper statement of reasons and, seventh, that it is vitiated by a misuse of powers.

42 At the hearing, the applicant, prompted by the Court, gave a more detailed explanation of its pleadings. First, it explained that in its arguments 'trade mark' must be understood as referring to the 'name' of the medicinal product. It went on to state that the difference between a 'trade mark' and a 'name' is artificial since the names of the medicinal product concerned are also trade marks. Finally, it stated that the relevant legislation requires neither the use of a single trade mark nor the use of a single name.

43 The Commission and the interveners took formal notice of that explanation, with which they concurred.

44 It is in the light of that explanation that the Court must consider the arguments relating to the requirement for a single name and a single package layout.

The requirement for a single name

Arguments of the parties

45 The applicant claims that the contested decision, in so far as it requires a single name for the purposes of the centralised procedure, has no legal basis and

infringes the principle of proportionality. It puts forward three lines of argument based on the text and purpose of the applicable legislation and on the Commission's practice in taking decisions.

46 First, as regards the wording of the applicable legislation, the applicant, supported by the EFPIA, starts by asserting that no provision of Regulation No 2309/93 or Regulation No 542/95 or of Directive 65/65 or Directive 92/27 makes the grant or retention of a Community MA subject to the condition that a single name must be used. The contested decision, in so far as it is based on such a condition, has no legal basis. At the hearing, the applicant and the EFPIA specifically drew attention to the fact that, in the absence of any specific provision to that effect, the Commission cannot take the place of the legislature and introduce a prohibition where the legislation does not provide for one. In that regard, they invoke the principle that anything which is not specifically prohibited is to be regarded as permitted.

47 The applicant goes on to criticise the literal construction of certain provisions of Directive 65/65 (point 2 of the third paragraph of Article 4) and Directive 92/27 (Article 1(2) (first indent), Article 2(1)(a) and Article 7(1)(a)), on which the contested decision is founded. The use of the expression 'name of the proprietary product' in the singular does not allow the inference to be drawn that there is a requirement to use a single name.

48 Finally, the Commission cannot contend that the requirement for a single name derives from the unitary nature of the Community MA, since no rule of law imposes such a requirement.

49 Second, the applicant submits that the sole purpose of the applicable legislation is to protect public health by checking the quality, the safety and the efficacy of medicinal products. The applicant draws two conclusions from that and claims that the contested decision infringes the principle of proportionality.

50 First, the Commission cannot refuse or withdraw a Community MA for reasons relating to the free movement of goods, since such reasons are unrelated to the protection of public health.

51 Second, the requirement that a single name be used in every case could prove to be a danger to public health owing, in particular, to linguistic differences or to a risk of confusion between several medicinal products. Thus, in this instance, the fact that the 'Daquiran' and 'Taxilan' names are phonetically similar could lead to confusion between those medicinal products, which are used to treat similar therapeutic indications (Parkinson's disease and diseases of the central nervous system). Furthermore, the Commission has not put forward any evidence to show that the use of different names for the same medicinal product can pose a particular danger to public health. Many medicinal products are marketed under national MAs under different names in the various Member States without the Commission ever having objected to that situation on the ground that it entails a risk to public health.

52 In the EFPIA's submission, the requirement for a medicinal product to have a single name delays the issue of a Community MA until such time as the person applying for it is in a position to use a single trade mark throughout the Community. The need to secure a single name which may be protected by trade mark law throughout the Community is a substantial and unnecessary burden for pharmaceutical companies, which may delay patients' access to the drug to the detriment of public health. Such a requirement is contrary to one of the objectives of Regulation No 2309/93, namely that Community MAs should be granted by a rapid procedure.

53 Third, as regards the Commission's practice in taking decisions, the applicant claims that the Commission has already authorised the company Hoechst Roussel Marion (now Aventis) to use the names 'Refludin' and 'Refludan' for a single product authorised under the centralised procedure.

54 The Commission, supported by the Council, refutes those arguments and contends that the requirement for a single name is derived from Article 6 of Regulation No 2309/93 and from the unitary nature of the Community MA. It would be anomalous, at Member State level, for a medicinal product to be authorised under different names. Likewise, the centralised procedure requires the use of a single name.

55 The contested decision clearly states that the single name requirement for a Community authorisation of a medicinal product derives from point 2 of the third paragraph of Article 4 of Directive 65/65 and Article 1(2) (first indent), Article 2(1)(a) and Article 7(1)(a) of Directive 92/27.

56 The single name requirement in respect of all Community MAs is also based on legitimate considerations concerning the free movement of goods but none the less does not prejudice the owners of trade marks.

57 As regards the risks which the requirement is alleged to pose for public health, the Commission rejects the EFPIA's arguments concerning delays in the issue of Community MAs which may occur owing to the time needed to secure an acceptable name. Should such a delay occur, a decision or a scientific opinion could be adopted on the sole basis of the international common name together with a trade mark or the name of the manufacturer, and a trade name could be introduced at a later stage via a Type I variation under Regulation No 542/95.

58 The Commission recognises, however, that in exceptional cases the requirement for a single name may be waived, as it stated in its Communication of 22 July 1998 on the Community marketing authorisation procedures for medicinal

products (OJ 1998 C 229, p. 4; 'the Communication of 22 July 1998'). The Commission thus takes account of intellectual property rights whenever an applicant provides sufficient evidence that his application interferes with a trade mark. It was on account of such exceptional circumstances that the Commission accepted the use for the same product of the names 'Refludin' and 'Refludan' (Decision C(98) 211 final of 30 January 1998) and, in another case, the names 'Infergen' and 'Inferax' (Decisions C(2000) 113 of 20 January 2000 and C(2000) 3396 of 29 November 2000).

59 The Commission contends that, in contrast to those cases, the applicant has not succeeded in showing that there were exceptional circumstances. All that the applicant sent the EMEA was an exchange of letters with the owner of the TAXILAN trade mark in Germany. The applicant did not provide any proof whatsoever that, so far as the German authorities were concerned, the trade mark DAQUIRAN was cancelled, opposed or objected to. As regards the request for the product to have a different name in Denmark, Sweden and Finland, the applicant put forward no arguments regarding conflict with existing trade marks in those Member States. Since there is no evidence to justify an exception to the general rule that there should be a single name, the Commission considers the contested decision to be well founded.

Findings of the Court

60 In the contested decision, the EMEA rejected the applicant's application for a variation of its MA on the ground that a Community MA must be for one name only. The EMEA based its decision on an interpretation of the applicable legislation, from which it concluded, first, that '[t]he granting of a single [Community MA] under the Centralised Procedure requires one single name for the Medicinal Product being authorised'. As to the variation of a Community MA, the EMEA, second, recalled the unitary nature of the Community MA,

pointing out that '[t]he new tradename proposed through a Type I variation must equally apply for all EU Member States'. Third, the EMEA drew the following conclusion from those propositions:

'Taking into account the above, your variation application proposing several tradenames within one marketing authorisation cannot be positively validated.'

61 The applicant's action challenges that interpretation of the relevant legislation and essentially raises the question as to whether the legislation precludes an application for variation of a Community MA, when the aim is to authorise several names for the same medicinal product.

62 To ascertain whether that interpretation is well founded, the Court must first consider (i) whether, on principle, the Community MA presupposes the use of a single name and (ii) whether the unitary nature of the Community MA precludes any variations seeking to secure the use of several names.

63 As regards the first of those questions, the Court notes that several aspects of the wording of the relevant legislation by implication bear out the interpretation that a Community MA may be issued, as a general rule, only for a single name. Point 2 of the third paragraph of Article 4, and Article 4a, point 1, of Directive 65/65, together with Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ 1975 L 147, p. 1), to which Article 11 of Regulation No 2309/93 refers indirectly, all refer to the name of the medicinal product in the

singular. None of those provisions contemplates expressly the possibility of a single marketing authorisation containing several names. As to Directive 92/27, to which Article 11 of Regulation No 2309/93 also refers, the first indent of Article 1(2), Article 2(1)(a) and Article 7(1)(a) refer to 'name' only in the singular. In addition, so far as 'minor variations' of a Community MA are concerned, Regulation No 542/95 also refers, at point B.2 of Annex I, to the name (in the singular) on the Community MA. It is implicit in these provisions that a Community MA contains, as a general rule, only one name.

64 Furthermore, support for that interpretation is lent by the purpose of the legislation applying to the Community MA. By making it easier to identify the medicinal product to which it relates, the single name is conducive to attaining both the primary objective of protecting public health (first recital in the preamble to Directive 65/65), inherent in the criteria of the quality, safety and efficacy of the medicinal product, and the objective of free movement of goods, pursued by the general scheme of the Treaty and referred to in the first recital in the preamble to Regulation No 2309/93.

65 As regards public health, use of a single name makes it easier to identify the medicinal product and can help to reduce any risk of confusion between such products in the Community as a whole.

66 As to the free movement of goods, apart from the fact that the 'one-stop-shop' system on which the centralised procedure is based simplifies the administrative steps needed to obtain a marketing authorisation, it is indisputable that the unitary nature of the Community MA facilitates the free movement of medicinal products.

67 As regards the second question, the parties to the dispute are agreed that no provision of secondary legislation expressly prohibits the grant of an application

for variation of a Community MA seeking to secure the use of several names. What the parties disagree on, however, is the question whether such a prohibition is implicit in the wording and purpose of the legislation applying to the Community MA.

68 Concerning, first, the wording of the provisions of the legislation applicable to variations of a Community MA, it must be borne in mind that, under Regulation No 2309/93, a variation of a Community MA may be granted only in so far as it satisfies the criteria relating to the quality, safety and efficacy of the medicinal product, criteria which are associated with the objective of protecting public health. The third recital in the preamble to Regulation No 2309/93 states the principle that 'in the interest of public health it is necessary that decisions on the authorisation of... medicinal products should be based on the objective scientific criteria of the quality, the safety and the efficacy of the medicinal product concerned to the exclusion of economic or other considerations', and this principle is put into effect by Article 68(1) of Regulation No 2309/93, by virtue of which a Community MA may not be varied 'except on the grounds set out in [the] Regulation'.

69 It is therefore necessary to ascertain whether the interpretation put forward in the contested decision is objectively justified on grounds of public health and the exclusive criteria of the quality, safety and efficacy of the medicinal product. On a preliminary examination, it appears that that interpretation is not risk-free as regards public health. Furthermore, it is at variance with the interpretation of the relevant legislation suggested by the Commission in its Communication of 22 July 1998. Finally, the Commission's practice in taking decisions casts doubt on that interpretation.

70 As regards, first, the risks for public health, it is not inconceivable that a general prohibition on any variation of a Community MA consisting of the addition of names might, in certain circumstances, be prejudicial to public health. As all the

parties have argued, pharmaceutical companies commonly use as names signs which they also register as trade marks. On conclusion of a dispute with the owner of a similar trade mark, the holder of a Community MA may find that use of the name is prohibited in a Member State, for example following an infringement action. In such a case, the holder of a Community MA could not lawfully market the medicinal product concerned in that Member State. Since the party concerned would be able neither to vary the Community MA by adding a further name nor to submit an application for a national MA in the Member State concerned, it would then be forced to stop marketing the product in that Member State or, for example, to obtain a new Community MA for the same medicinal product but under a different name. Apart from the adverse commercial consequences ensuing for the holder of the Community MA, such a situation might jeopardise, if only on a temporary basis, patients' access in that Member State to the product.

71 By contrast, the risks to public health that might arise as a result of its being possible, in circumstances such as those set out in the preceding paragraph, to vary a Community MA with a view to using several names, appear to be low. Apart from the risk of confusion, the use in exceptional circumstances of several names for a medicinal product with a Community MA would appear unlikely to affect the quality, safety or efficacy of the product. In that regard, attention should be drawn to the fact that variations of an MA concerning the name of the medicinal product are minor variations for the purposes of Regulation No 542/95. The name is a formal aspect of a Community MA and has no direct bearing on the chemical, pharmacological, biological or toxicological properties of the medicinal product. That is why point B.2 of Annex I to Regulation No 542/95 states that where there is a change in the name, confusion with the names of other existing medicinal products is to be avoided in order to protect public health.

72 It is appropriate to bear in mind that, in the context of the mutual recognition procedure and national MAs, one medicinal product may have names which vary from one Member State to another. A medicinal product which is marketed in the 15 Member States otherwise than under the centralised procedure must have 15 national MAs and may, at least in theory, have as many different names. As regards national MAs, use within the Community of several names for the same product is lawful. The Commission also acknowledged at the hearing that the use of different names for the same medicinal product in different Member States does not give rise to any specific risks for public health.

73 In those circumstances, it cannot be claimed that a prohibition on any variation of a Community MA consisting of the addition of names is rendered necessary by mandatory public-health requirements. Such a proposition would be paradoxical, to say the least. In the case of a medicinal product with a Community MA, it would amount to prohibiting on public-health grounds the use, in exceptional circumstances, of various names, whereas, as a matter of principle, a medicinal product subject to national MAs may lawfully be marketed under names which vary from one Member State to another.

74 Consequently, the Court finds that, although the letter and spirit of Regulation No 2309/93 suggest that a Community MA will contain, as a general rule, only one name, there are no grounds for concluding, in the absence of any express provision in Regulation No 2309/93 or Regulation No 542/95, that that name cannot be varied by the addition of other names where (i) the holder of the Community MA demonstrates that that is rendered necessary by exceptional circumstances which may adversely affect public health and (ii) the Commission has ascertained that the variation applied for satisfies the criteria of the quality, safety and efficacy of the medicinal product.

75 Second, the general rule set out by the EMEA in the contested decision that the applicable legislation does not allow a Community MA to be varied with a view

to several names being used conflicts with the interpretation advanced by the Commission at point C of its Communication of 22 July 1998. That provision shows that, in the context of the mutual recognition procedure, '[o]nly one brand name should normally be approved per marketing authorisation granted'. The Commission adds:

'This also applies in the case of a Community authorisation for which there is a single summary of product characteristics, a single leaflet and a single label approved. It is advisable for applicants using the centralised procedure to identify at an early stage, and before lodging the application, one brand name which can be used throughout the Community while keeping fall-back options (brand name(s)) in reserve.

However, in exceptional cases, in particular where the proposed brand name has been cancelled, opposed or objected to under trade mark law in a Member State, the Commission will address the issue in order not to disadvantage patients and their access to the concerned medicinal product in that Member State. If sufficient evidence is given by the marketing authorisation holder that, in spite of all its efforts, the chosen or foreseen trade mark cannot be used in a Member State, the Commission will — exceptionally — authorise the use of a different trade mark in that Member State. Should a derogation be granted, it will affect neither the legal obligations of the marketing authorisation holder, nor the validity of the marketing authorisation throughout the Community.'

76 That exception, the basis for which is public health protection, is consonant with the interpretation of Regulation No 2309/93 set out above (see paragraphs 63 to 74 above).

77 The Court finds that in the contested decision the EMEA did not adopt the interpretation set out in the Communication of 22 July 1998 and did not consider whether the applicant could rely on exceptional circumstances such as to justify the addition of names in respect of the medicinal product Daquiran. By contrast, the EMEA relied on another interpretative publication from the Commission, namely the 'Guideline on dossier requirements for Type I variations (November 1999)'. That document is intended to provide applicants for minor variations to a Community MA with clarification of a practical nature. Following an introductory section, the document is presented as a table which sets out, for 34 kinds of variations, the conditions to be met and the documents which the applicant must provide. The name is one of the terms of the MA which may be varied only by substitution. By implication, the guideline rules out the possibility of variation of a Community MA consisting of the addition of a name. That interpretation is thus inconsistent with the Communication of 22 July 1998, although there was no suggestion that the guideline was intended to amend the communication. That inconsistency is regrettable from the point of view of legal certainty, since the Communication of 22 July 1998 and the guideline at issue both seek to interpret Regulations No 2309/93 and No 542/95.

78 Third, it is necessary to add that it is apparent from the Commission's practice in taking decisions that on at least two occasions the Commission authorised a variation of a Community MA consisting of the addition of a name (medicinal products 'Refludin' and 'Refludan'; 'Infergen' and 'Inferax').

79 The Court must therefore conclude from the foregoing that the contested decision, in so far as it rejects an application to vary a Community MA by adding two names on the sole ground that a medicinal product may never have more than one name, is based on an incorrect interpretation of Regulations No 2309/93 and No 542/95. In the absence of any provision specifically prohibiting such a variation, the Commission may authorise the adding of a name to a Community MA where the holder of the Community MA shows that exceptional circumstances which may adversely affect public health so require

and that the variation applied for satisfies the criteria of the quality, safety and efficacy of the medicinal product.

80 Finally, the Court must address the Commission's arguments. The Commission, having acknowledged in its pleadings that the requirement for a single name may be waived in exceptional circumstances, argued that the applicant had not shown that such circumstances existed in this instance (see paragraphs 58 and 59 above). That argument cannot be accepted. In the contested decision, the EMEA did not determine whether the circumstances mentioned by the applicant (opposition in respect of use of the trade mark DAQUIRAN and availability of the marks FIROL and SIPNOK) were exceptional so as to allow its application to be granted. The interpretation of the applicable legislation just examined by the Court was all that the EMEA gave the applicant by way of explanation for its refusal.

81 Since a decision must be self-sufficient, the reasons on which it is based may not be stated in written or oral explanations given subsequently when the decision is already the subject of proceedings brought before the Community judicature (Case T-16/91 *Rendo and Others* v *Commission* [1996] ECR II-1827, paragraph 45). In such a situation, the Commission cannot now argue that the circumstances cited by the applicant were not exceptional. If such reasons were capable of proving decisive, it was for the EMEA to explain them to the applicant in the contested decision, in accordance with the obligation to state reasons deriving from Article 5(4) of Regulation No 542/95 and Article 67 of Regulation No 2309/93, pursuant to which all 'decisions to grant, refuse, vary, suspend, withdraw or revoke a marketing authorisation which are taken in accordance with this Regulation shall state in detail the reasons on which they are based'.

82 Furthermore, it is not for the Court to substitute itself for the Commission or the EMEA and consider of its own motion whether, in the present case, there are

exceptional circumstances such as to enable the application for variation of the name of the medicinal product Daquiran to be granted.

83 Therefore, the contested decision must be annulled in so far as it rejects the application for a variation of a Community MA concerning the name of the medicinal product and it is not necessary to consider the other pleas in law which relate to that aspect of the contested decision.

The requirement for a single package layout

84 The applicant claims that the requirement in the contested decision for a single package layout has no legal basis.

85 It observes that the contested decision is founded solely on the Guideline on packaging information of medicinal products for human use authorised by the Community (April 1999). Since the reasoning on which a measure is based must be self-sufficient, the Commission cannot invoke in these proceedings reasons deriving from Directives 65/65 and 92/27 (Case T-77/95 *Ufex and Others* v *Commission* [2000] ECR II-2167, paragraph 54).

86 In its Notice to Applicants, the Commission itself stated that the Guideline has no legal force and does not necessarily represent its definitive view. It also added that, in case of doubt, reference should be made to the appropriate Community directives and regulations.

87 In case the Court should find that the Guideline does have legal force, the applicant raises a plea of illegality, challenging the legality of the condition relating to the requirement for a single package layout on the ground that it is not founded on any provision of the relevant legislation. Directive 92/27, in particular Article 2(2) thereof, does not require the use of a single package layout for a medicinal product marketed in several Member States. Before introduction of the centralised procedure, the objective of that directive was to approximate the legislation of the Member States on the labelling of medicinal products and on package leaflets. In such circumstances, there are no grounds for concluding from Directive 92/27 that Community MAs are restricted to medicinal products whose package layout is the same in all Member States.

88 Finally, the applicant asserts that the requirement is at variance with the EMEA's practice with regard to parallel distributors. The EMEA has already allowed the medicinal product Zyprexa to be marketed under a Community MA with different package layouts, following the repackaging of the product by Eurim Pharm.

89 The applicant repeats the argument that a Community MA cannot be refused or withdrawn unless there are overriding requirements relating to the protection of public health. The requirement for a single package layout cannot be justified on grounds relating to the free movement of goods (Articles 3 EC and 28 EC). Thus, the Commission could withdraw or refuse to grant an MA where, owing to specific circumstances, the use of different package layouts entailed a risk for

public health because of, for example, language differences or a risk of confusion between several medicinal products. The Commission cannot plead protection of public health as a ground for systematically requiring use of a single package layout. Many products are currently marketed under different package layouts in the various Member States without any particular risk of confusion.

90 In this instance, the Commission has not claimed that there are any specific circumstances such as to put public health at risk. The applicant concludes that the requirement for a single package infringes the principle of proportionality.

91 The Commission refutes those arguments. It contends that Article 9(1) of Regulation No 2309/93 refers to the provisions of Directive 92/27. Those provisions form the basis for the reasoning in the Guideline to which the contested decision refers. According to the Guideline, 'the logo, format, layout, style, colour scheme and pack dimensions must be identical for all the versions of the packs of that medicinal product throughout the Community'.

92 Therefore the text of the label and the package leaflet form part of the Community MA and must be identical throughout the Community. The only exceptions to that rule concern the language used on the label (Article 4 of Directive 92/27) and the requirements which Member States may continue to make concerning indications of price or of reimbursement conditions by social security organisations (Article 5(2) of Directive 92/27).

93 The Commission points out that the applicant gave no reasons for its application for a different 'trade dress' in Germany. In its correspondence with the EMEA, the applicant confined itself to putting forward 'commercial reasons'.

94 As regards the applicant's criticisms based on the situation of parallel importers (see paragraph 88 above), the Commission denies that its practice has been inconsistent. It refers to its Communication of 22 July 1998 and states that a Community MA encompasses all language versions of the labelling and package leaflet and all available authorised pack sizes. The original condition of the product inside the packaging must never be directly or indirectly altered. Any changes in the size of the package must be duly justified. It is incumbent on parallel importers to prove that it is strictly necessary to make such changes. The Commission's practice is logical, consistent and founded in law.

95 Finally, the Commission contends that the plea of illegality raised in relation to the Guideline is inadmissible. The plea of illegality, provided for in Article 241 EC, is available only in respect of acts of general scope which produce similar effects to those of a regulation (Case 92/78 *Simmenthal* v *Commission* [1979] ECR 777, paragraph 40). Since the Guideline is not a legally binding measure, Article 241 EC does not apply to it. The Commission adds, in the alternative, that the plea of inadmissibility is unfounded, for the reasons set out above.

96 The applicant's reply to the Commission's acknowledgement that the Guideline is not legally binding is that the Commission has thereby confirmed that the Guideline cannot constitute a legal basis for the requirement relating to the use of a single package layout. The applicant declares that in those circumstances there is no longer a need for a plea of illegality against the Guideline.

Findings of the Court

97 First, the Court must reject the applicant's argument that the contested decision has no legal basis because the Guideline on which it is founded is not legally binding. Admittedly, the EMEA decided the application relating to the package layout exclusively by reference to the Guideline. Not being binding, the Guideline explains, by way of guidance, the construction which the Commission intends to put on the applicable legislation. However, that fact is not such as to render the contested decision devoid of any legal basis or to provide grounds for its annulment. The EMEA gave direct application to the provisions of the Guideline concerning the interpretation of Directive 92/27, and the legality of that interpretation can thus be reviewed in an action brought against the contested decision (see, by analogy, Joined Cases 32/58 and 33/58 *Snupat* v *High Authority* [1959] ECR 127, at 141).

98 Second, it is appropriate to consider whether the contested decision is based on a correct interpretation of the applicable legislation. Referring solely to the Guideline, the contested decision confined itself to stating 'the presentations of a medicinal product (logo, format, layout, style, colour scheme and pack dimensions) must be identical throughout the Community' and that the proposed specific package layout for the German market only could therefore not be accepted.

99 It is appropriate to bear in mind that Section D of the Guideline, which deals with presentation of the medicinal product, contains the following comments:

'2. Pack design

For practical and linguistic reasons holders of Community Marketing authorisations are likely to present medicinal product packaging in several linguistic and/or "national" versions... 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.

In accordance with Article 10 of Directive 92/27/EEC, all proposed changes to any aspect of the presentation shall be submitted to the EMEA, who will inform the Commission.'

100 In order to ascertain whether that interpretation is well founded, it is necessary, first, to point out that Regulation No 2309/93 does not specifically require use of a single package layout for a medicinal product with a Community MA. Under Articles 9 and 11 of Regulation No 2309/93, the package layout of a medicinal product in respect of which an application has been made for a Community MA must comply with the requirements of Directive 92/27. Article 2(1) of Directive 92/27 provides that the outer packaging of a medicinal product must contain certain compulsory particulars. Article 2(2) further 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'. Those provisions do not expressly deal with aspects of the package layout such as colour, logo, format and general layout.

101 However, considerations deriving from the unitary nature of the Community MA and the fundamental principle of the free movement of goods suggest that a medicinal product which is the subject of an application for a Community MA must, as a general rule, have a single package layout. That interpretation is consonant with the general scheme and purpose of the applicable legislation. In that regard, the Court must point out that it is not disputed that, as regards a national MA, a single package layout is authorised. In the present dispute, it is not for the Court to adjudicate on the circumstances in which third parties who, although they do not hold a Community MA for a medicinal product, are responsible for parallel distribution of the product may vary its package layout.

102 Finally, as regards the question whether that interpretation also precludes any application for variation of a Community MA, it is appropriate to point out that Regulation No 542/95, which specifically contemplates the possibility of a change of name, does not contain any comparable provision concerning the package layout. In the absence of any express provision, it is not possible to read into the silence of the legislature an intention on its part to prohibit any variation of that kind.

103 The package layout, like the name, is one of the formal aspects of a Community MA and has no direct bearing on the scientific properties of the medicinal product. Whilst the choice of name may have repercussions for public health owing to a risk of confusion with other medicinal products, it is unlikely — although not impossible — that such a risk may arise as a result of a variation of

some of the aspects of the package layout of a medicinal product, such as the logo, colour, format and general layout. By contrast, rejecting any application for a variation of a Community MA consisting of the addition of a package layout may entail risks for public health. It is conceivable that, after a Community MA has been obtained, the holder of the authorisation may find that use of the package layout in the Community MA is prohibited in a Member State, for example on conclusion of an infringement action. In such a situation, to refuse an application to vary a Community MA would risk, at least until the grant of a new Community MA for another package layout, jeopardising patients' access in that Member State to the medicinal product concerned.

104 In rejecting the application for a variation of a Community MA consisting of the addition of a specific package layout for the German market without considering whether there were exceptional circumstances, the contested decision is based on an incorrect interpretation of the applicable legislation. In those circumstances, the Court must declare well founded the applicant's claim challenging the interpretation that the package layout of a medicinal product must, without exception, be the same throughout the Community.

105 It is not the Court's place to substitute itself for the Commission or the EMEA and to consider whether, in this instance, there are exceptional circumstances such as to enable the application for a variation of the package layout of the medicinal product Daquiran to be granted.

106 Therefore, the contested decision must be annulled in so far as it rejects the application for a variation of a Community MA concerning the package layout of the medicinal product concerned and it is not necessary to consider the other pleas in law which relate to that aspect of the contested decision.

107 Therefore the decision must be annulled in its entirety.

Costs

108 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. In this instance, since the Commission has been unsuccessful in its pleadings and the applicant and the EFPIA, intervener, have applied for costs, the Commission must be ordered to bear its own costs and to pay the costs of both the applicant and the EFPIA.

109 Under the first subparagraph of Article 87(4) of the Rules of Procedure of the Court of First Instance, the Council, intervener, is to bear its own costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Fifth Chamber)

hereby:

1. **Annuls the decision of 1 March 2000 of the European Agency for the Evaluation of Medicinal Products, rejecting an application for variation of**

certain terms of the marketing authorisation for the medicinal product 'Daquiran';

2. **Orders the Commission to bear its own costs and to pay the costs incurred by the applicant and the EFPIA, intervener;**

3. **Orders the Council to bear its own costs.**

Cooke García-Valdecasas Lindh

Delivered in open court in Luxembourg on 10 December 2002.

H. Jung

Registrar

R. García-Valdecasas

President