JUDGMENT OF THE COURT (Fifth Chamber)

19 October 2004 *

In Case C-31/03,

REFERENCE for a preliminary ruling under Article 234 EC

from the Bundesgerichtshof (Germany), made by decision of 17 December 2002, received at the Court on 27 January 2003, in the proceedings brought by

Pharmacia Italia SpA, formerly Pharmacia & Upjohn SpA,

THE COURT (Fifth Chamber),

composed of: R. Silva de Lapuerta, President of the Chamber, C. Gulmann (Rapporteur) and S. von Bahr, Judges,

Advocate General: F.G. Jacobs,
Registrar: R. Grass,

having regard to the written procedure and further to the hearing on 17 March 2004,

* Language of the case: German.

— Pharmacia Italia SpA, by M. Kindler, Rechtsanwalt,

— the United Kingdom Government, by R. Caudwell, acting as Agent, and C. Birss, Barrister,

— the Commission of the European Communities, by K. Banks, acting as Agent, and W. Berg, Rechtsanwalt,

after hearing the Opinion of the Advocate General at the sitting on 29 April 2004,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 19(1) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1, 'the regulation').

2 The question was raised in proceedings between Pharmacia Italia SpA ('Pharmacia') and the Deutsches Patentamt (the German Patent Office) following that office's refusal to issue Pharmacia with a supplementary protection certificate ('the certificate').

Legal background

3 It follows from the second, third and fourth recitals in the preamble to the regulation that the Council found that the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place that medicinal product on the market ('marketing authorisation'), makes the period of effective protection under the patent insufficient to cover the investment put into the research. The regulation is intended to remedy that lack of protection.

4 Article 1 of the regulation provides inter alia that, for the purposes of that regulation, 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals, 'product' means the active ingredient or combination of active ingredients of a medicinal product, and 'basic patent' means a patent which protects a product as so defined.

5 Article 2 of the regulation provides:

'Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Council Directive 65/65/EEC or Directive 81/851/EEC may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.'

6 The two directives referred to in Article 2 of the regulation are respectively:

— Council Directive 65/65/EEC of 26 January 1965 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. 20), replaced 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),

— Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1), replaced by Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1).

7 Article 3 of the regulation provides:

'A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid [marketing authorisation for the product] as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in (b) is the first [marketing authorisation for the product] as a medicinal product.'

8 Article 4 of the regulation provides:

'Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the [marketing authorisation for the corresponding product] and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.'

9 Article 13(1) of the regulation provides that '[t]he certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first [marketing authorisation] in the Community, reduced by a period of five years'.

10 Article 19 of the regulation, which forms part of the transitional provisions, provides:

'1. Any product which, on the date on which this regulation enters into force, is protected by a valid basic patent and for which the first [marketing authorisation] in the Community was obtained after 1 January 1985 may be granted a certificate.

In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

... '

The dispute in the main proceedings and the question referred for a preliminary ruling

11 It is apparent from the decision to refer that:

— Pharmacia was the holder of German Patent No 31 12 861 lodged on 31 March 1981 which had since expired. The first patent claim covered ergoline derivatives and their pharmaceutically acceptable salts obtained by the addition of organic or inorganic acids. The second sub claim covered a compound known by the international non-proprietary name of 'Cabergoline';

— on 15 June 1994, the medicinal product 'Dostinex' was authorised in Germany. That was the first marketing authorisation at national level for the product protected as a medicinal product. The authorisation identifies the active ingredient of the medicinal product as being 'Cabergoline'. That active ingredient had been first authorised as a medicinal product for human use on 21 October 1992 in the Netherlands. The veterinary medicinal product 'Galastop' which also contains the active ingredient 'Cabergoline', had been authorised in Italy on 7 January 1987;

— on 13 December 1994 Pharmacia applied for a certificate to the Deutsches Patentamt. That application for a certificate was primarily in respect of the active ingredient 'Cabergoline' in the form of the free base or salt obtained by addition of an acid and, in the alternative, in respect of the active ingredient of the medicinal product 'Dostinex' in all forms protected by the basic patent.

12 The Deutsches Patentamt rejected the application, holding that, under Article 19 of the regulation, a certificate may be granted only where the product to be protected has obtained its first marketing authorisation in the Community after the date fixed for the Member State concerned (in the case of Germany, 1 January 1988), and that that condition was not satisfied in the present case since the first marketing authorisation obtained in the Community was that granted in 1987 in Italy. That decision was confirmed by the Bundespatentgericht (Federal Patent Court).

13 Taking the view that, for the purposes of the application of Article 19 of the regulation, the first marketing authorisation in the Community was that granted in the Netherlands for the medicinal product for human use, Pharmacia brought an appeal against that decision before the Bundesgerichtshof, which decided to stay the proceedings and refer the following question to the Court for a preliminary ruling:

'Is the grant of a supplementary protection certificate in a Member State of the Community on the basis of a medicinal product for human use authorised in that Member State precluded by a [marketing authorisation for that product] as a veterinary medicinal product granted in another Member State of the Community before the date specified in Article 19(1) of the Regulation No 1768/92, or is the sole determining factor the date on which the product was authorised in the Community as a medicinal product for human use?'

The question referred for a preliminary ruling

14 Article 19 of the regulation provides as a transitional measure that a certificate may be granted for any product, that is to say, any active ingredient or combination of active ingredients of a medicinal product, provided that:

— on the date of entry into force of the regulation, namely 2 January 1993, the product is protected by a valid basic patent, and

— the first marketing authorisation was obtained for the product as a medicinal product in the Community after a certain date (in the case of Germany, 1 January 1988).

15 The question referred concerns the interpretation of the second of those conditions. More precisely, it asks whether, in the case of an application for the grant of a certificate for a product which obtained marketing authorisation as a medicinal

product for human use in the Member State in which the application is made, the first marketing authorisation in the Community referred to in Article 19 of the regulation must be a marketing authorisation granted for a medicinal product for human use, as Pharmacia submits, or whether it may also be a marketing authorisation granted for a veterinary medicinal product, as the German authorities submit.

16 In its judgment in Case C-127/00 *Hässle* [2003] ECR I-14781, the Court interpreted Article 19 of the regulation and held, inter alia, that:

— the first marketing authorisation in the Community referred to by that article is not intended to take the place of the marketing authorisation provided for in Article 3(b) of the abovementioned regulation; instead, it constitutes a further condition applying in the event that the latter authorisation is not the first authorisation to place the product on the market as a medicinal product in the Community (paragraph 73);

— the words 'first marketing authorisation' must not be interpreted differently depending on the provision of Regulation No 1768/92 in which they appear. The same is particularly true of the words 'first marketing authorisation ... in the Community' (paragraph 72).

17 Whilst Pharmacia admits that the wording of Article 19(1) of the regulation refers in general terms to the first marketing authorisation in the Community without distinguishing between marketing authorisations for medicinal products for human use and veterinary medicinal products, it nevertheless submits that it follows from

an examination of the regulation as a whole, its broad logic and purpose, that the regulation draws a distinction in principle between medicinal products for human use and veterinary medicinal products so that in the present case, the first marketing authorisation to be taken into consideration is that granted for the medicinal product for human use in the Netherlands.

18 It should be noted in that regard that whilst it is true, as Pharmacia submits, that Article 1 of the regulation refers to disease in human beings or animals and Articles 2, 3(b), 8(1)(b) and 14(d) refer to Directives 65/65 and 81/851, it does not follow that the regulation draws a distinction in principle between the marketing authorisations granted for medicinal products for human use and those granted for veterinary medicinal products, with the consequences referred to by Pharmacia. The term medicinal product defined in Article 1(a) of the regulation does not distinguish between diseases in human beings and animals. Similarly, Articles 2, 3(b), 8(1)(b) and 14(d) do not distinguish between the various authorisation procedures for veterinary medicinal products and those for medicinal products for human use. Those provisions refer solely in different contexts to the marketing authorisation procedures 'as laid down in' Directive 65/65 or Directive 81/851 and to the marketing authorisations granted or withdrawn 'in accordance with' those directives.

19 It should furthermore be noted that:

— pursuant to Article 1(b) of the regulation, the term product as used in the regulation is defined as an active ingredient or combination of active ingredients of a medicinal product;

— pursuant to Article 3 of the regulation, the certificate is to be granted, inter alia, provided that the product has been granted a marketing authorisation as a medicinal product in accordance with Directive 65/65 or Directive 81/851; and

— pursuant to Article 4 of the regulation, the protection conferred by a certificate is to extend only to the product covered by the marketing authorisation for the corresponding medicinal product for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

20 It follows, first, that the decisive factor for the grant of the certificate is not the intended use of the medicinal product and, second, that the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product.

21 Whilst noting that the term 'first marketing authorisation in the Community' must be interpreted in the same way in each of the provisions of the regulation in which it is used, it should be pointed out that, according to the sixth recital in its preamble, that regulation seeks to provide a uniform solution at Community level to the problem of inadequate patent protection, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community. However, an interpretation such as that proposed by Pharmacia would prevent the realisation of that objective. Under Pharmacia's interpretation, the duration of the protection conferred by the certificate, calculated in accordance with Article 13 of the regulation, might be different for the same product.

22 Lastly, and for the reasons set out in points 41 to 43 and 48 to 50 of the Advocate General's Opinion, it must be found that neither the purpose of Article 19 nor the broad logic of the regulation militate in favour of the interpretation put forward by Pharmacia.

23 In those circumstances, and in accordance with the observations submitted by the United Kingdom Government and the Commission, the answer to the question referred for a preliminary ruling must be that the grant of a certificate in a Member State of the Community on the basis of a medicinal product for human use authorised in that Member State is precluded by a marketing authorisation for that product as a veterinary medicinal product granted in another Member State of the Community before the date specified in Article 19(1) of the regulation.

Costs

24 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fifth Chamber) rules as follows:

The grant of a supplementary protection certificate in a Member State of the Community on the basis of a medicinal product for human use authorised in that Member State is precluded by an authorisation to place the product on the market as a veterinary medicinal product granted in another Member State of the Community before the date specified in Article 19(1) of Council Regulation No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

Signatures.