# JUDGMENT OF THE COURT (Sixth Chamber)

11 December 2003 *

In Case C-127/00,

REFERENCE to the Court under Article 234 EC by the Bundesgerichtshof (Germany) for a preliminary ruling in the proceedings pending before that court between

**Hässle AB**

and

**Ratiopharm GmbH,**

on the interpretation of Articles 15 and 19 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),

* Language of the case: German.

THE COURT (Sixth Chamber),

composed of: V. Skouris, acting for the President of the Chamber, C. Gulmann, J.N. Cunha Rodrigues, R. Schintgen and F. Macken (Rapporteur), Judges,

Advocate General: C. Stix-Hackl,
Registrar: D. Louterman-Hubeau, Head of Division,

after considering the written observations submitted on behalf of:

— Hässle AB, by O. Brändel, Rechtsanwalt,

— Ratiopharm GmbH, by T. Bopp, Rechtsanwalt,

— the Danish Government, by J. Molde, acting as Agent,

— the Spanish Government, by S. Ortiz Vaamonde, acting as Agent,

— the French Government, by K. Rispal-Bellanger and R. Loosli-Surrans, acting as Agents,

— the Netherlands Government, by M. Fierstra, acting as Agent,

— the Commission of the European Communities, by K. Banks and M. Niejahr, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Hässle AB, Ratiopharm GmbH, the Danish Government and the Commission at the hearing on 8 November 2001,

after hearing the Opinion of the Advocate General at the sitting on 26 February 2002,

gives the following

## Judgment

1 By order of 1 February 2000, received at the Court on 3 April 2000, the Bundesgerichtshof (Federal Supreme Court) referred to the Court for a preliminary ruling under Article 234 EC four questions on the interpretation of Articles 15 and 19 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).

2 Those questions were raised in proceedings between Hässle AB ('Hässle') and Ratiopharm GmbH ('Ratiopharm') regarding the validity of a supplementary protection certificate issued to Hässle by the Deutsches Patentamt (German patents office) relating to omeprazol, an active ingredient in various medicinal products.

## Community legislation

3 Article 3 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ, English Special Edition 1965-1966, p. 20) lays down the principle that 'no medicinal product may be placed on the market of a Member State unless an authorisation has been issued by the competent authority of that Member State'.

4 The second, third and fourth recitals of the preamble to Regulation No 1768/92 are worded as follows:

'Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;

Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;

Whereas this situation leads to a lack of protection which penalises pharmaceutical research'.

5 According to the sixth recital in the preamble to Regulation No 1768/92, a uniform solution at Community level should be provided for, 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 and thus directly affect the establishment and the functioning of the internal market. It is therefore necessary, according to the seventh recital of the abovementioned regulation, to create a supplementary protection certificate (hereinafter: 'a certificate') granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted.

6 The 10th recital of Regulation No 1768/92 states: 'a fair balance should also be struck with regard to the determination of the transitional arrangements;... such arrangements should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and Community level'.

7 According to Article 1 of Regulation No 1768/92, for the purposes of that regulation, a 'product' means the active ingredient or combination of active ingredients of a medicinal product, and a 'basic patent' means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for obtaining a certificate.

8 Article 2 of Regulation No 1768/92 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.'

9 Article 3 of Regulation No 1768/92 provides as follows:

'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 authorisation to place the product on the market 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 authorisation to place the product on the market as a medicinal product.'

10 Under Article 7 of Regulation No 1768/92, the application for a certificate must be lodged within six months of the date on which the authorisation referred to in Article 3(b) thereof to place the product on the market as a medicinal product was granted or, where the marketing authorisation is granted prior to the basic patent being granted, within six months of the date on which the patent is granted.

11 Article 8(1) of Regulation No 1768/92 provides:

'The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

...

(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(b) and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;

(c) if the authorisation referred to in (b) is not the first authorisation for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication.'

12 According to Article 13(1) of Regulation No 1768/92, '[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 authorisation to place the product on the market in the Community reduced by a period of five years'.

13 Article 15 of Regulation No 1768/92 provides:

'The certificate shall be invalid if:

(a) it was granted contrary to the provisions of Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

2. Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the institution responsible under national law for the revocation of the corresponding basic patent.'

14 Article 19 of Regulation No 1768/92, 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 authorisation to place it on the market as a medicinal product 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.

In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

2. An application for a certificate as referred to in paragraph (1) shall be submitted within six months of the date on which this regulation enters into force.'

15 Regulation No 1768/92 entered into force on 2 January 1993.

16 The 17th recital in the preamble to Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30) provides that 'the detailed rules in... Article 17(2) of this Regulation are also valid, *mutatis mutandis*, for the interpretation in particular of recital 9 and Articles 3, 4, 8(1)(c) and 17 of Council Regulation (EEC) No 1768/92'.

17 Article 17(2) of Regulation No 1610/96, entitled 'Appeals', provides:

'The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.'

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

18 Hässle was the holder of a European patent covering the chemical compound '2-[2-(3.5-dimethyl-4-methoxypyridyl)-methylsulfinyl]-5-methoxybenzimidazol',

whose international designation recommended by the World Health Organisation is 'omeprazol'. That patent, which was valid, among others, in Germany, was granted to Hässle with effect from 3 April 1979, so that it expired on 2 April 1999.

19 In Germany, by two decisions of the Bundesgesundheitsamt (Federal Office of Health) of 6 October 1989, Hässle obtained, in accordance with Directive 65/65, authorisations to market medicinal products having omeprazol as their active ingredient. In France and Luxembourg, authorisations had already been granted in accordance with the same directive, one to Laboratoires Astra France and the other to Astra-Nobelpharma SA, which both belong to the Hässle group, for medicinal products having that same active ingredient, on 15 April 1987 and 11 November 1987 respectively.

20 In Luxembourg, the marketing of proprietary medicinal products is subject not only to the marketing authorisation provided for by Directive 65/65 but also to authorisation required under pricing legislation, where the price exceeds LUF 400. By letter of 8 December 1987 Astra-Nobelpharma SA therefore informed the competent Luxembourg ministry of its intention to place a medicinal product on the market, having omeprazole as an active ingredient, at the price of LUF 2 456 per pack of 28 capsules. By decision of 17 December 1987, which was received on 31 December 1987, the abovementioned Ministry authorised the proposed price less a reduction of 1.56%. On 21 March 1988, that medicinal product was included in the list of proprietary medicinal products authorised for sale in Luxembourg.

21 In France, the medicinal product was entered on 22 November 1989 in the list of medicinal products eligible for reimbursement to persons insured under the social security scheme

22 On 9 June 1993 Hässle applied to the Deutsches Patentamt for a certificate for omeprazol as a medicinal product and gave 'March 1988 Luxembourg' as time and place of the first authorisation to place that product on the market as a medicinal product in the European Community and attached the Luxembourg list of proprietary medicinal products authorised for sale as drawn up on 21 March 1988.

23 By decision of 10 November 1993, the Deutsches Patentamt issued it with the requisite certificate and fixed as its duration the period until 21 March 2003.

24 Ratiopharm brought an action before the Bundespatentgericht (Federal Patent Court) for a declaration of invalidity of that certificate on the ground that a first authorisation to place medicinal products having omeprazol as their active ingredient on the market in the Community had already been granted before the relevant date which, for Germany, was 1 January 1988, in accordance with the second sentence of Article 19(1) of Regulation No 1768/92. The Bundespatentgericht upheld the application made by Ratiopharm and declared the certificate invalid.

25 Hässle appealed that ruling before the Bundesgerichtshof, which decided to stay the proceedings and refer the following questions to the Court of Justice for a preliminary ruling:

'1. (a) For the purpose of applying the transitional provision in Article 19(1) of the Regulation, in so far as that provision refers to the "first authorisation to place... on the market... in the Community" before a specified relevant date, does that refer exclusively to an authorisation within the meaning of Directive 65/65/EEC or Directive 81/851/EEC as the case may be, or may another authorisation granted later (after the relevant date) relating in

particular to the prices of the medicinal product also be material in this respect, if

(aa) without such a further authorisation, for example one for price-law purposes, marketing of the medicinal product is not permissible under the law of the Member State concerned, or

(bb) without such a further authorisation the medicinal product may in principle be marketed in the Member State concerned, but effective marketing is nevertheless not possible, in particular because the sickness funds reimburse the costs of the medicinal product only if the further authorisation, in particular for price-law purposes, has been granted or a determination of the price eligible for reimbursement has been made?

(b) Is the material authorisation for this purpose a first authorisation in any Member State of the Community (as with Articles 8 and 13 of the Regulation) or the first authorisation in the Member State for which the grant of the supplementary protection certificate has been applied for?

2. Is there doubt as to the validity of the transitional provision in Article 19(1) of the Regulation in so far as it lays down different relevant dates for different Member States?

3. Is the list of grounds of invalidity in Article 15(1) of the Regulation exhaustive?

If not:

(a) Does it constitute a ground of invalidity that a certificate was granted under the transitional provision in Article 19(1) of the Regulation even though a first authorisation to place the product on the market in the Community was already granted before the relevant date for the Member State in which the certificate was applied for and granted?

(b) In that case is the certificate completely invalid, or should its duration merely be rectified accordingly?

4. If a breach of the transitional provision in Article 19(1) of the Regulation does not constitute a ground of invalidity:

May and must national law provide, as under Article 17(2) of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 June 1996 concerning the creation of a supplementary protection certificate for plant protection products, for an appeal aimed at rectifying the duration of the protection certificate for a medicinal product in the event of a breach of the transitional provision in Article 19(1) of Regulation No 1768/92?'

## Introductory remarks

26 According to Article 7 of Regulation No 1768/92, read in conjunction with Article 3(b) and (d) thereof, the application for a certificate must be submitted within six months of the date on which the first authorisation to place the product on the market as a medicinal product is granted in the Member State for which the application is made or, where the marketing authorisation is granted prior to the basic patent, within six months of the date on which the patent is granted.

27 Where the first marketing authorisation in the Member State in which the application is made or, in the event that such authorisation is granted prior to the patent, where the patent is granted after the entry into force of Regulation No 1768/92, the holder of the patent has the six-month period provided for by Article 7 in which to submit an application for a certificate.

28 That is not the case, however, where the first marketing authorisation in the Member State in which the application is submitted or, where such marketing authorisation is granted prior to the patent, the patent is granted prior to the entry into force of the abovementioned regulation. Where the marketing authorisation or the patent was granted more than six months prior to the entry into force of Regulation No 1768/92, the holder of the patent may not submit an application for a certificate on the basis of Article 7 of that regulation, the six-month period provided for by that article having expired even before the abovementioned regulation entered into force. Where, however, that marketing authorisation or that patent was granted within the six months prior to the entry into force of Regulation No 1768/92, the holder of the patent has less time within which to submit an application for a certificate on the basis of Article 7 of that regulation, since the six-month period provided for by that article will have begun to run even before the entry into force of the regulation.

29 It was with the intention of limiting such consequences and making it possible for products which had already obtained authorisation to be marketed as medicinal products on the date on which Regulation No 1768/92 entered into force to take

advantage of the scheme established by the regulation that the legislature included Article 19, which forms part of the transitional provisions. Article 19(2) operates, in the circumstances provided for in Article 19(1), as a derogation from Article 7 of the regulation (see, to that effect, Case C-110/95 *Yamanouchi Pharmaceutical* [1997] ECR I-3251, paragraph 19).

30 In view of its objective, Article 19 of Regulation No 1768/92 is therefore intended to apply only to products for which a first authorisation to place them on the market as medicinal products in the Member State in which the application was submitted was granted before the entry into force of that regulation.

## The second question

31 By its second question, which it is appropriate to examine first, the national court is asking whether Article 19 of Regulation No 1768/92 is invalid on the ground that it lays down different relevant dates for different Member States.

32 Hässle submits that, because of the different relevant dates laid down by that article, the products protected by patents issued in Belgium and Italy may obtain an extension of their protection by means of a certificate six years earlier than for the same patents in Denmark and Germany, and takes the view that that situation is contrary to the objective of harmonisation within the internal market.

33 Hässle therefore concludes that Article 19 of Regulation No 1768/92 is invalid, first, because of an inadequate statement of reasons inasmuch as that regulation does not set forth the legal and factual considerations which gave rise to different relevant dates being set. Secondly, that provision discriminates unlawfully, inasmuch as there is no equality of treatment, which also entails its invalidity.

34 On the other hand, Ratiopharm, the Danish, French and Netherlands Governments and the Commission contend that Article 19 of Regulation No 1768/92 is valid.

*Reply of the Court*

35 So far as concerns, first, the alleged breach of the general principle of equality, according to which, in particular, similar situations must not be treated differently unless differentiation is objectively justified, it should be noted that Regulation No 1768/92 was adopted on the basis of Article 100a of the EEC Treaty (after amendment, Article 100a of the EC Treaty, now in turn, after amendment, Article 95 EC), which makes it possible to harmonise at Community level certain aspects of national law, including industrial property law.

36 In that regard, it must also be borne in mind that recourse to Article 100a as a legal basis is possible if the aim is to prevent the emergence of future obstacles to trade resulting from the heterogenous development of national laws provided that the emergence of such obstacles is likely and the measure in question is designed to prevent them (see, among others, Case C-376/98 *Germany* v *Parliament and Council* [2000] ECR I-8419, paragraph 86, and Case C-377/98 *Netherlands* v *Parliament and Council* [2001] ECR I-7079, paragraph 15).

37 In that connection, as the Court found at paragraphs 34 and 35 of its judgment in Case C-350/92 *Spain* v *Council* [1995] ECR I-1985, at the time Regulation No 1768/92 was adopted, provisions concerning the creation of a supplementary protection certificate for medicinal products existed in two Member States and were at the draft stage in another State. That regulation establishes, as a matter of fact, a uniform Community approach by creating a certificate which may be obtained by the holder of a national or European patent under the same conditions in each Member State and by providing, in particular, for a uniform

duration of protection. It thus aims to prevent 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 and thus directly affect the establishment and the functioning of the internal market.

38 However, although, when Regulation No 1768/92 was adopted, all the Member States wished to protect innovation in the pharmaceutical industry by making it possible, by granting a certificate, to provide sufficient protection for holders of patents, enabling them to cover the investment put into the research (see, in that connection, the third recital of Regulation No 1768/92), a number of them wished to protect for a longer period the pursuit of other legitimate objectives concerning their public-health policies (see, in that regard, the 10th recital of that regulation) and, in particular, ensure the financial stability of their health system by supporting the generic medicinal product manufacturing industry.

39 It is in order to take account of those different criteria that Article 19 of Regulation No 1768/92 made transitional provision for different relevant dates.

40 The setting of different relevant dates for different Member States thus appears to be justified insofar as each of those dates reflects the assessment made by each Member State in the light, in particular, of its health system, the organisation and financing of which varies from one Member State to the next.

41 Moreover, as stated in paragraph 30 of the present judgment, Article 19 of Regulation No 1768/92 is intended to apply only to products for which a first authorisation to be placed on the market as medicinal products in the Member

State in which the application was submitted had already been granted when that regulation entered into force. The absence of harmonisation is therefore restricted to those products for which a first authorisation to be placed on the market as medicinal products in the Community was granted between 1 January 1982 and 1 January 1988.

42 It follows from the foregoing that the principle of equality of treatment was not infringed by that scheme.

43 Secondly, so far as concerns the obligation to state reasons, it should be noted that, whilst the statement of reasons required by Article 190 of the EEC Treaty (after amendment, Article 190 of the EC Treaty, now in turn, Article 253 EC) must show clearly and unequivocally the reasoning of the Community authority which adopted the contested measure so as to enable the persons concerned to ascertain the reasons for it and to enable the Court to exercise its review, it is not required to go into every relevant point of fact and law. The question whether a statement of reasons for a measure satisfies those requirements must be assessed with reference not only to its wording but also to its context and the entire body of legal rules governing the matter in question (see, in particular, Case C-466/93 *Atlanta Fruchthandelsgesellschaft and Others (II)* [1995] ECR I-3799, paragraph 16; Case C-122/94 *Commission* v *Council* [1996] ECR I-881, paragraph 29; and Case C-183/95 *Affish* [1997] ECR I-4315, paragraph 63).

44 In that regard, the Court has previously held (see, among others, Case C-168/98 *Luxembourg* v *Parliament and Council* [2000] ECR I-9131, paragraph 62) that, in the case of a measure of general application, the statement of reasons may be confined to indicating the general situation which led to its adoption, on the one hand, and the general objectives which it is intended to achieve, on the other.

45 Those conditions are fulfilled in the case of Regulation No 1768/92, the 10th recital of which states that a fair balance should also be struck with regard to the determination of the transitional arrangements which should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and Community level.

46 Those legitimate objectives concerning health policies include, in some circumstances, the financial stability of the health system of the Member States.

47 For all those reasons, it must be held that consideration of the second question referred has disclosed no factor capable of affecting the validity of Article 19 of Regulation No 1768/92.

## The first question

*The first part of the first question*

48 By the first part of its first question, the national court is asking whether the concept of 'first authorisation to place... on the market', which appears in Article 19(1) of Regulation No 1768/92, refers solely to a marketing authorisation in accordance with Directive 65/65 or 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), or whether it may also include authorisations required under national legislation on the pricing of medicinal products, where they may only actually be marketed after agreement by the competent national authorities regarding the setting of the price of or the reimbursement for medicinal products.

49 According to Hässle, there is no first marketing authorisation within the meaning of Article 19(1) of Regulation No 1768/92 until the medicinal product concerned may actually be marketed. The concept of 'first authorisation to place... on the market' in that provision thus refers, in the absence of express reference to Directive 65/65, to the authorisations required under national legislation on pricing or to those granted by national social security bodies which reimburse proprietary medicinal products.

50 Such an interpretation is corroborated by the wording and the purpose of Regulation No 1768/92. With regard to the wording, Article 19(1), unlike other provisions in the regulation, does not specify that the first marketing authorisation must be obtained in accordance with Directive 65/65. From a teleological point of view, Hässle submits that the purpose of creating the certificate extending the duration of protection of the patent was to make it possible to compensate for the time necessary to obtain various authorisations. However, such protection would be illusory if the time which may have elapsed between the grant of the marketing authorisation in accordance with that directive and actual exploitation of a patent was not compensated.

51 On the other hand, Ratiopharm, the Danish, Spanish, French and Netherlands Governments and the Commission contend that the authorisation mentioned in Article 19(1) of Regulation No 1768/92 refers to the marketing authorisation issued in accordance with Directive 65/65, and obtention of any other authorisation issued subsequently, concerning in particular authorisation for or establishment of the price of the medicinal product in those States where it is fixed by the authorities, is of no relevance.

Reply of the Court

52 It should be pointed out that the authorisation procedure in issue in the main proceedings concerns a medicinal product for human use rather than a veterinary medicinal product, so that the first question is to be examined solely in the light of Directive 65/65.

53 It is therefore appropriate to ascertain whether the words 'first authorisation to place... on the market' in Article 19(1) of Regulation No 1768/92 refer solely to a marketing authorisation in accordance with Directive 65/65 or whether they also refer to an authorisation required under national legislation on the fixing of prices of or reimbursement for medicinal products, such as the authorisation granted on 17 December 1987 to Hässle by the Luxembourg authorities in the case in the main proceedings.

54 In that connection, while the wording of Article 19(1) of Regulation No 1768/92 does not make it clear that the first marketing authorisation mentioned therein must be obtained in accordance with Directive 65/65, in the absence of an express reference to that directive, neither does that fact rule out such an interpretation.

55 It is, therefore, necessary to place that expression in its context and to interpret it in relation to the spirit and purpose of the provision in question.

56 First, neither Article 19 of Regulation No 1768/92, nor any other provision of that regulation, nor the recitals therein mentions, whether expressly or by implication, any authorisation other than that relating to provisions on medicinal products in accordance with Directive 65/65, and in particular no mention is made of any authorisation issued by the competent national authorities with regard to the fixing of prices or reimbursement for medicinal products. The scope of Regulation No 1768/92 is specifically defined, in Article 2 thereof, as

extending to products protected by a patent which are subject, prior to being placed on the market as medicinal products, to an administrative authorisation procedure as laid down in Council Directive 65/65.

57 There is thus nothing to justify the words 'authorisation to place... on the market' being interpreted differently depending on which provision of Regulation No 1768/92 they appear in. In particular, those words cannot be construed as having a different meaning according to whether they appear in Article 3 or Article 19, especially when it is apparent from Article 8(1)(a)(iv) and (c) that the marketing authorisation referred to in Article 3(b) may also be the first marketing authorisation in the Community.

58 It follows therefrom that the 'first authorisation to place... on the market... in the Community', mentioned in, among others, Article 19(1) of Regulation No 1768/92, must, like the 'authorisation to place... on the market' mentioned in Article 3 of that regulation, be a marketing authorisation issued in accordance with Directive 65/65.

59 Secondly, contrary to Hässle's contention, even if the certificate does no more than compensate for the time which elapses between lodging the patent application and the issuing of a marketing authorisation in accordance with Directive 65/65, the protection conferred by that certificate, which extends that conferred by the patent, is not illusory. Furthermore, it is clear from the eighth recital and from Article 13(1) of Regulation No 1768/92 that the duration of the certificate is at least five years shorter than the period which may have elapsed between the patent application and the issuing of a marketing authorisation, which shows that the Community legislature did not pursue at all the objective of compensating in its entirety the loss of effective protection conferred by a patent as a result of lead times required by protected products.

60 Thirdly, that interpretation is the only one which can satisfy the requirements of legal certainty. Contrary to the marketing authorisation procedure provided for by Directive 65/65, the other authorisation procedures relied upon by Hässle concerning the fixing of prices or reimbursement for medicinal products are entirely national matters inasmuch as they have not been harmonised at Community level. Consequently, if Article 19 of Regulation No 1768/92 were to be interpreted as referring to such authorisations, the persons covered by that regulation would not be aware of the existence or the nature of other obstacles to the placing of products on the market in the various Member States, thus creating the kind of legal uncertainty which the abovementioned regulation was precisely intended to remedy.

61 It follows that the 'first authorisation to place... on the market' mentioned in Article 19(1) of Regulation No 1768/92 refers only to the marketing authorisation relating to provisions on medicinal products in accordance with Directive 65/65.

*The second part of the first question*

62 By the second part of its first question, the national court is essentially asking whether the words 'first authorisation to place... on the market... in the Community' in Article 19(1) of Regulation No 1768/92 refer to the first marketing authorisation in the Member State in which the application was submitted or the first marketing authorisation in any of the Member States.

63 Hässle submits that a certificate may not be issued pursuant to Article 19 of Regulation No 1768/92 unless the 'first authorisation to place... on the market... in the Community' is subsequent to the relevant date fixed by that article, so that it seems to be a condition for granting the certificate. However, relying on *Yamanouchi Pharmaceutical*, cited above, it argues that the only condition for granting a certificate pursuant to Article 19 of Regulation No 1768/92 is the marketing authorisation referred to in Article 3(b) and (d) thereof, namely the first marketing authorisation issued in the Member State in which the certificate

was applied for. On the other hand, another marketing authorisation issued previously in another Member State would serve only to determine the duration of the certificate granted. Accordingly, the 'first authorisation to place... on the market... in the Community' mentioned in Article 19 of Regulation No 1768/92 is the first marketing authorisation issued in the Member State in which the application for a certificate was submitted.

64 That interpretation is borne out, according to Hässle, by the use of the indefinite article in the German, French, Italian and Dutch versions of Article 19(1) of Regulation No 1768/92, which purportedly shows that there could be several first marketing authorisations in the Community, one for each Member State.

65 Moreover, the proposed interpretation is the only one which is compatible with the purpose of Regulation No 1768/92, which is to improve as rapidly as possible the protection conferred on the patent holder.

66 On the other hand, Ratiopharm, the Spanish, French and Netherlands Governments and the Commission claim that, in order to apply Article 19 of Regulation No 1768/92, account must be taken of the first marketing authorisation issued in any of the Member States.

67 The Spanish and French Governments, recalling the wording of Articles 8 and 13 of Regulation No 1768/92, point out that there is perfect consistency between Articles 13 and 19 of that regulation both of which make reference to the date of the first marketing authorisation in the Community.

68 The Danish Government merely points out that the application of Article 19(1) of Regulation No 1768/92 assumes that a valid marketing authorisation was obtained in the Member State in which the certificate is applied for.

Reply of the Court

69 The textual argument put forward by Hässle that the use of the indefinite article in the German, French, Italian and Dutch version of Article 19(1) of Regulation No 1768/92 purportedly shows that there could be several first marketing authorisations in the Community founders where other language versions of that provision, in particular the English version, use the definite article.

70 According to settled case-law, the various language versions of a provision of Community law must be uniformly interpreted and, in the case of divergence between those versions, the provision in question must be interpreted by reference to the purpose and general scheme of the rules of which it forms part (Case C-257/00 *Givane and Others* [2003] ECR I-345, paragraph 37, and the case-law cited).

71 Since a literal interpretation of the words 'first authorisation to place... on the market... in the Community' in Article 19(1) of Regulation No 1768/92 does not provide an unequivocal answer to the question referred, it is thus necessary to place that expression in its context and to interpret it in relation to the purpose of the provision in question.

72 In that connection, as stated in paragraph 57 of the present judgment, the words 'first authorisation to place... on the market' 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 authorisation to place... on the market ... in the Community' (see, to that effect, *Yamanouchi Pharmaceutical*, cited above, paragraphs 23 and 24).

73 At paragraph 24 of *Yamanouchi Pharmaceutical*, the Court held that the effect of Articles 8(1)(a)(iv) and (b), 9(2)(d) and 11(1)(d) of Regulation No 1768/92 is that the first marketing authorisation in the Community is not intended to take the place of the marketing authorisation provided for in Article 3(b) of the abovementioned regulation, that is to say, the authorisation granted by the Member State in which the application is submitted; 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.

74 If Regulation No 1768/92 were to be interpreted as meaning that the first marketing authorisation in the Community is the first marketing authorisation issued in the Member State in which the application is submitted, it would be systematically confused with the marketing authorisation provided for in Article 3(b) and (d) of that regulation and would thus not constitute an additional condition. Articles 8(1)(a)(iv) and (c), 9(2)(e) and 11(1)(d) of the abovementioned regulation would thus be rendered devoid of purpose.

75 Thus, contrary to Hässle's argument, its interpretation of Article 19(1) of Regulation No 1768/92 is invalidated by the judgment in *Yamanouchi Pharmaceutical*.

76 Furthermore, the interpretation to the effect that the words 'first authorisation to place... on the market... in the Community' in Article 19(1) of Regulation No 1768/92 refer to the first marketing authorisation issued in any of the Member States of the Community is supported by the purpose of the abovementioned regulation, set out in the sixth recital thereof, which is that a uniform solution at Community level should be provided for.

77 As the Advocate General pointed out in paragraph 85 of her Opinion, in view of the method for calculating the duration of the certificate laid down in Article 13 of Regulation No 1768/92, only that interpretation makes it possible to ensure that the extension of the protection conferred by the patent, so far as concerns the product covered by the certificate, will come to an end at the same moment in all the Member States where the certificate was granted.

78 It follows that the words 'first authorisation to place... on the market... in the Community' in Article 19(1) of Regulation No 1768/92 refer to the first marketing authorisation granted in any of the Member States.

79 The answer to the first question must be that, so far as concerns medicinal products for human use, the concept of 'first authorisation to place... on the market... in the Community', in Article 19(1) of Regulation No 1768/92, refers solely to the first authorisation required under provisions on medicinal products, in accordance with Directive 65/65, granted in any of the Member States, and does not therefore refer to authorisations required under legislation on pricing of or reimbursement for medicinal products.

## The third question

80 By its third question, the national court is asking, in essence, whether a certificate which, contrary to Article 19 of Regulation No 1768/92, has been delivered where the first marketing authorisation in the Community was obtained prior to the relevant date fixed by that provision is invalid pursuant to Article 15 of that regulation or whether all that is necessary is to rectify the duration of its validity.

81 According to Hässle and the Danish and Netherlands Governments, the grounds of invalidity listed in Article 15(1) of Regulation No 1768/92 are exhaustive, so that infringement of Article 19(1) thereof cannot result in the invalidity of the certificate. They base their arguments in particular on the exhaustive nature of the grounds of invalidity mentioned in Article 15(1). Hässle and the Danish Government claim that the only possible penalty for non-compliance with the relevant date is rectification of the duration of the validity of the certificate. The Netherlands Government, for its part, maintains that penalties are a matter for national law.

82 On the other hand, Ratiopharm, the French Government and the Commission submit that Articles 15(1)(a) and 19(1) of Regulation No 1768/92 must be interpreted as meaning that a certificate issued contrary to the relevant-date rule laid down in Article 19(1) is invalid.

83 According to the Commission, the grounds of invalidity set out in Article 15(1) of Regulation No 1768/92 should be applied by analogy to non-compliance with the relevant date in Article 19(1) thereof. Infringement of the former provision is comparable to the case of the certificate being issued contrary to the requirements of Article 3 of the abovementioned regulation.

*Reply of the Court*

84 It is clear from paragraphs 26 to 30 of the present judgment that the purpose of Article 19 of Regulation No 1768/92 is to provide, in certain circumstances, the possibility of obtaining, within a period of six months from the date on which that regulation enters into force, a certificate for the products for which the first authorisation to place them on the market as medicinal products was granted before the abovementioned date in the Member State in which the application was submitted.

85 Article 19(2) of Regulation No 1768/92 thus operates, in the circumstances provided for in Article 19(1), as a derogation from Article 7, pursuant to which an application for a certificate must be lodged within six months of the date on which the marketing authorisation or, as the case may be, the basic patent is granted.

86 One of the conditions for the application of those derogatory transitional arrangements is the requirement that the first marketing authorisation in the Community should have been obtained after the relevant date fixed for the Member State in which the application is submitted, in Article 19(1) of Regulation No 1768/92. That requirement has the appearance of a further material condition, in addition to the conditions laid down in Article 3 thereof (see *Yamanouchi Pharmaceutical*, cited above, paragraph 28), for obtaining a certificate in the context of those arrangements. It therefore constitutes a condition which defines the material scope of Article 19 of Regulation No 1768/92.

87 Failure to comply with that requirement is not without relevance when assessing the validity of a certificate. Any interpretation to the contrary would jeopardise the practical effect of Article 19(1) of Regulation No 1768/92, which is to make it impossible that a certificate could still be issued where the first marketing authorisation in the Community was obtained too long ago.

88 It follows that, when a mistake has been committed regarding the date of the first marketing authorisation in the Community but that date is subsequent to the relevant date fixed in Article 19(1) of Regulation No 1768/92, so that the article is not infringed, it is necessary only to rectify the date of expiry of the certificate (see, in that connection, recital 17 and Article 17(2) of Regulation No 1610/96).

89 However, where a mistake has been committed regarding the date of the first marketing authorisation in the Community and it appears that that date is in point of fact prior to the relevant date fixed in Article 19(1) of Regulation No 1768/92, so that the article has been infringed, the certificate must be declared invalid pursuant to Article 15 of that regulation.

90 Article 19 of Regulation No 1768/92 cannot be interpreted independently but must be interpreted in conjunction with Article 3 thereof. However, as the Commission rightly pointed out, infringement of Article 19 is comparable to the case of the certificate being issued contrary to the requirements of Article 3.

91 That must be the outcome of non-compliance with the relevant date provided for in Article 19(1) of Regulation No 1768/92 even if it is not possible to infer from the wording or the origin of Article 15(1) of the aforementioned regulation that the list of grounds of invalidity of a certificate set out therein is not exhaustive.

92 The answer to the third question must therefore be that a certificate which, contrary to the requirements of Article 19 of Regulation No 1768/92, has been delivered where the first marketing authorisation in the Community was obtained prior to the relevant date fixed by that provision is invalid pursuant to Article 15 thereof.

## The fourth question

93 In view of the answer to the third question, it is unnecessary to reply to the fourth question.

## Costs

94 The costs incurred by the Danish, Spanish, French and Netherlands Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Sixth Chamber),

in answer to the questions referred to it by the Bundesgerichtshof by order of 1 February 2000, hereby rules:

1. **Consideration of the second question referred has disclosed no factor capable of affecting the validity of Article 19 of Council Regulation (EEC)**

No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

2. So far as concerns medicinal products for human use, the concept of 'first authorisation to place... on the market... in the Community' in Article 19(1) of Regulation No 1768/92 refers solely to the first authorisation required under provisions on medicinal products, within the meaning of 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, granted in any of the Member States, and does not therefore refer to authorisations required under legislation on pricing of or reimbursement for medicinal products.

3. A supplementary protection certificate which, contrary to the requirements of Article 19 of Regulation No 1768/92, has been delivered where the first marketing authorisation in the Community was obtained prior to the relevant date fixed by that provision is invalid pursuant to Article 15 thereof.

Skouris Gulmann Cunha Rodrigues

Schintgen Macken

Delivered in open court in Luxembourg on 11 December 2003.

R. Grass

Registrar

V. Skouris

President