JUDGMENT OF THE COURT (Second Chamber)

28 July 2011

(Patent law – Medicinal products – Supplementary protection certificate for medicinal products – Regulation (EEC) No 1768/92 – Article 2 – Scope – Safety and efficacy testing laid down by Directive 65/65/EEC – Absence – Invalidity of the certificate)

In Case C-195/09,

REFERENCE for a preliminary ruling under Article 234 EC from the High Court of Justice (England and Wales), Chancery Division (Patents Court) (United Kingdom), made by decision of 3 April 2009, received at the Court on 29 May 2009, in the proceedings

Synthon BV

v

Merz Pharma GmbH & Co. KGaA,

THE COURT (Second Chamber),

composed of J.N. Cunha Rodrigues, President of the Chamber, A. Arabadjiev, A. Rosas, U. Lõhmus (Rapporteur) and P. Lindh, Judges,

Advocate General: P. Mengozzi,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 9 December 2010,

after considering the observations submitted on behalf of:

– Synthon BV, by R. Williams, Barrister, and M. Herschdorfer, advocaat,

– Merz Pharma GmbH & Co. KGaA, by A. von Falck, Rechtsanwalt, and R. Anderson, Solicitor-Advocate,

– the European Commission, by H. Krämer, acting as Agent,

after hearing the Opinion of the Advocate General at the sitting on 31 March 2011,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 2, 13 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), as amended by the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21, and OJ 1995 L 1, p. 1; 'Regulation No 1768/92').

2 The reference has been made in proceedings between Synthon BV ('Synthon') and Merz Pharma GmbH & Co. KGaA ('Merz') concerning the supplementary protection certificate ('SPC') granted for the product called 'memantine'.

Legal context

European Union legislation

Regulation No 1768/92

3 The first to fourth recitals and the eighth recital in the preamble to Regulation No 1768/92 state:

'Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;

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;

…

Whereas the duration of the protection granted by the [SPC] should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and [an SPC] should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community'.

4 Article 1 of Regulation No 1768/92, entitled 'Definitions', provides:

'For the purposes of this Regulation:

...

(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

...'.

5 Article 2 of that regulation, entitled 'Scope', is worded as follows:

'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 [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. 24), as amended by Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11; "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), as amended by Council Directive 90/676/EEC of 13 December 1990 (OJ 1990 L 373, p. 15)], may, under the terms and conditions provided for in this Regulation, be the subject of [an SPC].'

6 Article 3 of Regulation No 1768/92, entitled 'Conditions for obtaining [an SPC]', provides:

'[An SPC] 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] or Directive [81/851], as appropriate …;

(c) the product has not already been the subject of [an SPC];

(d) the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product.'

7 Article 4 of Regulation No 1768/92, entitled 'Subject-matter of protection', provides:

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

8 According to Article 8(1) of Regulation No 1768/92, the application for an SPC is to contain:

'(a) a request for the grant of [an SPC], 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] or Article 5a of Directive [81/851];

(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.'

9 Article 9 of Regulation No 1768/92, entitled 'Lodging of an application for [an SPC]', provides:

'1. The application for [an SPC] shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

2. Notification of the application for [an SPC] shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:

...

(d) the number and date of the authorisation to place the product on the market, referred to in Article 3(b), and the product identified in that authorisation;

(e) where relevant, the number and date of the first authorisation to place the product on the market in the Community.'

10 Article 11(1)(d) and (e) of Regulation No 1768/92 provides that the number and date of the authorisation to place the product on the market referred to in Article 3(b) of the regulation, the product identified in that authorisation and, where relevant, the number and date of the first authorisation to place the product on the market in the Community must be included in the notification of the fact that an SPC has been granted, published by the authority referred to in Article 9(1) of the regulation.

11 Article 13 of Regulation No 1768/92, relating to the duration of the SPC, provides:

'1. The [SPC] 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.

2. Notwithstanding paragraph 1, the duration of the [SPC] may not exceed five years from the date on which it takes effect.'

12 Article 15 of Regulation No 1768/92 provides:

'1. The [SPC] shall be invalid if:

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

...

2. Any person may submit an application or bring an action for a declaration of invalidity of the [SPC] before the body responsible under national law for the renovation of the corresponding basic patent.'

13 Article 19 of the regulation, relating to transitional provisions, provides:

'1. Any product which, on the date of accession, 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 or within the territories of Austria, Finland or Sweden was obtained after 1 January 1985 may be granted [an SPC].

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

...

2. An application for [an SPC] as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force.'

Directive 65/65

14 Chapter II of Directive 65/65, entitled 'Authorisation to place medicinal products on the market', comprised Articles 3 to 10.

15 Article 3 of Directive 65/65 provided:

'No medicinal product may be placed on the market in a Member State unless an authorisation has been issued by the competent authority of that Member State.'

16 The second paragraph of Article 4 of that directive listed the particulars and documents that were to accompany the application for marketing authorisation, which included, in particular, the result of any safety and efficacy testing on the product concerned, that is, the results of physico-chemical, biological or microbiological tests, pharmacological and toxicological tests, and clinical trials.

17 Under Article 5 of that directive, the marketing authorisation was to be refused if, 'after verification of the particulars and documents listed in Article 4, it prove[d] that the medicinal product [was] harmful in the normal conditions of use, or that its therapeutic efficacy [was] lacking or [was] insufficiently substantiated by the applicant, or that its qualitative and quantitative composition [was] not as declared.' Authorisation was likewise to be refused 'if the particulars and documents submitted in support of the application [did] not comply with Article 4.'

18 Article 24 of that directive provided:

'Within the time-limits and under the conditions laid down in Article 39(2) and (3) of Second [Council] Directive 75/319/EEC [of 20 May 1975 on the approximation of provisions laid down by law, regulation and administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13)], the rules laid down in this Directive shall be applied progressively to medicinal products

covered by an authorisation to place on the market by virtue of previous provisions.'

Directive 75/319

19 It is clear from Article 39(2) of Directive 75/319 that the period given to Member States to apply progressively the provisions of that directive to medicinal products placed on the market by virtue of previous provisions expired on 21 May 1990.

20 According to Article 39(3) of that directive, Member States were to notify the Commission of the European Communities, by 21 May 1978 at the latest, of the number of medicinal products covered by Article 39(2) and, each subsequent year, of the number of those products for which a marketing authorisation referred to in Article 3 of Directive 65/65 had not yet been issued.

National legislation

21 In Germany, under Paragraph 3 of Annex 7 to the Law restructuring the legislation on medicinal products (Gesetz zur Neuordnung des Arzneimittelrechts) of 24 August 1976 ('the German Law of 1976'), which transposed Directive 65/65, products already on the market in Germany which remained there on 1 January 1978, the date on which that Law entered into force, were automatically granted continuing authorisation without further enquiry, subject to a requirement of notification. Provided notification occurred within six months of 1 January 1978, that authorisation was to remain in force for twelve years as of that date.

22 In Luxembourg, the provisions of Directive 65/65 were transposed by the Law of 11 April 1983 regulating the placing on the market and advertising of proprietary medicinal products and ready-made medicinal products (Loi portant réglementation de la mise sur le marché et de la publicité des spécialités pharmaceutiques et des médicaments préfabriqués) (*Mémorial* A 1983, p. 702; 'the Luxembourg Law of 1983'). The grand-ducal regulation of 29 April 1983 provided for the implementation of that Law.

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

23 It is apparent from the file that before 1 September 1976 Merz was already offering memantine for sale on the German market as a medicinal product for human use under the brand name Akatinol. That product, used in the treatment of Parkinson's disease and for other indications, was covered by an authorisation issued in accordance with German legislation from 1961, which did not provide for medicinal products to be tested for safety or efficacy. Under Paragraph 3 of Annex 7 to the German Law of 1976, memantine was granted a marketing

authorisation in Germany ('the German marketing authorisation') without going through the procedures required under Directive 65/65.

24 On 30 June 1983, Merz applied to the competent Luxembourg authorities for a marketing authorisation for that medicinal product, which was issued on 19 September 1983 under the Luxembourg Law of 1983 ('the Luxembourg marketing authorisation'). However, those authorities relied on the German marketing authorisation issued previously and did not test the safety and efficacy of memantine.

25 On 14 April 1989, Merz applied for a European patent for memantine hydrochloride. The order for reference states that that patent was granted notwithstanding the fact that memantine was already available commercially, on the ground that the patent was for a second medical use of memantine, that is, for the preparation of a medicinal product to treat Alzheimer's disease. The patent expired on 13 April 2009.

26 The order for reference states that the German and Luxembourg marketing authorisations were withdrawn when, on 15 May 2002, a series of marketing authorisations valid within the European Community ('the 2002 marketing authorisations') were issued to H. Lundbeck A/S, the licensee of Merz, pursuant to 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 authorisation was for the medicinal product Ebixa, the brand name adopted in order to market that second medical use of memantine. It is apparent from the written observations lodged by Merz that, before that authorisation was issued, the safety and efficacy of Ebixa had been tested by the European Agency for the Evaluation of Medicinal Products, in accordance with Directive 65/65.

27 On 13 November 2002, Merz made an application to the United Kingdom Patent Office for an SPC for memantine. In its application, Merz referred to the basic patent valid in the United Kingdom and also to the 2002 marketing authorisation, but not the German or Luxembourg marketing authorisations. The SPC was granted on 14 August 2003 for a term of five years.

28 By its action before the High Court of Justice (England and Wales), Chancery Division (Patents Court), Synthon, a manufacturer of generic medicinal products, requests that the SPC be declared invalid or that its term of protection be fixed at zero.

29 Since the High Court of Justice had doubts as to both the scope of Regulation No 1768/92 and the definition of 'first authorisation to place … on the market in the Community', within the meaning of Articles 13 and 19 of that regulation, it

decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) For the purposes of Articles 13 and 19 of [Regulation No 1768/92], is an authorisation a "first authorisation to place … on the market in the Community" if it is granted in pursuance of a national law which is compliant with [Directive 65/65], or is it necessary that it be established in addition that, in granting the authorisation in question, the national authority followed an assessment of data as required by the administrative procedure laid down in that directive?

(2) For the purposes of Articles 13 and 19 of [Regulation No 1768/92], does the expression "first authorisation to place … on the market in the Community" include authorisations which had been permitted by national law to co-exist with an authorisation regime which complies with [Directive 65/65]?

(3) Is a product which is authorised to be placed on the market for the first time in the EEC without going through the administrative procedure laid down in [Directive 65/65] within the scope of [Regulation No 1768/92] as defined by Article 2?

(4) If not, is an SPC granted in respect of such a product invalid?'

The application for the oral procedure to be reopened

30 By letter of 24 May 2011, Merz requested the reopening of the oral procedure, maintaining, in essence, that in his Opinion the Advocate General examined the issue of the second medical use of the product – an issue developed by the Commission in Case C-427/09 *Generics (UK)* [2011] ECR I-0000 – on the basis of Article 4 of Regulation No 1768/92, without the parties having considered that article or that issue in their written observations.

31 Having regard to the very purpose of the adversarial procedure, which is to avoid a situation in which the Court may be influenced by arguments which could not have been discussed by the parties, the Court may of its own motion, or on a proposal from the Advocate General, or at the request of the parties, order the reopening of the oral procedure in accordance with Article 61 of its Rules of Procedure if it considers that it lacks sufficient information, or that the case must be dealt with on the basis of an argument which has not been debated between the parties (see, inter alia, order in Case C-17/98 *Emesa Sugar* [2000] ECR I-665, paragraph 18, and Case C-42/07 *Liga Portuguesa de Futebol Profissional and Bwin International* [2009] ECR I-7633, paragraph 31 and the case-law cited).

32 In the present case, having heard the Advocate General, the Court considers, however, that it has all the material necessary to answer the questions referred and that the observations submitted before it at the hearing, inter alia by Merz, related to that material.

33 Consequently, the request that the oral procedure be reopened must be rejected.

Consideration of the questions referred

The third question

34 By its third question, which should be examined first, the national court asks, in essence, whether Article 2 of Regulation No 1768/92 must be interpreted as meaning that a product which was placed on the market in the Community as a medicinal product for human use without first being subject to an administrative authorisation procedure as laid down in Directive 65/65, and, in particular, to safety and efficacy testing, is within the scope of that regulation and may, therefore, be the subject of an SPC.

35 It follows from Article 2 of Regulation No 1768/92 that, for the purposes of obtaining an SPC, the product concerned must be protected by a valid patent in the national territory and it must have been subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 65/65.

36 As regards, first, the concept of 'placing … on the market', for the purposes of Article 2 of Regulation No 1768/92, Merz submits that it refers to the market of the Member State in which the application for a patent was submitted. A product is within the scope of the regulation provided that it is protected by a valid patent in the territory of the Member State in question and has been subject, prior to being placed on the market of that Member State as a medicinal product, to an administrative authorisation procedure as laid down in Directive 65/65, for that Member State.

37 In that connection, it is not apparent from the wording of Article 2 of Regulation No 1768/92 whether in using the concept of 'placing … on the market' the legislature intended to refer to the Community market or the market of the Member State for which the SPC application was submitted and in whose territory the patent is valid.

38 In those circumstances, in order to determine the market to which Article 2 refers, that provision must be interpreted in the light of the context in which it occurs and the objective pursued by the rules of which it is part (see, to that effect, Case 292/82 *Merck* [1983] ECR 3781, paragraph 12; Case C-34/05 *Schouten* [2007] ECR I-1687, paragraph 25; Case C-466/07 *Klarenberg* [2009] ECR I-803,

paragraph 37, and Case C-433/08 *Yaesu Europe* [2009] ECR I-11487, paragraph 24).

39 As regards the context of Article 2 of Regulation No 1768/92, it is true, as Merz argues, that the reference in that provision to the 'protect[ion] by a patent in the territory of a Member State' could imply that the market referred to by that provision is the national market of the Member State in respect of which the SPC is applied for. That interpretation would, moreover, be consistent with the concept of an SPC as a national right.

40 However, as the Advocate General has observed at point 39 of his Opinion, such an interpretation would mean that the conditions laid down for obtaining an SPC, listed in Article 3(a) and (b) of Regulation No 1768/92 – namely, that a product is protected by a basic patent in the Member State in which the application for an SPC was submitted and has obtained marketing authorisation as a medicinal product in that Member State in accordance with Directive 65/65 – would already be provided for in Article 2 of that regulation. It follows that Article 2 would simply replicate the content of Article 3(a) and (b) of the regulation. Such an interpretation would therefore deprive Article 2 of any raison d'être.

41 Indeed, as is apparent from the respective headings of Articles 2 and 3 of Regulation No 1768/92, namely, 'Scope' and 'Conditions for obtaining [an SPC]', first, Article 2 of that regulation seeks to determine in a general manner which products may be the subject of an SPC and, then, Article 3 sets out the conditions under which those products may be granted an SPC.

42 Those considerations therefore militate against interpreting the word 'market' in Article 2 of Regulation No 1768/92 as referring to the market of a Member State. On the contrary, they imply that the Community market is being referred to.

43 As regards, second, the administrative authorisation procedure to which the product, as a medicinal product, must be subject, as laid down in Directive 65/65, it follows from Article 3(b) of Regulation No 1768/92 and from Article 3 of Directive 65/65 that that procedure is the one referred to in Chapter II of that directive, for obtaining a marketing authorisation. That procedure includes testing the safety and efficacy of the medicinal product, the results of which must accompany the application for marketing authorisation, in accordance with Article 4(2) of Directive 65/65.

44 It follows from this that Article 2 of Regulation No 1768/92 must be interpreted as meaning that only a product which is protected by a valid patent in the territory of the Member State concerned and which obtained a marketing authorisation after being subject, prior to being placed on the market in the Community as a medicinal product, to an administrative authorisation procedure as laid down in

Directive 65/65, which included safety and efficacy testing, could be the subject of an SPC.

45 That interpretation of Article 2 of Regulation No 1768/92 is borne out by the objective pursued by that regulation.

46 As is apparent from the first to fourth recitals in the preamble to Regulation No 1768/92, in order to ensure sufficient protection to encourage pharmaceutical research, that regulation seeks, through the creation of an SPC for medicinal products granted marketing authorisation, to make up for the fact that the period of effective protection under the patent is insufficient to cover the investment put into the research, given the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place that product on the market (see, to that effect, in particular, Case C-110/95 *Yamanouchi Pharmaceutical* [1997] ECR I-3251, paragraph 7; Case C-392/97 *Farmitalia* [1999] ECR I-5553, paragraph 19; and Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295, paragraph 30).

47 It would be contrary to that objective of offsetting the time taken to obtain a marketing authorisation – which requires long and demanding testing of the safety and efficacy of the medicinal product concerned – if an SPC, which amounts to an extension of exclusivity, could be granted for a product which has already been sold on the Community market as a medicinal product before being subject to an administrative authorisation procedure as laid down in Directive 65/65, including safety and efficacy testing.

48 In addition, the interpretation of Article 2 of Regulation No 1768/92 put forward by Merz would give rise to a difference in treatment between certain products placed on the market before the date laid down in Article 19(1) of the regulation, which is not justified in the light of the objective pursued by the regulation. Whereas – as a result of Article 19(1) – products issued with a compliant marketing authorisation before that date cannot be granted an SPC even if that authorisation was issued in accordance with Directive 65/65, products marketed before that date on a non-compliant basis which would have obtained a marketing authorisation in a Member State, in accordance with Directive 65/65, after that date could be granted an SPC.

49 In the present case, it is common ground that memantine was marketed as a medicinal product in the Community under the German and Luxembourg authorisations at issue in the main proceedings, without having first undergone safety and efficacy testing as prescribed by Directive 65/65. Such testing was carried out for the first time when the 2002 marketing authorisation was issued.

50 It follows that such a product is not within the scope of Regulation No 1768/92, as defined by Article 2 thereof, and may not, therefore, be the subject of an SPC.

51 In the light of all the foregoing, the answer to the third question is that Article 2 of Regulation No 1768/92 must be interpreted as meaning that a product, such as that at issue in the main proceedings, which was placed on the market in the Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with Directive 65/65, and, in particular, without undergoing safety and efficacy testing, is not within the scope of Regulation No 1768/92 and may not, therefore, be the subject of an SPC.

The fourth question

52 By its fourth question, the national court asks, in essence, whether an SPC granted for a product outside the scope of Regulation No 1768/92, as that scope is defined by Article 2 thereof, is invalid.

53 The grounds on which an SPC is invalid are set out in Article 15 of that regulation. Infringement of Article 2 of the regulation is not included among those grounds.

54 By contrast, under Article 15(1)(a) of Regulation No 1768/92, the SPC is to be invalid if it was granted contrary to the provisions of Article 3 of that regulation.

55 The Court has already held, at paragraphs 90 and 91 of the judgment in Case C-127/00 *Hässle* [2003] ECR I-14781, that, even if it is not possible to infer from the wording or the origin of Article 15(1) of the regulation that the list of grounds of invalidity of an SPC set out therein is not exhaustive, the infringement of an article of that regulation not referred to in Article 15(1) – in the present case Article 19 of the regulation – can render an SPC invalid owing to the connection between the provision in question and Article 3 of the regulation.

56 The concept of 'product' in Article 3 of Regulation No 1768/92 refers necessarily to a product within the scope of that regulation, as defined in Article 2 thereof. Consequently, issuing an SPC for a product outside the scope of that regulation disregards the meaning of 'product'. Therefore, an SPC issued in such circumstances is invalid pursuant to Article 15 of Regulation No 1768/92.

57 Consequently, the answer to the fourth question is that an SPC granted for a product outside the scope of Regulation No 1768/92, as that scope is defined in Article 2 of that regulation, is invalid.

The first and second questions

58 In view of the answers to the third and fourth questions, there is no need to answer the first and second questions.

Costs

59 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 (Second Chamber) hereby rules:

1. **Article 2 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, as amended by the Act concerning the conditions of accession of the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded, must be interpreted as meaning that a product, such as that at issue in the main proceedings, which was placed on the market in the European Community as a medicinal product for human use before obtaining a marketing authorisation in accordance with 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, as amended by Council Directive 89/341/EEC of 3 May 1989, and, in particular, without undergoing safety and efficacy testing, is not within the scope of Regulation No 1768/92, as amended, and may not, therefore, be the subject of a supplementary protection certificate.**

2. **A supplementary protection certificate granted for a product outside the scope of Regulation No 1768/92, as amended, as that scope is defined in Article 2 of that regulation, is invalid.**

[Signatures]

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* Language of the case: English.