Court of Justice EU, 28 July 2011, Synthon v Merz

PATENT LAW - SPC

Supplementary Protection Certificate ('SPC') only available for medicinal products with a market authorisation under Directive 65/65 having undergone safety and efficacy tests

- **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 me-dicinal product for human use before obtaining a mar-keting 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.**

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Court of Justice EU, 31 March 2010

(J.N. Cunha Rodrigues, A. Arabadjiev, A. Rosas, U. Lõhmus and P. Lindh)

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]

OPINION OF ADVOCATE GENERAL MENGOZZI

delivered on 31 March 2011 (1)
Case C‑195/09
Synthon BV
v Merz Pharma GmbH & Co KG
(Reference for a preliminary ruling from the High Court of Justice (Chancery Division) (United Kingdom))
(Regulation No 1768/92 – Supplementary protection certificate – Conditions for its grant – Concept of first marketing authorisation)
1. Under the Community harmonising legislation concerning medicinal products, such products may be placed on the market only on completion of a lengthy authorisation procedure, introduced in order to protect public health. As a result, there are cases in which it may not be possible to begin exploiting patents for medicinal products until several years after they have been conferred. Introduced by Regulation 1768/92, (2) the supplementary protection certificate (SPC) is designed specifically to limit the extent to which the period of exclusive use of such patents may be eroded. (3)
2. In this case, four questions for a preliminary ruling have been raised concerning the interpretation of Articles 13 and 19 of the regulation. Those questions arose in the context of a dispute between Synthon BV ('Synthon') and Merz Pharma GmbH & Co KGaA ('Merz') concerning the validity and term of an SPC granted to Merz by the United Kingdom Trade Mark

Office for an active ingredient which had already been present on the market for several years, although as an ingredient in a medicinal product used for different therapeutic purposes from those described in the basic patent. In essence, the national court asks the Court of Justice to clarify whether the authorisations to place that medicinal product on the market, which were accorded to Merz in two Member States without the product's being subjected to the tests of efficacy and safety required under Community harmonising legislation, must, in any event, be taken into account in determining the validity and term of the SPC granted to Merz.

I – Legislative background

A – European Union law

1. Directives 65/65/EEC and 75/319/EEC

3. According to Article 3 of Council Directive 65/65/EEC of 26 January 1965 (4) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, in the version applicable to the facts of the main proceedings, (5) no proprietary medicinal product (6) may be placed on the market in a Member State unless an authorisation has been issued by the competent authority of that Member State.

4. In order to obtain that authorisation, the person responsible for placing the product on the market had to submit to the competent authority of the Member State concerned an application supported by the particulars and documents specified in Article 4(2) of the directive. As well as information such as the qualitative and quantitative particulars of all the constituents of the proprietary product, a brief description of the method of preparation, the therapeutic indications, contra-indications and side-effects, posology and a description of the control methods employed by the manufacturer, Article 4(8) of the directive listed, among the particulars and documents that were to accompany the application, the results of physico-chemical, biological or microbiological tests, pharmacological and toxicological tests and clinical trials.

5. Directive 75/319 (7) laid down the procedures to be used by the Member States when examining SPC applications. These included, in particular, the possibility of submitting the proprietary medicinal product for testing by a State laboratory and of requesting additional documentation.

6. According to Article 5 of Directive 65/65:

'The authorisation provided for in Article 3 shall be refused if, after verification of the particulars and documents listed in Article 4, it proves that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared'.

7. According to Article 24 of Directive 65/65, as replaced by Article 37 of Directive 75/319:

'Within the time limits and under the conditions laid down in Article 39(2) and (3) of second Directive 75/319/EEC, the rules laid down in this directive shall be applied progressively to proprietary medicinal products covered by an authorisation to place on the market by virtue of previous provisions'.

8. According to Article 39(2) and (3) of Directive 75/319:

'2. Within 15 years of the notification referred to in Article 38, the other provisions of this directive shall be applied progressively to proprietary medicinal products placed on the market by virtue of previous provisions.

3. Member States shall notify the Commission, within three years following the notification of this Directive, of the number of proprietary medicinal products covered by paragraph 2, and, each subsequent year, of the number of these products for which a marketing authorisation referred to in Article 3 of Directive 65/65/EEC, has not yet been issued'.

9. According to Article 22 of Directive 65/65, 'Member States shall put into force the measures needed in order to comply with this directive within 18 months of its notification (8) and shall inform the Commission forthwith'.

2. Regulation No 1768/92

10. The reason for extending the duration of the protection conferred by the patent in the case of medicinal products is set out in the preamble to Regulation No 1768/92 (9) ('the regulation'). According to recitals 3, 4, 6 and 7 in particular:

'[w]hereas 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;

[w]hereas this situation leads to a lack of protection which penalises pharmaceutical research;

[...]

[w]hereas 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 functioning of the internal market;

[w]hereas, therefore, the creation of a supplementary protection 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 is necessary; whereas a regulation is therefore the most appropriate legal instrument;

11. Under Article 1 of the regulation: '[f]or the purposes of this regulation:

(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

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

(c) “basic patent” means a patent which protects as defined in (b) 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 grant of a certificate’.

12. Article 2 of the regulation, entitled ‘Scope’ 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 authorization procedure as laid down in ... Directive 65/65 ... may, under the terms and conditions provided for in this regulation, be the subject of a certificate’.

13. Under Article 3 of the regulation, entitled ‘Conditions for obtaining a certificate’:

‘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 ... . For the purpose of Article 19 (1), an authorisation to place the product on the market granted in accordance with the national legislation of Austria, Finland, or Sweden is treated as an authorisation granted in accordance with Directive 65/65/EEC;

(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’.

14. 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 and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

15. Under Article 7(1) and (2) of the regulation, the application for a certificate is to be lodged within six months of the date on which the authorisation to place the product on the market was granted or within six months of the date on which the basic patent was granted, if later.

16. Under Article 8(1)(a), (b) and (c) of the regulation:

‘The application for a certificate shall contain:

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

[...]

(iii) the number of the basic patent and the title of the invention;

(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 ...;

(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’.

17. Under Article 9(1) of the regulation, the application for a certificate must 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. Under Article 9(2), notification of the application for a certificate is be published by the authority referred to in paragraph 1, and must state, inter alia, the number and date of the authorisation to place the product on the market, referred to in Article 3(b), as well as the product identified in that authorisation (Article 9(1)(d)) and, where relevant, the number and date of the first authorisation to place the product on the market in the Community (Article 9(1)(e)). Under Article 11, the same information must appear in the publication containing the notification of the fact that a certificate has been granted.

18. Article 13(1) and (2) of the regulation, entitled ‘Duration of the certificate’:

‘1. The 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.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect’.

19. Article 15 of the regulation sets out the reasons for which a certificate is invalid. According to Article 15(1):

‘1. 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’.

20. Finally, in its original version, (10) Article 19(1) laid down the following transitional provision:

‘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'.

B – National legislation

21. In Germany, Directive 65/65 was transposed by the Gesetz zur Neuordnung des Arzneimittelrechts of 24 August 1976 (Law restructuring the legislation on medicinal products: the 'AMG 1976'). Under Article 3(7) of the AMG 1976, medicinal products which were present on the market on 1 September 1976, the date of its publication, and were still on the market on 1 January 1978, the date of its entry into force, automatically continued to be authorised for a period of 12 years, subject to notification. Under the system previously in force, the placing of medicinal products on the market was not subject to any test of efficacy and/or safety.

22. In Luxembourg, the directive was transposed by the grand-ducal regulation of 29 April 1983 implementing 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). Article 3 of the law makes the placing on the market of a proprietary medicinal product or ready-made medicinal product subject to the grant of prior authorisation by the Ministry of Health.

II – The dispute in the main proceedings and the questions referred

23. Before 1 September 1976, Memantine was marketed in Germany, under the trade mark Akatinol, (11) in accordance with the system in force at that time. On application from Merz, the trade mark holder and defendant in the main proceedings, the placing on the market of Akatinol was authorised on the basis of Article 3(7) of the AMG 1976. Granted as of 26 June 1976, that authorisation to place Akatinol on the market ('the German marketing authorisation') expired on 1 January 1990. (12) Akatinol appears, however, to have remained on the market in Germany until 9 July 2002.

24. On 30 June 1983, Merz applied for authorisation to place memantine on the market in Luxembourg. That authorisation was obtained from the Luxembourg Ministry of Health on 19 September 1983. Despite the fact that the grand-ducal regulation, cited at point 22 above, had already entered into force, the authorisation ('the Luxembourg marketing authorisation') was granted without carrying out the product efficacy and safety tests required under Directive 65/65, and was based solely on the earlier German authorisation.

25. On 14 April 1989, Merz applied for a European patent for the product memantine hydrochloride. According to Merz, in its written observations, its patent application comprised two separate claims for uses of adamantine derivatives (for the preparation of drugs to treat brain cell lesions caused by cerebral ischemia and for the preparation of a drug to treat Alzheimer's disease). Memantine hydrochloride is an adamantine derivative. The patent was granted on 15 September 1993 and expired on 13 April 2009 ('the basic patent'). According to the order for reference, the patent was granted despite the earlier commercial availability of memantine because it concerned a second medical use of memantine.

26. On 15 May 2002, the European Medicines Agency (EMA) granted H Lundbeck A/S, the licensee of Merz, a series of marketing authorisations, valid within Community territory, for the product memantine hydrochloride and the drug Ebixa, designed for the treatment of Alzheimer's disease (collectively designated: 'the 2002 marketing authorisation'). The German and Luxembourg marketing authorisations were, consequently, revoked.

27. On 13 November 2002, Merz applied to the United Kingdom Patent Office for an SPC, citing the basic patent and the 2002 marketing authorisation. The SPC was obtained on 14 August 2003 for a period of five years as of the expiry of the basic patent ('the Merz SPC' or the 'SPC at issue'). It therefore took effect as of 14 April 2009 and will expire on 13 April 2014.

28. Synthon, a manufacturer of generic drugs, brought an action before the High Court of Justice (Chancery Division) Patents Court, seeking revocation of Merz's SPC or a declaration that the latter's term of protection is fixed at zero.

29. By its action, Synthon claims that the 2002 marketing authorisation is not the first marketing authorisation for memantine as a medicinal product, for it had already been authorised, in 1983, in Luxembourg, as an ingredient of Akatinol. Merz's SPC is, therefore, invalid in that it fails to satisfy the requirements of Article 3 of the regulation or, in the alternative, is invalid or has zero term, pursuant to Article 13 of the regulation, because the first marketing authorisation in the Community predates the filing of the patent application. In the further alternative, Synthon claims that the SPC at issue is invalid because the first marketing authorisation in the Community was obtained before 1 January 1985 in breach of Article 19(1) of the regulation, or because memantine was marketed as a medicinal product before authorisation was obtained in accordance with Directive 65/65, in breach of Articles 2 and 3 of the regulation.

30. In its examination of the case, the national court entertained doubts concerning the proper interpretation of certain provisions of the regulation and submitted the four following questions for a preliminary ruling;

'(1) For the purposes of Articles 13 and 19 of Council Regulation (EC) 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 Council Directive 65/65/EEC, 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 Council Regulation (EC) 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 Council Directive 65/65/EEC?

(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 Council Directive 65/65/EEC within the scope of Council Regulation (EC) 1768/92 as defined by Article 2?
(4) If not, is an SPC granted in respect of such a product invalid?'

III – Procedure before the Court

31. Synthon, Merz and the Commission submitted written observations pursuant to Article 23 of the Statute of the Court of Justice and were heard at the hearing on 9 December 2010.

IV – Assessment

32. The third and fourth questions, by which the national court seeks to ascertain the substantive scope of the regulation, raise an issue that needs to be resolved before the points raised by the first and second questions can be settled. I shall therefore begin my analysis by examining that issue.

A – The third and fourth questions

33. By its third and fourth questions, the national court, in essence, asks the Court of Justice to clarify whether, on the one hand, the products for which a marketing authorisation under Directive 65/65 was granted after those products had first been placed on the market fall within the scope of the regulation, as defined by Article 2 thereof, and, on the other, if this is not the case, whether an SPC obtained for such products must be deemed to be invalid in accordance with the regulation.
34. According to Merz, only authorisations obtained in accordance with Directive 65/65 in the Member State in which the SPC application is made are covered by the regulation. It takes the view that a product placed on the market in the Community for the first time without adhering to the procedure laid down in the directive, as in the case of memantine, falls within the scope of the regulation if it is covered by a patent in the Member State in question and if, before being placed on the market in that Member State, it was subject to an administrative authorisation procedure pursuant to Directive 65/65. However, Synthon and the national court are of the view that memantine does not fall within the scope of the regulation, for it was marketed in the Community before a marketing authorisation consistent with Directive 65/65 was obtained.
35. Under Article 2 of the regulation, '[a]ny 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' may be the subject of a certificate.
36. The Court is asked, in essence, to clarify whether, as Merz contends, Article 2 refers to the placing on the market in the Member State in which the SPC application was made or, as Synthon argues, to the first placing on the market in the territory of the Community. (13)
37. Opting for either one or the other of the interpretations advanced on the basis of literal and/or systematic arguments does not appear to be easy, given that, as the parties to the main proceedings and the national court itself have pointed out, there are factors that argue for one interpretation and others that argue for the contrary interpretation.
38. In particular, it is certainly true, as Merz submits, that Article 2 refers to products covered by a patent in a Member State, and that it would, therefore, be logical to conclude that, when Article 2 refers to the placing of the product on the market, this must be construed as referring to the territory of that Member State. More generally, that interpretation would be consistent with the establishment of the SPC as a national intellectual property right.
39. However, it is also true that, if the expression 'placing on the market' were interpreted as Merz seeks to construe it, Article 2 would end up pointlessly duplicating Article 3, while it would seem logical to construe Article 2 as a provision defining the scope of the regulation, restricting it to 'new medicinal products', (14) that is to say, products which have been subject to a procedure under Directive 65/65 before being placed on the market in Community territory, and to interpret Article 3 as a provision laying down the conditions for obtaining an SPC.
40. In those circumstances, therefore, it is on the basis of the objectives of the regulation that the question referred for an interpretation by the High Court must be resolved.
41. As is evident from the preamble to the regulation (and recitals 2, 3 and 4 in particular), the purpose of the regulation is to limit the extent to which the duration of the exclusive right is eroded as a result of the implementation of the administrative authorisation procedure which, by delaying the placing of the product on the market, defers the point at which the patent can begin to be commercially exploited. In that way, the Community legislature sought to provide the Community pharmaceutical industry with a means of securing an adequate economic return on the investment needed for research, and to enable it to bridge the competitive gap with non-member countries.
42. At the same time, the regulatory scheme of the regulation is clearly based on striking a balance between the conflicting interests of, on the one hand, the pharmaceutical manufacturers and their licensees and, on the other, the generic medicines industry that stimulates price competition in the pharmaceuticals sector. Striking that balance has resulted in the imposition of a maximum time-limit on the exclusive right of exploitation guaranteed by the combination of patent and SPC – a time-limit which is, moreover, set at a level lower than is accorded under the patent (15 rather than 20 years).
43. The Court's case-law displays a tendency to adhere to the system based on that balance of interests. For instance, on the one hand, it protects the whole function of the regulation as an instrument for protecting the pharmaceuticals industry which relies on research, by guaranteeing the effectiveness of that research, (15) and, on the other, it ensures that such protection does

not go beyond the objectives pursued by the regulation itself. (16)
44. Moreover, the regulation is designed to provide a uniform solution at Community level to the problem of the inadequacy of the protection under patent and thus prevent the heterogeneous development of national laws. As emphasised by Advocate General Jacobs, '[t]hat uniformity [is] probably the most significant result of the certificate introduced by the regulation'. (17)
45. It is in the light of all of the factors set out in the preceding points that I tend towards the argument set out by Synthon. I do not, in fact, consider it compatible with the objectives of the regulation to extend the protection provided under the SPC to products which were already present on the Community market on a different basis before the marketing authorisation was obtained in accordance with Directive 65/65. (18)
46. On the one hand, it does not appear justified to confer that protection on products which, although covered by a patent in the Member State in which the certificate was applied for, and although marketed in that State only after having obtained marketing authorisation in accordance with the relevant Community legislation, were already on the market, in another part of Community territory, on a different basis and without the tests required under Community law having been carried out. The fact that, at the time when they were first placed on the market, those products may not have been covered by an exclusive marketing right is immaterial in that regard. (19)
47. On the other hand, if, in such cases, the protection afforded by the regulation were recognised, then the period of exclusive commercial exploitation of a patent-protected product, beginning when that product is first placed on the Community market, could, in certain specific cases, exceed the 20-year period of the patent's validity.
48. I do not consider that any other solution can be justified solely in view of the national character of the SPC. In point of fact, while there is no doubt that the regulation is designed to establish an intellectual property right of national character, one of its principal objectives remains, as we have seen, to ensure the uniformity of the rules on certificates issued within the territory of the Union, in particular as regards their duration and the overall extent in time of the guarantee of exclusivity. Were Merz's argument to be adopted, that objective would be undermined, not only for the reasons set out above, but also because that argument implies that, for one and the same product, it would be possible to obtain a certificate in some Member States (those in which a marketing authorisation was obtained in accordance with the Community law before the product was placed on the market in that State), but not in others (States in which the product had already been marketed earlier on a different basis).
49. Furthermore, the interpretation which Merz suggests would create an unjustified disparity of treatment in relation to products placed on the market before the date fixed by Article 19 of the regulation. In effect, for products for which marketing authorisation in accordance with Directive 65/65 was obtained before that date, the possibility of applying for an SPC would be precluded by that provision. However, the same would not apply to products placed on the market, before the date set by Article 19 of the regulation, on a different basis and for which marketing authorisation pursuant to Directive 65/65 was not obtained until after that date.
50. On the basis of the foregoing, I consider that, in accordance with Article 2 thereof, the regulation must be interpreted as meaning that products placed on the market as medicinal products in Community territory before a marketing authorisation in accordance with the relevant Community legislation has been obtained do not fall within the scope of the regulation. Having been obtained for a product which does not fall within the scope of the regulation, the SPC at issue in the main proceedings must be regarded as invalid. That finding flows from the interpretation of Article 2 proposed above, and it does not seem to me that Article 15 of the regulation, which lists the reasons why an SPC may be invalid, stands in its way.
51. In the light of the answers which I propose be given to the third and fourth questions, it is solely in the alternative, should the Court not agree with that solution, that I shall go on to assess the first and second questions.

B – The first and second questions

52. By its first and second questions, which it is appropriate to examine together, the national court asks, in essence, both whether a marketing authorisation obtained without the tests required under Article 4(8) of Directive 65/65 having been carried out may constitute a first marketing authorisation in the Community, for the purpose of Articles 13 and 19 of the regulation and, also, whether a marketing authorisation which is permitted, under the national law transposing the directive, to co-exist with a system of authorisation consistent with the directive may also constitute a first marketing authorisation. (20)
53. Article 13 of the regulation lays down the procedures for calculating the term of the SPC in such a way as to harmonise the date of expiry of the various national SPCs obtained in the territory of the Union. So, while, as Merz correctly points out, it is the first marketing authorisation obtained in the requested Member State which counts for the purposes of submitting the SPC application, when, on the other hand, it comes to calculating the term of the SPC, the marketing authorisation to be taken into consideration is the first marketing authorisation obtained in the Community. This may be the first marketing authorisation obtained in the requested Member State, but it can also be a marketing authorisation obtained earlier.
54. In this case, Merz maintains that the first marketing authorisation in the Community for the purpose of Article 13 is the 2002 marketing authorisation, for it was the first marketing authorisation for memantine that satisfied the substantive requirements of Directive 65/65. Synthon, however, contends that either the German marketing authorisation or the Luxembourg au-

thorisation should be regarded as the first marketing authorisation in the Community, despite the fact that neither was obtained after completion of the tests required under the directive.
55. The Court has already had occasion to interpret the concept of 'first authorisation to place on the market' in its judgments in Hässle (21) and Novartis, (22) which are cited by both parties in the main proceedings, although with contrary arguments.
56. In Hässle, the Court held that an authorisation provided for under a national law on the pricing of medicinal products, which must be obtained before those products can actually be marketed, cannot constitute a 'first authorisation to place on the market' pursuant to Article 19 of the regulation.
57. In Novartis, however, the Court found that the concept of 'first authorisation to place on the market' under Article 13 of the regulation, as it has to be construed for the purposes of interpreting the Agreement on the European Economic Area ('EEA Agreement'), includes a marketing authorisation granted by the Swiss authorities and automatically recognised by the Principality of Liechtenstein in the context of its regional union with Switzerland.
58. As the national court points out, neither of the solutions adopted by the Court in those judgments can automatically be transposed to this case.
59. Indeed, on the one hand, in Hässle, the Court was dealing with a national authorisation which was, by its very nature, different from a marketing authorisation under Directive 65/65, although comparable to such an authorisation in terms of the effects on the possibility of marketing the product. On the other hand, the interpretation of Article 13 of the regulation in Novartis is specifically restricted to the context of the application of the EEA Agreement.
60. Nonetheless, both precedents provide important interpretative guidance
61. In Hässle, the Court found, and did not mince its words, that '[t]here 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' and that 'those words cannot be construed as having a different meaning according to whether they appear in Article 3 or Article 19'. (23) Synthon's argument that different significance should be attributed to the concept of a marketing authorisation for the purposes of calculating the term of the SPC does not, therefore, appear to be tenable. The Court has in fact found unequivocally in favour of a uniform interpretation of that concept, wherever it appears in the regulation.
62. In the same judgment, and equally unambiguously, after stating that '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', the Court concluded 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 ... be a marketing authorisation issued in accordance with Directive 65/65'. (24)
63. The Court thus opted for a formalistic approach – founded on what are essentially reasons bound up with the need for legal certainty (25) – which differs from an approach that focuses to a greater degree on the objectives of the regulation, as set out in his Opinion in Novartis by Advocate General Ruiz Jarabo-Colomer. According to the approach taken by the latter, for the purposes of calculating the term of the SPC, the concept of 'first authorisation to place on the market in the Community' should extend to any measure which makes possible the lawful distribution of a medicinal product in a part of the Union's territory. (26)
64. In its judgment in Novartis, albeit in a specific context, the Court appears to have moderated the formalistic approach which it adopted in its judgment in Hässle. Without ever citing the latter judgment, the Court still included in the concept of first marketing authorisation in the EEA, in accordance with Article 13 of the regulation, a Swiss authorisation which was automatically recognised in the Principality of Liechtenstein and, therefore, clearly not consistent with Directive 65/65. At paragraphs 29 and 30 of the judgment, the Court's reasoning in reaching that finding is linear: since the EEA Agreement recognises that two types of marketing authorisation may co-exist in the Principality of Liechtenstein, namely marketing authorisations issued by the Swiss authorities which, because of the regional union between Switzerland and Liechtenstein, are automatically recognised in Liechtenstein, and marketing authorisations issued in Liechtenstein in accordance with Directive 65/65, the former, like the latter, must be taken into consideration for the purposes of applying Article 13 of the regulation. (27)
65. The High Court is not, however, of the view that the guidance which may be derived from the judgment in Novartis is sufficient to justify moving away from the Court's position in Hässle. Moreover, in a judgment handed down in the context of a dispute which arose in relation to an SPC application for memantine by Merz, in Germany, the German Patentgericht (Patent Court) took the view that the Court's position in its judgment in Hässle meant that neither the German market authorisation nor the Luxembourg market authorisation could be recognised as the first authorisation to place the product on the market in accordance with Article 13 of the regulation. (28)
66. It is necessary, at this juncture, to look in greater detail at the marketing authorisation in question.
67. It is not disputed that neither the German marketing authorisation, obtained by Merz following notification in accordance with Article 3(7) of the AMG 1976, nor the Luxembourg marketing authorisation, granted on the basis of the earlier German authorisation, was issued on the basis of dossiers containing the results of the toxicological and pharmacological tests and clinical trials required at the time under Directive 65/65. (29) Nor is it disputed that those results were not provided at

a later date during the period of validity of those marketing authorisations.
68. Both marketing authorisations were adopted under the respective national laws transposing Directive 65/65, but there are significant differences.
69. The German authorisation was granted in accordance with transitional arrangements, provided for under the national legislation transposing Directive 65/65, which exempted medicinal products already on the market from the application of the Community authorisation procedure for a period of 12 years as of 1 January 1978, provided that the competent authorities were notified. Those arrangements implemented Article 24 of that directive, in conjunction with Article 39 of Directive 75/319, and as amended by Article 37 of the latter, (30) which made it possible progressively to apply (31) the provisions of Directive 65/65 to medicinal products placed on the market before the directive's entry into force and, consequently, permitted, on a transitional basis, the circulation of medicinal products on which the requisite tests had not been carried out, as in the case of Akatinol.
70. The Luxembourg marketing authorisation, however, was granted solely on account of the fact that Akatinol was lawfully marketed in Germany on the basis of a so-called 'fictitious' authorisation ('fiktive Zulassung'). (32) Unlike the German authorisation, the Luxembourg authorisation was not, therefore, issued on the basis of national transitional arrangements implementing Article 24 of Directive 65/65.
71. Consequently, in order to answer the first and second questions, it is necessary to clarify whether a marketing authorisation with the features described above can be regarded as having been 'issued in accordance with Directive 65/65' within the meaning of the judgment in Hässle and can, therefore constitute a first authorisation to place on the market in the Community for the purposes of calculating the term of the SPC in accordance with Article 13, as well as for the purposes of the application of Article 19.
72. Pursuing the line of reasoning employed by the national court when drawing up the first and second questions, it is necessary to begin by considering whether a marketing authorisation which, although issued in accordance with the national legislation transposing Directive 65/65, did not comply with the administrative procedure laid down by the directive, may constitute a first marketing authorisation in accordance with Articles 13 and 19 of the regulation.
73. In my view, a marketing authorisation issued pursuant to the provisions transposing Directive 65/65 must certainly be regarded, where appropriate, as the 'first authorisation to place on the market in the Community', even if the administrative procedure laid down under the directive has not, in fact, been implemented or has not been properly implemented, particularly as regards the toxicological and pharmacological tests and clinical trials.
74. Indeed, in a case of that nature, although the marketing authorisation fails to satisfy the substantive requirements of Directive 65/65, it nonetheless fits, from a formal perspective, within the scheme of the directive. In those circumstances, it does not appear justified to impose on the authorities responsible for granting the SPC the burden of verifying whether the procedure followed for the purpose of granting a marketing authorisation, accorded on the basis of the national legislation transposing Directive 65/65, is compatible with the Community legislation. Moreover, the regulation itself does not require such verification. By requiring that the SPC application must state the number and date of the first authorisation to place the product on the market in the Community, information regarding the identity of the product, the legal provision under which the authorisation procedure took place and a copy of the notice publishing the authorisation in the appropriate official publication, Article 8(a)(iv) (b) and (c) of the regulation merely requires verification that the authorisation actually exists, as well as verification of the identity of the authorised product and, at most, purely formal verification that it was issued under harmonised legislation. (33)
75. In this case, however, the circumstances set out at point 73 above do not appear to be present. While it is true that both the German and the Luxembourg marketing authorisations were issued on the basis of the respective national provisions transposing Directive 65/65, neither may be regarded as having been issued pursuant to national provisions transposing the administrative authorisation procedure laid down by the directive. As we in fact saw earlier, the German marketing authorisation was obtained under the transitional arrangements permitted by Article 24 of the directive, and the Luxembourg marketing authorisation by virtue of the automatic recognition of the German marketing authorisation, by means of a mechanism falling outside the system of mutual recognition provided for by the directive, which relates solely to marketing authorisations issued on completion of the administrative procedure which it lays down.
76. In those circumstances, the marketing authorisations at issue cannot, in my view, be regarded as being 'consistent' with Directive 65/65. In particular, the Commission seems to me to go too far in arguing that in order to secure such compliance for the purposes of applying the provisions of the regulation, it is sufficient that the marketing authorisation was issued by the competent authorities of a State in which there is an obligation to refrain from authorising the placing on the market of medicinal products which have not been subjected to the procedure laid down by the directive. On the basis of that argument, in fact, it would also be necessary to regard authorisations that may have been issued on the basis of national provisions which are not those transposing the directive as being consistent with Directive 65/65. (34)
77. Having ruled out the possibility that the German and Luxembourg marketing authorisations obtained by Merz for memantine and Akatinol can be deemed to be 'consistent' with Directive 65/65, it is necessary to consider whether, nonetheless, as Synthon contends, such authorisations may, none the less, be taken into

account in determining which was the first marketing authorisation in the Community for memantine.
78. In my view, particularly as regards the German marketing authorisation, the answer must be in the affirmative, based on a line of reasoning similar to that set out by the Court at paragraphs 29 and 30 of its judgment in Novartis which may well extend beyond the specific context of that case.
79. Since Directive 65/65 permitted, albeit on a transitional basis, the possible co-existence in the Member States of two authorisation regimes, namely, the regime actually established by the directive and the regime permitted under Article 24 thereof, authorisations issued on the basis of Article 24 must, if appropriate, be regarded as the first marketing authorisations within the meaning of Articles 13 and 19 of the regulation. In this case, that would be the German marketing authorisation.
80. That solution is consistent with the rationale underlying the regulation which, as we have seen, is designed to limit the extent to which the period of exclusivity under the patent is eroded as a result of the time elapsing between the filing of the patent application and the completion of the administrative procedure for marketing the product required under Directive 65/65, but without exceeding a 15-year period of exclusive use, which the legislature considered appropriate in order to strike a balance between the conflicting interests involved. (35) If, when calculating the term of the SPC, account were not taken of the authorisations issued under national arrangements set in place pursuant to Article 24 of Directive 65/65, it would be possible to retain for far longer marketing exclusivity for products covered by a patent at the time they were placed on the market. Furthermore, as emphasised by Synthon, the contrary solution would have the perverse effect of allowing reappraisal of the period of exclusivity under the patent without taking account of the fact that, as in the case of memantine, it was possible for the product in question to be in circulation under transitional arrangements without satisfying the requirements of Community law. (36).

81. In my view, the same solution should also apply in circumstances in which the system selected by the Member State in order progressively to achieve compliance with the provisions of the directive in relation to medicinal products which have already been placed on the market, as laid down by Article 24 of Directive 65/65 and Article 39 of Directive 75/319, provides not for the grant of new authorisations (those described as fictitious or post-marketing authorisations), as in the case of Germany, but solely for extension of the validity of the original authorisations. (37) In such cases, the reference point for the application of Articles 13 and 19 of Directive 65/65 should be the date on which that extension first takes effect.
82. I do not, however, consider that significance need be attached to the period before that extension or the grant of a post-marketing authorisation. In effect, it is only on the basis of an extension or authorisation of that nature that the circulation of the medicinal products placed on the market of one Member State, pursuant to provisions which predate the entry into force of Directive 65/65, may be regarded as lawful under the provisions of that directive, albeit solely on a transitional basis and subject to subsequent compliance with its requirements (see the conditions laid down in Article 39(2) and (3)) [of Directive 75/319/EEC]. Consequently, I do not consider that the basis on the strength of which a medicinal product of that nature was originally placed on the market may be regarded as the first marketing authorisation in the Community, even if it does coincide with the time when the marketing of the product in Community territory was authorised for the first time.
83. Moreover, a finding of that nature satisfies the requirements of legal certainty to which the Court itself referred in its judgment in Hässle, (38) and also the requirement that the rules on the SPC be uniform and simple to apply, to which particular emphasis was attached during the legislative process for the adoption of the regulation. Verifying the existence and the date of initial validity of national authorisations granted prior to the harmonisation brought about by Directive 65/65 may prove to be a complex process, whereas it is certainly simpler to undertake that verification when it turns on the authorisation based on which medicinal products already placed on the market may continue to be marketed lawfully under the transitional arrangements set in place by Directive 65/65.
84. Before I draw the conclusions from the above analysis, it is necessary to consider a further issue which, although it was not raised by the national court may, nonetheless, influence the answer to be given to the first and second questions and, more generally, the solution of the dispute before it.
85. That issue, on which the parties in the main proceedings had the opportunity to state a view at the hearing, is raised by the Commission in the context of the request for a preliminary ruling referred by the Court of Appeal in the case of Generics v Synaptech, which was mentioned earlier, and it concerns the possibility of taking into account, when determining the term of the SPC, an authorisation issued for a use of the product different from that protected by the basic patent. In essence, relying on the text of Article 4 of the regulation, the Commission argues that the protection conferred by the SPC covers all of the uses of the product for which a marketing authorisation has been obtained, provided that those uses are caught by the subject-matter of the basic patent. According to the Commission, it follows that, for the purposes of applying Articles 13 and 19 of the regulation, it is not possible to regard as the first marketing authorisation in the Community a marketing authorisation issued for a product use other than the use or uses covered by the basic patent.
86. I do not find the Commission's argument compelling. Article 4 of the regulation defines the subject-matter of the protection conferred by the SPC, making it clear both that such protection extends only to the protection conferred by the basic patent and that the

SPC covers any subsequent marketing authorisation in relation to the product's use as a medicinal product granted during the term of validity of the SPC, thereby precluding the possibility of obtaining an SPC for each marketing authorisation for the product obtained in a single Member State.

87. However, Article 13 of the regulation concerns the duration of the SPC and Article 19 introduces transitional provisions laying down certain conditions governing the issuing of the SPC. It is apparent from both the wording and scheme of those provisions that the marketing authorisation in the Community to which they refer is the first marketing authorisation for the product as a medicinal product. (39) For the purposes of the application of those articles, no reference is made to a specific therapeutic use, still less to the use or uses covered by the basic patent, despite the fact that the regulation provides specifically that a basic patent may cover both a product as such and an application of that product. (40)

88. The regulation therefore justifies an interpretation according to which, for the purposes of the application of Articles 13 and 19, the first marketing authorisation for the product as a medicinal product must be regarded as the first marketing authorisation in the Community, regardless of the kind of medical use which constitutes the subject-matter of that authorisation and regardless of whether that use may possibly be the same as the use protected by the basic patent.

89. That interpretation is, above all, in keeping with the concept of product for the purpose of the regulation, as interpreted by the Court's case-law. I would point out, in that connection, that, according to Article 1(b) of the regulation, product means 'the active ingredient or combination of active ingredients of a medicinal product'. In its judgment in Massachusetts Institute of Technology, the Court provided clarification that the concept of 'product', within the meaning of Article 1(b) of the regulation, must be interpreted in the strict sense of an 'active substance' or 'active ingredient'. (41) Relying on that judgment, in its Order in Yissum, the Court explained that the concept of product 'cannot include the therapeutic use of an active ingredient protected by a basic patent' and that 'Article 1(b) of Regulation No 1768/92 is to be interpreted as meaning that in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product'. (42)

90. Moreover, the interpretation suggested at point 88 above is borne out by a number of the Court's judgments. In its judgment in Pharmacia Italia, the Court held 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'. (43) At paragraph 20 of that judgment, after recalling, in paragraph 19, the concept of 'product' within the meaning of Article 1(b) of the regulation, and also the wording of Articles 3 and 4, the Court stated that 'the decisive factor for the grant of the certificate is not the intended use of the medicinal product' and that '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'. (44) Lastly, in its judgment in Biogen, the Court held that when a product is protected by a number of basic patents,(45) each of those patents may be designated for the purpose of the procedure for the grant of a certificate, (46) making plain, however, that 'as is clear from Article 13 of the regulation, the duration of such certificates is to be calculated uniformly on the basis of the date of the first authorisation to place the product on the market in the Community'. (47)

91. On the basis of what I have set out at points 86 to 90 above, I am of the view that there is nothing to preclude a marketing authorisation granted for a use of the product different from the use or uses protected by the basic patent from being regarded as the first marketing authorisation in the Community, for the purposes of the application of Articles 13 and 19 of the regulation.

92. In the light of all the foregoing considerations, I propose that the Court's answer to the first and second questions should be that an authorisation granted by the authorities of a Member State in accordance with the national provisions transposing Directive 65/65 may constitute the first marketing authorisation in the Community for the purpose of Articles 13 and 19 of the regulation, even when the administrative procedure for which the directive provides has, in fact, not been implemented or has not been properly implemented, particularly as regards the carrying out of the toxicological and pharmacological tests and the clinical trials required by Article 4(8) of the directive and the notification of the results of those tests and trials.

93. Similarly, a marketing authorisation granted by the competent authorities of a Member State, under the transitional arrangements provided for by Article 24 of Directive 65/65, in conjunction with Article 39 of Directive 75/319, and as amended by Article 37 of the latter directive, on the basis of a marketing authorisation granted before the transposition of Directive 65/65 into the legal order of that Member State, may be regarded as the first marketing authorisation in the Community within the meaning of the abovementioned provisions.

94. Based on the solution which I propose, even supposing that the SPC obtained by Merz was validly granted, (48) the term of that SPC was, in any event, calculated incorrectly inasmuch as the 2002 marketing authorisation was taken into consideration for the purposes of that calculation, rather than the German authorisation which, on the basis of the foregoing, must be regarded as the first marketing authorisation in the Community for the purpose of Article 13 of the regulation. Assuming the German marketing authorisation to be the authorisation of reference, the term of the SPC granted to Merz must be fixed at zero.

V – Conclusions

95. On the basis of all of the foregoing considerations, I propose that the Court should give the following answers to the questions submitted by the High Court of Justice (Chancery Division):

'Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, must be interpreted, pursuant to Article 2 thereof, as meaning that products placed on the market as medicinal products in Community territory before obtaining a marketing authorisation in accordance with Council Directive 65/65/EEC on the approximation of the provisions laid down by law, regulation or administrative action relating to proprietary medicinal products or with Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products do not fall within the scope of the regulation.

Supplementary protection certificates granted for such products must be deemed to be invalid.'

96. Should the Court not adopt that solution, I propose that it should give the following answers to the first and second questions submitted by the High Court of Justice (Chancery Division):

'A marketing authorisation granted by the authorities of a Member State in accordance with the national provisions transposing Directive 65/65 may constitute the first marketing authorisation in the Community for the purpose of Articles 13 and 19 of Regulation No 1768/92, even when the administrative procedure for which the directive provides has not been implemented or has not been properly implemented, particularly as regards the carrying out of the toxicological and pharmacological tests and the clinical trials required by the directive.

A marketing authorisation granted by the competent authorities of a Member State, under the transitional arrangements provided for by Article 24 of Directive 65/65, in conjunction with Article 39 of Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, and as amended by Article 37 of that directive, may also constitute the first marketing authorisation of the product in the Community, on the basis of a marketing authorisation granted before the transposition of Directive 65/65 into the legal order of that Member State.

For the purposes of the application of Articles 13 and 19 of Regulation No 1768/92, a marketing authorisation granted for a use of the product as a medicinal product different from the use or uses protected by the patent constituting the basic patent under Article 1(c) of that regulation may also be regarded as the first marketing authorisation in the Community'.

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1 – Original language: Italian

2 – Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1).

3 – The first certificates of this kind were granted in the United States in 1985, with the Japanese certificates following as of 1988. In Europe, that form of supplementary protection under patent was first introduced in certain Member States (Italy, France and Sweden) and subsequently regulated at Community level.

4 – OJ, English Special Edition 1965-1966, p. 20. As of 18 December 2001, Directive 65/65 was replaced by Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use (OJ 2001 L 311, p. 67).

5 – Namely the amended version of the Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13). The later amendments post-date the marketing of Akatinol in Germany and Luxembourg.

6 – According to Article 1, first subparagraph, (1), for the purposes of the directive, 'proprietary medicinal product' meant '[a]ny ready-prepared medicinal product placed on the market under a special name and in a special pack', and medicinal product' '[a]ny substance or combination of substances presented for treating or preventing disease in human beings or animals'.

7 – Cited in footnote 5. That directive too was repealed by Directive 2001/83.

8 – It was notified on 3 February 1965.

9 – As of 6 July 2009, Regulation No 1768 was repealed and replaced by Regulation No 469/2009, cited in footnote 2.

10 – Subsequently amended by the Act of Accession of Austria, Finland and Sweden to the European Union (OJ 1994 C 241, p. 21).

11 – In its observations, Merz explains that Akatinol was used in the treatment of Parkinson's disease and for certain other applications.

12 – In reality, the first marketing authorisation for Memantine and Akatinol in Germany dates back earlier and was granted on the basis of legislation from 1961. However, for the purposes of this Opinion, I shall regard the authorisation to keep Akatinol on the market, which was granted under the AMG 1976, as the German marketing authorisation.

13 – As pointed out by the national court, in the text of the regulation, Article 2 is the only article which contains an ambiguity of that nature. In all the other provisions, in fact, the Community legislature was careful to specify whether the authorisation to place on the market had to be construed as relating to the territory of the Member State in which the SPC was applied for or to the territory of a different Member State (see Article 3(b), Article 8(1)(a)(iv) (b) and (c), Article 9(2)(d) and (e), Article 11(1)(d) and (e), Article 13(1), Article 19(1) and Article 19a). The Court itself has made a distinction between the two, emphasising, in its judgment in Yamanouchi Pharmaceutical, the different function, within the scheme of the regulation, of the two requirements consisting in the first marketing authorisation in the Community and the first marketing authori-

sation in the Member State in which the SPC is applied for (see Case C‑110/95 [1997] ECR I-3251).
14 – See the Proposal for a Council regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM (90) 101 final (the 'Commission's proposal for a regulation'), paragraph 24.
15 – See Case C-392/97 Farmitalia [1997] ECR I-5553, paragraphs 19 and 22, and paragraph 1 of the operative part of the judgment.
16 – See Case C-31/03 Pharmacia Italia [2004] ECR I-10001.
17 – See the Opinion of Advocate General Jacobs in Pharmacia Italia, cited in footnote 16.
18 – Often not fulfilling the same pharmacological safety requirements.
19 – It does not in fact seem to me that a different conclusion must be reached if, at the time it was placed on the market as a medicinal product, the product at issue was not covered by a patent. Furthermore, in providing, in Article 13, that the duration of the certificate is to be calculated as of the date of the first marketing authorisation for the Community, the regulation itself does not specify that, at the time when the marketing authorisation is granted, the product at issue must be protected by a patent or be the subject of a patent application (which was not, for example, the case in Case C-258/99 BASF [2001] ECR I-3643 concerning a question of the interpretation of Regulation (EC) No 1610/96/EC of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products.
20 – Since the SPC at issue concerns a medicinal product for human use, only Directive 65/65 is relevant in this case.
21 – Case C-127/00 Hässle [2003] ECR I-14781.
22 – Joined Cases C-207/03 and C-252/03 Novartis and Others [2005] ECR I-3209.
23 – See also Pharmacia Italia (cited in footnote 16), paragraph 16.
24 – Paragraphs 56-58.
25 – See paragraph 60.
26 – See point 49 of the Opinion.
27 – Paragraphs 29 and 30.
28 – A similar position was, moreover, adopted, at first instance, by the national court hearing this case, in the context of a different dispute which gave rise, on appeal, to the reference for a preliminary ruling forming the subject-matter of Case C-427/09 Generics (UK), on which I am today delivering my Opinion.
29 – The purpose of the requirement that applicants for a marketing authorisation for a medicinal product must attach to the application the results of the toxicological and pharmacological tests and the clinical trials under Article 8(3)(i) of Directive 2001/83 (formerly required by Article 4 of Directive 65/65) is to provide evidence that a medicinal product is safe and efficacious. See, to that effect, Case C-440/93 Scotia Pharmaceuticals [1995] ECR I-2851, paragraph 17, as well as Case C-368/96 Generics (UK) and Others [1998] ECR I-7967, paragraph 23, and Case C-527/07 Generics (UK) [2009] ECR I-5259, paragraph 22.
30 – Merz considers that the transitional arrangements under Article 3(7) of the AMG 1976 were not in accordance with Article 24 of the directive. In that connection, it submits, attached to its observations, a Reasoned Opinion of the Commission addressed to the German Government, by which the Commission disputes the compatibility with the directive of the system of implicit authorisation provided initially by Article 3(7) of the AMG 1976 and, subsequently, by Article 105 of the amended version of the AMG. It is, however, clear from reading that document that the criticisms are related solely to the possibility of marketing products not subjected to the requisite tests after the expiry of the transitional stage, that is to say after 21 May 1990.
31 – For 15 years from the date of the notification of Directive 75/319 (which took place on 21 May 1975), according to Article 39 of that directive.
32 – See the letter of 3 July 2009 of the Luxembourg Minister of Health, attached to Merz' observations. According to that letter, the Luxembourg authorities too were expecting the documentation on the pharmacological and toxicological tests and the clinical trials to be completed during the transitional period, but that documentation never materialised.
33 – The purpose of the regulation is to establish a 'simple transparent' system for granting SPCs. The Commission's proposal for a regulation emphasises, at paragraph 16 that 'the patents offices should be able to implement the procedure for granting the certificate without an excessive burden being placed on their administrations' and that 'examination of the conditions to be fulfilled for the certificate to be granted involves the use of objective data that are easy to verify', as well as that 'the adoption of a standard system to calculate the duration of the protection given by the certificate ... means that the calculation is easy to make'.
34 – I would point out that in Case C-427/09 Generics (UK), on which I am today delivering my Opinion, the Commission has substantially changed the stance it adopted during the written procedure in this case.
35 – See paragraph 24 of the Commission's proposal for a regulation.
36 – Moreover, in this case, the German and Luxembourg authorisations were never made consistent with the requirements of Directive 65/65, despite the expiry of the time-limit laid down for that purpose by the directive. Consequently, as far as it is possible to determine, memantine was able to remain on the market after that that time-limit had expired and in breach of the directive, until the 2002 marketing authorisations were granted.
37 – As, for instance, in the case of Luxembourg under Article 22 of the abovementioned law of 11 April 1983.
38 – Paragraph 60.

39 – See Article 19 of the regulation, as well as Article 13, read in the light of Article 3(d) of the regulation.

40 – See Article 1(c) of the regulation.
41 – Case C-431/04 Massachusetts Institute of Technology [2004] ECR I-4089, paragraph 21. At paragraph 19 of the judgment, the Court drew attention to point 11 of the Explanatory Memorandum to the Proposal for a Council Regulation (EEC), of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), stating that '(...)[t]he proposal for a regulation therefore concerns only new medicinal products. It does not involve granting an [SPC] for all medicinal products that are authorised to be placed on the market. Only one [SPC] may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new [SPC].'
42 – Case C-202/05 Yissum [2007] ECR I-2839, paragraphs 18 and 20.
43 – Cited in footnote 16, paragraph 23.
44 – Emphasis added.
45 – Case C-181/95 Biogen [1997] ECR I-357. The dispute in the main proceedings concerned patents held by a number of owners, but the Court's reasoning may also be applied to the situation of patents which protect the product for different therapeutic uses.
46 – On condition, according to the Court, that, in accordance with Article 3(c) of the regulation, only one SPC is granted for each patent.
47 – Paragraph 29.
48 – Apart from the invalidity that would result were the Court to adopt the answer I have proposed to the third and fourth questions, it is not clear whether, in this case, the conditions for the application of Article 19(1) of the regulation have been met. It is not actually apparent from the case-file whether, on the date the regulation entered into force, memantine was protected by a patent in force, as Article 19(1) requires. If Article 19(1) were applicable, Merz' SPC would be invalid because the German marketing authorisation, which was the first marketing authorisation in the Community, dates from before 1 January 1985 and, in any event, because it was applied for after the time-limit of six months from the date of the regulation's entry into force, laid down by Article 19(2).