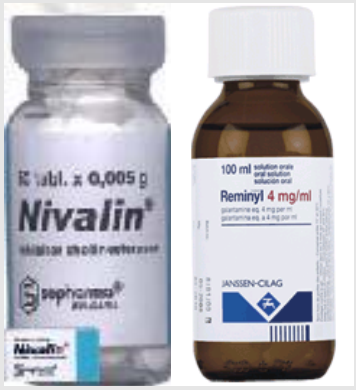
Court of Justice EU, 28 July 2011, Generics v Synaptech



PATENT - ABC

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

- **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, as defined in Article 2 of that regulation, and may not be the subject of an SPC.**

Source: **curia.europa.eu**

Court of Justice EU, 28 July 2011
(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)
In Case C‑427/09,
REFERENCE for a preliminary ruling under Article 234 EC from the Court of Appeal (England and Wales) (Civil Division) (United Kingdom), made by decision of 22 October 2009, received at the Court on 28 October 2009, in the proceedings
Generics (UK) Ltd
v
Synaptech Inc.,
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,
Registrars: L. Hewlett, Principal Administrator, and B. Fülöp, Administrator,
having regard to the written procedure and further to the hearings on 9 December 2010 and 17 February 2011,
after considering the observations submitted on behalf of:
– Generics (UK) Ltd, by M. Tappin QC, K. Bacon, Barrister, and S. Cohen and G. Morgan, Solicitors,
– Synaptech Inc., by S. Thorley QC and C. May, Barrister,
– the Italian Government, by G. Palmieri, acting as Agent, and by L. Ventrella, avvocato dello Stato,
– the Portuguese Government, by L. Inez Fernandes and A.P. Antunes, acting as Agents,
– 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 Article 13(1) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), 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 Generics (UK) Ltd ('Generics') and Synaptech Inc. ('Synaptech') concerning the supplementary protection certificate ('SPC') granted for the product 'Galantamine or acid addition salts thereof' ('galantamine').
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 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.'

9 Article 19(1) of the regulation, relating to transitional provisions, provides:

'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.

In the case of [SPCs] to be granted in Belgium, in Italy and in Austria, the date of 1 January 1985 shall be replaced by that of l January 1982.'

Directive 65/65

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

11 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.'

12 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 medical product concerned, that is, the results of physico-chemical, biological or microbiological tests, pharmacological and toxicological tests, and clinical trials.

13 Under Article 5 of that directive, the marketing authorisation for medicinal products 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.'

14 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

15 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.

16 According to Article 39(3) of that directive, Member States were to notify the Commission of the Euro-

pean 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

17 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.

18 In Austria, at the time of the facts in the main proceedings, the legislation on medicinal products in force was the 1947 medicines regulations (Spezialitätenordnung). These did not meet the conditions required by Directive 65/65.

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

19 It is apparent from the order for reference that galantamine had been on sale as a medicinal product in various European countries for more than 40 years. In central Europe, it was used to treat neuromuscular conditions.

20 In 1963 a marketing authorisation was issued in Austria, under the 1947 medicines regulations, for galantamine to be used as a medicinal product in the treatment of poliomyelitis under the trade mark Nivalin ('Nivalin').

21 In Germany, galantamine was already on the market in the 1960s under the same trade mark. Under the German Law of 1976, galantamine could remain on the German market as a product deemed to be authorised as a medicinal product under a 'fictitious' authorisation.

22 On 16 January 1987, Synaptech filed an application for a basic galantamine patent in the European Patent Office, claiming the use of galantamine for the treatment of Alzheimer's disease.

23 In 1997 Janssen-Cilag took over distribution of Nivalin in Austria and, in 1999, filed an application in Sweden for a marketing authorisation for the use of galantamine in a medicinal product to treat Alzheimer's disease under the brand name Reminyl ('Reminyl'). After an assessment carried out in accordance with Directive 65/65, Reminyl was authorised on 1 March 2000.

24 In September 2000 a marketing authorisation was issued in the United Kingdom for Reminyl.

25 The fictitious German authorisation from which Nivalin had benefited following the entry into force, on 1 January 1978, of the German Law of 1976 and the Austrian marketing authorisation issued in 1963 covering the same medicinal product were withdrawn in the second half of 2000 and in 2001 respectively.

26 On 7 December 2000, Synaptech made an application to the United Kingdom Patent Office for an SPC for galantamine, listing the Swedish marketing authorisation as the first authorisation to place the product on the market as a medicinal product in the Community. Based on that marketing authorisation, the SPC applied for was granted with a maximum term of five years, expiring in January 2012, with the basic galantamine patent expiring on 16 January 2007.

27 Taking the view that the SPC's date of expiry had not been calculated correctly by the UK Patent Office, which had relied on the Swedish marketing authorisation, Generics brought a claim in the High Court of Justice (England and Wales), Chancery Division (Patents Court), seeking rectification under section 34 of the Patents Act 1977. Since that claim was rejected, Generics brought an appeal before the Court of Appeal.

28 In the context of the present proceedings, Generics accepted before the national court that the German and Austrian marketing authorisations had never complied with the requirements of Directive 65/65 and that the first marketing authorisation covering galantamine, compliant with that directive, was the Swedish authorisation.

29 Since the Court of Appeal (England and Wales) (Civil Division) had doubts as to the interpretation which should be given to the concept of 'first authorisation to place the product on the market in the Community', referred to in Article 13(1) of Regulation No 1768/92, 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 Article 13(1) of [Regulation No 1768/92], is the "first authorisation to place the product on the market in the Community" the first authorisation to place the product on the market in the Community which was issued in accordance with [Directive 65/65] (now replaced with Directive 2001/83/EC [of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67)]) or will any authorisation that enables the product to be placed on the market in the Community or [European Economic Area] suffice?

(2) If, for the purposes of Article 13(1) of [Regulation No 1768/92], an "authorisation to place the product on the market in the Community" must have been issued in accordance with [Directive 65/65] (now replaced with Directive 2001/83/EC), is an authorisation that was granted in 1963 in Austria in accordance with the national legislation in force at that time (which did not comply with the requirements of [Directive 65/65]) and that was never amended to comply with [that directive] and was ultimately withdrawn in 2001, to be treated as an authorisation granted in accordance with [that directive] for that purpose?'

Consideration of the questions referred

30 By those questions, the national court asks, in essence, which was the first authorisation to place the product on the market in the Community, within the meaning of Articles 13(1) and 19 of Regulation No

1768/92, in order to determine the duration of the SPC granted for galantamine.
31 First of all, it should be observed that the answer to those questions is relevant only if the product at issue in the main proceedings is within the scope of that regulation and could, thus, be the subject of an SPC.
32 Therefore, in order to give an answer which will be of use to the national court, it is first necessary to consider whether a product, such as the galantamine at issue in the main proceedings, is within the scope of Regulation No 1768/92, as defined in Article 2 of that regulation.
33 As regards the scope of the regulation, the Court has held, at **paragraph 51 of the judgment in Case C‑195/09 Synthon [2011] ECR I-0000, 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 giving rise to that judgment, which had been 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, was not within the scope of Regulation No 1768/92 and could not therefore be the subject of an SPC.
34 It is clear from the order for reference that, in the present case, when the SPC application was submitted, galantamine had already been 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.
35 It follows that a product such as galantamine is outside the scope of Regulation No 1768/92, as defined in Article 2 of that regulation, and that it may not be the subject of an SPC. Thus, Articles 13 and 19 of Regulation No 1768/92, referred to by the national court, do not apply to such a product. There is therefore no need to interpret those provisions.
36 In the light of the foregoing considerations, the answer to the questions raised is 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, as defined in Article 2 of that regulation, and may not be the subject of an SPC.
Costs
37 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:
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 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, as that scope is defined in Article 2 of that regulation, as amended, and may not be the subject of a supplementary protection certificate.
[Signatures]

OPINION OF ADVOCATE GENERAL MENGOZZI

delivered on 31 March 2011 (1)
Case C‑427/09
Generics (UK) Ltd
v
Synaptech Inc
(Reference for a preliminary ruling from the Court of Appeal, Civil Division (United Kingdom))
(Regulation (EEC) 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, which was 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 granted. Introduced by Regulation (EEC) No 1768/92, (2) the supplementary protection certificate (SPC) is designed to limit the extent to which the period of exclusive use of such patents may be eroded. (3)
2. The present case is concerned with two questions relating to Article 13(1) of Regulation No 1768/92, referred for a preliminary ruling by the Court of Appeal, Civil Division (United Kingdom) in the context of a dispute between Generics (UK) Limited (‘Generics’) and Synaptech Inc. (‘Synaptech’) concerning the determination of the date of expiry of an SPC owned by Synaptech and granted by the United Kingdom Patent Office for the product ‘Galantamine or acid addition salts thereof’ (‘the galantamine SPC’).
3. The national court is, in essence, asking the Court to clarify the concept of ‘the first authorisation to place the product on the market’ for the purposes of Article 13(1) of the Regulation No 1768/92. The first question is substantially the same as one of the questions referred for a preliminary ruling by the High Court of Justice (Chancery Division) (United Kingdom), which

has arisen, as the present case, in the context of a dispute between a manufacturer of generic drugs and a pharmaceutical company concerning the validity and duration of an SPC granted to the latter. (4) Although the two references have not resulted in the joinder of the relevant proceedings, they have been examined by the Court at the same time, since they raise similar issues overall. The present Opinion is delivered on the same date as that in Synthon and contains various references to that Opinion.

I – Legislative background

A – European Union law

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

4. In accordance with Article 3 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, (5) in the version applicable to the facts of the main proceedings, (6) no proprietary medicinal product (7) may be placed on the market in a Member State unless a marketing authorisation has been issued by the competent authority of that Member State.

5. In order to obtain that authorisation, the person responsible for placing the product on the market had to submit an application to the competent authority of the Member State concerned, supported by the particulars and documents specified in Article 4, second paragraph, of the directive. As well as information such as the qualitative and quantitative particulars of 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, point 8 of Article 4, second paragraph, of the directive included, 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.

6. Directive 75/319 (8) 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.

7. In accordance with 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 proprietary 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.'

8. Article 24 of Directive 65/65, as replaced by Article 37 of Directive 75/319, provided:

'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.'

9. Article 39(2) and (3) of Directive 75/319 provided:

'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], has not yet been issued.'

10. In accordance with 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 (9) and shall inform the Commission forthwith'.

2. Regulation No 1768/92

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

'… 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;

… this situation leads to a lack of protection which penalises pharmaceutical research;

[…]

… a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;

… 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'.

12. Under Article 1 of the regulation:

'For 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 a product 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'.

13. 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 authorisation 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.'

14. 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 …; (11)

(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'.

15. 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.

16. 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 marketing authorisation was granted or within six months of the date on which the basic patent was granted, if later.

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

'1. 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.'

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

19. Article 13(1) and (2) of the regulation, entitled 'Duration of the certificate', provides as follows:

'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.'

20. Article 15 of the regulation sets out the reasons for which a certificate is invalid. In accordance with Article 15(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.'

21. Lastly, Article 19(1), as amended as of 1 January 1995 by the Act of Accession of Austria, Finland and Sweden to the European Union, (12) laid down the following transitional provision:

'Any product which on the date of accession is protected by a valid 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, Fin-

land or Sweden was obtained after 1 January 1985 may be granted a certificate.
In the case of certificates 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.
In the case of certificates to be granted in Belgium, in Italy and in Austria, the date of 1 January 1985 shall be replaced by that of 1 January 1982.'

B – The Agreement on the European Economic Area

22. Point 6 of Annex XVII to the Agreement on the European Economic Area of 2 May 1992 ('the EEA Agreement'), (13) as amended by Annex 15 to Decision No 7/94 of the EEA Joint Committee of 21 March 1994, (14) states that, for the purposes of that Agreement, the following is to be added in Article 3(b) of the regulation:
'for the purpose of this subparagraph and the Articles which refer to it, an authorisation to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorisation granted in accordance with Directive 65/65/EEC …'.

C – National law

23. 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 of Annex 7 to the AMG, 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.

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

24. The facts of the main proceedings, as established by the national court, are as follows.
25. Galantamine, known since the 1950s as a treatment for neuromuscular conditions, received marketing authorisation in Austria in 1963 as a treatment for polio, under the trademark 'Nivalin' ('the Austrian marketing authorisation'). The authorisation, granted under the Austrian medicines regulations then in force, the Spezialitätenordnung of 1947, was withdrawn in 2001.
26. In the 1960s, Nivalin was also marketed in Germany pursuant to the legislation then in force. After the AMG 1976 came into force, Nivalin remained on the market in Germany under the provisions of the AMG. The authorisation granted under the AMG 1976 ('the German marketing authorisation') was withdrawn between July 2000 and January 2001.
27. In 1987, Synaptech, the defendant in the main proceedings, filed an application for a galantamine patent at the European Patent Office, claiming the use of galantamine for the treatment of Alzheimer's disease. The patent expired on 16 January 2007 ('the basic patent').
28. In 1999, Janssen-Cilag filed an application for a marketing authorisation in Sweden for galantamine as a treatment for Alzheimer's disease under the brand name Reminyl. The authorisation was granted on 1 March 2000 ('the Swedish marketing authorisation').
29. A marketing authorisation for Reminyl was granted in the United Kingdom in September 2000 based on the earlier Swedish authorisation.
30. On 7 December 2000, Synaptech made an application to the United Kingdom Patent Office for an SPC for the basic patent, listing the Swedish marketing authorisation as the first marketing authorisation for galantamine in the Community. The SPC for galantamine was granted with a term of 5 years, expiring on 15 January 2012.
31. Taking the view that the SPC's date of expiry had not been calculated correctly in accordance with the regulation, Generics brought an action in the United Kingdom Patents Court seeking rectification of the register of patents under section 34 of the Patents Act 1977.
32. Generics' action was dismissed by a judgment dated 20 May 2009. Generics brought an appeal before the Court of Appeal, which referred the following two questions for a preliminary ruling:
'(1) For the purposes of Article 13(1) of Council Regulation (EEC) No 1768/92, is the "first authorisation to place the product on the market in the Community" the first authorisation to place the product on the market in the Community which was issued in accordance with Council Directive 65/65/EEC (now replaced with Directive 2001/83/EC) or will any authorisation that enables the product to be placed on the market in the Community or EEA suffice?
(2) If, for the purposes of Article 13(1) of Council Regulation (EEC) No 1768/92, an "authorisation to place the product on the market in the Community" must have been issued in accordance with Directive 65/65/EEC (now replaced with Directive 2001/83/EC), is an authorisation that was granted in 1963 in Austria in accordance with the national legislation in force at that time (which did not comply with the requirements of Directive 65/65/EEC) and that was never amended to comply with Directive 65/65/EEC and was ultimately withdrawn in 2001 to be treated as an authorisation granted in accordance with Directive 65/65/EEC for that purpose?'

III – Analysis

A – Preliminary remarks

33. In the Opinion which I am delivering today in Synthon, referred to above, I propose that, in reply to the third and fourth questions referred by the High Court for a preliminary ruling, the Court should declare that products, such as galantamine, which have been placed on the market as medicinal products in Community territory before a marketing authorisation in compliance with Directive 65/65 has been obtained, do not fall within the scope of the regulation as laid down in Article 2 thereof.
34. Although not raised by the Court of Appeal, the issue of the regulation's scope in relation to such prod-

ucts must, in the context of the dispute between Generics and Synaptech, logically be resolved first, inasmuch as it affects the actual validity of the SPC granted to Synaptech. If the Court were to adopt my conclusions in relation to the third and fourth questions raised in Synthon, the questions referred by the Court of Appeal in the present proceedings would become irrelevant for the purposes of resolving the dispute in the main proceedings, and the Court would not be required to answer them.

35. I shall therefore now turn to consider those questions, in case the Court does not adopt the view that I have expressed on the third and fourth questions in Synthon or intends in any event to answer the questions referred by the national court in the present proceedings.

B – The first question referred for a preliminary ruling

36. By its first question, the Court of Appeal asks, in essence, whether, for the purposes of applying Article 13 of the regulation, the 'first authorisation to place the product on the market in the Community' is the first authorisation granted in accordance with Directive 65/65 or the first authorisation that enables the product to be placed on the market in the European Union or the EEA.

37. Article 13 of the regulation lays down the procedures for calculating the duration 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 European Union.

38. Generics submits that a literal and systematic interpretation of the regulation and an analysis of the Court's case-law lead to the conclusion that, for the purposes of Article 13 of the regulation, the concept of 'the first authorisation to place the product on the market' includes any authorisation that enables the product to be marketed in a part of the European Union or the EEA. By contrast, Synaptech, relying, in essence, on a systematic and purposive interpretation of the regulation, and also referring to the Court's case-law, contends that such a concept refers only to the first marketing authorisation granted in the Community in accordance with Directive 65/65.

39. I would observe that the first question referred by the national court in the present proceedings is, in essence, the same as the second question raised in Synthon. In addition, as the applicant in the main proceedings itself points out, the German marketing authorisation for galantamine was granted pursuant to the same provisions of the German legislation under which memantine was granted marketing authorisation after Directive 65/65 had been transposed into German law. In other words, the transitional rules of 'fictitious authorisation', applied to the circulation of the two products in Germany on the basis of the provisions of the AMG 1976 which implemented Article 24 of Directive 65/65, are the same in the two cases.

40. Accordingly, for the purposes of resolving the first question referred by the Court of Appeal in the present proceedings, I would refer to the analysis in point 55 et seq. of my Opinion delivered today in Synthon.

41. It is apparent, inter alia, from that analysis that an authorisation such as that obtained in Germany for galantamine, granted by the competent authorities of a Member State pursuant to the transitional arrangements introduced by Article 24 of Directive 65/65, in conjunction with Article 39 of Directive 75/319, and as amended by Article 37 of that directive, on the basis of a marketing authorisation granted prior to 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 for the purposes of Article 13 of the regulation.

42. I therefore propose that the first question referred for a preliminary ruling by the Court of Appeal should be answered in the terms set out above.

C – The second question referred for a preliminary ruling

43. By its second question, the national court asks, in essence, whether an authorisation granted in 1963 in Austria in accordance with the national legislation in force at that time, which did not comply with the requirements of Directive 65/65, was maintained in force after the accession of Austria to the EEA and to the Community and was never amended to comply with those requirements, is relevant for the purposes of the application of Article 13 of the regulation.

44. As was noted above, both the EEA Agreement and the Act of Accession of Austria, Finland and Sweden contain provisions under which an authorisation to place a product on the market granted in accordance with the national legislation of an EFTA State or of one of the abovementioned States is to be treated as granted in accordance with Directive 65/65.

45. Admittedly, such provisions relate, in particular, to Articles 3(b) and 19 of the regulation. However, there is no reason not to extend the interpretative rule embodied in them to Article 13 also, if the latter is interpreted as meaning that, for the purposes of calculating the duration of an SPC, the first marketing authorisation in the Community (or in the EEA) must be construed as a marketing authorisation granted in accordance with Directive 65/65.

46. Such an extension of that rule is supported by the judgment in Novartisand Others, (15) in which the Court held that a marketing authorisation granted by the Swiss authorities and automatically recognised in the Principality of Liechtenstein under that State's legislation must be regarded as a first marketing authorisation in the EEA for the purposes of Article 13 of the regulation as it must be construed for the purposes of interpreting the EEA Agreement. The Court reached such a conclusion on the basis of the fact that '[t]he EEA Agreement recognises therefore 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 that State are automatically recognised in the latter, and marketing authorisations issued in Liechtenstein in accordance

with Directive 65/65'. (16) In my estimation, authorisations granted under an EFTA State's national legislation, which, although not satisfying the requirements laid down by Directive 65/65, are treated as authorisations granted in accordance with that directive on the basis of an express provision of that Agreement, must, a fortiori, be considered relevant for the purpose of the application of Article 13 of the regulation as it has to be construed for the purposes of interpreting the EEA Agreement.

47. The application of the provisions of the Agreement on the Accession of Austria, Finland and Sweden which amended, inter alia, Articles 3(b) and 19 of the regulation, treating marketing authorisations granted in accordance with the national legislation of those States as authorisations granted in accordance with Directive 65/65, leads, in my view, to a similar interpretation of Article 13 of the regulation.

48. It follows that an authorisation granted in 1963 in Austria in accordance with the national legislation in force at that time, although not satisfying the requirements of Directive 65/65, must be treated as an authorisation granted in accordance with that directive for the purposes of applying Article 13 of the regulation.

IV – Conclusion

49. In the light of all of the foregoing considerations and, without prejudice to the observations at points 33 to 35 above, I propose that the following reply be given to the questions referred by the Court of Appeal for a preliminary ruling:

(1) A marketing authorisation for a medicinal product granted by the competent authorities of a Member State pursuant to the transitional arrangements introduced by Article 24 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products – in conjunction with Article 39 of 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 – on the basis of a marketing authorisation granted prior to the transposition of Directive 65/65 into the legal order of that Member State, may constitute the first marketing authorisation for the purposes of Article 13 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

For the purposes of the application of Article 13 of Regulation No 1768/92, an authorisation granted for use of a product, as a medicinal product, other than that or those protected by the patent which is the basic patent within the meaning of Article 1(c) of the regulation, may also constitute the first authorisation to place the product on the market in the Community.

(2) A marketing authorisation for a medicinal product granted by the competent Austrian authorities in accordance with the national legislation, and maintained in force following the accession of Austria to the European Economic Area, initially, and to the Community, subsequently, must be treated as an authorisation granted in accordance with Directive 65/65 for the purposes of applying Article 13 of Regulation No 1768/92.

1 – Original language: Italian.

2 – Council Regulation of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1).

3 – The first certificates of this type 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 – The order for reference from the High Court of Justice is the subject of Case C‑195/09 Synthon.

5 – 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 of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p 67).

6 – This was the version amended by 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).

7 – According to the first paragraph of Article 1 of Directive 65/65, for the purposes of the application of that 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' meant '[a]ny substance or combination of substances presented for treating or preventing disease in human beings or animals'.

8 – Cited in footnote 6. That directive too was repealed by Directive 2001/83.

9 – It was notified on 3 February 1965.

10 – As of 6 July 2009, Regulation No 1768/92 was repealed and replaced by codifying Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

11 – The second sentence of Article 3(b) was inserted by the Act of Accession of Austria, Finland and Sweden to the European Union (OJ 1994 C 241, p. 21).

12 – As adopted by Decision 95/1/EC, Euratom, ECSC of the Council of the European Union of 1 January 1995 (OJ 1995 L 1, p. 1). The Act of Accession is referred to in footnote 11.

13 – OJ 1994 L 1, p. 3, 482.

14 – OJ 1994 L 160, p. 1.

15 – Joined Cases C‑207/03 and C‑252/03 [2005] ECR I‑3209.

16 – Paragraph 29.