JUDGMENT OF THE COURT (Second Chamber)

28 July 2011 *

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,

* Language of the case: English.

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 1 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 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*

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-7011, 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]