Reports of Cases

JUDGMENT OF THE COURT (Fourth Chamber)

19 July 2012*

(Medicinal products for human use — Supplementary protection certificate — Regulation (EC) No 469/2009 — Article 3 — Conditions for obtaining a supplementary protection certificate — Medicinal product having obtained a valid marketing authorisation — First authorisation — Product successively authorised as a veterinary medicinal product and a human medicinal product)

In Case C-130/11,

REFERENCE for a preliminary ruling under Article 267 TFEU from the Court of Appeal (England and Wales) (Civil Division) (United Kingdom), made by decision of 11 March 2011, received at the Court on 16 March 2011, in the proceedings

Neurim Pharmaceuticals (1991) Ltd

v

Comptroller-General of Patents,

THE COURT (Fourth Chamber),

composed of J.-C. Bonichot (Rapporteur), President of the Chamber, A. Prechal, K. Schiemann, C. Toader and E. Jarašiūnas, Judges,

Advocate General: V. Trstenjak,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 15 March 2012,

after considering the observations submitted on behalf of:

— Neurim Pharmaceuticals (1991) Ltd, by J. Turner QC, A. Waugh, barrister, and E. Oates and H. Goodfellow, attorneys,

— the United Kingdom Government, by S. Ossowski and A. Robinson, acting as Agents, assisted by C. May, barrister,

— the Portuguese Government, by L. Inez Fernandes and P.A. Antunes, acting as Agents,

— the European Commission, by F. Bulst and J. Samnadda, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 3 May 2012,

* Language of the case: English.

gives the following

Judgment

1 This reference for a preliminary ruling relates to the interpretation of, first, Articles 3 and 13(1) of 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 (codified version) (OJ 2009 L 152, p. 1; 'the SPC Regulation'), and secondly, Article 8(3) of 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).

2 The reference has been made in the context of a dispute between Neurim Pharmaceuticals (1991) Ltd ('Neurim') and the Comptroller-General of Patents, representing the United Kingdom Intellectual Property Office ('IPO'), relating to a refusal to grant a supplementary protection certificate ('SPC') for a medicinal product protected by a European patent.

Legal context

The SPC Regulation

3 Recitals 1 and 4 to 10 of the SPC Regulation read as follows:

'(1) Council Regulation (EEC) No 1768/92 … has been substantially amended several times. In the interests of clarity and rationality the said Regulation should be codified.

...

(4) 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 [the "MA"] makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

(7) 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 functioning of the internal market.

(8) Therefore, the provision of an [SPC] 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 [MA] has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

(9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains [an MA] in the Community.

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.'

4 Article 1 of the regulation provides:

'Definitions

For the purposes of this Regulation, the following definitions shall apply:

(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 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;

(d) "certificate" means the supplementary protection certificate;

...'

5 Article 2 of the SPC 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 2001/83/EC ... or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [OJ 2001 L 311, p. 1] may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.'

6 Article 3 of the SPC Regulation, entitled 'Conditions for obtaining a certificate', provides:

'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 ...;

(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.'

7 Article 4 of the SPC Regulation, entitled 'Subject matter of protection', provides:

'Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate 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 certificate.'

8 Article 7(1) of the SPC Regulation, entitled 'Application for a certificate' provides:

'The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.'

9 Article 13(1) of the SPC Regulation, entitled 'Duration of the certificate', provides:

'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 [MA] in the Community, reduced by a period of five years.'

10 In accordance with Article 23, the SPC Regulation entered into force on 6 July 2009.

Directive 2001/83

11 Article 8(3) of Directive 2001/83 lists the information and documents which must be submitted with the application for an MA of a medicinal product for human use.

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

12 Following research carried out on melatonin, a natural hormone which has not, as such, been patented, Neurim discovered that appropriate formulations of melatonin could be used as a medicine for insomnia. Neurim subsequently obtained a European patent, which it applied for on 23 April 1992, concerning its formulation of melatonin, in order to sell it in the form of a medicinal product for human use called 'Circadin'.

13 When the European Commission issued Neurim with an MA enabling it to market that medicinal product ('the Circadin MA') on 28 June 2007, the patent protecting that new medicinal product had less than five years to run.

14 Neurim therefore applied for an SPC, basing its application on the Circadin MA which it had just obtained.

15 By a decision of 15 December 2009, after the SPC Regulation had come into force, the IPO refused to grant that request. It had identified an earlier MA, dating from 2001, for melatonin for use in sheep and sold under the mark Regulin. Regulin, which was used as a method of regulating the seasonal breeding activity of sheep, had been protected by a patent held by the company Hoechst since 1987 but which had expired in May 2007. The IPO's refusal was thus based on the fact that, contrary to the requirement of Article 3(d) of the SPC Regulation, the Circadin MA was not the first MA relating to melatonin.

16 That refusal was challenged before the High Court of Justice (Chancery Division — Patents Court) by Neurim, which argued, in essence, that the relevant MA for the application of Article 3(d) of the SPC Regulation is that which concerns the product for which the application for the SPC is made. Since its

action was dismissed, Neurim appealed to the Court of Appeal (England & Wales) (Civil Division). Although that court considered that Neurim's arguments were well founded, none the less it decided to stay the proceedings in order to refer the following questions to the Court for a preliminary ruling:

'1. In interpreting Article 3 of [the SPC Regulation], when [an MA] (A) has been granted for a medicinal product comprising an active ingredient, is Article 3(d) to be construed as precluding the grant of an SPC based on a later [MA] (B) which is for a different medicinal product comprising the same active ingredient where the limits of the protection conferred by the basic patent do not extend to placing the product the subject of the earlier MA on the market within the meaning of Article 4?

2. If the grant of the SPC is not precluded, does it follow that in interpreting Article 13(1) of the SPC Regulation, "the first [MA] in the Community" needs to be an authorisation to place a medicinal product on the market within the limits of the protection conferred by the basic patent within the meaning of Article 4?

3. Are the answers to the above questions different if the earlier [MA] has been granted for a veterinary medicinal product for a particular indication and the later [MA] has been granted for a medicinal product for human use for a different indication?

4. Are the answers to the above questions different if the later [MA] required a full application for marketing approval in accordance with Article 8(3) of Directive 2001/83/EC (formerly a full application under Article 4 of Directive 65/65/EEC)?

5. Are the answers to the above questions different if the product covered by the authorisation (A) to place the corresponding medicinal product on the market is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant?'

The questions referred

The first and third questions

17 As a preliminary point, it should be noted that in the main proceedings it is undisputed that, first, the active ingredient in the two medicinal products at issue is not, as such, protected by a patent. Secondly, the basic patent for which the application for the SPC was made protects an application of that active ingredient which, as a medicinal product for human use, has obtained a valid MA. Finally, another MA, also valid, was granted previously to a veterinary medicinal product comprising the same active ingredient.

18 Accordingly, by its first and third questions, which must be examined together, the referring court asks, in essence, whether the provisions of Article 3 and 4 of the SPC Regulation are to be interpreted as meaning that, in a case such as that in the main proceedings, the existence of an earlier MA for a veterinary medicinal product is sufficient to preclude the grant of an SPC for the product application which obtained the other MA.

19 As the Commission pointed out in its observations submitted to the Court, those questions are essentially aimed at establishing whether there is a link between, on the one hand, the MA referred to in Article 3(b) and (d) of the SPC Regulation, and on the other, the basic patent referred to in Article 3(a) of that regulation.

20 As is apparent from the respective headings of Articles 2 and 3 of the SPC Regulation, 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 (see Case C-195/09 *Synthon* [2011] ECR I-7011, paragraph 41).

21 The first three conditions set out in Article 3 of the SPC Regulation for the grant of an SPC concern the relevant 'product' and require it to be protected by a basic patent in force, to have obtained a valid MA as a medicinal product, and to have not already been the subject of a certificate.

22 That being so, it must also be noted that the fundamental objective of the SPC Regulation is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health (see Case C-322/10 *Medeva* [2011] ECR I-12051, paragraph 30 and the case-law cited, and Case C-422/10 *Georgetown University and Others* [2011] ECR I-12157, paragraph 24).

23 The reason given for the adoption of the SPC Regulation is the fact that the period of effective protection under the patent is insufficient to cover the investment put into pharmaceutical research and the regulation thus sought to make up for that insufficiency by creating an SPC for medicinal products (see *Medeva*, paragraph 31, and *Georgetown University and Others*, paragraph 25).

24 It is apparent from paragraph 29 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), that, like a patent protecting a 'product' or a patent protecting a process by which a 'product' is obtained, a patent protecting a new application of a new or known product, such as that at issue in the main proceedings, may, in accordance with Article 2 of the SPC Regulation, enable an SPC to be granted and, in that case, in accordance with Article 5 of the regulation, the SPC confers the same rights as conferred by the basic patent as regards the new use of that product, within the limits laid down by Article 4 of that regulation (see, by analogy, *Medeva*, paragraph 32, and order of 25 November 2011 in Case C-630/10 *University of Queensland and CSL*, ECR I-12231, paragraph 38).

25 Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for veterinary or human use, for other therapeutic indications, whether or not protected by an earlier patent, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product.

26 In such a situation, only the MA of the first medicinal product, comprising the product and authorised for a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC, may be considered to be the first MA of 'that product' as a medicinal product exploiting that new use within the meaning of Article 3(d) of the SPC Regulation.

27 In the light of all the above considerations, the answer to the first and third questions is that Articles 3 and 4 of the SPC Regulation are to be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of an SPC for a different application of the same product for which an MA has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

The second question

28 By its second question, the referring court asks, in essence, whether, inasmuch as it determines the duration of the protection conferred by the SPC by referring to, inter alia, the date of the first MA in the European Union, Article 13(1) of the SPC Regulation is to be interpreted as meaning that it also refers to the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

29 It must be pointed out that the MA in the European Union referred to in Article 13(1) of the SPC Regulation is not intended to take the place of the MA provided for in Article 3(b) of that regulation, that is to say, the authorisation granted by the Member State in which the application is submitted; instead, it constitutes a further condition applying in the event that the latter authorisation is not the first authorisation to place the product on the market as a medicinal product in the European Union (see, to that effect, Case C-127/00 *Hässle* [2003] ECR I-14781, paragraph 73).

30 However, although those two provisions of the SPC Regulation thus refer to the two different territorial areas of the authorisations in question in defining the duration of the protection conferred by the SPC in a particular situation, there is no reason why, as regards the assessment of the very nature of those authorisations, it is necessary to use different criteria according to which the article is applicable. Therefore, the MA referred to in Article 13(1) of the SPC Regulation is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

31 It follows from the above that the answer to the second question is that Article 13(1) of the SPC Regulation is to be interpreted as meaning that it refers to the MA of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

The fourth and fifth questions

32 By its fourth and fifth questions, which must be examined together, the referring court asks, in essence, whether, in a situation such as that in the main proceedings where the same active ingredient is present in two medicinal products having obtained successive MAs, the answer to the previous questions would be different if (i) the second MA required a full application for an MA in accordance with Article 8(3) of Directive 2001/83 or (ii) the product covered by the first MA of the corresponding medicinal product is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant.

33 Suffice it to note, first, that the provisions of Article 8(3) of Directive 2001/83 have a purely procedural object. Therefore, they cannot by themselves, in any event, have an effect on the assessment of the substantive conditions laid down in the SPC Regulation for determining, as regards that regulation, which of the successive MAs it refers to. Since the preceding questions concern the examination of those substantive conditions, the answers given to them do not depend on the provisions of Article 8(3) of Directive 2001/83.

34 Secondly, the preceding questions called for answers justified by considerations concerning, in essence, the link between the successive MAs and the limits of the protection conferred by the basic patent for which the application for the SPC is made. Hence, those considerations are wholly distinct from those concerning the determination of the proprietors of the authorisations, patents, or the application for the SPC. Those answers do not, therefore, depend on those latter considerations.

35 Consequently, the answer to the fourth and fifth questions is that the answers to the preceding questions would not be different if, in a situation such as that in the main proceedings where the same active ingredient is present in two medicinal products having obtained successive MAs, the second MA required a full application in accordance with Article 8(3) of Directive 2001/83, or if the product covered by the first MA of the corresponding medicinal product is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant.

Costs

36 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 (Fourth Chamber) hereby rules:

1. **Articles 3 and 4 of 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 must be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.**

2. **Article 13(1) of Regulation (EC) No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.**

3. **The answers to the above questions would not be different if, in a situation such as that in the main proceedings where the same active ingredient is present in two medicinal products having obtained successive marketing authorisations, the second marketing authorisation required a full application in accordance with Article 8(3) of 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, or if the product covered by the first marketing authorisation of the corresponding medicinal product is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant.**

[Signatures]