ORDER OF THE COURT (Fourth Chamber)

25 November 2011 *

In Case C-6/11,

REFERENCE for a preliminary ruling under Article 267 TFEU from the High Court of Justice of England and Wales, Chancery Division (Patents Court) (United Kingdom), made by decision of 8 December 2010, received at the Court on 5 January 2011, in the proceedings

Daiichi Sankyo Company

v

Comptroller General of Patents, Designs and Trade Marks,

THE COURT (Fourth Chamber),

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

Advocate General: V. Trstenjak,
Registrar: A. Calot Escobar,

* Language of the case: English.

the Court proposing to give its decision by reasoned order in accordance with the first subparagraph of Article 104(3) of its Rules of Procedure,

after hearing the Advocate General,

makes the following

Order

1 This reference for a preliminary ruling concerns the interpretation of Article 3 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 (OJ 2009 L 152, p. 1).

2 The reference has been made in proceedings between Daiichi Sankyo Company ('Daiichi Sankyo') and the Comptroller General of Patents, Designs and Trade Marks ('the Patent Office') concerning the latter's refusal to grant Daiichi Sankyo's application for a supplementary protection certificate ('SPC').

Legal context

European Union law

3 Recital 1 and recitals 4 to 10 in the preamble to Regulation No 469/2009 are worded as follows:

'(1) 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] 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 ["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 a [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 [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 Regulation No 469/2009, headed 'Definitions', provides as follows:

'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 …;

(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 Regulation No 469/2009, 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 Directive 2001/81/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 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 Regulation No 469/2009, entitled 'Conditions for obtaining a certificate', provides as follows:

'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 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

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

7 Article 4 of Regulation No 469/2009, entitled 'Subject matter of protection', is worded as follows:

'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 5 of Regulation No 469/2009, entitled '[e]ffects of the certificate', provides that '[s]ubject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.'

The European Patent Convention

9 Under the heading 'Extent of Protection', Article 69 of the Convention on the Grant of European Patents, signed on 5 October 1973, in the amended version applicable at the time of the facts in the main proceedings ('the European Patent Convention'), provides as follows:

'(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.'

10 Article 1 of the Protocol on the Interpretation of Article 69 of the European Patent Convention, which forms an integral part of the convention in accordance with Article 164(1) thereof, provides as follows:

'Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, lit-

eral meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.'

National law

11 Section 60 of the United Kingdom Patents Act 1977 ('UK Patents Act 1977'), headed '[m]eaning of infringement', provides as follows:

'(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say:

(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

…'

12 Section 125 of the UK Patents Act 1977, headed '[e]xtent of invention', is worded as follows:

'(1) For the purposes of this Act an invention … for which a patent has been granted, shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the … patent … as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent … shall be determined accordingly.

…

(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.'

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

13 Daiichi Sankyo is the holder of European patent EP 0503785, entitled 'Biphenylimidazole derivatives, their preparation and their therapeutic use'. The referring court states that the principle ingredient olmesartan medoxomil is specifically disclosed in the wording of claim 4 of the patent. That active ingredient is an angiotensin II receptor antagonist and is used as a medicinal product for the treatment and prophylaxis of hypertension.

14 The active ingredient hydrochlorothiazide is a diuretic which can also be used as an antihypertensive agent.

15 On 13 November 2003, the Patent Office granted to Daiichi Sankyo a SPC (SPC/GB03/24), due to expire on 17 February 2017, for which the 'product' within the meaning of Regulation No 469/2009 is the active ingredient olmesartan medoxomil. In support of its SPC application, Daiichi Sankyo submitted the MA in force in the United Kingdom for the medicinal product Olmotec, containing olmesartan as the sole active ingredient, that authorisation having been granted by the national authorities on 22 May 2003, and, as the first MA for that medicinal product in the European Union, the authorisation for a corresponding medicinal product granted by the German authorities on 13 August 2002.

16 On 14 February 2006, Daiichi Sankyo obtained in the United Kingdom a MA for Olmetec Plus, a medicinal product comprising a combination of the two active ingredients olmesartan medoxomil and hydrochlorothiazide. That medicinal product enables those active ingredients to be administered to patients in a single dose as part of dual therapy. The referring court points out in that regard that Daiichi Sankyo invested considerable time and resources in undertaking clinical trials and studies in order to secure a MA in respect of such a combination therapy.

17 Relying on its patent, on the basis of which the SPC relating to Olmetec had been granted, and on the MA for Olmetec Plus, together with a MA for a corresponding medicinal product granted by the German authorities on 12 May 2005, Daiichi Sankyo filed a SPC application with the Patent Office for the combination of the active ingredients olmesartan medoxomil and hydrocholorothiazide (SPC/GB06/019). If granted, the SPC would expire on 17 February 2017, that is, the same date as the SCP granted on 13 November 2003.

18 By decision of 5 February 2010, the Patent Office refused to grant the SPC that is the subject of application SPC/GB06/019 on the ground that the product concerned, namely the combination of the active ingredients olmesartan medoxomil and hydrocholorothiazide, was not, in the light of Article 3(a) of Regulation No 469/2009, protected by the basic patent held by Daiichi Sankyo, because that patent disclosed only the ingredient olmesartan medoxomil, not that active ingredient in conjunction with one or more active ingredients.

19 The referring court points out that SPCs parallel to that refused by the Patent Office have nevertheless been granted in several Member States, including by the competent authorities of the Kingdom of Belgium, the Italian Republic, the Grand Duchy of Luxembourg, the Republic of Finland and the Kingdom of Norway. However, in France a similar application has been rejected by the Director of the National Institute for Industrial Property. By judgment of 6 November 2009, the cour d'appel de Paris (Court of Appeal, Paris) (France) upheld that decision, taking the view inter alia that 'the combination of olmesartan medoxomil and hydrocholorothiazide is not protected by the basic patent, since that combination does not form part of the patent claims' and that 'lastly, olmesartan medoxomil, alone covered by the patent, has already been the subject of MA No NL 28292 of 6 August 2003 and SPC No 03C0037 granted on 11 February 2005 on the basis of the same patent. The referring court states that Daiichi Sankyo appealed against that judgment to the Cour de cassation (Court of Cassation) (France) and will request a stay of those proceedings pending the ruling of the Court in the present case.

20 In those circumstances, the High Court of Justice of England and Wales, Chancery Division (Patents Court) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Regulation No 469/2009 … recognises amongst the other purposes identified in the recitals, the need for the grant of a SPC by each of the Member States of the Community to holders of national or European patents to be under the same

conditions, as indicated in recitals 7 and 8 [of the Regulation]. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force" and what are the criteria for deciding this?

(2) In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of … Regulation [No 469/2009] and, if so, what are those further or different criteria?

(3) In order for a combination of active ingredients cited in a [MA] to be the subject of a SPC, and having regard to the wording of Article 4 of the Regulation, is the condition that the product be "protected by a basic patent" within the meaning of Articles 1 and 3 of the Regulation satisfied if the product infringes the basic patent under national law?

(4) In order for a combination of active ingredients cited in a [MA] to be the subject of a SPC, and having regard to the wording of Article 4 of … Regulation [No 469/2009], does satisfaction of the condition that the product be "protected by a basic patent" within the meaning of Articles 1 and 3 of the Regulation depend upon whether the basic patent contains one (or more) claims which specifically mention a combination of (1) a class of compounds which includes one of the active ingredients in the said product and (2) a class of further active ingredients which may be unspecified but which includes the other active ingredient in the

said product; or is it sufficient that the basic patent contains one (or more) claims which (1) claim a class of compounds which includes one of the active ingredients in the said product and (2) use specific language which as a matter of national law extends the scope of protection to include the presence of further other unspecified active ingredients including the other active ingredient in the said product?'

Consideration of the questions referred

21 The first subparagraph of Article 104(3) of its Rules of Procedure provides that where a question referred for a preliminary ruling is identical to a question on which the Court has already ruled, or where the answer to such a question may be clearly deduced from existing case-law, the Court may, after hearing the Advocate General, at any time give its decision by reasoned order. The Court considers that that is the case here.

22 The questions referred in the present case by the High Court of Justice are, for all essential purposes, similar to those referred by the Court of Appeal (England and Wales) (Civil Division) in the case which gave rise to the judgment of 24 November 2011 in Case C-322/10 *Medeva* [2011] ECR I-12051.

23 Consequently, the answers and clarifications given by the Court in that judgment are equally valid as regards the question raised by the referring court in the present case.

24 By its questions, which it is appropriate to consider together, the referring court asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC where the active ingredients specified in the SPC application include active ingredients not identified in the wording of the claims of the basic patent relied on in support of that application.

25 As regards whether national rules on infringement may be used for the purpose of determining whether a product is 'protected by a basic patent in force' within the meaning of Article 3(a) of Regulation No 469/2009, it should be noted that, as European Union law currently stands, the provisions concerning patents have not yet been made the subject of harmonisation at European Union level or of an approximation of laws (see Case C-392/97 *Farmitalia* [1999] ECR I-5553, paragraph 26, and *Medeva*, paragraph 22).

26 Accordingly, in the absence of European Union harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-European Union rules which govern patents (see *Farmitalia*, paragraph 27, and *Medeva*, paragraph 23).

27 It should be noted that Regulation No 469/2009 establishes a uniform solution at European Union level by creating a SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State. It thus aims to prevent 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 European Union and thus directly affect the establishment and functioning of the internal market (see Case C-350/92 *Spain* v *Council* [1995]

ECR I-1985, paragraphs 34 and 35; Case C-127/00 *Hässle* [2003] ECR I-14781, paragraph 37; Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295, paragraph 35; and *Medeva,* paragraph 24).

28 Moreover, it should be recalled that Article 5 of Regulation No 469/2009 provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. It follows that Article 3(a) of the regulation precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent (*Medeva*, paragraph 25).

29 That being so, it should be noted, as the Czech Government correctly submitted, that, in accordance with Article 5 of Regulation No 469/2009, a SPC granted in connection with a product confers, upon the expiry of the basic patent, the same rights as were conferred by that patent in relation to the product, within the limits of the protection conferred by the basic patent, as provided for in Article 4 of the regulation. Accordingly, if, during the period in which the patent was valid, the holder of that patent could oppose, on the basis of his patent, all use or certain uses of his product in the form of a medicinal product consisting of such a product or containing it, the SPC granted in relation to that product would confer on the holder the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of the certificate (see *Medeva*, paragraph 39).

30 In view of the foregoing, the answer to the questions referred is that Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC relating to active ingredients which are not identified in the wording of the claims of the basic patent relied on in support of the SPC application.

Costs

31 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:

Article 3(a) 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 precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not identified in the wording of the claims of the basic patent relied on in support of the application for such a certificate.

[Signatures]