ORDER OF THE COURT (Fourth Chamber)

25 November 2011 (*)

(Article 104(3), first subparagraph, of the Rules of Procedure – Medicinal products for human use – Supplementary protection certificate – Regulation (EC) No 469/2009 – Article 3 – Conditions for obtaining a certificate – Concept of a 'product protected by a basic patent in force' – Criteria – Marketing authorisation – Medicinal product placed on the market containing only one active ingredient whereas the patent claims a combination of active ingredients)

In Case C-518/10,

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 10 October 2010, received at the Court on 2 November 2010, in the proceedings

Yeda Research and Development Company Ltd,

Aventis Holdings Inc,

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,

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 Yeda Research and Development Company Ltd and Aventis Holdings Inc, ('Yeda Research'), the appellants in the main proceedings, and the Comptroller General of Patents, Designs and Trade Marks ('the Patent Office') concerning the latter's refusal to grant one of Yeda Research's two applications for supplementary protection certificates ('SPCs').

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, literal 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;

...

(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

...'

12 According to the information provided by the referring court, Section 60(2) of the UK Patents Act 1977 has its origins in Article 26 of the Convention for the European Patent for the common market, signed at Luxembourg on 15 December 1989, annexed to the Agreement relating to Community Patents (OJ 1989 L 401, p. 1), which is entitled 'Prohibition of indirect use of the invention' and provides in paragraph 1 thereof as follows:

'A Community patent shall also confer on its proprietor the right to prevent all third parties not having his consent from supplying or offering to supply within the territories of the Contracting States a person, other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or it is obvious in the circumstances, that these means are suitable and intended for putting that invention into effect.'

13 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 facts of the main proceedings and the question referred for a preliminary ruling

14 Yeda Research is the holder of European patent EP 0667165, entitled 'Therapeutic compositions containing monoclonal antibodies specific to the human epidermal growth factor (EGF) receptor', the application for which was registered by the European Patents Office (EPO) on 15 September 1989. The patent was granted by the EPO on 27 March 2002 and expired on 15 September 2009.

15 According to the information provided by the Court of Appeal, Claim No 1 of the patent concerns a therapeutic composition comprising:

'(a) a monoclonal antibody which inhibits the growth of human tumour cells by said antibody binding to the extra-cellular domain of the human EGF receptors of said tumour cells in an antigen-antibody complex, said tumour cells being characterised by their expression of human EGF receptors and mitogenic stimulation by human EGF; and

(b) an anti-neoplastic agent …'

16 Claim No 2, on the other hand, refers to '[t]he therapeutic composition of claim 1 for separate administration of the components'.

17 The Court of Appeal points out that the patent specifically states that treatment with a combination of one of the antibodies and an anti-neoplastic drug provides more effective treatment than the use of either the monoclonal antibody or anti-neoplastic agent alone. Moreover, the patent specifically discloses and claims the administration of both components separately, provided they are part of the same composition.

18 On 2 November 2004, Yeda Research filed two SPC applications with the Patent Office. In the first application (SPC/GB04/037), it identified the 'product' within the meaning of Article 1(b) of Regulation No 469/2009 as 'cetuximab in combination with irinotecan', whereas in the second application (SPC/GB04/037) it identified only the active ingredient cetuximab.

19 In support of those applications, Yeda Research submitted, as the first MA for the purposes of Article 13 of Regulation No 469/2009, the authorisation granted by the Swiss regulatory authority (SwissMedic) on 1 December 2003 for the medicinal product Erbitux, containing the active ingredient cetuximab. That authorisation was granted by SwissMedic for the following indication, namely, '[i]n combination with irinotecan for the treatment of patients with epidermal growth factor receptor (EGFR) expressing metastatic colorectal cancer after failure of irinotecan-including cytotoxic therapy'. Moreover, that authority stated, when granting that authorisation, that 'the side-effects of irinotecan, a substance associated with the authorised treatment, must also be taken into consideration'.

20 Yeda Research submitted as MA for the purpose of Article 3(b) of Regulation No 469/2009 the authorisation granted on 29 June 2004 by the European Medicines Agency (EMA) to Merck KGaA for the medicinal product Erbitux, which is described as a 'solution for infusion (drip into a vein) that contains the active substance cetuximab'. It should be noted in that regard that that MA was sought from the EMA for use in combination therapy with irinotecan or as a single agent for the treatment of patients with epidermal growth factor receptor (EGFR) expressing metastatic colorectal cancer after irinotecan-based cytotoxic therapy has failed.

21 Following assessment, the Committee for Proprietary Medicinal Products (CPMP) expressed doubts as to whether there was sufficient evidence to establish a positive risk-benefit profile for the use of Erbitux as a single agent treatment and, initially, gave a favourable opinion only in respect of a MA solely for the use of Erbitux in conjunction with irinotecan. However, in a subsequent opinion of 10 September 2008, that committee gave a favourable opinion, resulting in the MA being amended to extend the indication so that it also covered the use of Erbitux as a single agent where previous treatment using oxaliplatin and irinotecan has failed and the patient cannot receive irinotecan.

22 The active ingredient irinotecan is marketed inter alia in the medicinal product Campto by the Pfizer Laboratory, which has MAs in several Member States, in which it is indicated that that medicinal product may be administered as a single agent treatment or in conjunction with other medicinal products for the treatment of cancer, including the product containing the active ingredient cetuximab.

23 By decision of 23 February 2010, the Patent Office refused to grant the two SPCs sought. With regard to application SPC/GB04/037, the Patent Office considered that the MA granted by the EMA covered the active ingredient cetuximab alone, so that the application did not satisfy the condition laid down in Article 3(b) of Regulation No 469/2009. As regards application SPC/GB04/038, the Patent Office refused to grant a SPC for the active ingredient cetuximab alone since, unlike the combination consisting of the two active ingredients cetuximab and irinotecan, cetuximab was not individually protected by the basic patent within the meaning of Article 3(a) of that regulation.

24 Yeda Research appealed against that decision before the High Court of Justice of England and Wales, Chancery Division (Patents Court) and at the same time requested that court to make a reference to the Court of Justice for a preliminary ruling in the wake of the reference made 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* ECR I-0000.

25 By judgment of 12 July 2010, the High Court of Justice dismissed the action, taking the view that the MA granted by the EMA for Erbitux, being the only relevant MA for the purposes of examining the SPC applications at issue in the main proceedings, covered the single active ingredient cetuximab alone, irrespective of the restrictions as to use set out in the MA for that medicinal product, which required that it be used in conjunction with another active ingredient contained in another medicinal product. As regards the MA granted in Switzerland, that court stated that it was not established whether that authorisation related to a combined product or a combined use of medicinal products.

26 Moreover, relying on the case-law of the Court of Justice, in particular paragraph 25 of the judgment in Case C-431/04 *Massachusetts Institute of Technology* [2006] ECR I-4089 and paragraph 18 of the order in Case C-202/05 *Yissum* [2007] ECR I-2839, decisions in which the Court considered that the concept of 'product' cannot include the therapeutic use of an active ingredient protected by a basic patent and that a substance which does not have any therapeutic effect of its own and is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of 'active ingredient', the High Court of Justice concluded that the fact that the indication for the therapeutic use of Erbitux referred to combination therapy in conjunction with another active ingredient, namely irinotecan, contained in another medicinal product did not support the conclusion that the MA granted for Erbitux covered the combination of the active ingredients cetuximab and irinotecan for which SPC protection was sought. That court also took the view that the basic patent protected that therapeutic combination but did not disclose a single active ingredient.

27 Yeda Research appealed against the judgment of the High Court of Justice to the Court of Appeal as regards the rejection of its application for a SPC covering the active ingredient cetuximab alone (SPC/GB04/038). It submitted that, while its patent was still valid, it was in a position, under national patents law, to oppose any use by a third party of the active ingredient cetuximab, including use as a single agent treatment, in that such use would constitute indirect infringement of its invention or contributory infringement for the purpose of Section 60(2) of the UK Patents Act 1977. It should therefore be concluded, for the purposes of the application of Article 3(a) of Regulation No 469/2009, that, under the national law applicable, the active ingredient at issue was protected by the patent, notwithstanding the fact that the patent identifies a combination of that active ingredient and another active ingredient, namely, in the main proceedings, irinotecan.

28 On the other hand, the Patent Office submitted that, even if the test of infringement of the basic patent may be used for the purpose of the application of Article 3(a) of Regulation No 469/2009, such application should be limited to direct infringement of the basic patent and not be extended to indirect infringement of that patent, on which Yeda Research's claims are based. In particular, it states that, if it were to apply the indirect infringement test, it would then be required to determine the use of the product, in this instance in conjunction with the active ingredient irinotecan, even though, according to

the Court's case-law, the intended use of a product is irrelevant for the purpose of defining the product and, in the context of a SPC application, such use would be theoretical, since it would depend on the scope of the MA at the time the application was submitted. In the main proceedings, the initial MA authorised an indication for use in combination therapy with another active ingredient, whereas, in the amended version, it subsequently also authorised an indication for the use of the active ingredient cetuximab as a single agent treatment.

29 In those circumstances, and taking the view that it is relevant that certain national intellectual property offices have granted to Yeda Research SPCs similar to that which was refused by the Patent Office, the Court of Appeal (England and Wales) (Civil Division) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'If the criteria for deciding whether a product is "protected by a basic patent in force" under Article 3(a) of ... Regulation [No 469/2009] include or consist of an assessment of whether the supply of the product would infringe the basic patent, does it make any difference to the analysis if infringement is by way of indirect or contributory infringement based on Article 26 of the [European] Patent Convention, enacted as Section 60(2) of the [UK] Patents Act 1977 in the United Kingdom, and the corresponding provisions in the laws of other Member States of the Community?'

Consideration of the question referred

30 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.

31 Indeed, the question referred by the Court of Appeal in the present case is, for all essential purposes, similar to those referred by that court in the case which gave rise to the judgment in *Medeva*.

32 Consequently, the answers and clarifications given by the Court in that judgment are equally valid as regards the question referred by the Court of Appeal in the present case.

33 By its question, the Court of Appeal 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 ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone.

34 As to whether the 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 recalled 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).

35 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).

36 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).

37 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).

38 Similarly, if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, a SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation (*Medeva*, paragraph 26).

39 In view of the foregoing considerations, the answer to the question 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 where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone.

Costs

40 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 where the active ingredient specified in the application, even though identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone.

[Signatures]

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* Language of the case: English.