JUDGMENT OF THE COURT (Fourth Chamber)

24 November 2011 *

In Case C-422/10,

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 19 July 2010, received at the Court on 27 August 2010, in the proceedings

Georgetown University,

University of Rochester,

Loyola University of Chicago,

v

Comptroller General of Patents, Designs and Trade Marks,

* Language of the case: English.

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: K. Sztranc-Sławiczek, Administrator,

having regard to the written procedure and further to the hearing on 12 May 2011,

after considering the observations submitted on behalf of:

— Georgetown University, the University of Rochester and Loyola University of Chicago, by J. Miles, acting as Agent, and D. Alexander, QC,

— the Portuguese Government, by L. Inez Fernandes and P. 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 13 July 2011,

gives the following

Judgment

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 Georgetown University, the University of Rochester and Loyloa University of Chicago, the applicants in the main proceedings, and the Comptroller of Patents, Designs and Trade Marks ('the Patent Office') concerning the latter's refusal to grant some of the applicants' 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;

...'

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 On 24 June 1993, Georgetown University filed an application for a European patent entitled 'Papillomavirus vaccine', registered by the European Patents Office (EPO) under number EP 0647140 for a human papillomavirus (PV) L1 protein capable of inducing neutralising antibodies against papillomavirus virions. There are many human papillomavirus (HPV) genotypes, which are grouped according to the

similarity of their DNA sequences. Types 6 and 11 are responsible for condylomas, whereas types 16 and 18 are responsible for precancerous lesions in the genital region and also cervical cancer.

14 The Georgetown University patent claims include a vaccine for the prevention of papillomavirus infection, comprising at least that protein, or fragment thereof, of, among others, HPV-16, HPV-18 or HPV-16 and HPV-18 together. That patent was granted on 12 December 2007 and is due to expire on 23 June 2013.

15 On 14 December 2007, relying on the MA granted to Sanofi Pasteur MSD SNC on 20 September 2006 for the medicinal product Gardasil, containing HPV-6, HPV-11, HPV-16 and HPV-18 purified proteins obtained from yeast cells (Saccharomyces cerevisiae), Georgetown University files four SPC applications, identifying the product as 'the recombinant L1 protein' of HPV-6, HPV-11, HPV-16 and HPV-18 (SCP/GB07/079, SCP/GB07/073, SCP/GB07/080 and SCP/GB07/078), respectively. Moreover, relying on the MA granted to GlaxoSmithKline Biologicals SA on 20 September 2007 for the medicinal product Cervarix, containing HPV-16 and HPV-18 purified proteins obtained from insect cells (Trichoplusia ni), Georgetown University filed two SPC applications identifying the product as 'the recombinant L1 protein of papillomavirus type 16 as expressed by an insect cell' (SCP/GB07/071) and 'the recombinant L1 protein of papillomavirus type 18 as expressed by an insect cell' (SPC/GB07/70), respectively.

16 Those applications were all rejected by decision of the Patent Office of 29 December 2009 for failure to comply with the condition laid down in Article 3(b) of Regulation No 469/2009, since the medicinal product for which the MA was granted contained more active ingredients than those for which SPC protection was sought. Georgetown University challenged those decisions before the referring court. As regards two other applications filed by Georgetown University, relying on the MAs for Gardasil and Cervarix, respectively, and identifying the product as 'the recombinant L1 protein

of papillomavirus' types HPV-6, HPV-11, HPV-16 and HPV-18 (SCP/GB07/074) and types 16 and 18 alone (SCP/GB07/072), the Patent Office informed Georgetown University that those applications complied with the conditions laid down in the regulation and SPCs could therefore be granted but would be delayed pending the outcome of its appeals before the referring court in respect of the six applications referred to above.

17 On 8 March 1994, the University of Rochester filed an application for a patent entitled 'Production of human papillomavirus capsid protein and virus-like particles', registered by the EPO under number EP 0688227 for 'a method of expressing the human papillomavirus capsid protein coding sequence of type 6 ([HPV]-6), type 11 ([HPV]-11) …'. The patent claims include, first, a 'purified recombinant human papilloma virus-like particle or capsomere which comprises human papillomavirus 16 ([HPV]-16) L1 capsid protein expressed from an L1 protein coding sequence …' and, second, '… a multivalent vaccine comprising a virus-like particle from different human papilloma viruses'. That patent was granted on 25 May 2005 and is due to expire on 7 March 2014.

18 By decisions of 4 and 5 October 2009, the Patent Office granted the University of Rochester SPCs based on the MAs for Gardasil and Cervarix, respectively, and identifying the product as 'the combination of the virus-like particles of the recombinant Ll protein of human papillomavirus types 6, 11, 16 and 18' (SCP/GB07/018) and 'the combination of the virus-like particles of the recombinant Ll protein of human papillomavirus types 16 et 18' (SCP/GB07/076). However, the Patents Office refused, by decision of 29 December 2009, to grant a SPC based on the MA for Cervarix identifying the product as 'the virus-like particle of the recombinant L1 protein of human papillomavirus type 16 as expressed in an insect cell' (SCP/GB07/075), for failure to comply with the condition laid down in Article 3(b) of Regulation No 469/2009.

19 On 9 October 1995, Loyola University of Chicago filed an application for a patent entitled 'Papilloma virus-like particles, fusion proteins and process for producing same', registered by the EPO under number EP 0809700. The patent claims include 'recombinant-produced papilloma virus-like particles that are formed after expression of the viral structure proteins Ll or Ll and L2, characterised in that one or more sections of the Ll protein are deleted, wherein the ability to form virus-like particles remains'. That patent was granted on 10 May 2006 and is due to expire on 8 October 2015.

20 By decision of 5 October 2009, the Patent Office granted a SPC to Loyola University of Chicago identifying the product as 'the combination of the virus-like particle of the recombinant L1 protein of human papillomavirus types 16 and 18' based on the MA for Cervarix (SCP/GB07/077). However, by decision of 29 December 2009, the Patent Office refused to grant a SPC based on the MA for Cervarix identifying the product as 'the virus-like particle of the recombinant L1 protein of human papillomavirus type 16 as expressed in an insect cell' (SCP/GB07/069), since the application thus worded, based on the MA for Cervarix, failed to comply with the conditions laid down in Article 3(b) of Regulation No 469/2009.

21 The High Court of Justice of England and Wales, Chancery Division (Patents Court), before which the applicants in the main proceedings brought actions for annulment of the Patent Office's decisions refusing to grant SPCs on the ground that the medicinal products for which the MA was granted contained more active ingredients than those specified in the respective SPC applications, decided to stay the proceedings and refer the following question to the Court for a preliminary ruling, which

is worded in the same terms as the sixth question referred by the Court of Appeal (England and Wales) (Civil Division) in Case C 322/10.

'Does … Regulation [No 469/2009] and, in particular, Article 3(b), permit the grant of a [SPC] for a single active ingredient or combination of active ingredients where:

(a) a basic patent in force protects the single active ingredient or combination of active ingredients within the meaning of Article 3(a) of … Regulation [No 469/2009]; and

(b) a medicinal product containing the single active ingredient or combination of active ingredients together with one or more other active ingredients is the subject of a valid authorisation granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC which is the first [MA] that places the single active ingredient or combination of active ingredients on the market?'

22 By order of the President of the Court of 12 January 2011, Cases C-322/010 and C-422/10 were joined for the purposes of the oral procedure and the judgment, in accordance with Article 43 of the Court's Rules of Procedure. However, in view of the factual differences between the situations at issue in the main proceedings, by order of the President of the Fourth Chamber of the Court of 11 October 2011, those cases were disjoined, pursuant to Article 43 of those rules, for the purposes of the judgment.

Consideration of the question referred

23 By its question, the referring court asks, in essence, whether Article 3(b) of Regulation No 469/2009 may be interpreted as not precluding the competent industrial property office of a Member State from granting a SPC for an active ingredient specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the MA is submitted in support of the SPC application contains not only that active ingredient but also other active ingredients.

24 First, it must be noted that the fundamental objective of Regulation No 469/2009 is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health (see Case C-392/97 *Farmitalia* [1999] ECR I-5553, paragraph 19, and Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295, paragraph 30).

25 The reason given for the adoption of that 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 seeks to make up for that insufficiency by creating a SPC for medicinal products (see Case C-181/95 *Biogen* [1997] ECR I-357, paragraphs 26, and *AHP Manufacturing*, paragraph 30).

26 Moreover, as is apparent in particular from subparagraphs 4 and 5 of paragraph 28 of the explanatory memorandum to the proposal for Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final) ('the explanatory memorandum'), the protection conferred by a SPC is largely intended to cover the cost of research leading to the discovery of new 'products', that term being used as a common denominator covering the three different types of patent which can confer entitlement to a SPC. Further, if the conditions laid down in Regulation No 469/2009 are met, even a patent protecting the process by which a 'product' within the meaning of the regulation

is obtained may, in accordance with Article 2 of the regulation, enable a SPC to be granted and, in that case, in accordance with Article 5 of the regulation and as stated at paragraph 44 of the explanatory memorandum, the SPC confers the same rights as conferred by the basic patent as regards the process by which the product is obtained, and, if the law applicable to that patent so provides, the protection of the process by which the product is obtained will be extended to the product thus obtained (Case C-322/10 *Medeva* [2011] ECR I-12051, paragraph 32).

27 As the referring court stated and as is apparent from the observations submitted to the Court, at present medicinal products placed on the market, in particular for complex diseases, often consist of combinations of active ingredients for multiple therapeutic uses which can be administered to patients in a single preparation. Similarly, vaccines are often developed, in particular having regard to the recommendations of the health authorities of the Member States, in the form of multivalent vaccines (*Medeva,* paragraph 33).

28 If the holder of such a basic patent relating to an innovative active ingredient or an innovative combination of active ingredients were to be refused a SPC on the ground that, in the commercial version of the medicinal product which places that active ingredient or that combination on the market for the first time, the active ingredient or the combination coexists in the medicinal product alongside other active ingredients or combinations which have other therapeutic purposes and may or may not be protected by another basic patent in force, the fundamental objective of Regulation No 469/2009, which is to ensure sufficient protection to encourage pharmaceutical research and play a decisive role in the continuing improvement in public health, could be undermined (*Medeva*, paragraph 34).

29 It is clear that such an outcome cannot be compatible with the fundamental objectives pursued by Regulation No 469/2009 by the creation of a SPC for medicinal products (*Medeva*, paragraph 36).

30 The requirement in Regulation No 469/2009 that the 'product' must be covered, as a medicinal product, by a MA confirms that approach in that that requirement does not in itself rule out the possibility that the MA may cover other active ingredients contained in such a medicinal product. Moreover, in accordance with Article 4 of Regulation No 469/2009, a SPC is intended to protect the 'product' covered by the MA, not the medicinal product as such (*Medeva*, paragraph 37).

31 Furthermore, such a situation corresponds to that described at paragraphs 34 and 39 of the explanatory memorandum, in which the Commission of the European Communities stated, first, that the requirement that the product must have obtained a valid MA is met 'if the proprietary medicinal product containing it has been granted the [MA] concerned' and, second, that in such a situation, 'where the product authorised consists of a combination of compound X and another active ingredient, only compound X will be protected by the certificate' (*Medeva,* paragraph 38).

32 In accordance with Article 5 of Regulation No 469/2009, a SPC thus granted in connection with such a product confers, upon the expiry of the patent, the same rights as were conferred by the basic 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 patent holder 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 (*Medeva*, paragraph 39).

33 However, it should be added that, in such a situation, first, only the authorisation in respect of the first medicinal product placed on the European Union market comprising, among its active ingredients, the active ingredient which is the subject of the application may be regarded as the first MA for that 'product' as a medicinal product within the meaning of Article 3(d) of Regulation No 469/2009 (*Medeva*, paragraph 40).

34 Second, where a patent protects a product, in accordance with Article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent (see *Biogen*, paragraph 28, and *Medeva*, paragraph 41).

35 In view of the foregoing, the answer to the question referred is that Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a SPC for an active ingredient specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the MA is submitted in support of the SPC application contains not only that active ingredient but also other active ingredients.

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:

Article 3(b) 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, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for an active ingredient specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the supplementary protection certificate application contains not only that active ingredient but also other active ingredients.

[Signatures]