ORDER OF THE COURT (Fourth Chamber)

25 November 2011 *

In Case C-630/10,

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 14 December 2010, received at the Court on 24 December 2010, in the proceedings

University of Queensland,

CSL Ltd,

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: 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 the University of Queensland and CSL Ltd ('the University of Queensland'), the applicants in the main proceedings, and the Comptroller General of Patents, Designs and Trade Marks ('the Patent Office') concerning the latter's refusal to grant the University of Queensland's 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 20 July 1992, the University of Queensland submitted an application for a European patent which was registered by the European Patents Office (EPO) under number EP 0595935 and entitled 'Vaccine against the papillomavirus'. The patent relates to methods of production of papillomavirus-like particles ('VLPs') of the Human papillomavirus ('HPV') Type 6 (HPV-6) and Type 11 (HPV-11), the VLPs per se and vaccines produced from or comprising VLPs. The mother patent was granted

on 19 March 2003 and is due to expire on 19 July 2012. There are many HPV genotypes, which are grouped according to the similarity of their DNA sequence.

14 Claim Nos 1, 16 and 17 of the patent are worded as follows:

'(1) A method of production of papillomvirus virus-like particles (VLPs) of HPV-11 or HPV-6, including the steps of:

(i) constructing: a recombinant DNA molecule which encodes a papillomavirus L1 protein of HPV-11 or HPV-6; or one or more recombinant DNA molecules which encodes or encode a combination of papillomavirus L1 protein of HPV-11 and a papillomavirus L2 protein of HPV-11 or which encodes or encode a combination of a papillomavirus L1 protein of HPV-6 and a papillomavirus L2 protein of HPV-6;

(ii) transfecting a host cell with said recombinant DNA molecule or molecules so that virus-like particles (VLPs) of HPV-11 or HPV-6 are produced within the cell after expression of the L1 protein or of the combination of L1 and L2 proteins; and

(iii) obtaining virus-like partciles (VLPs) of HP-V11or HPV-6 from the host cells.

...

16. Virus-like particles (VLPs) of HPV-11 or HPV-6 obtainable by a method according to any one of the preceding claims.

17. A vaccine produced from papillomavirus virus-like particles (VLPs) of HPV-11 or HPV-6 obtainable by a method according to any one of claims 1 to 15.'

15 Relying on that patent and the MA granted on 20 September 2006 by the European Medicines Agency (EMA) to Sanofi Pasteur MSD SNC for the medicinal product Gardasil containing HPV-6, HPV-11, HPV-16 and HPV-18 purified proteins obtained from yeast cells (Saccharomyces cerevisiae), the University of Queensland submitted SPC applications on 21 February 2007 covering a combination of VLPs of types HPV-6, HPV-11, HPV-16 and HPV-18 (SPC/GB07/014), the HPV-11 VLP alone (SPC/GB/015) and the HPV-6 VLP alone (SPC/GB07/016).

16 The University of Queensland is also the holder of European patent EP 1359156 B1, entitled 'Vaccine against Human Papillomavirus (Type 18)', the subject of a divisional patent application which was granted on 7 March 2006 and is due to expire on the same date as the parent patent, namely on 19 July 2012.

17 Relying on that patent and on the MA granted for Gardasil, the University of Queensland filed an application with the Patent Office on 8 March 2007 for a SPC covering the HPV-18 VLP (SCP/GB07/021). Moreover, relying on the same patent but on the MA granted on 20 September by the EMA to GlaxoSmithKline Biologicals SA for the medicinal product Cervarix containing purified HPV-16 and HPV-18 proteins

obtained from insect cells (Trichoplusia ni), the University of Queensland applied on 14 December 2007 for two other SPCs covering HPV-18 VLPs (SPC/GB07/082) and a combination of HPV-16 and HPV-18 VLPs (SPC/GB/084), respectively.

18 Lastly, the University of Queensland is the holder of a third European Patent, registered under number EP 1298221 B1, entitled 'polynucleotide segment of the HPV-16 genome'. That patent, which was also the subject of a divisional patent application, was granted on 12 July 2006 and is also due to expire on 19 July 2012.

19 Relying on that patent and the MA granted for Gardasil, the University of Queensland filed an application on 21 February 2007 for a SPC covering the HPV-16 VLP alone (SPC/GB07/017). Furthermore, relying on that patent but, additionally, on the MA granted for Cervarix, the University of Queensland applied on 14 December 2007 for a SPC covering the HPV-16 VLP (SPC/GB07/081).

20 By decision of 24 September 2010, the Patent Office rejected all the SPC applications submitted to it, either because the combination of active ingredients in question was not, as such, claimed in the patents concerned (SPC/GB07/014 and SPC/GB07/084), or because, while the applications related to individual active ingredients, claimed as such in the patents concerned, the MAs provided in support of the SPC applications related to medicinal products containing other active ingredients, not claimed as such in any of those patents (SPC/GB07/015, SPC/GB07/016, SPC/GB07/017, SPC/GB07/021, SPC/GB07/081 and SPC/GB07/082).

21 By application of 20 October 2010, the University of Queensland brought an action against the Patent Office's decision before the referring court.

22 In those circumstances, the High Court of Justice of England and Wales, Chancery Division (Patents Court) decided to stay the proceedings before it and to refer the following questions to the Court 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) Is one of these further or different criteria whether the active ingredients are admixed together rather than being delivered in separate formulations but at the same time?

(4) For the purposes of Article 3(a) [of the Regulation], is a multi-disease vaccine comprising multiple antigens “protected by a basic patent” if one antigen of the vaccine is “protected by the basic patent in force”?

(5) In a case like the present one involving a medicinal product comprising more than one active ingredient, is it relevant to the assessment of whether or not "the product is protected by a basic patent" according to Article 3(a) [of Regulation No 469/2009] that the basic patent is one of a family of patents based on the same original patent application and comprising a parent patent and two divisional patents which between them protect all the active ingredients in the medicinal product?

(6) In a case like the present one involving a basic patent with claims to "a process to obtain a product" in the sense of Article 1(c) [of Regulation No 469/2009], does the "product" of Article 3(a) [of the Regulation] have to be obtained directly by means of that process?

…

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

(a) a basic patent in force protects the single active ingredient within the meaning of Article 3(a) of the … Regulation; and

(b) a medicinal product containing the single active ingredient together with one or more 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 on the market?

(8) Does the answer to Question 7 differ depending on whether the authorisation is for the single active ingredient admixed with the one or more other active ingredients rather than being delivered in separate formulations but at the same time?'

Consideration of the questions referred

23 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.

24 The questions referred in the present case are, for all essential purposes, similar to those referred by the Court of Appeal (England and Wales) (Civil Division) and by the referring court in the cases which gave rise to the judgments of 24 November 2011 in Case C-322/10 *Medeva* [2011] ECR I-12051 and Case C-422/10 *Georgetown University and Others* [2011] ECR I-12051.

25 Consequently, the answers and clarifications given by the Court in those judgments are equally valid as regards the question raised by the referring court in the present case.

Questions 1 to 5

26 By its first five 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 in support of that application.

27 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).

28 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).

29 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).

30 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).

31 The answer to the first five questions is, therefore, 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.

Questions 7 and 8

32 By Questions 7 and 8, which it is appropriate to consider together, the referring court asks, in essence, whether Article 3(b) of Regulation No 469/2009 must 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.

33 Article 3(b) of Regulation No 469/2009 does not, in principle, 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 (see *Medeva*, paragraph 42, and *Georgetown University and Others*, paragraph 35).

34 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, and *Georgetown University and Others*, paragraph 32).

35 Moreover, where a product is protected by a number of basic patents in force, each of those patents may be designated for the purpose of the procedure for the grant of a certificate but only one certificate may be granted for a basic patent (see Case C-181/95 *Biogen* [1997] ECR I-357, paragraph 28; *Medeva,* paragraph 41; and *Georgetown University and Others*, paragraph 34).

36 In view of the foregoing, the answer to Questions 7 and 8 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.

Question 6

37 By Question 6, the referring court asks whether, in a case involving a basic patent relating to a process by which a product is obtained, it is necessary for the purpose of granting a SPC, in the light in particular of Article 1(c) of Regulation No 469/2009, for it to be possible for the 'product' to be obtained directly by means of that process.

38 It is sufficient to point out that a patent protecting the process by which a 'product' within the meaning of Regulation No 469/2009 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, the SPC confers the same rights as conferred by the basic patent as regards the process by which the product is obtained (see *Medeva*, paragraph 32).

39 If the law applicable to such a patent so provides, a SPC granted on the basis of that patent will also extend the protection of the process by which the product is obtained to the product thus obtained (see, to that effect, *Medeva*, paragraph 32).

40 However, just as Article 3(a) of Regulation No 469/2009 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), where the basic patent relied on in support

of a SPC application relates to the process by which a product is obtained, that provision also precludes a SPC being granted for a product other than that identified in the wording of the claims of that patent as the product deriving from that process. The grant of a SPC is not conditional on whether it is possible to obtain a product directly as a result of the process by which the product is obtained, where that process has been the subject of a patent.

41 The answer to Question 6 is therefore that, in the case of a basic patent relating to a process by which a product is obtained, Article 3(a) of Regulation No 469/2009 precludes a SPC being granted for a product other than that identified in the wording of the claims of that patent as the product deriving from the process in question. Whether it is possible to obtain the product directly as a result of that process is irrelevant in that regard.

Costs

42 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. 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.

2. **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 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.**

3. **In the case of a basic patent relating to a process by which a product is obtained, Article 3(a) of Regulation No 469/2009 precludes a supplementary protection certificate being granted for a product other than that identified in the wording of the claims of that patent as the product deriving from the process in question. Whether it is possible to obtain the product directly as a result of that process is irrelevant in that regard.**

[Signatures]