JUDGMENT OF THE COURT (Fourth Chamber)

24 November 2011 *

In Case C-322/10,

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 24 June 2010, received at the Court on 5 July 2010, in the proceedings

Medeva BV

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,

* Language of the case: English.

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:

— Medeva BV, by A. Waugh, Barrister, instructed by D. Sternfeld, Solicitor,

— the United Kingdom Government, by S. Hathaway, acting as Agent, and T. Micheson, Barrister,

— the Latvian Government, by M. Borkoveca and K. Krasovska, acting as Agents,

— the Lithuanian Government, by V. Balčiūnaitė and R. Mackevičienė, acting as Agents,

— 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 was made in proceedings between Medeva BV ('Medeva') and the Comptroller of Patents, Designs and Trade Marks ('the Patent Office') concerning the latter's refusal to grant Medeva'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 26 April 1990, Medeva filed an application for a European patent, registered by the European Patents Office (EPO) under EP number 1666057, for a method for the preparation of an acellular vaccine against Bordetella pertussis (whooping cough agent), also known as 'Pa', consisting of a combination of two antigens as active ingredients, namely pertactin and filamentous haemagglutinin ('filamentous haemagglutinin

antigen'), in such a ratio as to provide a synergistic effect in vaccine potency. The patent was granted by the EPO on 18 February 2009 and expired on 25 April 2010.

14 Medeva filed five SPC applications with the Patent Office, primarily seeking supplementary protection for DTPa-IPV/HIB vaccines covering diphtheria (D), tetanus (T), whooping cough (Pa), poliomyelitis (IPV) and/or meningitis (Haemophilus influenzae, also known as 'HIB'). In support of those applications, Medeva submitted MAs granted by the French, German and United Kingdom authorities for medicinal products named Infanrix DTCaP, Infanrix IPV, Infanrix IPV+HIB, Infanrix Quinta, Pediacel and Repevax, each of which contained, in addition to the combination of pertactin and filamentous haemagglutinin, other active ingredients, the total number of which was between 8 and 11.

15 The Patent Office, by decision of 16 November 2009, refused to grant the SPCs applied for, concluding inter alia that, in the case of four of the applications (SCP/GB09/015, 09/016, 09/017 and 09/019), more active components or ingredients were specified in the applications for SPCs covering those components than were identified in the wording of the claims of the basic patent, and they were not therefore protected by the basic patent within the meaning of Article 3(a) of Regulation No 469/2009. In the case of the fifth application (SPC/GB09/018), the Patent Office concluded inter alia that, although the active components or ingredients identified in the patent were the same as those specified in the SPC application, namely the combination of pertactin and filamentous haemagglutinin, the MAs submitted in support of that application did not fulfil the conditions laid down in Article 3(b) of the Regulation, inter alia because they related to medicinal products containing 9 active ingredients, that is to say vaccines which did not contain only the active components or ingredients specified in the SPC application and in the patent claims.

16 Medeva lodged an appeal against that decision before the High Court of Justice of England and Wales (Civil Division), which was dismissed by judgment of 27 January 2010.

17 Medeva then appealed against that judgment to the Court of Appeal (England and Wales) (Civil Division), which decided to stay the proceedings and 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 an 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 [in the preamble to that regulation]. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of … Regulation [No 469/2009] 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 a case like the present one involving a multi-disease vaccine, 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?

4 For the purposes of Article 3(a) [of Regulation No 469/2009], 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 For the purposes of Article 3(a) [of Regulation No 469/2009], is a multi-disease vaccine comprising multiple antigens "protected by a basic patent" if all antigens directed against one disease are "protected by the basic patent in force"?

…

6 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 the SPC Regulation; 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?'

18 By order of the President of the Court of 12 January 2011, Cases C-322/10 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 questions referred

Questions 1 to 5

19 By its first five questions, which it is appropriate to examine together, 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 ingredients specified in the application include active ingredients not mentioned in the wording of the claims of the basic patent relied on in support of such an application.

20 While the Latvian, Lithuanian and Portuguese Governments submit that only the wording of the claims is relevant 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, Medeva and the United Kingdom Government maintain that the concept of a 'product … protected by a basic patent in force' within the meaning of that provision corresponds to any combination of substances of a medicinal product directly infringing the patent.

21 In the case which gave rise to the judgment in Case C-392/97 *Farmitalia* [1999] ECR I-5553, the question was raised as to the criteria to be used for determining whether a product is protected by a basic patent in force within the meaning of Article 3(a) of Regulation No 1768/92, which, as stated in recital 1 in the preamble to Regulation No 469/2009, was codified by the latter regulation.

22 At paragraph 26 of *Farmitalia*, the Court stated that, as Community law then stood – a situation which has not substantially changed in the context of European Union law – the provisions concerning patents had not yet been made the subject of harmonisation at European Union level or of an approximation of laws.

23 The Court therefore concluded at paragraph 27 of that judgment that, 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 governing patents.

24 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; and Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295, paragraph 35).

25 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.

26 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.

27 That approach is also borne out by the second subparagraph of paragraph 20 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'), which, in so far as concerns what is 'protected by the basic patent', refers expressly and solely to the wording of the claims of the basic patent. That interpretation also accords with that given in recital 14 in the preamble to Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30), which refers to the need for 'products' to be 'the subject of patents specifically covering them'.

28 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 specified in the wording of the claims of the basic patent relied on in support of the SPC application.

Question 6

29 By its sixth question, the Court of Appeal 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 a combination of two active ingredients, corresponding to that 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 combination of the two active ingredients but also other active ingredients.

30 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 *Farmitalia*, paragraph 19, and *AHP Manufacturing*, paragraph 30).

31 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).

32 Moreover, as is apparent in particular from subparagraphs 4 and 5 of paragraph 28 of 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.

33 As the Court of Appeal 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 recommendation of the health authorities of the Member States, in the form of multivalent vaccines.

34 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.

35 First, the holder of such a patent would enjoy only the period of effective protection conferred by the patent, which, according to European Union legislature, is insufficient to cover the investment put into pharmaceutical research, which is why that legislature created a SPC for medicinal products designed to make up for that insufficiency. Second, such an approach would tend to favour the development of

monovalent medicinal products, in particular vaccines, which may not be in the interests of patients or national public health authorities. In such a situation, the holders of such patents would be forced to develop commercially and maintain on the market medicinal products containing only the active ingredients specified as such in the basic patent in order to obtain a MA for a medicinal product covering precisely those active ingredients which, as such, the holder could be certain would confer entitlement to a SPC.

36 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.

37 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.

38 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'.

39 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.

40 However, it should be added that, in a situation such as that in the main proceedings, first, only the authorisation in respect of the first medicinal product placed on the European Union market comprising, among its active ingredients, the combination of the two active ingredients identified in the wording of the claims of the patent, namely pertactin and filamentous haemagglutinin, 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.

41 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).

42 In view of the foregoing, the answer to Question 6 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 a combination of two active ingredients, corresponding to that 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 combination of the two active ingredients but also other active ingredients.

Costs

43 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 specified 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**

a combination of two active ingredients, corresponding to that 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 application for a supplementary protection certificate contains not only that combination of the two active ingredients but also other active ingredients.

[Signatures]