Court of Justice EU, 12 December 2013, Georgetown University v NL Octrooicentrum

v

PATENT – SPC

A patent which protects several different products can obtain several SPC's

- **In that regard, it is possible, in principle, on the basis of a patent which protects several different 'products', to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is 'protected' as such by that 'basic patent' within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation (Case C‑443/12 Actavis Group PTC and Actavis UK [2013] ECR I-0000, paragraph 29), and is contained in a medicinal product with an MA.**

31 Indeed, the wording of Article 1(b) and Article 3(c) of Regulation No 469/2009 does not preclude such an interpretation. That interpretation is also borne out by the objective pursued by that regulation, which, as is apparent from paragraph 11 of the Explanatory Memorandum to the Proposal for a Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), is to encourage research in the pharmaceutical sector by granting one SPC per product, a product being understood to mean an active substance in the strict sense. Any other interpretation might, moreover, give rise to circumvention tactics, entailing additional costs which may discourage innovation, in the sense that those concerned would be minded to apply for a separate basic patent for each of their 'products'.

- **In the main proceedings, in the light of paragraph 30 above, the combination of the four active ingredients in question (which includes HPV-16) as well as HPV‑16 as an active ingredient individually, are protected by Georgetown University's basic patent within the meaning of Article 3(a) of Regulation No 469/2009.**

Therefore, Article 3(c) of that regulation does not, in principle, preclude Georgetown University being granted, on the basis of that patent and the same MA, namely the marketing authorisation for Gardasil, an SPC both for the combination of active ingredients (HPV-6, HPV-11, HPV-16 and HPV-18) and for the active ingredient HPV-16 individually. Even if the protection conferred by two such SPCs were to overlap, they would, in principle, expire on the same date.

- **In the light of the foregoing considerations, the answer to Question 1 is that, in circumstances such as those in the main proceedings, where, on the basis of a basic patent and an MA for a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained an SPC for that combination of active ingredients, protected by that patent within the meaning of Article 3(a) of Regulation No 469/2009, Article 3(c) of that regulation must be interpreted as not precluding the proprietor from also obtaining an SPC for one of those active ingredients which, individually, is also protected as such by that patent.**

Source: **curia.europa.eu**

Court of Justice EU, 12 December 2013

(M. Ilešič, C.G. Fernlund, A. Ó Caoimh, C. Toader (Rapporteur) and E. Jarašiūnas)

JUDGMENT OF THE COURT (Third Chamber)

12 December 2013 (*)

"Medicinal products for human use – Supplementary protection certificate – Regulation (EC) No 469/2009 – Article 3 – Conditions for obtaining such a certificate – Whether it is possible to obtain a number of supplementary protection certificates on the basis of just one patent"

In Case C‑484/12,

REQUEST for a preliminary ruling under Article 267 TFEU

from the Rechtbank's-Gravenhage (Netherlands), made by decision of 12 October 2012, received at the Court on 31 October 2012, in the proceedings

Georgetown University

v

Octrooicentrum Nederland, operating under the name NL Octrooicentrum,

THE COURT (Third Chamber),

composed of M. Ilešič, President of the Chamber, C.G. Fernlund, A. Ó Caoimh, C. Toader (Rapporteur) and E. Jarašiūnas, Judges, Advocate General: N. Jääskinen, Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 12 September 2013,

after considering the observations submitted on behalf of:

–Georgetown University, by K.A.J. Bisschop, advocaat,

– the Netherlands Government, by C. Schillemans, M. Bulterman and J. Langer, acting as Agents,
– the French Government, by D. Colas and S. Menez, acting as Agents,
– the European Commission, by F.W. Bulst, F. Wilman and J. Samnadda, acting as Agents,
after hearing the **Opinion of the Advocate General** at the sitting on 14 November 2013,
gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Articles 3 and 14 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 request has been made in proceedings between Georgetown University and Octrooicentrum Nederland, operating under the name NL Octrooicentrum (the 'OCN'), concerning the latter's refusal to grant a supplementary protection certificate ('SPC') for a single active ingredient.

Legal context

European Union law

3 Recitals 4, 5, 9 and 10 in the preamble to Regulation No 469/2009 read as follows:

'(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.

[...]

(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 authorisation to be placed on the market 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 [SPC];

[...]'

5 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 [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)] ...;

(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.'

6 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.'

7 Article 5 of Regulation No 469/2009, entitled *'Effects of the certificate', provides as follows:*

'Subject 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.'

8 Article 13 of Regulation No 469/2009, entitled 'Duration of the certificate', is drafted in the following terms:

'1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

[...]'

9 Article 14 of Regulation No 469/2009, entitled 'Expiry of the certificate', is worded as follows:

'The certificate shall lapse:

(a) at the end of the period provided for in Article 13;

(b) if the certificate holder surrenders it;

(c) if the annual fee laid down in accordance with Article 12 is not paid in time;
(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorisation or authorisations to place on the market […] The authority […] may decide on the lapse of the certificate either of its own motion or at the request of a third party.'

Netherlands law

10 Article 63 of the Netherlands Law on patents 1995 (Nederlandse Rijksoctrooiwet 1995) provides as follows:

'1. A patent proprietor may surrender the patent wholly or in part. The surrender shall have retroactive effect in accordance with Article 75(5) to (7).
[…]'

11 Article 75 of that law is worded as follows:

'[…]
5. A patent shall be deemed not to have had from the outset any or some of the legal effects specified in Articles 53, 53a, 71, 72 and 73 where the patent has been wholly or partially invalidated.
6. The retroactive effect of the invalidation shall not extend to:
(a) a decision, not being a provisional measure, relating to acts infringing the exclusive right of the proprietor of the patent set out in Articles 53 and 53a, or to acts referred to in Articles 71, 72 and 73 which have become res judicata and have been enforced prior to the invalidation;
(b) any agreement concluded prior to the invalidation in so far as it has been implemented prior to the invalidation; on grounds of fairness, however, repayment of sums paid under the agreement may be claimed to the extent justified by the circumstances.
7. For the purposes of paragraph (6)(b), the conclusion of an agreement shall also be deemed to include a licence created in another manner as provided for in Articles 56(2), 59 or 60.'

The facts of the main proceedings and the questions referred for a preliminary ruling

12 On 24 June 1993, Georgetown University filed an application for a European patent entitled 'Papillomavirus vaccine', registered by the European Patents Office (EPO) under No 0 647 140 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. HPV types 6 and 11 are responsible for condylomas, whereas HPV types 16 and 18 are responsible for precancerous lesions in the genital region and for cervical cancer.

13 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. The patent was granted on 12 December 2007 and expired on 23 June 2013.

14 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), and 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 eight SPC applications with the OCN in connection with patent No 0 647 140.

15 Two of those applications (Nos 300318 and 300315) concerned the combination of HPV-6, HPV-11, HPV-16 and HPV-18 and the combination of HPV-16 and HPV-18. Four other applications (Nos 300316, 300317, 300319 and 300320) were for SPCs in respect of, respectively, HVP-16, HPV-18, HPV-6 and HPV-11 individually. The two other applications (Nos 300321 and 300322) also related to HPV-16 individually and HPV-18 individually.

16 On 15 January 2008, the OCN granted application Nos 300315 and 300318.

17 On 19 May 2010, the SPC application (No 300321) based on the MA granted for Gardasil, which referred to the recombinant L1 protein of the human papillomavirus (HPV) type 16 as the 'product' within the meaning of Regulation No 469/2009, was rejected.

18 Initially, the OCN based its decision on Article 3(b) of Regulation No 469/2009 in so far as the MA relied on in support of the SPC application related to a medicinal product containing other active ingredients in addition to the recombinant protein of HPV-16. Georgetown University appealed against the OCN's decision to the referring court.

19 Following the judgments in Case **C-322/10 Medeva [2011] ECR I‑12051** and Case **C-422/10 Georgetown University and Others [2011] ECR I-12157**, the referring court established that the parties to the main proceedings had agreed, in the light of the answers provided by the Court in those judgments, that it was not possible to refuse to grant an SPC for the active ingredient HPV-16 individually on the basis of Article 3(b) of Regulation No 469/2009, with the result that the OCN's decision should be annulled.

20 However, the OCN contends that its decision to refuse to grant an SPC could also be based on Article 3(c) of Regulation No 469/2009, given that, according to the OCN, it is apparent from that provision, as interpreted by the Court, that only one SPC may be granted for each basic patent. Georgetown University has, however, already obtained two SPCs on the basis of its basic patent.

21 The five other SPC applications lodged by Georgetown University are still being considered by the OCN.

22 The referring court observes that a rule to the effect that only one SPC may be granted per basic patent could be easily circumvented by the holders of patents protecting several products. It would be sufficient for such holders to separate their patents in such a way that

each basic patent protected only one product, thus enabling them to obtain an SPC for each individual product.

23 Georgetown University has indicated to the referring court that it would be prepared to surrender the two SPCs already granted in respect of the combination HPV-6, HPV-11, HPV-16 and HPV-18 and the combination HPV-16 and HPV-18 and to withdraw its pending SPC applications if that enabled it to obtain, in accordance with the Court's interpretation of Regulation No 469/2009, an SPC in respect of HPV-16.

24 However, the Rechtbank's-Gravenhage is uncertain whether the surrender of the two SPCs already granted may have retroactive effect, thus potentially enabling Georgetown University to obtain an SPC in respect of HPV-16. It refers in that regard to the retroactive effect of surrender of a patent by the patent holder provided for in Article 63 of the Netherlands Law on patents 1995, observing that Article 14 of Regulation No 469/2009 does not provide for any such retroactive effect. According to the referring court, the term 'surrender' in Article 14(b) of that regulation must be regarded and interpreted as an autonomous concept of European Union law. However, the referring court is inclined to the view that, even assuming that Article 3(c) of Regulation No 469/2009 does not permit more than one SPC to be granted per basic patent, it is not possible, in the main proceedings, by simply withdrawing the SPC applications, to escape the application of Article 3(c), with the result that the application in respect of HPV-16 individually must be rejected.

25 In those circumstances, the Rechtbank's-Gravenhage decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Does Regulation No 469/2009 ..., more particularly Article 3(c) thereof, preclude, in a situation where there is a basic patent in force which protects several products, the holder of the basic patent from being granted a certificate for each of the protected products?

(2) If the first question must be answered in the affirmative, how should Article 3(c) of Regulation No 469/2009 be interpreted in the situation where there is one basic patent in force which protects several products and where, at the date of the application for a certificate in respect of one of the products (A) protected by the basic patent, no certificates had yet been granted in respect of other products (B, C) protected by the same basic patent, but where certificates were nevertheless granted in respect of the products (B, C) before a decision was made with regard to the application for a certificate in respect of the first-mentioned product (A)?

(3) Is it significant for the answer to the previous question whether the application in respect of one of the products (A) protected by the basic patent was submitted on the same date as the applications in respect of other products (B, C) protected by the same patent?

(4) If the first question must be answered in the affirmative, may a certificate be granted for a product protected by a basic patent which is in force if a certificate has already been granted for another product protected by the same basic patent, but where the applicant surrenders the latter certificate with a view to obtaining a new certificate on the basis of the same basic patent?

(5) If the issue of whether the surrender has retroactive effect is relevant for the purpose of answering the previous question, is the question of whether surrender has retroactive effect governed by Article 14(b) of Regulation No 469/2009 or by national law? If the question of whether surrender has retroactive effect is governed Article 14(b) of Regulation No 469/2009, should that provision be interpreted to mean that surrender does have retroactive effect?'

Consideration of the questions referred

Question 1

26 By its first question, the referring court asks, in essence, whether, in circumstances such as those in the main proceedings, where, on the basis of a basic patent and an MA in respect of a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained an SPC for that combination of active ingredients, which is protected by the basic patent within the meaning of Article 3(a) of Regulation No 469/2009, Article 3(c) of that regulation must be interpreted as precluding that patent holder from also obtaining an SPC in respect of one of those active ingredients which is also protected as such, individually, by that patent.

27 It should be noted, first of all, that there are many HPV genotypes, which are grouped according to the similarity of their DNA sequence, and that, as is apparent from, inter alia, paragraphs 13, 14, 17 and 19 of the judgment in Georgetown University and Others and paragraphs 13, 14, 16 and 18 of the order in Case **C-630/10 University of Queensland and CSL [2011] ECR I-12231**, a number of those HPVs, as well as the process or processes by which they are obtained, are protected by a number of basic patents belonging to different proprietors.

28 The Court has already held, in a situation in which a 'product' within the meaning of Article 1 of Regulation No 469/2009 is protected by a number of basic patents which may belong to different patent holders and may be patents for that product, patents for processes by which the product is obtained or patents relating to an application of the product, that, under Article 3(c) of that regulation, each of those patents may confer entitlement to an SPC but that only one certificate may be granted for each basic patent (see Case **C-181/95 Biogen [1997] ECR I-357, paragraph 28**, and Case C-482/07 AHP Manufacturing [2009] ECR I-7295, paragraphs 22 and 23). In such a situation, the type of patent held, as the case may be, by each of those proprietors will affect the protection that may be obtained if an SPC is granted, since, for a patent

protecting a product as such, the protection conferred by the SPC will cover that product, whereas for a patent protecting a process by which a product is obtained, that protection will extend only to the process by which that product is obtained or, if the law applicable to such a patent so provides, possibly to the product directly obtained by that process (see the order in Queensland University and CSL, paragraph 39), and, for a patent relating to a new therapeutic application of an active ingredient, known or otherwise, the protection conferred by the SPC will not cover the active ingredient as such but only the new use of that product (Case **C-130/11 Neurim Pharmaceuticals (1991) [2012] ECR I-0000, paragraph 25**).

29 However, the main proceedings concern a different situation, namely that in which the same basic patent may be regarded as protecting a number of products within the meaning of Article 3(a) of Regulation No 469/2009, thus raising a different question, namely whether such a patent may permit its holder to obtain several SPCs.

30 In that regard, it is possible, in principle, on the basis of a patent which protects several different 'products', to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is 'protected' as such by that 'basic patent' within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation (Case C‑443/12 Actavis Group PTC and Actavis UK [2013] ECR I-0000, paragraph 29), and is contained in a medicinal product with an MA.

31 Indeed, the wording of Article 1(b) and Article 3(c) of Regulation No 469/2009 does not preclude such an interpretation. That interpretation is also borne out by the objective pursued by that regulation, which, as is apparent from paragraph 11 of the Explanatory Memorandum to the Proposal for a Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), is to encourage research in the pharmaceutical sector by granting one SPC per product, a product being understood to mean an active substance in the strict sense. Any other interpretation might, moreover, give rise to circumvention tactics, entailing additional costs which may discourage innovation, in the sense that those concerned would be minded to apply for a separate basic patent for each of their 'products'.

32 In the main proceedings, it would appear to be common ground that the basic patent held by Georgetown University protects, at the very least, both the HPV-6, HPV-11, HPV-16 and HPV-18 and the HPV-16 and HPV-18 combinations, as contained in Gardasil and Cervarix, and HPV-16, as marketed in Gardasil.

33 Accordingly, the facts in the main proceedings may also be distinguished from those in the case which gave rise to the judgment in Actavis Group PTC and Actavis UK. In that case, a basic patent protecting an active ingredient as such enabled the patent holder to obtain, on the basis of an MA for a medicinal product containing that active ingredient alone, an SPC relating to that active ingredient. The issue in that case was whether, on the basis of that basic patent but a subsequent MA for a medicinal product containing that same active ingredient in combination with another active ingredient not protected as such by that patent, the patent holder was entitled to apply for a second SPC relating to the combination of the active ingredient which had already led to the grant of an SPC and the active ingredient not protected as such by that patent.

34 It follows that the answer given by the Court to the second question referred in the case which gave rise to the judgment in Actavis Group PTC and Actavis UK cannot be applied to the question at issue in the present case.

35 In the main proceedings, in the light of paragraph 30 above, the combination of the four active ingredients in question (which includes HPV-16) as well as HPV‑16 as an active ingredient individually, are protected by Georgetown University's basic patent within the meaning of Article 3(a) of Regulation No 469/2009. Therefore, Article 3(c) of that regulation does not, in principle, preclude Georgetown University being granted, on the basis of that patent and the same MA, namely the marketing authorisation for Gardasil, an SPC both for the combination of active ingredients (HPV-6, HPV-11, HPV-16 and HPV-18) and for the active ingredient HPV-16 individually. Even if the protection conferred by two such SPCs were to overlap, they would, in principle, expire on the same date.

36 Accordingly, the grant of such multiple SPCs relating to different 'products' makes it possible re-establish a sufficient period of effective and uniform protection for the two SPCs referred to above, by permitting the holder to enjoy an additional period of exclusivity on the expiry of his patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention or inventions by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first MA in the European Union was granted (see Case **C-229/09 Hogan Lovells International [2010] ECR I-11335, paragraph 50**, and Actavis Group PTC and Actavis UK, paragraph 31).

37 However, it would appear from the information provided in the order for reference that the active ingredient protected by the basic patent in respect of which Georgetown University has applied, in the main proceedings, for an SPC on the basis of the MA for Gardasil, namely HPV-16, may also be found in another medicinal product, Cervarix, which was subsequently granted an MA.

38 It should be noted in that regard that, where the holder of a patent obtains an SPC relating to an active ingredient on the basis of the MA for the first medicinal product placed on the market comprising, among its active ingredients, the active ingredient protected by the basic patent (Medeva, paragraph 40), such as, in the main proceedings, an SPC relating to HPV-16 on the

basis of the MA for Gardasil, the wording of Article 3(c) of Regulation No 469/2009 itself precludes that holder from obtaining, on the basis of that same patent, another SPC relating to the very same HPV-16 as a 'product' on the basis of a subsequent MA for another medicinal product which also contains HPV-16, unless, in that other medicinal product, the 'product' that is the subject of the SPC application relates in fact to a different HPV-16 falling within the limits of the protection conferred by the basic patent relied upon for the purposes of that application (see, to that effect, Neurim Pharmaceuticals (1991), paragraph 30).

39 In accordance with Article 5 of Regulation No 469/2009, SPCs, such as those referred to at paragraph 35 above, granted in connection with products such as those referred to in that paragraph, confer, upon the expiry of the basic patent, the same rights as were conferred by that patent in relation to those products, 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, any use or certain uses of his products in the form of a medicinal product consisting of such a product or containing it, the SPCs granted in relation to those products would confer on the holder the same rights for all uses of the products, as medicinal products, which were authorised before the expiry of those certificates (see the judgments in **Medeva, paragraph 39**, and **Georgetown University and Others, paragraph 32, and the orders in University of Queensland and CSL, paragraph 34**, and in Case C-6/11 Daiichi Sankyo [2011] ECR I-12255, paragraph 29).

40 Moreover, Article 13 of Regulation No 469/2009 dictates that, upon expiry of such SPCs, the holder thereof may no longer, in connection with the basic patent used as the basis for the grant of those SPCs, oppose the marketing by third parties of the single active ingredient, protected by one of those two SPCs, or the marketing of the combination, protected by the other certificate. This means that, after the date on which those two SPCs expire, it must be possible for third parties to place on the market not only medicinal products consisting of that single active ingredient or that combination of active ingredients, which were formerly protected, but also any medicinal product containing that active ingredient or that combination, in conjunction, in the present case, with other active ingredients.

41 In the light of the foregoing considerations, the answer to Question 1 is that, in circumstances such as those in the main proceedings, where, on the basis of a basic patent and an MA for a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained an SPC for that combination of active ingredients, protected by that patent within the meaning of Article 3(a) of Regulation No 469/2009, Article 3(c) of that regulation must be interpreted as not precluding the proprietor from also obtaining an SPC for one of those active ingredients which, individually, is also protected as such by that patent.

Questions 2 to 5

42 Questions 2 to 5 require a reply only if the Court answers Question 1 in the affirmative.

43 In view of the answer given to Question 1, there is no need to answer Questions 2 to 5.

Costs

44 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 (Third Chamber) hereby rules:

In circumstances such as those in the main proceedings, where, on the basis of a basic patent and a marketing authorisation for a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained a supplementary protection certificate for that combination of active ingredients, protected by that patent within the meaning of 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, Article 3(c) of that regulation must be interpreted as not precluding the proprietor from also obtaining a supplementary protection certificate for one of those active ingredients which, individually, is also protected as such by that patent.

OPINION ADVOCATE GENERAL N. JÄÄSKINEN

delivered on 14 November 2013 (2)

Case C‑484/12

Georgetown University

v

Octrooicentrum Nederland, operating under the name NL Octrooicentrum

(Request for a preliminary ruling from the Rechtbank 's-Gravenhage (Netherlands))

"Medicinal products for human use — Regulation (EC) No 469/2009 — Articles 3 and 14 — Supplementary protection certificate (SPC) — Surrender of a certificate: Law applicable and temporal effects — Choice between several pending certificate applications"

I – Introduction

1. This Opinion essentially concerns the effect, for the purposes of interpreting 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 (3) (the 'SPC Regulation'), of the case-law of the Court to the effect that Article 3(c) of that regulation must be interpreted as meaning that, where a basic patent in force protects several products, it precludes the grant of a supplementary protection certificate for medicinal

products ('SPC') to the patent holder for each product protected.

2. An SPC extends the protection of a product which is protected by a basic patent. According to the SPC Regulation and the case-law of the Court, a product is either an active ingredient, or a combination of active ingredients, of a medicinal product. The aim of the system is to compensate for the disadvantages associated with the length of the marketing authorisation procedure, which shortens the period of actual protection afforded by the patent. However, the system established by the SPC Regulation does not seek to extend the life of a basic patent per se, but only to protect a product. (4)

3. It should be noted that patent law is not harmonised in the European Union. For this reason, SPCs are granted in a context in which the rules governing SPCs have been standardised by the SPC Regulation but their basis (patents) has not, which creates problems. The interaction between the system applicable to SPCs and national law is covered by Article 19 of the SPC Regulation.

4. The SPC Regulation has already been interpreted by the Court, in particular in its judgments of 24 November 2011 in Medeva (5) and Georgetown University and Others, (6) which concerned requests for a preliminary ruling by two British courts. (7)

5. In this case, the Rechtbank 's-Gravenhage (Netherlands) refers five questions for a preliminary ruling, the first of which bears similarities to the questions dealt with in Medeva. Indeed, the present reference is the direct consequence of the interpretation of the SPC Regulation given by the Court on that occasion, namely that, where a patent protects a product in accordance with Article 3(c) of that regulation, only one SPC may be granted for that basic patent. (8)

6. As to the present case, Georgetown University seeks, through the interpretation that it proposes to the referring court, to remedy the situation in which a patent holder has obtained an SPC for a product which is not the one that he ultimately intended to protect and only one SPC may be granted for each basic patent.

7. In the light of the Court's case-law and the Opinion of Advocate General Trstenjak in Medeva and Georgetown University and Others, the Court already has the information necessary to enable it to answer the first question. Therefore, in the present case, it is necessary to rule on only questions 2 to 5, which raise issues not previously addressed by the Court. It should also be noted that the last four questions require an answer only in the event that the first question is answered in the affirmative, which explains the premiss set out in point 1 of this Opinion.

8. The questions referred for a preliminary ruling to be considered in this Opinion may be grouped together. They concern, first, whether the holder of an SPC which has already been granted may surrender it with retroactive effect (questions 4 and 5) and, secondly, certain procedural aspects specific to a situation in which several SPCs applications are pending at the same time (questions 2 and 3).

9. I would point out, moreover, that two other cases now pending before the Court also concern the interpretation of the SPC Regulation. As the questions referred by the High Court of Justice (Chancery Division) (England and Wales) (United Kingdom) in Case C‑443/12 Actavis Group and Actavis UK and Case C‑493/12 Eli Lilly and Company partially overlap with the questions in the present case, the Court organised a joint hearing for the three cases on 12 September 2013, although it should be borne in mind that it has decided to rule on the latter two cases without an opinion.

II – Legal framework

A – SPC Regulation

10. Under Article 3 of the SPC Regulation, a certificate must be granted if, in the Member State in which the application is submitted and at the date of that application, the product is protected by a basic patent in force (subparagraph a) and the product has not already been the subject of an SPC (subparagraph c).

11. Under Article 14 of the SPC Regulation, the SPC will lapse, inter alia, at the end of the period of validity (subparagraph a), if the SPC holder surrenders it (subparagraph b) or if the annual fee laid down is not paid in time (subparagraph c).

12. Article 15(1) of the SPC Regulation provides that the SPC will be invalid if it was granted contrary to the provisions of Article 3 (subparagraph a), if the basic patent has lapsed before its lawful term expires (subparagraph b) or if 'the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation' (subparagraph c).

13. Article 19(1) of the SPC Regulation provides that, in the absence of procedural provisions in that regulation, the procedural provisions applicable under national law to the basic patent will apply to the certificate, unless the national law lays down special procedural provisions for SPCs.

B – Netherlands Law on Patents 1995

14. In order to answer the fifth question referred, it is appropriate to reproduce here Article 63 of the Nederlandse Rijksoctrooiwet 1995 (Netherlands Law on Patents 1995), which provides as follows:

'1. A patent proprietor may surrender the patent wholly or in part. The surrender shall have retroactive effect in accordance with Article 75(5) to (7).

[…]'

15. Article 75 of that Law states as follows:

'[…]

5. A patent shall be deemed not to have had from the outset any or some of the legal effects specified in Articles 53, 53a, 71, 72 and 73 where the patent has been wholly or partially invalidated.

6. The retroactive effect of the invalidation shall not extend to:

a. a decision, not being a provisional measure, relating to acts infringing the exclusive right of the proprietor of the patent set out in Articles 53 and 53a or to acts referred to in Articles 71, 72 and 73 which have become res judicata and have been enforced prior to the invalidation;
b. any agreement concluded prior to the invalidation in so far as it has been implemented prior to the invalidation; on grounds of fairness, however, repayment of sums paid under the agreement may be claimed to the extent justified by the circumstances.
7. For the purposes of paragraph (6)(b), the conclusion of an agreement shall also be deemed to include a licence created in another manner as provided for in Articles 56(2), 59 or 60.'

16. It should be noted that it is not apparent from the request for a preliminary ruling that Netherlands legislation contains special procedural rules governing SPCs.

III – The dispute in the main proceedings, the questions referred for a preliminary ruling and the procedure before the Court

17. On 24 June 1993, Georgetown University filed an application for a European patent entitled 'Papillomavirus vaccine', registered by the European Patents Office under number EP 0 647 140 for a human papillomavirus protein capable of inducing neutralising antibodies against papillomavirus virions. The patent was granted on 12 December 2007.

18. On 14 December 2007, on the basis of marketing authorisations issued for the medicinal products Gardasil and Cervarix respectively, Georgetown University lodged seven SPC applications with NL Octrooicentrum in connection with patent EP 0 647 140. Two SPCs were granted on 15 January 2008, one application bearing reference No 300321 was rejected on 19 May 2010 and four others are still pending.

19. Georgetown University contested the decision refusing to grant an SPC before the referring court.

20. Following the Medeva and Georgetown University and Others judgments, Georgetown University informed the referring court that it would be prepared to surrender the SPCs already granted and to withdraw all the pending applications if NL Octrooicentrum adopted a favourable decision on SPC application No 300321.

21. As it considers that the resolution of the dispute before it depends, in particular, on the interpretation of Articles 3 and 14 of the SPC Regulation, the Rechtbank 's-Gravenhage decided, by order of 12 October 2012, received at the Court Registry on 31 October 2012, to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'1.Does [the SPC Regulation], more particularly Article 3(c) thereof, preclude, in a situation where there is a basic patent in force which protects several products, the holder of the basic patent from being granted a certificate for each of the protected products?
2. If the first question must be answered in the affirmative, how should Article 3(c) of [the SPC Regulation] be interpreted in the situation where there is one basic patent in force which protects several products, and where, at the date of the application for a certificate in respect of one of the products (A) protected by the basic patent, no certificates had yet been granted in respect of other products (B, C) protected by the same basic patent, but where certificates were nevertheless granted in respect of the products (B, C) before a decision was made with regard to the application for a certificate in respect of the first-mentioned product (A)?
3. Is it significant for the answer to the previous question whether the application in respect of one of the products (A) protected by the basic patent was submitted on the same date as the applications in respect of other products (B, C) protected by the same basic patent?
4. If the first question must be answered in the affirmative, may a certificate be granted for a product protected by a basic patent which is in force if a certificate had already been granted earlier for another product protected by the same basic patent, but where the applicant surrenders the latter certificate with a view to obtaining a new certificate on the basis of the same basic patent?
5. If the issue of whether the surrender has retroactive effect is relevant for the purpose of answering the previous question, is the question of whether surrender has retroactive effect governed by Article 14(b) of [the SPC Regulation] or by national law? If the question of whether surrender has retroactive effect is governed by Article 14(b) of [the SPC Regulation], should that provision be interpreted to mean that surrender does have retroactive effect?'

22. Written observations have been submitted by Georgetown University, the Netherlands and French Governments and the European Commission, the French Government having submitted observations only on questions 1, 4 and 5 and the Commission observations only on question 1.

IV – Analysis

A – Preliminary remarks

23. As I have already stated, this Opinion will focus on questions 2 to 5, which are referred by the national court in the event that the first question is answered in the affirmative. Consequently, although the majority of the parties in these proceedings and in the case pending in Actavis Group and Actavis UK have proposed that that question, namely whether EU law precludes an SPC from being granted, on the basis of one and the same patent covering several products, for each product protected, should be answered in the negative, my analysis will proceed on the assumption that the first question should be answered in the affirmative.

24. My analysis will group the questions together, as stated in point 8 above.

B – Questions 4 and 5

25. By its fourth and fifth questions, the referring court essentially seeks to ascertain what rules are applicable to the surrender of a certificate by the holder of an SPC and to determine the effects of such surrender. More

specifically, it seeks to determine whether the surrender of the SPC granted for a product protected by a basic patent is governed by national law or by Article 14(b) of the SPC Regulation and, if the latter case applies, whether such surrender has only future effects or whether it has retroactive effect, so that the applicant could lodge a new SPC application for another product.

26. Georgetown University has indicated its readiness before the referring court to surrender the two SPCs granted to it in connection with European basic patent EP 0 647 140 and to withdraw all the other SPC applications pending in respect of that patent so that it may be granted an SPC on the basis of application No 300321. It is of the view that, under Netherlands patent law, the surrender of an SPC has retroactive effect.

27. All the parties who have submitted written observations to the Court agree that the concept of 'surrender' is a concept of EU law which must be given a uniform interpretation. However, while Georgetown University considers that such surrender should have retroactive effect, the Netherlands and French Governments take the view, for their part, that such surrender can have only future effects.

28. First, I am of the view that the effects of surrendering an SPC are governed solely by Article 14 of the SPC Regulation and not by national law.

29. I would point out that the wording of Article 14 of the SPC Regulation does not contain any reference to national law and does not provide for the possibility for each Member State to define the effects of expiry as provided in Article 14. (9) I would add that the effects of an SPC lapsing cannot be regarded as procedural matters covered by Article 19(1) of the SPC Regulation, which states that, in the absence of procedural provisions in the SPC Regulation, the procedural provisions applicable under national law to the basic patent are to apply. It is, in fact, not a procedural matter, but a substantive matter.

30. As to the objective of that provision, it should be noted that the SPC Regulation seeks to establish a uniform solution at EU level by creating an SPC granted under the same conditions in each Member State in order 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'. (10)

31. Therefore, according to a literal and teleological interpretation, Article 14 of the SPC Regulation precludes the effects of surrendering an SPC being defined by national law.

32. Secondly, it is clear from the wording of Articles 14 and 15 of the SPC Regulation that the effect of surrendering an SPC cannot be retroactive. An interpretation of the regulation's objectives produces the same conclusion.

33. It should be noted in this regard that Article 14 of the SPC Regulation sets out the circumstances in which an SPC will lapse, which include surrender, the others being the end of the SPC's period of validity, the fact that the annual fee has not been paid and the fact that authorisation to place the product on the market has been withdrawn. As the referring court points out, these grounds for lapse relate to situations or events which result in the SPC no longer having any effects in the future; in other words, they do not result in the retroactive invalidation of the SPC.

34. Moreover, the French Government rightly points out that, in current legal parlance, the term 'lapse' refers to the fact, particularly in respect of a right, obligation or legal situation, of ceasing to exist and therefore of no longer having any effect, due to a specific event which terminated any such effects. On the other hand, that term does not imply the retroactive disappearance of that right, obligation or legal situation. This interpretation of Article 14 of the SPC Regulation is borne out by Article 15 of that regulation, which sets out the circumstances in which an SPC will be invalid.

35. Thus, under Article 15(1) of that regulation:

'The [SPC] shall be invalid if:

'(a) it was granted contrary to the provisions of Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the [SPC] was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.'

36. It should be noted that surrender of an SPC is not one of the grounds of invalidity listed in Article 15(1) of the SPC Regulation.

37. By the interpretation that it proposes, Georgetown University therefore seeks to remedy the situation in which the patent holder has been granted an SPC for a product which is not the product for which he intended to obtain protection, and only one SPC per basic patent may be granted.

38. The concern thereby expressed is understandable. Nevertheless, it must be noted that, even though the patent holder may surrender his patent with retroactive effect (11) and thereby nullify its legal effects, within the limits defined by the applicable legal order, the fact never the less remains that he forsakes by such surrender the possibility of filing a new application for a patent for the same invention. Indeed, the existence of the earlier patent placed it in the public domain, such that the invention cannot fulfil the requirement of novelty universally applicable under patent law. Similarly, just as a patent holder does not enjoy such a right to reconsider, enabling him to redefine the scope of protection retroactively, so that possibility cannot be accorded to an SPC holder who seeks to rely on a provision such as Article 63 of the Netherlands Law on Patents 1995.

39. I therefore consider that the surrender of an SPC referred to in Article 14(b) of the SPC Regulation cannot have retroactive effect and that such surrender is

incompatible with the requirement that the product has not already been the subject of an SPC.

40. In my view, only this interpretation can preserve legal certainty for third parties, who have rightly been able to rely on the SPC granted to inform them of the product protected by it and of the date on which that protection will end. If it were accepted that, by surrendering such an SPC after its entry into force, the SPC holder could retroactively revoke the SPC in order to replace it with an SPC with a different subject or duration, the objective of legal certainty of the system established by the SPC Regulation would be compromised.

41. The SPC Regulation establishes a procedure which guarantees the transparency of the system, since the decision to grant the SPC and the SPC application are both published, the latter having being lodged sufficiently early after marketing authorisation was given to enable third parties to be swiftly informed. (12) Such an objective means that the published information cannot be retroactively called into question by the holder at any time in accordance with his interests.

42. To conclude, I propose that the Court answer Questions 4 and 5 to the effect that surrender of an SPC is governed solely by Article 14(b) of the SPC Regulation and that, as any such surrender will have only future effects, it cannot subsequently be argued that the product in question has never been the subject of an SPC within the meaning of Article 3(c) of the SPC Regulation.

C – Questions 2 and 3

43. By its second and third questions, the referring court essentially seeks to ascertain whether, under Article 3(c) of the SPC Regulation, an applicant who has simultaneously lodged several SPC applications is free to choose, before an SPC is granted, which application takes priority, or whether it is for the national authority responsible for granting SPCs to make that choice.

44. The parties who have submitted written observations on this question all agree that it is for the patent holder to choose which SPC application takes priority in this situation. However, the Netherlands Government considers that this choice must be made at the time when the applications are lodged.

45. It should be recalled that these questions are asked in the event that the answer to the first question is that only one SPC may be granted per basic patent. This hypothesis contains, in itself, the answer to the situation envisaged by the national court in the second question, namely that in which a basic patent in force protects several products and, on the date of lodging of the SPC application in respect of one of the protected products (product A), no SPC has yet been granted in respect of other products protected by the same basic patent (products B and C), but SPCs were subsequently granted in respect of products B and C before a decision was made with regard to the application for an SPC in respect of the first-mentioned product (product A).

46. I consider that it is for the patent holder to determine which application takes priority over the others. The patent holder, or his successor in title, must be able to lodge several SPC applications, either simultaneously or in succession, for the various products covered by the basic patent, within the period laid down in Article 7(1) of the SPC Regulation, as the basic patent or the marketing authorisation may be limited after the applications are lodged.

47. It should be noted in this regard that it does not really matter whether the SPC applications were lodged simultaneously or in succession, so long as the period laid down in Article 7(1) of the SPC Regulation was respected, as the order of priority does not depend on the date on which the SPC application was lodged but on that of the basic patent.

48. However, no specific provision of the SPC Regulation determines which application must take priority where several SPC applications are pending at the same time.

49. The patent holder's key role in determining what will be protected under an SPC was perfectly summarised by the Commission in 1990 in the Explanatory Memorandum. (13) In her Opinion in the case which gave rise to the judgment in Medeva, Advocate General Trstenjak similarly observes that the patent holder himself determines the medicinal product protected by the same basic patent for which he is lodging an SPC application. (14)

50. Where the patent holder has not made a choice when the SPC applications are lodged and in view of the possibility that the basic patent and/or marketing authorisation may be limited after those applications are lodged, the patent holder is not under any legal obligation to make such a choice. In such a situation, several applications may be pending at the same time.

51. I consider that, in such a case, the authorities responsible for granting the SPC should ask the patent holder concerned to make a choice before it is granted and to state the active ingredient or combination of active ingredients for which he wishes to obtain an SPC based on the basic patent.

52. The SPC Regulation allows the authorities to make such a request. In my view, this may even be required of national authorities responsible for implementing the SPC Regulation, as the right to good administration is a general principle of EU law. (15)

53. The Court's case-law appears to confirm that it is possible to make such a request to the person who has applied for an SPC. It is clear from AHP Manufacturing (16) that the SPC Regulation does not indicate an order for SPC applications pending at the same time. Although that case concerned two or more patent holders for the same product, that interpretation, in my view, also applies by analogy to cases where one and the same patent holder has lodged several applications in respect of different products.

54. Where a patent holder does not make a choice, despite being requested to do so by the competent authorities, it is for the national authorities, pursuant to

Article 19 of the SPC Regulation, to take any appropriate action under national law.

55. I therefore propose that the Court answer the second and third questions to the effect that, where an applicant has lodged several SPC application in respect of different products which are protected by the same patent, it is for the applicant to decide which of those applications takes priority and, if no choice is made, it is for the national authorities to take any appropriate action under national law.

V – Conclusion

56. In the light of the foregoing considerations, I propose that the Court should answer questions 2 to 5 referred by the Rechtbank 's Gravenhage (Netherlands) as follows:

'(1)The surrender of a supplementary protection certificate is governed by Article 14(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 and not by national law. Moreover, as such surrender will have only future effects, it cannot subsequently be argued that, following surrender, the product in question has never been the subject of a certificate within the meaning of Article 3(c) of that regulation.

(2)Where an applicant has lodged several applications for supplementary protection certificates in respect of different products which are protected by the same patent, it is for the applicant to decide which of those applications takes priority. If no choice is made, it is for the national authorities to take any appropriate action under national law.'

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2 –Original language: French.

3 –OJ 2009 L 152, p. 1.

4 –A similar system exists for plant protection products; see 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); see also Case C‑258/99 BASF [2001] ECR I‑3643; Case C‑482/07 AHP Manufacturing [2009] ECR I‑7295, and Case C‑229/09 Hogan Lovells International [2010] ECR I‑11335.

5 –Case C‑322/10, ECR I‑12051.

6 –Case C‑422/10, ECR I‑12157.

7 –As regards the other cases, see, inter alia, the judgments in Case C‑181/95 Biogen [1997] ECR I‑357; AHP Manufacturing; and the order in Case C‑630/11 University of Queensland and CSL [2011] ECR I‑12231; the order of 9 February 2012 in Case C‑442/11 Novartis [2012] ECR, and the order in Case C‑130/11 Neurim Pharmaceuticals (1991) [2012] ECR.

8 –.Medeva (paragraph 41) and Georgetown University and Others (paragraph 34).

9 –On the demarcation between concepts of EU law and application of national law, see points 27 to 30 of my Opinion in the case which gave rise to the judgment in Case C‑401/11 Soukupová [2013] ECR.

10 –See Medeva (paragraph 24 and the case-law cited) and recital 7 of the SPC Regulation.

11 –See, for example, Article 63 of the Netherlands Law on Patents 1995 and Article 68 of the Convention on the Grant of European Patents, signed in Munich on 5 October 1973, in conjunction with Article 105a(1) thereof.

12 –See paragraph 17 of the Explanatory Memorandum to the Proposal for a 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'.

13 –See Explanatory Memorandum, paragraph 33, second sentence.

14 –Point 66 of that Opinion.

15 –See, to this effect, Case C‑349/07 Sopropé [2008] ECR I‑10369, paragraphs 37 and 38. The EU institutions are required to respect this right under Article 41(2)(a) of the Charter of Fundamental Rights of the European Union; see, to this effect, the Opinion of Advocate General Bot in the case which gave rise to the judgment in Case C‑277/11 M [2012] ECR.

16 –See, in particular, paragraphs 24 to 26. It should be noted that this case related to the previous SPC Regulation and Regulation No 1610/96.