



Reports of Cases

OPINION OF ADVOCATE GENERAL
JÄÄSKINEN
delivered on 14 November 2013¹

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 products² (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.³

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.

¹ — Original language: French.

² — OJ 2009 L 152, p. 1.

³ — 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.

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

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.⁷

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).

4 — Case C-322/10, ECR I-12051.

5 — Case C-422/10, ECR I-12157.

6 — 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.

7 — *Medeva* (paragraph 41) and *Georgetown University and Others* (paragraph 34).

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 14.⁸ 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’.⁹

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.

8 — 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.

9 — See *Medeva* (paragraph 24 and the case-law cited) and recital 7 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 effect¹⁰ 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.¹¹ 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.

10 — 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.

11 — 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’.

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.¹² 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.¹³

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.¹⁴

12 — See Explanatory Memorandum, paragraph 33, second sentence.

13 — Point 66 of that Opinion.

14 — 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.

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*¹⁵ 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.

15 — 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.