Court of Justice EU, 6 October 2015, Seattle Genetics v Patentamt

PATENT LAW

The 'date of the first authorisation to place the product on the market in the European Union' of Article 13(1) SPC Regulation is determined by EU law

- **Article 13(1) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that the 'date of the first authorisation to place the product on the market in the [European Union]' is determined by EU law.**

The 'date of the first authorisation to place the product on the market in the European Union' is the date on which notification of the decisions granting marketing authorisation was given to the addressee of the decision

- **Article 13(1) of Regulation No 469/2009 is to be interpreted as meaning that the 'date of the first authorisation to place the product on the market in the [European Union]' within the meaning of that provision is the date on which notification of the decision granting marketing authorisation was given to the addressee of the decision.**

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Court of Justice EU, 6 October 2015
(A. Ó Caoimh, C. Toader and E. Jarašiūnas)
JUDGMENT OF THE COURT (Eighth Chamber)
6 October 2015 (*)
(Reference for a preliminary ruling — Intellectual and industrial property — Proprietary medicinal products — Regulation (EC) No 469/2009 — Article 13(1) — Supplementary protection certificate — Duration — Concept of the *'date of the first authorisation to place the product on the market in the European Union'* — Whether account is to be taken of the date of the decision granting authorisation or the date on which notification was given of that decision)
In Case C‑471/14,
REQUEST for a preliminary ruling under Article 267 TFEU from the Oberlandesgericht Wien (Higher Regional Court, Vienna, Austria), made by decision of 2 October 2014, received at the Court on 15 October 2014, in the proceedings
Seattle Genetics Inc.
v
Österreichisches Patentamt,
THE COURT (Eighth Chamber),
composed of A. Ó Caoimh, President of the Chamber, C. Toader (Rapporteur) and E. Jarašiūnas, Judges,
Advocate General: N. Jääskinen,
Registrar: A. Calot Escobar,
having regard to the written procedure,
after considering the observations submitted on behalf of:
– Seattle Genetics Inc., by K. Bacon, Barrister, and M. Utges Manley, M. Georgiou and E. Amos, Solicitors,
– the Greek Government, by G. Alexaki and L. Kotroni, acting as Agents,
– the Italian Government, by G. Palmieri, acting as Agent, and M. Russo, avvocato dello Stato,
– the Latvian Government, by I. Kalniņš, acting as Agent,
– the Lithuanian Government, by D. Kriaučiūnas and G. Taluntytė, acting as Agents,
– the European Commission, by G. Braun and J. Samnadda, acting as Agents,
after hearing **the Opinion of the Advocate General** at the sitting on 10 September 2015,
gives the following
Judgment
1. This request for a preliminary ruling concerns the interpretation of Article 13(1) 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 Seattle Genetics Inc. ('Seattle Genetics') and the Österreichisches Patentamt (Austrian Patent Office) concerning the rectification of the date of expiry of a supplementary protection certificate ('SPC').
Legal context
EU law
Regulation (EC) No 726/2004
3. Article 3(1) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), as amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 (OJ 2010 L 348, p. 1), ('Regulation No 726/2004') provides as follows:
'No medicinal product appearing in the Annex may be placed on the market within the Community unless a marketing authorisation has been granted by the Community in accordance with the provisions of this Regulation.'
4. Article 10 of Regulation No 726/2004 provides that the European Commission is to issue marketing authorisations on the basis of that regulation.
5. Article 14(1) of that regulation states that *'[w]ithout prejudice to paragraphs 4, 5 and 7 a marketing authorisation shall be valid for five years'*.
Regulation No 469/2009
6. Recitals 3 to 5 and 7 to 9 in the preamble to Regulation No 469/2009 are worded as follows:
'(3) Medicinal products, especially those that are the result of long, costly research, will not continue to be

developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.
(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 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.
[…]
(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 supplementary protection certificate 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 marketing authorisation 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 authorisation to be placed on the market in the Community.'

7. Article 3 of Regulation No 469/2009, entitled *'Conditions for obtaining a certificate'*, is worded 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.'

8. Article 7 of Regulation No 469/2009, entitled *'Application for a certificate'*, provides, in paragraph 1 thereof, as follows:

'The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.'

9. Article 13 of Regulation No 469/2009, entitled *'Duration of the certificate'*, provides in paragraph 1 thereof that *'[t]he 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'*.

The dispute in the main proceedings and the questions referred for a preliminary ruling

10. Seattle Genetics is the holder of European Patent No EP 1 545 613 ('the basic patent'), entitled *'Auristatin conjugates and their use for treating cancer, an autoimmune disease or an infectious disease'*. The basic patent was applied for on 31 July 2003 and granted on 20 July 2011.

11. On 31 May 2011, Takeda Global Research and Development Centre (Europe) Ltd ('Takeda') submitted an application under the centralised procedure laid down by Regulation No 726/2004 for a conditional marketing authorisation for a new active substance (Brentuximab vedotin) under the commercial name Adcetris, which it had developed using the basic patent.

12. By Implementing Decision C(2012) 7764 final of 25 October 2012, granting a conditional authorisation under Regulation No 726/2004 for *'Adcetris — Brentuximab vedotin'*, an orphan medicinal product for human use, the Commission granted Takeda a marketing authorisation under number EU/1/12/794/001 for that medicinal product, in accordance with Articles 3, 10 and 14 of that regulation. Article 4 of that decision states as follows:

'The period of validity of the authorisation shall be one year from the date of notification of this Decision.'

13. On 30 October 2012, Takeda was given notification of that decision.

14. Both the date of the decision granting marketing authorisation for Adcetris and the date on which notification was given to Takeda are set out in the summary of that decision which was published in the *Official Journal of the European Union* of 30 November 2012 (OJ 2012 C 371, p. 8), pursuant to Article 13(2) of Regulation No 726/2004.

15. On 2 November 2012, Seattle Genetics filed an application for an SPC based on the basic patent with the Austrian Patents Office, which granted the application. Taking the view that the date of the first authorisation to place the product on the market in the European Union within the meaning of Article 13(1) of Regulation No 469/2009 was the date of the Commission's decision on marketing authorisation, namely 25 October 2012, the Österreichisches Patentamt fixed the expiry date for the SPC as 25 October 2027.

16. In October 2013, Takeda transferred the marketing authorisation for Adcetris to Takeda Pharma A/S, a licencee of Seattle Genetics.

17. On 22 April 2014, Seattle Genetics brought proceedings before the referring court against the

Austrian Patents Office's decision, claiming that the SPC issued by that office should be rectified so that that certificate expires on 30 October 2027.

18. In that regard, Seattle Genetics contends that the date of the first authorisation to place the product on the market within the meaning of Article 13(1) of Regulation No 469/2009 must be the date on which the applicant was given notification of the decision granting authorisation to place Adcetris on the market, namely 30 October 2012. As a consequence, the date of expiry of the SPC should be 30 October 2027.

19. As is apparent from the documents available to the Court, the Commission stated, in Article 3 of Implementing Decision C(2014) 6095 final of 22 August 2014 on the annual renewal of the conditional marketing authorisation for the orphan medicinal product for human use 'Adcetris — Brentuximab vedotin', granted by Decision C(2012) 7764 final and amending that decision, as follows:

'The period of validity of the renewed authorisation shall be one year from 30 October 2014.'

20. With regard to the action brought by Seattle Genetics, the Oberlandesgericht Wien stated that it would appear that the patents offices of Member States differ in their practice with regard to the determination of the period covered by SPCs referred to in Article 13(1) of Regulation No 469/2009.

21. In those circumstances, the Oberlandesgericht Wien decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Is the date of the first authorisation to place the product on the market in the [European Union] pursuant to Article 13(1) of Regulation No 469/2009 determined according to [EU] law or does that provision refer to the date on which the authorisation takes effect under the law of the Member State in question?

(2) If the Court's answer is that the date referred to in Question 1 is determined by [EU] law, which date must be taken into account — the date of authorisation or the date of notification?'

Question 1

22. By its first question, the referring court seeks to ascertain, in essence, whether Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that the concept of *'the date of the first authorisation to place the product on the market in the [European Union]'* is defined by EU law or whether that provision must be interpreted as meaning that that concept is defined by the law of the Member State in which the marketing authorisation in question took effect.

23. It is the Court's established case-law that the need for a uniform application of EU law requires that, where a provision of EU law makes no reference to the law of the Member States with regard to a particular concept, that concept must be given an independent and uniform interpretation throughout the European Union (see, to that effect, judgment in **Brüstle, C‑34/10, EU:C:2011:669**, paragraph 25).

24. While Article 13 of Regulation No 469/2009 does not define *'the date of the first authorisation to place the product on the market in the [European Union]'*, to which that provision refers for the purpose of determining the date of expiry of an SPC, nor does it contain any reference to national laws as regards the meaning to be applied to those words. It therefore follows that that provision must be regarded, for the purposes of the application of that regulation, as containing an autonomous concept of EU law which must be interpreted in a uniform manner throughout the territory of the European Union.

25. That conclusion is supported by the purpose of Regulation No 469/2009.

26. It should be noted in that regard that, as is apparent from recitals 7 and 8 in the preamble thereto, Regulation No 469/2009 establishes a uniform solution at European Union level by creating an 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, to that effect, judgment in **Medeva, C‑322/10, EU:C:2011:773,** paragraph 24 and the case-law cited).

27. If the 'date of the first authorisation to place the product on the market in the [European Union]' could be determined on the basis of national law, the objective of establishing a uniform solution at European Union level would be undermined.

28. In the light of the foregoing considerations, the answer to Question 1 is that Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that the 'date of the first authorisation to place the product on the market in the [European Union]' is determined by EU law.

Question 2

29. By its second question, the referring court seeks to ascertain, in essence, whether Article 13(1) of Regulation No 469/2009 is to be interpreted as meaning that the 'date of the first authorisation to place the product on the market in the [European Union]' within the meaning of that provision is the date of the decision granting marketing authorisation or whether that provision is to be interpreted as meaning that that date is the date on which the addressee was given notification of that decision.

30. First, as observed by the Advocate General at **points 30 to 33 of his Opinion**, it is not possible on the basis of either the wording of that provision in its various language versions or the other provisions of that regulation to give an unequivocal answer to that question.

31. The concept in question must therefore be interpreted in the light of the objective which Regulation No 469/2009 seeks to attain.

32. It should be noted in that regard that the fundamental objective of Regulation No 469/2009, as

mentioned, inter alia, in recitals 3 to 5 and 8 and 9 in the preamble thereto, is to re-establish a sufficient period of effective protection of a basic patent 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 by reason of the time which has elapsed between the date on which the application for that patent was filed and the date on which the first marketing authorisation in the European Union was granted (see, to that effect, judgment in **Actavis Group PTC and Actavis UK, C‑577/13**, EU:C:2015:165, paragraph 34).

33. Moreover, that conclusion is borne out by paragraph 14 of the explanatory memorandum of 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), which states that the duration of the protection given by the SPC must be such as to enable it to afford *'actual'* protection. According to paragraph 50 of the explanatory memorandum, that duration must be sufficiently long to meet the objectives of the proposal for a regulation.

34. Since the EU legislature's intention was to give the holder of an SPC adequate effective protection, the calculation of the duration of supplementary protection cannot be carried out without taking into account the determination of the date from which the recipient of an SPC is in fact able to enjoy the benefit of his marketing authorisation by marketing his product.

35. It is clear that the holder of an SPC is entitled to market his product only from the date on which he is given notification of the decision granting the marketing authorisation in question, not from the date on which that decision was adopted.

36. As observed by both the Advocate General, **in point 39 of his Opinion**, and by the Commission, short of adopting an interpretation which would be at odds with the objective of Regulation No 469/2009 of providing adequate effective protection to the holder of an SPC, it cannot be accepted that procedural steps carried out between the decision granting marketing authorisation and the notification of that decision — the duration of which is not within the control of the SPC holder — reduce the period of validity of an SPC.

37. That interpretation is all the more appropriate since decisions granting marketing authorisations issued by the Commission, such as Implementing Decision C(2012) 7764 final, are subject to the requirements laid down in the third subparagraph of Article 297(2) TFEU, which provides that decisions which specify to whom they are addressed are to be notified to those to whom they are addressed and take effect upon such notification.

38. Thus, in accordance with that provision, the Commission stated in Article 4 of Implementing Decision C(2012) 7764 final that the date on which the marketing authorisation for Adcetris was to take effect was 30 October 2012. Moreover, the date of 30 October 2014 was given in Article 3 of Implementing Decision C(2014) 6095 final as the date on which the renewal of that marketing authorisation was to take effect.

39. The requirement to give notification of a Commission decision to the person to whom it is addressed, laid down in the third subparagraph of Article 297(2) TFEU, in order for the decision to take effect cannot be disregarded when calculating the period of supplementary protection under Article 13(1) of Regulation No 469/2009.

40. In the light of all the foregoing considerations, the answer to Question 2 is that Article 13(1) of Regulation No 469/2009 is to be interpreted as meaning that the 'date of the first authorisation to place the product on the market in the [European Union]' within the meaning of that provision is the date on which notification of the decision granting marketing authorisation was given to the addressee of the decision.

Costs

41. 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 (Eighth Chamber) hereby rules:

1. Article 13(1) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that the *'date of the first authorisation to place the product on the market in the [European Union]'* is determined by EU law.

2. Article 13(1) of Regulation No 469/2009 is to be interpreted as meaning that the *'date of the first authorisation to place the product on the market in the [European Union]'* within the meaning of that provision is the date on which notification of the decision granting marketing authorisation was given to the addressee of the decision.

[Signatures]

* Language of the case: German.

OPINION OF ADVOCATE GENERAL JÄÄSKINEN

delivered on 10 September 2015 (1)

Case C‑471/14

Seattle Genetics Inc.

(Request for a preliminary ruling from the Higher Regional Court, Vienna (Oberlandesgericht Wien, Austria))

(Industrial property — Patent right — Regulation (EC) No 469/2009 — Article 13(1) — Supplementary protection certificate for medicinal products — Period of validity of the certificate — Concept of the 'date of the first authorisation to place the product on the market in the Community' — Independent concept — Whether account is to be taken of the date on which the

authorisation was granted or the date on which the addressee was given notification of the authorisation decision)

I – Introduction

1. This request for a preliminary ruling from the Higher Regional Court, Vienna (Oberlandesgericht, Wien) arises out of an appeal brought by Seattle Genetics Inc. ('Seattle Genetics') against a decision of the Austrian Patent Office (Österreichisches Patentamt). By its appeal, Seattle Genetics seeks the rectification of the date fixed in the decision for the expiry of a supplementary protection certificate ('SPC' or 'certificate') issued to it in respect of a medicinal product for human use developed on the basis of a patent of which it is the proprietor.

2. The request for a preliminary ruling concerns the interpretation of Article 13(1) of Regulation (EC) No 469/2009 (2) and, more specifically, the concept of the 'date of the first authorisation to place the product on the market in the [European Union]' to which that provision refers and by reference to which the date of expiry of an SPC may be determined in accordance with that provision.

3. The Court is asked, first, whether that concept is to be defined in accordance with the legislation of the Member States or in accordance with EU law and, secondly, in the latter case, whether the relevant date is the date of the decision granting the first authorisation to place the product on the market or the date on which the addressee was given notification of that decision.

II – Legal framework

4. Recitals 4, 8 and 9 in the preamble to Regulation No 469/2009 are worded 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 makes the period of effective protection under the patent insufficient to cover the investment put into the research.

[…]

(8) Therefore, the provision of [an 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 market authorisation 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 authorisation to be placed on the market in the Community.'

5. Article 3 of Regulation No 469/2009, entitled *'Conditions for obtaining a certificate'*, provides that *'[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 [(3)] or Directive 2001/82/EC [(4)] as appropriate [(5)];

(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. Pursuant to Article 7(1) of Regulation No 469/2009, *'[t]he application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted'*.

7. Article 11(1)(d) and (e) of Regulation No 469/2009 provides that a notice of the fact that an SPC has been granted must be published by the competent authority and that the notice must at least contain the information listed in paragraph 1, including:

'(d) the number and date of the authorisation to place the product on the market, referred to in Article 3(b), and the product identified in that authorisation;

(e) where relevant, the number and date of the first authorisation to place the product on the market in the Community.'

8. Article 13 of the same regulation, entitled *'Duration of the certificate'*, provides in paragraph 1 thereof that *'[t]he 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'*. (6) Article 13(2) adds that, *'[n]otwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect'*.

III – The dispute in the main proceedings, the questions referred and the procedure before the Court

9. It is apparent from the information placed on the file that Seattle Genetics, a company established in the United States, is the holder of a European basic patent (7) which was applied for on 31 July 2003 and granted on 20 July 2011.

10. On 31 May 2011, Takeda Global Research and Development Centre (Europe) Ltd ('Takeda Global'), a company established in the United Kingdom, applied, in accordance with the provisions of Regulation No 726/2004, for a conditional marketing authorisation for a new active substance bearing the international non-proprietary name 'Brentuximab vedotin' and the commercial name 'Adcetris', which had been developed using the abovementioned patent.

11. The European Commission granted Takeda Global a marketing authorisation for the medicinal product Adcetris (8) by decision dated 25 October 2012, Article 4 of which states that '[t]he period of validity of the authorisation shall be one year from the date of notification of this Decision'. (9) The marketing

authorisation thus granted was notified to Takeda Global on 30 October 2012 and published in the Official Journal of the European Union ('the OJ') for 30 November 2012, (10) pursuant to Article 13(2) of Regulation No 726/2004.

12. On 2 November 2012, Seattle Genetics applied to the Austrian Patent Office for an SPC based on the basic patent. (11) The Patent Office granted the application and stated that the SPC would take effect upon the expiry of the basic patent and would expire on 25 October 2027, (12) thus taking the view that the 'date of the first authorisation to place the product on the market in the [European Union]', within the meaning of Article 13(1) of Regulation No 469/2009, should be the date of the decision granting the marketing authorisation, adopted by the Commission on 25 October 2012.

13. In October 2013, Takeda Global assigned the marketing authorisation in question to Takeda Pharma A/S, a licencee of Seattle Genetics.

14. On 22 April 2014, Seattle Genetics brought proceedings before the Higher Regional Court, Vienna, against the Austrian Patent Office's decision, seeking rectification of the expiry date of the SPC so that it would not expire until 30 October 2027, that is, five days later than the date given in the decision. In support of its action, it argued that the 'date of the first authorisation to place the product on the market', within the meaning of Article 13(1) of Regulation No 469/2009, should in fact be taken to be date on which the decision authorising Adcetris was notified to the addressee, that is to say, 30 October 2012.

15. On 22 August 2014, the Commission renewed the marketing authorisation in question by a decision Article 3 of which stated: '*[t]he period of validity of the renewed authorisation shall be one year from 30 October 2014*'. (13)

16. In those circumstances, and having regard to the apparently differing practices followed in other Member States when determining the duration of an SPC in accordance with Article 13(1) of Regulation No 469/2009, (14) the Higher Regional Court, Vienna, decided by Order of 2 October 2014, received at the Court on 15 October 2014, to stay the proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) Is the date of the first authorisation to place the product on the market in the [European Union] pursuant to Article 13(1) of Regulation [No 469/2009] determined according to [EU] law or does that provision refer to the date on which the authorisation takes effect under the law of the Member State in question?

(2) If the Court's answer is that the date referred to in Question 1 is determined by [EU] law, which date must be taken into account — the date of authorisation or the date of notification?'

17. Written observations have been submitted to the Court by Seattle Genetics, the Greek, Italian, Latvian and Lithuanian Governments and by the Commission. No hearing has been held.

IV – Analysis

A – Is the 'date of the first authorisation to place the product on the market in the [European Union]', within the meaning of Article 13(1) of Regulation No 469/2009, an independent concept? (the first question)

18. As a preliminary point, I would observe that the aims of the system of special protection certificates introduced at Community level are to remedy the shortcomings of national patent schemes in protecting pharmaceutical research and to check the development of too great a disparity between those schemes, which would be likely to impede the free movement of medicinal products between Member States and thus impair the proper functioning of the internal market. (15)

19. By its first question, the referring court asks the Court, in substance, whether the 'date of the first authorisation to place the product on the market in the [European Union]', within the meaning of Article 13(1) of Regulation No 469/2009, is to be identified by means of the application of EU law or in accordance with the legislation of the Member States, in particular the legislation of the Member State in which the marketing authorisation under consideration was used as the basis for obtaining an SPC.

20. In setting out the reasons for its request for a preliminary ruling, the Higher Regional Court, Vienna, points out that Article 13 does not indicate clearly whether the rule for the calculation of the period of exclusivity conferred by an SPC also refers to the procedural law of the Member State concerned (16) or whether the method for determining the period of exclusivity is governed entirely by that provision. It adds that, in German legal literature, different answers are given to the question of the relevant date and that it appears that the solution varies depending on the laws of the Member States. (17)

21. Like all the parties that have submitted observations to the Court, with the exception of the Italian Government, I take the view that the concept of the 'date of the first authorisation to place the product on the market in the [European Union]' referred to in Article 13(1) of Regulation No 469/2009 must be defined solely on the basis of EU law. That approach rests, first of all, on the general principles which govern the interpretation of EU law, secondly, on the legal nature and purpose of the regulation in question, thirdly, on the parameters of the concept at issue, which have been partially circumscribed in the Court's case-law and, lastly on considerations of a practical nature.

22. Indeed, according to settled case-law, for the purpose of determining the meaning and scope of the terms of a provision of EU law which makes no express reference to the law of the Member States, as is the case with Article 13(1), the provision must be given an autonomous and uniform interpretation that will apply throughout the Union. That interpretation must take into account the context of the provision and the purpose of the legislation in question. It follows that the method by which the date in question is determined

under the legislation of a Member State is of no relevance to the interpretation of Article 13(1). (18) I would observe in this connection that, inasmuch as it concerns the duration of an SPC as provided for in Article 13 of Regulation No 469/2009, this request for a preliminary ruling raises questions which, in my view, are of a substantive, rather than a procedural nature. (19) Therefore, contrary to the Italian Government's assertion, the issue raised does not, I think, concern the procedural autonomy of the Member States. (20)

23. Moreover, it would appear that, by opting for a legal instrument such as a regulation in order to introduce a 'standard system' for supplementary protection certificates at Community level, the legislature expressed its wish that the rules adopted in this area should be common rules, so as to remove any obstacles to the free movement of medicinal products and prevent distortion of competition within the internal market, (21) as well as its intention that all Member States should apply simultaneously the provisions on extending the protection afforded by patents. (22) This desire to achieve a 'uniform solution' and thus a single model for the SPC applicable in all Member States, in particular as regards the conditions for issue and the certificate's duration, was expressed in the preamble to Regulation No 1768/92 and reiterated even more clearly in the preamble to Regulation No 469/2009, which codified the earlier regulation. (23)

24. As regards, more specifically, the concept of 'the first authorisation to place the product on the market in the [European Union]', referred to in Article 13(1) of Regulation No 469/2009, the Court has already held that that concept must be interpreted in the same way, irrespective of the content of the provision of the regulation in which it appears. (24) The Court has also pointed out that, by referring to the first marketing authorisation in the Community, the system introduced by Regulation No 1768/92 was intended to prevent the grant of certificates whose validity varied in duration from one Member State to another. (25) I would observe in this connection that a marketing authorisation issued by the Commission in accordance with Regulation No 726/2004 is valid at the same time 'throughout the Community'. (26)

25. If it were accepted that the date on which a marketing authorisation took effect and consequently the date on which, by reference to that criterion, a SPC expired had to be determined in accordance with national law, then both the objectives and the general scheme, and indeed the effectiveness of Regulation No 469/2009 would be compromised, since the result would be that, for one and the same medicinal product, the duration of the SPCs could vary from one Member State to another. The Commission rightly points out that any disparity in the dates of expiry of SPCs could, in practice, give rise to an unwanted parallel trade between Member States in which SPCs had already expired and those in which they were still valid. In addition to the fact that differences in the protection afforded to one and the same medicinal product would entail fragmentation of the market, the very thing that the Community legislature wished to avoid, (27) I consider that the existence of different categories would also make for legal uncertainty prejudicial to the interests of the economic actors concerned.

26. Therefore, I propose that the answer to the first question should be that the concept of the 'date of the first authorisation to place the product on the market in the [European Union]' referred to in Article 13(1) of Regulation No 469/2009 must be given a uniform and autonomous interpretation in conformity with EU law and that it cannot, therefore, depend on the rules applicable in the Member States, in particular in the Member State in which the market authorisation has taken effect.

B – Does the 'date of the first authorisation to place the product on the market in the [European Union]' referred to in Article 13(1) of Regulation No 469/2009 correspond to the date of the decision granting marketing authorisation or the date on which notification was given of that decision? (the second question)

1. The subject-matter of the second question

27. By its second question, the referring court asks the Court, in substance, to rule on the question whether, in the event that Article 13(1) of Regulation No 469/2009 is to be interpreted on the basis of EU law, the 'date of the first authorisation to place the product on the market in the [European Union]' that must be taken into account in order to determine the duration of an SPC, to which that provision refers, is to be construed as being the date on which the marketing authorisation was granted or the date on which notification of the decision containing that authorisation was given to the addressee.

28. Referring to certain judgments of the Court of Justice, (28) the Higher Regional Court, Vienna, submits that it can be inferred from those rulings that it is not the date on which notification of the marketing authorisation is given that is decisive but the date on which the authorisation itself is granted, and that that solution reinforces the case for uniform interpretation. While the Greek, Latvian and Lithuanian Governments share the referring court's view, Seattle Genetics, the Commission and, expressing its alternative opinion, the Italian Government (29) submit, on the contrary, that it is the date on which notification of the marketing authorisation decision is given that is decisive.

29. It is the latter view that I find convincing. It is corroborated by a number of criteria drawn from the primary law of the European Union, which defines the starting point of the legal effects of decisions adopted by the Commission. (30) Even though the EU legislature can, in my view, derogate from such provisions in individual decisions implementing a legislative act, (31) it nevertheless seems to me that Article 13(1) of Regulation No 469/2009 contains no suggestion of any such derogation, when viewed in the light of the usual interpretative criteria. (32) It is those criteria that I shall address first of all.

2. Interpretative criteria drawn from Regulation No 469/2009

30. In so far as concerns the wording of the provision which the Court is asked to interpret, a reading of that provision affords no easy answers, in my view. Indeed, the expression 'the date of the first authorisation to place the product on the market in the [European Union]', of which there are several slight variations of no significance in the various language versions of Regulation No 469/2009, (33) is not in itself sufficiently clear as to whether or not that date in fact corresponds to the date of the Commission decision granting marketing authorisation, as the Greek, Latvian and Lithuanian Governments maintain. (34)

31. Admittedly, that solution does appear to have the advantage of simplicity, inasmuch as that date is printed on the cover page of the authorisation decision. However, as the Commission points out, that is only a minimal advantage because, under the centralised marketing authorisation procedure, the date on which notification of the marketing decision is given to the addressee is just as easy to find, since, as in the present case, (35) the date of notification is always published in the OJ also. (36) The question which of those dates is the relevant date therefore remains open.

32. As regards the general structure surrounding Article 13(1) of Regulation No 469/2009, it may be observed that other provisions of that regulation also refer to the 'date of the first authorisation to place the product on the market' or the 'date of the authorisation to place the product on the market', (37) without really being any more explicit than that in defining those dates. On the other hand, certain other provisions of the regulation are slightly more precise, inasmuch as they state that the relevant date is the date on which the marketing authorisation or first marketing authorisation was 'granted' or 'obtained'. (38)

33. In this connection, the Latvian and Lithuanian Governments refer to certain judgments of the Court of Justice according to which, in their view, the date of the 'grant' or the 'obtaining' of the first authorisation to place the product on the market must be construed, for the purposes of Regulation No 469/2009, as being the date on which the decision granting that authorisation was adopted. However, I do not think that those judgments offer anything of decisive value for the purpose of answering the question posed in the present case. Admittedly, in its judgment in Merck Sharp & Dohme, the Court referred to the date on which the first authorisation to place the product on the market was 'granted' or 'obtained' in its interpretation of Article 13 of Regulation No 1768/92 (39) and, in its judgment in Kirin Amgen, it pointed out, when interpreting other provisions of the same regulation, that 'the obtaining of a marketing authorisation occurs at the time when it is granted'. (40) However, the fact remains that, in the absence of any clearer guidance from the case-law, the concept of 'obtaining' marketing authorisation may relate equally well in my view, if not better, to the date on which the marketing authorisation granted came to the notice of the addressee of that decision and thus became capable of producing actual effects.

34. In so far as concerns the objectives which the provision at issue seeks to attain, it is common ground that the SPC for medicinal products introduced by Regulation No 1768/92 and codified by Regulation No 469/2009 increases the duration of the period of exclusivity enjoyed by inventors under basic patents, (41) by extending the effects of the basic patent beyond its statutory expiry date. (42) That mechanism is designed to attenuate the erosive effect of the long period of time that can elapse between the lodging of a patent application, which often occurs soon after clinical tests are completed, and obtaining authorisation to place the medicinal product in question on the market. (43) That long period, which reduces by a corresponding period the duration of the exclusive right guaranteed by a patent, can make it difficult to recover the sometimes costly investments required for pharmaceutical research, which none the less contributes to continuing improvement in public health. (44)

35. Accordingly, the Court has repeatedly held that the SPC is '*designed to re-establish an adequate period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of the basic patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention 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 marketing authorisation in the European Union was granted*'. (45)

36. The Court has also pointed out that the SPC is thus intended to '*make up for the fact that the period of effective protection under the patent is insufficient to cover the investment put into [pharmaceutical] research*'. (46) This concern to enable the holders of patents for medicinal products to recover, to a large extent, the funds invested in research, which is regarded as being '*vital, both for the pharmaceuticals industry itself and for society as a whole*', has clearly informed the action of the EU legislature in this field. (47)

37. Moreover, emphasis has frequently been placed, both in legislative texts (48) and in the case-law, (49) on the intention to ensure, by means of the SPC provided for under EU law, that the protection afforded by a patent is effective, in particular in terms of its duration.

38. The right to exploit a new medicinal product by marketing it, and thus the possibility of beginning to recover the investments associated with its invention, only become effective once the beneficiary of that right becomes aware of the fact that he is authorised to put the medicinal product on the market. Consequently, the 'date of the first authorisation to place the product on the market in the [European Union]', within the meaning of Article 13(1) of Regulation No 469/2009, must in my view correspond to the date on which

notification of the decision is given to the addressee thereof and thus takes effect.

39. If, contrary to that view, the Court should regard the date of the decision granting marketing authorisation as the relevant date, such an interpretation would reduce the period of validity of SPCs in a manner inconsistent with the fundamental objectives of that regulation. As the Commission argues, it would be unacceptable for the period of supplementary protection granted by the legislature, with the precise aim of prolonging the opportunities for marketing medicinal products, to be shortened by procedural steps carried out between the decision granting marketing authorisation and the notification of that decision, the duration of which is not within the control of the SPC applicant.

3. Interpretative criteria drawn from primary law

40. The interpretation of Article 13(1) of Regulation No 469/2009 that I propose, to the effect that the date of notification of the decision granting marketing authorisation is the relevant date, is supported by considerations of a more general nature than those which relate to the instrument itself which I have just set out.

41. It is important first of all to remember that the marketing authorisation for the medicinal product for human use at issue in the main proceedings was granted by decision of the Commission adopted under the centralised procedure laid down in Regulation No 726/2004, as opposed to a national marketing authorisation granted by the competent authorities of a Member State on the basis of Directive 2001/83.

42. A decision of that nature falls within the category of legal acts adopted by the EU institutions referred to in the fourth paragraph of Article 288 TFEU. (50) Therefore, as Seattle Genetics maintains, account must be taken of the third paragraph of Article 297(2) TFEU, from which it is clear that notification of a decision which specifies the person to whom it is addressed must be given to that person in order to take effect and takes effect only upon such notification. That provision enshrines a general legal principle according to which notification must be given of all acts of an individual nature, in particular acts of an administrative nature, to the addressee and the rights and obligations arising under them cannot be relied on against the addressee until he has been duly made aware of the act in question. (51)

43. Similarly, according to its written observations, the Commission takes the view that, since derogation from that principle would have the consequence of shortening the period of validity of an SPC and would therefore be prejudicial to the holder of that SPC, the better option is to take as the relevant date the date on which notification was given of the decision granting marketing authorisation.

44. This suggested approach is consistent with the practice adopted by the Commission not only in the present case (52) but systematically with regard to SPCs granted for medicinal products in respect of which an EU marketing authorisation has been granted, which has been mentioned in various public position statements. (53) Similarly, the European Medicines Agency takes the date of notification of marketing authorisations as the relevant date for calculating the period of protection provided for by provisions of EU law relating to the marketing of medicinal products. (54)

45. Consequently, I recommend that the answer to the second question should be that the ‘date of the first authorisation to place the product on the market in the [European Union]’, within the meaning of Article 13(1) of Regulation No 469/2009, is not the date on which the decision granting marketing authorisation is adopted, but the date on which notification of that decision is given to the addressee thereof.

V – Conclusion

46. In light of the foregoing considerations, I propose that the Court of Justice answer the questions referred to it for a preliminary ruling by the Higher Regional Court, Vienna, as follows:

(1) The concept of the ‘date of the first authorisation to place the product on the market in the [European Union]’, referred to in Article 13(1) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, is an independent concept of EU law.

(2) Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that the ‘date of the first authorisation to place the product on the market in the [European Union]’, is the date on which notification of the decision granting marketing authorisation is given to the addressee of the decision.

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1 - Original language: French.

2 - Regulation 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), which codified and repealed, with effect from 6 July 2009, 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).

3 - Directive 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).

4 - Directive 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).

5 - Whilst it is not expressly stated in Article 3, an SPC may, as the Commission has stated, also be issued under Regulation No 469/2009 in respect of products which, like the product at issue in the main proceedings, are subject to a Community market authorisation procedure under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of

medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), since, as is stipulated in Article 13(1) of Regulation No 726/2004, such an authorisation '*[confers] the same rights and obligations in each of the Member States as a marketing authorisation granted by that Member State in accordance with Article 6 of Directive 2001/83/EC*'.

6 - In accordance with Article 13(3), the validity of an SPC may nevertheless be extended by six months if the conditions are met for granting the extension provided for in Article 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use (OJ 2006 L 378, p. 1).

7 - European patent E 516 818, published under number EP 1 545 613 and bearing the heading *'Auristatin conjugates and their use for treating cancer, an autoimmune disease or an infectious disease'*.

8 - The authorisation was registered in the Community register of medicinal products under number EU/1/12/794/001.

9 - Commission implementing decision of 25 October 2012 granting a conditional marketing authorisation under Regulation No 726/2004 for 'Adcetris — Brentuximab vedotin', an orphan medicinal product for human use (C(2012) 7764 final), produced in the English version by Seattle Genetics and available at: http://ec.europa.eu/health/documents/community-register/2012/20121025124324/dec_124324_en.pdf.

10 - See the 'Summary of European Union decisions on marketing authorisations in respect of medicinal products from 1 October 2012 to 31 October 2012, OJ 2012 C 371, p. 7. That publication contained, for the marketing authorisations issued pursuant to Article 13 of Regulation No 726/2004, the following customary headings: 'Date of the decision', 'Name of the medicinal product', 'INN (international non-proprietary name)', 'Holder of the marketing authorisation', 'Number of the entry in the Community Register', 'Pharmaceutical form', 'ATC code (Anatomical Therapeutic Chemical Code)' and 'Date of notification' (my emphasis).

11 - Application for the grant of an SPC for the product 'Brentuximab vedotin or pharmaceutically acceptable salts thereof'.

12 - The expiry date was subject to the timely payment of the annual fees.

13 - Commission Implementing Decision C(2014) 6095 (final) of 22 August 2014 on the annual renewal of the conditional marketing authorisation for the orphan medicinal product for human use 'ADCETRIS — Brentuximab vedotin', granted by Decision C(2014) 7764 (final), and amending that decision, produced in the English version by Seattle Genetics.

14 - The order for reference refers, in this connection, to decisions adopted in Belgium, Portugal, Slovenia and the United Kingdom. Seattle Genetics states that the date of notification of the decision granting market authorisation has been taken to be the relevant date by competent patent authorities and courts in Belgium, Estonia, Portugal, Slovenia and the United Kingdom, whereas the date of adoption of the decision has been taken as the relevant date in Denmark, the Netherlands and Sweden. The Commission confirms that that approach has indeed been taken in those three Member States and states that there has been a shift in the practice followed by the competent authorities in Portugal, Slovenia and the United Kingdom, where the date of notification is now used, rather than the date of the decision.

15 - See recital 7 in the preamble to Regulation No 469/2009 and paragraphs 18 and 27 of the explanatory memorandum for the Commission's proposal of 11 April 1990, which led to the adoption of Regulation No 1768/92 (COM(90) 101 final).

16 - The referring court states that, in this case, under Austrian rules of procedure, the decisive criterion would be the date of publication or notification of the administrative decision and that, if those rules were to be applied to the case in the main proceedings, the date of notification of the marketing authorisation decision would then be taken as the relevant date, such that the date of expiry of the SPC at issue would be deferred to 30 October 2027.

17 - The referring court states that, according to one author (Sredl, V., *'Das ergänzende Schutzzertifikat im deutschen Patentnichtigkeitsverfahren'*, in Gewerblicher Rechtsschutz und Urheberrecht (GRUR), 2001, vol. 7, pp. 596 and 598), the legal situation varies according to the national law of the Member State in question and that, under the laws of a significant number of Member States, the authorisation takes effect upon signature of the authorisation instrument, rather than at the time it is notified.

18 - See, in particular, the judgment in Zentrale zur Bekämpfung unlauteren Wettbewerbs (C‑59/12, EU:C:2013:634, paragraphs 25 and 26).

19 - See, by analogy, my Opinion in Georgetown University (C‑484/12, EU:C:2013:745, point 29).

20 - The Italian Government maintains that '*in the absence of any [EU] rules governing the procedure before the competent authorities of each Member State'*, the concept in question must be appraised on the basis of the law of the Member State in which the marketing authorisation takes effect.

21 - These considerations are apparent from the Commission's proposal which led to the adoption of Regulation No 1768/92 (explanatory memorandum, COM(90) 101 final, paragraphs 16, 18 and 27).

22 - See, in particular, the Opinion of the Economic and Social Committee on the Commission's proposal which led to the adoption of Regulation No 1768/92 (OJ 1991 C 69, p. 23, section 3.2).

23 - See the sixth recital in the preamble to Regulation No 1768/92, which is repeated, in substance, and expanded upon in recitals 7 and 8 in the preamble to Regulation No 469/2009. The Court has referred to these objectives repeatedly (see, inter alia, the judgment in Medeva, C‑322/10, EU:C:2011:773, paragraph 24 and the case-law cited).

24 - See the Order in Astrazeneca (C‑617/12, EU:C:2013:761, paragraph 48) and, prior to that, with regard to Regulation No 1768/92, the judgment in Hässle (C‑127/00, EU:C:2003:661, paragraphs 57, 58 and 72).

25 - See, with regard to Regulation No 1768/92, the judgment in Yamanouchi Pharmaceutical (C‑110/95, EU:C:1997:291, paragraph 25).

26 - Pursuant to Article 13(1) of that regulation.

27 - In this connection, see, with regard to Regulation No 1768/92, the judgment in AHP Manufacturing (C‑482/07, EU:C:2009:501, paragraphs 35 and 36 and the case-law cited).

28 - The referring court mentions, in particular, the judgment in Yamanouchi Pharmaceutical (C‑110/95, EU:C:1997:291, paragraph 24), in which the Court stated that '*[t]he first marketing authorisation in the Community … serves a purely temporal purpose*', the judgment in Neurim Pharmaceuticals (1991) (C‑130/11, EU:C:2012:489), according to which 'Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the [SPC]', and the Order in Astrazeneca (C‑617/12, EU:C:2013:761, paragraph 48, to which I alluded in point 24 of this Opinion).

29 - Bearing in mind that the principal position advocated by the Italian Government is that the concept of which the Court's interpretation is sought should be defined on the basis of the laws of the Member States.

30 - See points 40 et seq. of this Opinion.

31 - Special rules governing the way in which the legal effects of such decisions adopted by the Union come into being may be found, for example, in the field of intellectual property rights.

32 - According to settled case-law, in order to interpret a provision of EU law in autonomous and uniform fashion, '*it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part*' (see, inter alia, the judgments in Kirin Amgen, C‑66/09, EU:C:2010:484, paragraph 41, and Zentrale zur Bekämpfung unlauteren Wettbewerbs, C‑59/12, EU:C:2013:634, paragraph 25).

33 - The Latvian Government maintains that the wording in its own language version ('*the date on which the first [marketing authorisation] was obtained*', in the Latvian version) is more precise than that in other language versions and suggests that the relevant date is the date on which the decision granting the authorisation was adopted. For its part, the Lithuanian Government maintains that the forms of words used in the German, French, Lithuanian and English versions also suggest that meaning. Those arguments are not decisive, in my opinion or in that of the Commission, which considers that the wording used in the other language versions of the text gives no clear indication as to which solution to choose. In any event, if the various language versions of the provision of EU law at issue are to be regarded as truly divergent, then the provision 'must be interpreted by reference to the purpose and general scheme of the rules of which it forms part' (see, inter alia, the judgment in Hässle, C‑127/00, EU:C:2003:661, paragraph 70).

34 - Recital 9 in the preamble to the regulation offers no further clarification, merely stating that the duration of the protection granted by an SPC commences '*from the time the medicinal product in question first obtains authorisation to be placed on the market*'.

35 - See footnote 10 to this Opinion.

36 - Indeed, although Article 13(2) of Regulation No 726/2004 merely provides that '*notification of marketing authorisation shall be published in the [OJ]*', and even though the non-exhaustive list of the information to be published that is set out in Article 13(2) includes only 'the date of authorisation', the Commission's usual practice is to mention both the 'date of the decision' granting marketing authorisation and the 'date of notification' of the decision.

37 - See, in particular, Article 8(1)(a), which concerns the content of the application for an SPC, Article 9(2)(d) and (e), which concerns publication of applications for an SPC, and Article 11(1)(d) and (e), which concerns publication of the grant of SPCs.

38 - See, in particular, Article 7(1), which concerns the time-limit for lodging an application for an SPC, and Article 20, which sets out additional provisions relating to the enlargement of the Community.

39 - C‑125/10, EU:C:2011:812, paragraphs 39, 42 and 45, concerning the duration of the SPC, as provided for in Article 13(1) of Regulation No 1768/92 (which corresponds to Article 13(1) of Regulation No 469/2009), read together with Article 36 of Regulation No 1901/2006.

40 - C‑66/09, EU:C:2010:484, paragraphs 42 and 52, in which the Court sought, by this form of words, to draw a distinction between '*the entry into force of the Community marketing authorisation*' and '*its grant within the meaning of Article 3(b)*' of Regulation No 1768/92 in its interpretation of Articles 7 and 19a of that regulation.

41 - A basic patent is a guarantee, 'to reward the creative effort of the inventor,' that the patentee 'has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licences to third parties, as well as the right to oppose infringements' (judgment in Centrafarm and de Peijper, 15/74, EU:C:1974:114, paragraph 9).

42 - See recital 9 in the preamble to Regulation No 469/2009.

43 - In its proposal of 11 April 1990, which led to the adoption of Regulation No 1768/92 (COM(90) 101 final), the Commission pointed out that the period of protection offered by a European patent was generally 20 years, but the period during which a medicinal product could actually be exploited was reduced to 8 years on average (explanatory memorandum, COM(90) 101 final, paragraph 2). See also the Opinion of the

Economic and Social Committee on the Commission's proposal (OJ 1991 C 69, p. 22, section 1.4).

44 - See recitals 2 to 5 in the preamble to Regulation No 469/2009.

45 - See, in particular, the judgments in Forsgren (C‑631/13, EU:C:2015:13, paragraph 33) and Actavis Group PTC and Actavis UK (C‑577/13, EU:C:2015:165, paragraph 34).

46 - See, in particular, the judgments in Synthon (C‑195/09, EU:C:2011:518, paragraph 46 and the case-law cited) and Merck Sharp & Dohme, paragraph 32) and the Opinion of Advocate General Fennelly in Farmitalia (C‑392/97, EU:C:1999:277, point 20, in which the Advocate General stated that *'the extent to which patentees can recover investment in research ... is the essential purpose of ... Regulation [No 1768/92]'*).

47 - See the explanatory memorandum for the Commission's proposal which led to the adoption of Regulation No 1768/92 (COM(90) 101 final, paragraphs 5 and 36), the Opinion of the Economic and Social Committee on the Commission's proposal (OJ 1991 C 69, p. 22, section 2.1), the third recital in the preamble to Regulation No 1768/92 and recital 4 in the preamble to Regulation No 469/2009.

48 - See the explanatory memorandum for the Commission's proposal which led to the adoption of Regulation No 1768/92 (COM(90) 101 final, paragraphs 36, 51 and 52), the third and eighth recitals in the preamble to Regulation No 1768/92 and recitals 4 and 9 in the preamble to Regulation No 469/2009. According to the eighth recital in the preamble to the proposal for a regulation, the Commission's initial intention was for the *'duration of the protection granted by [an SPC to] be determined to enable a medicinal product to be given the effective protection it would have if it were not subject to authorisation to be placed on the market'*.

49 - In addition to the judgments of the Court whose content I mentioned in points 35 and 36 of this Opinion, see the judgments in Neurim Pharmaceuticals (1991) (C‑130/11, EU:C:2012:489, paragraph 23 and the case-law cited) and Actavis Group PTC and Actavis UK (C‑443/12, EU:C:2013:833, paragraph 31).

50 - See, by analogy, the judgment in Mensch und Natur (C‑327/09, EU:C:2011:249, paragraphs 24 and 25) and my Opinion in that case (C‑327/09, EU:C:2010:709, point 42), which concerned a Commission decision refusing authorisation to place a product on the EU market as a food or food ingredient, which the Court regarded as a decision within the meaning of the fourth paragraph of Article 249 EC, which became the fourth paragraph of Article 288 TFEU.

51 - Legal consequences flow from this principle in fields other than administrative law, in particular where a party has not been apprised of a writ of summons or a judicial decision (see, in particular, Article 19(4) of Regulation (EC) No 1393/2007 of the European Parliament and of the Council of 13 November 2007 on the service in the Member States of judicial and extrajudicial documents in civil or commercial matters (service of documents), and repealing Council Regulation (EC) No 1348/2000 (OJ 2007 L 324, p. 79) and the judgment in Plumex, (C‑473/04, EU:C:2006:96, paragraph 32).

52 - The decisions which the Commission adopted on 25 October 2012 and 22 August 2014, granting marketing authorisation for the medicinal product Adcetris and then renewing that authorisation, expressly state that the period of validity of the authorisation commences on the date of notification of the decision (see points 11 and 15 of this Opinion). In the observations which it submitted to the Court, the Commission stated that this was standard wording.

53 - Seattle Genetics cites the minutes of the second meeting of SPC experts held on 9 October 2006 in Brussels, and to the recommendations to applicants for a marketing authorisation (usually referred to as a Notice to Applicants), which are published by the Commission and to which the Commission also referred in its observations (see the Commission's Health and Consumers Directorate-General's Notice to Applicants, Revision 4, Volume 2A — Procedures for marketing authorisation, Chapter 1 — Marketing Authorisation, June 2013, at http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap1_2013-06_en.pdf.

54 - See, on the Agency's website, in EMA Procedural advice for users of the centralised procedure for generic/hybrid applications, EMEA/CHMP/225411/2006, March 2015, the answer to question 12: *'When can I submit my generic/hybrid application considering the protection period of the reference medicinal product?'*), available at the following address: http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004018.p