Court of Justice EU, 20 December 2017, Incyte v Szellemi Tuljdon Nemzeti Hivatala

PATENT LAW - SPC

Date of the first MA, as stated in an application for the SPC, on the basis of which the duration of the certificate is calculated, is incorrect

- **when the incorrect date led to a method for calculating the durating of the certificate which does not comply with the requirements of Article 13(1) of SPC Regulation for Medicinal Products, as interpreted by a subsequent judgment of the Court**

In the light of the foregoing considerations, the answer to the first question referred is that Article 18 of Regulation No 469/2009, read in the light of Article 17(2) of Regulation No 1610/96, must be interpreted as meaning that the date of the first MA, as stated in an application for the SPC, on the basis of which the national authority competent for granting such a certificate calculated the duration of the certificate, is incorrect in a situation, such as that at issue in the main proceedings, where the date led to a method for calculating the duration of the certificate which does not comply with the requirements of Article 13(1) of Regulation No 469/2009, as interpreted by a subsequent judgment of the Court.

42. Accordingly, the interpretation adopted by the Court, in **the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)**, in relation to the concept of 'date of the first [MA] in the [European Union]', as it appears in Article 13(1) of Regulation No 469/2009, clarifies and defines the meaning and scope of that rule as it must be, or ought to have been, understood and applied from the date of its entry into force.

43. It follows that the date which should have been stated in the application for the SPC made by Incyte, and should have been used by the Office in calculating the duration of the SPC, is the date that the notification of the decision granting the MA was given to the addressee, and that the inclusion of any other date in the application for the SPC must be regarded as incorrect.

When the date of the first MA is incorrect, the holder of an SPC may, under Article 18 of SPC Regulation for Medicinal Products, bring an appeal for ectification of the duration stated in the SPC

- **provided that the SPC has not expired**

In the light of the foregoing, the answer to the second question is that Article 18 of Regulation No 469/2009, read in the light of recital 17 and of Article 17(2) of Regulation No 1610/96, must be interpreted as meaning that, in a situation such as that set out in paragraph 44 above, the holder of an SPC may, under Article 18 of Regulation No 469/2009, bring an appeal for rectification of the duration stated in the SPC, provided that the SPC has not expired.

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Court of Justice EU, 20 December 2017

(M. Ilešič, President of the Chamber, A. Rosas, C. Toader (Rapporteur), A. Prechal and E. Jarašiūnas)

JUDGMENT OF THE COURT (Second Chamber)

20 December 2017 (*)

(Reference for a preliminary ruling — Intellectual and industrial property — Patents — Medicinal products for human use — Regulation (EC) No 469/2009 — Article 18 — Plant-protection products — Regulation (EC) No 1610/96 — Article 17(2) — Supplementary protection certificate — Duration — Fixing the date of expiry — Consequences of a judgment of the Court — Possibility or requirement to rectify the date of expiry)

In Case C‑492/16,

REQUEST for a preliminary ruling under Article 267 TFEU from the Fővárosi Törvényszék (Budapest High Court, Hungary), made by decision of 31 August 2016, received at the Court on 14 September 2016, in the proceedings

Incyte Corporation

v

Szellemi Tulajdon Nemzeti Hivatala,

THE COURT (Second Chamber),

composed of M. Ilešič, President of the Chamber, A. Rosas, C. Toader (Rapporteur), A. Prechal and E. Jarašiūnas, Judges,

Advocate General: Y. Bot,

Registrar: I. Illéssy, Administrator,

having regard to the written procedure and further to the hearing on 11 October 2017,

after considering the observations submitted on behalf of:

– Incyte Corporation, by J.K. Tálas, E.E. Szakács, Zs. Lengyel, ügyvédek and W. Devroe, advocaat,

– the Hungarian Government, by M.Z. Fehér and E.E. Sebestyén, acting as Agents,

– the Italian Government, by G. Palmieri, acting as Agent, and by S. Fiorentino and F. De Luca, avvocati dello Stato,

– the Lithuanian Government, by D. Kriaučiūnas and G. Taluntytė, acting as Agents,

– the Portuguese Government, by L. Inez Fernandes and M. Figueiredo and by M. Rodrigues and S. Duarte Afonso, acting as Agents,

– the European Commission, by J. Samnadda and A. Sipos, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1. This request for a preliminary ruling concerns the

interpretation of Article 18 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), read in conjunction with Article 17(2) of 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), and the consequences of **the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)**.

2. The request has been made in proceedings between Incyte Corporation and Szellemi Tulajdon Nemzeti Hivatala (National Intellectual Property Office, Hungary, 'the Office') concerning the latter's refusal to grant an application for rectification of the date of expiry of a supplementary protection certificate (SPC) for a medicinal product developed by Incyte.

Legal context

European Union law

Regulation No 1610/96

3. Recitals 9 and 10 of Regulation No 1610/96 read as follows:

'*(9) … 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 hinder the free movement of plant protection products within the Community and thus directly affect the functioning of the internal market; … this is in accordance with the principle of subsidiarity as defined by Article [5 TEU];*

(10) … therefore, there is a need to create a[n] [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 plant protection product for which marketing authorisation has been granted is necessary; … a Regulation is therefore the most appropriate legal instrument'.

4. Recital 17 of that regulation states:

'*… the detailed rules in recitals 12, 13 and 14 and in Articles 3(2), 4, 8(1)(c) and 17(2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8(1)(c) and 17 of 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)]*'.

5. Article 2 of Regulation No 1610/96, headed 'Scope', provides:

'*Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorisation procedure as laid down in Article 4 of [Council] Directive 91/414/EEC [of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1]), or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorisation was lodged before Directive 91/414/EEC was implemented by the Member State concerned, may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.*'

6. Article 17 of that regulation, headed 'Appeals', states:

'*1. The decisions of the authority referred to in Article 9(1) or of the body referred to in Article 15(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.*

2. The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorisation to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.'

Regulation No 469/2009

7. Recitals 1, 3 to 5 and 7 to 9 of Regulation No 469/2009 read as follows:

'*(1) Council Regulation … No 1768/92 … has been substantially amended several times … In the interests of clarity and rationality the said Regulation should be codified.*

…

(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[n] [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 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.'

8. Under Article 2 of Regulation No 469/2009:

'*Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/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] or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [OJ 2001 L 311, p. 1] may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.*'

9. Article 8(1) of the regulation provides:

'*1. The application for a certificate shall contain:*

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;

(ii) if he has appointed a representative, the name and address of the representative;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorisation to place the product on the market, as referred to in Article 3(b) and, if this authorisation is not the first authorisation for placing the product on the market in the Community, the number and date of that authorisation;

(b) a copy of the authorisation to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC;

…'

10. Article 13(1) of Regulation No 469/2009 provides:

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

11. Under Article 14(a) of that regulation, the certificate is to lapse at the end of the period provided for in Article 13.

12. Article 18 of the regulation, headed 'Appeals', provides:

'*The decisions of the authority referred to in Article 9(1) or of the bodies referred to in Articles 15(2) and 16(2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.*'

13. Article 19 of the regulation states:

'*1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless the national law lays down special procedural provisions for certificates.*

2. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.'

14. Article 22 of Regulation No 469/2009 provides:

'*Regulation (EEC) No 1768/92, as amended by the acts listed in Annex I, is repealed.*

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.'

Hungarian law

15. Article 22/A of the a találmányok szabadalmi oltalmáról szóló 1995. évi XXXIII. törvény (Law No XXXIII of 1995 on patent protection of inventions) provides:

'*1. The subject matter of the invention shall enjoy supplementary protection in the cases, under the conditions and for the duration provided for in the European Community regulations as soon as the protection conferred by the patent ends on expiry of the period of protection.*

2. The detailed rules for implementing the European Community regulations referred to in paragraph 1 are set out in specific legislation.

3. Unless the provisions of the European Community regulations referred to in paragraph 1 or those of the specific legislation referred to in paragraph 2 provide otherwise, the provisions of the present law shall apply mutatis mutandis to [SPC].'

16. Article 45(1) of that law provides:

'*Subject to the exceptions provided for in the present Law, the [Office] shall act in patent cases within its competence in accordance with the rules of the Law laying down general provisions on administrative procedure.*'

17. Article 81/A(1) of the a közigazgatási hatósági eljárás és szolgáltatás általános szabályairól szóló 2004. évi CXL. törvény (Law No CXL of 2004 laying down general provisions on administrative services and procedure, 'the Law on administrative procedure') provides:

'*Where the decision contains a clerical error in a name, a figure or elsewhere, or it contains a miscalculation, the authority shall rectify the error — after hearing the interested party, if necessary — provided that such a rectification does not affect the substance of the case, the costs of the proceedings or the obligation to bear costs.*'

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

18. Incyte is a pharmaceutical company established in Wilmington (Delaware, United States). It is the owner of European patent No E013235 ('the basic patent').

19. On 24 January 2013, Incyte submitted an application for an SPC to the Office, by reference to the basic patent and to a marketing authorisation ('MA') granted by the European Commission for the whole of the European Union, dated 23 August 2012 in respect of the pharmaceutical product 'Jakavi', used in the treatment of myelofibrosis.

20. By decision of 7 October 2014, the Office granted

the SPC applied for. That decision contained information on the basic patent and the MA, in particular the date on which that authorisation was granted, namely on 23 August 2012, and the date of expiry of the SPC, namely on 24 August 2027.

21. The decision stated that Incyte could bring an appeal before the Fővárosi Törvényszék (Budapest High Court, Hungary) within 30 days of notification of that decision.

22. On 6 October 2015, **the Seattle Genetics judgment (C‑471/14, EU:C:2015:659)** was delivered.

23. On 18 November 2015, Incyte requested rectification of the SPC at issue in the main proceedings to the effect that the expiry date of the certificate be changed to 28 August 2027. According to Incyte, the Office made a miscalculation by using, as the basis for calculating the duration of the SPC, not the date on which the addressee was given notification of the decision on the MA, but the date on which it was granted, which disregards the interpretation adopted in **the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)**.

24. The Office rejected that application on the ground that Article 81/A of the Law on administrative procedure was inapplicable, since the decision granting the SPC at issue in the main proceedings did not contain any miscalculations or clerical errors.

25. Incyte requested that the referring court overrule that decision and rectify the date of expiry of the SPC.

26. That court states that it is common ground that, in its application for the SPC, Incyte gave the date that the MA was granted as the date of the first MA in the European Union rather than the date of notification of that decision to its addressee; it notes, however, that the possibility of retrospectively changing the date of expiry of the SPC in question is provided for by two rules, namely a national procedural rule and a procedural rule of EU law, in the present case, Article 81/A of the Law on administrative procedure and Article 17(2) of Regulation No 1610/96, respectively.

27. In that context, the referring court harbours doubts as to whether the present case concerns a date which is '*incorrect*' '*in the application for a certificate as provided for in Article 8*', within the meaning of Article 17(2) of Regulation No 1610/96, given that it was on the basis of a preliminary ruling delivered after the application for the SPC at issue was lodged that it appeared that the relevant date was stated on the basis of an incorrect interpretation of the law. The referring court also asks what is the meaning of the term '*shall be open to an appeal aimed at rectifying*', employed in that provision, and in particular whether or not it excludes a requirement of the competent national authorities to rectify ex officio the date of the expiry of an SPC which did not comply with **the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)**.

28. In those circumstances, the Fővárosi Törvényszék (Budapest High Court) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'*(1) Must Article 17(2) of Regulation … No 1610/96 … be interpreted as meaning that "the date of the first [MA] in the [European Union]" is incorrect in an application for a[n] [SPC], within the meaning of that regulation and of Regulation … No 469/2009, where that date was determined without taking account of the Court of Justice's interpretation of the law in* ***the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)****, with the result that it is appropriate to rectify the date of expiry of the [SPC] even if the decision to grant that certificate was made prior to* ***that judgment*** *and the time limit for appealing against that decision has already expired?*

(2) Is the industrial property authority of a Member State which is entitled to grant a[n] [SPC] required to rectify, of its own motion, the date of expiry of that [SPC] in order to ensure that that certificate complies with the interpretation of the law set out in ***the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)****?*'

Consideration of the questions referred

The first question

29. As a preliminary matter, the Court notes that the first question expressly refers to Article 17(2) of Regulation No 1610/96, whereas the SPC at issue in the main proceedings was granted for a medicinal product rather than a plant-protection product. An SPC granted for a medicinal product falls within the scope of Regulation No 469/2009.

30. However, the fact that a national court has, formally speaking, worded a request for a preliminary ruling with reference to certain provisions of EU law does not preclude the Court from providing to the national court all the elements of interpretation which may be of assistance in adjudicating on the case pending before it, whether or not that court has referred to them in its questions (judgment of 10 September 2014, Kušionová, C‑34/13, EU:C:2014:2189, paragraph 71).

31. In the present case, Article 18 of Regulation No 469/2009 must also be included in the following analysis.

32. It must therefore be considered that, by its first question, the referring court asks, in essence, whether Article 18 of Regulation No 469/2009, read in the light of Article 17(2) of Regulation No 1610/96, must be interpreted as meaning that the date of the first MA, as stated in an application for an SPC, on the basis of which the national authority competent for granting such a certificate calculated the duration of the certificate, is incorrect in a situation, such as that at issue in the main proceedings, where the date led to a method for calculating the duration of the certificate which does not comply with the requirements of Article 13(1) of Regulation No 469/2009, as interpreted by a subsequent judgment of the Court.

33. As regards the relevance of Article 17(2) of Regulation No 1610/96 to a situation, such as that at issue in the main proceedings, in which the SPC was granted for a medicinal product rather than a plant-protection product, it should be noted that, according to recital 17 of that regulation, the detailed rules set out

inter alia in Article 17(2) of the regulation are also valid, mutatis mutandis, for the interpretation, in particular, of Article 17 of Regulation No 1768/92.
34. Regulation No 1768/92, which had been amended on several occasions, was codified, repealed and replaced by Regulation No 469/2009, Article 22 thereof stating that references to the repealed regulation are to be construed as references to Regulation No 469/2009. According to the correlation table in Annex II thereto, Article 17 of Regulation No 1768/92 corresponds to Article 18 of Regulation No 469/2009.
35. Under Article 18 of Regulation No 469/2009, the decisions for granting an SPC are to be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.
36. Thus, Article 18 of Regulation No 469/2009, which reproduces the wording of Article 17 of Regulation No 1768/92, does not expressly provide for a procedure such as that set out in Article 17(2) of Regulation No 1610/96.
37. Nevertheless, having regard to recital 17 of Regulation No 1610/96, Article 18 of Regulation No 469/2009 must be interpreted in the light of Article 17(2) of Regulation No 1610/96.
38. Under Article 17(2) of Regulation No 1610/96, the decision to grant the certificate is open to an appeal aimed at rectifying the duration of the SPC where the date of the first MA in the European Union, contained in the application for a certificate, is incorrect.
39. Although it is clear from the case file that, in accordance with the prevailing practice, in its application for the SPC the applicant gave the date of the decision granting MA as the date of the first MA in the European Union and that that date was used as such by the Office, the fact remains that the date was incorrect.
40. In paragraph 40 of **the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)**, the Court held that Article 13(1) of Regulation No 469/2009 must be interpreted as meaning that the 'date of the first [MA] in the [European Union]', within the meaning of that provision, is the date on which notification of the decision granting MA was given to the addressee of the decision.
41. In that regard, it should be noted that, in accordance with settled case-law, the interpretation which the Court, in the exercise of the jurisdiction conferred upon it by Article 267 TFEU, gives to a rule of EU law clarifies and, where necessary, defines the meaning and scope of that rule as it must be, or ought to have been, understood and applied from the date of its entry into force. It follows that the rule as thus interpreted may, and must, be applied by the courts even to legal relationships arising and established before the delivery of the judgment ruling on the request for interpretation, provided that in other respects the conditions under which an action relating to the application of that rule may be brought before the courts having jurisdiction are satisfied (judgment of 14 April 2015, Manea, C‑76/14, EU:C:2015:216, paragraph 53 and the case-law cited).
42. Accordingly, the interpretation adopted by the Court, in **the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)**, in relation to the concept of 'date of the first [MA] in the [European Union]', as it appears in Article 13(1) of Regulation No 469/2009, clarifies and defines the meaning and scope of that rule as it must be, or ought to have been, understood and applied from the date of its entry into force.
43. It follows that the date which should have been stated in the application for the SPC made by Incyte, and should have been used by the Office in calculating the duration of the SPC, is the date that the notification of the decision granting the MA was given to the addressee, and that the inclusion of any other date in the application for the SPC must be regarded as incorrect.
44. In the light of the foregoing considerations, the answer to the first question referred is that Article 18 of Regulation No 469/2009, read in the light of Article 17(2) of Regulation No 1610/96, must be interpreted as meaning that the date of the first MA, as stated in an application for the SPC, on the basis of which the national authority competent for granting such a certificate calculated the duration of the certificate, is incorrect in a situation, such as that at issue in the main proceedings, where the date led to a method for calculating the duration of the certificate which does not comply with the requirements of Article 13(1) of Regulation No 469/2009, as interpreted by a subsequent judgment of the Court.

The second question

45. By its second question, the referring court asks, in essence, whether EU law must be interpreted as meaning that the national authority competent for granting an SPC is required to rectify ex officio the date of the expiry of that SPC, granted before delivery of the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659), in order that that certificate be consistent with the interpretation of EU law adopted in that judgment, in a situation, such as that at issue in the main proceedings, where the period for bringing an appeal under the national legislation against a decision granting that SPC has already lapsed.
46. In that regard, it should be noted that, according to settled case-law, finality of an administrative decision, which is acquired upon expiry of the reasonable time limits for legal remedies or by exhaustion of those remedies, contributes to legal certainty, and it follows that EU law does not require that an administrative body be, in principle, under an obligation to reopen an administrative decision which has become final (see, inter alia, judgments of 13 January 2004, Kühne & Heitz, C‑453/00, EU:C:2004:17, paragraph 24; of 12 February 2008, Kempter, C‑2/06, EU:C:2008:78, paragraph 37; and of 4 October 2012, Byankov, C‑249/11, EU:C:2012:608, paragraph 76).
47. Nonetheless, the Court has held that an administrative body has, under the principle of

cooperation, an obligation to review a decision, where an application for such review is made to it, in order to take account of the interpretation of the relevant provision of EU law given in the meantime by the Court where, (i) under national law, it has the power to reopen that decision, (ii) the administrative decision in question has become final as a result of a judgment of a national court ruling at final instance, (iii) that judgment is, in the light of a decision given by the Court subsequent to it, based on a misinterpretation of EU law which was adopted without a question being referred to the Court for a preliminary ruling under the third paragraph of Article 267 TFEU and (iv) the person concerned complained to the administrative body immediately after becoming aware of that decision of the Court (see, to that effect, judgment of 13 January 2004, Kühne & Heitz, C‑453/00, EU:C:2004:17, paragraph 28).

48. It can thus be seen from that case-law that particular circumstances may be capable, by virtue of the principle of sincere cooperation arising from Article 4(3) TEU, of requiring a national administrative body to review an administrative decision that has become final to take account of the interpretation of a relevant provision of EU law which the Court has given subsequently. A balance between the requirement for legal certainty and the requirement for legality under EU law is thereby struck (judgment of 4 October 2012, Byankov, C‑249/11, EU:C:2012:608, paragraph 77 and the case-law cited).

49. Contrary to the cases which gave rise to the case-law cited in paragraphs 46 to 48 above, this case does not concern whether the national administrative body in question must review its decision, but whether that body must rectify the duration of the certificate, where the date of the first MA in the European Union, as stated in the application for the certificate laid down in Article 8, is incorrect. The balance between the requirement for legal certainty and the requirement for legality under EU law is, in such circumstances, not the same as that set out in paragraphs 46 and 47 above. A change, such as replacing the date of 24 August 2027, as the date of the expiry of the SPC, with the date of 28 August 2027, as requested by Incyte on the basis of **the judgment of 6 October 2015, Seattle Genetics (C‑471/14, EU:C:2015:659)**, is by its nature less capable of affecting legal certainty than the more substantive changes which require a review.

50. In that regard, it should be noted, in addition, that, as is clear from the analysis of the first question, Article 18 of Regulation No 469/2009 must, read in the light of recital 17 and Article 17(2) of Regulation No 1610/96, be interpreted as meaning that an appeal for rectification of the decision granting the certificate aimed at rectifying the duration of that certificate must be heard where the date of the first MA in the European Union, as stated in the application for the certificate, is incorrect. It also follows from that analysis that this applies to the case in the main proceedings.

51. Accordingly, Article 18 of Regulation No 469/2009 must be interpreted as meaning that where the date of the first MA in the European Union, as stated in the application for the certificate, is incorrect and, as a result, the duration of that certificate is also incorrect, the holder of the certificate may, under that provision, bring an appeal for rectification directly with the authority that granted the certificate. Furthermore, in the absence of any indication to the contrary in Article 17(2) of Regulation No 1610/96, it must be held that such an appeal for rectification be capable of being brought before the authority, provided that the certificate in question has not expired.

52. Such an interpretation is supported both by the scheme of the EU legislation of which it forms part and by the objectives of that legislation.

53. As regards its scheme, it is clear from Article 13(1) of Regulation No 469/2009 that the certificate is to take effect 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 MA in the European Union, reduced by a period of five years. It therefore follows from that provision that the duration during which the SPC granted ‘shall take effect’ is wholly determined by the application of the detailed criteria laid down by that provision and the authority responsible for granting the SPC enjoys no degree of discretion in that regard.

54. Similarly, Article 14(1) of Regulation No 469/2009 provides that the SPC is to lapse on the date laid down in Article 13 and not on a date to be determined by the authority which grants the certificate.

55. As regards the objectives pursued by Regulation No 469/2009, it should be noted, first, that the fundamental objective of Regulation No 469/2009, as mentioned, inter alia, in recitals 3 to 5 and 8 and 9 of that regulation, 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, inter alia, **judgment of 6 October 2015, Seattle Genetics, C‑471/14, EU:C:2015:659**, paragraph 32 and the case-law cited).

56. Furthermore, as is apparent from recitals 7 and 8 thereof, 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 the functioning of the internal market (see, inter alia, **judgment of 6 October 2015, Seattle Genetics, C‑471/14, EU:C:2015:659**, paragraph 26 and the case-law cited).

57. It is consistent with those twin objectives of

protection for the holder and uniform application of the conditions under which that protection is ensured, that the holder may require rectification of the instrument granting an SPC in respect of its duration at any time, provided that the certificate has not expired.

58. Furthermore, as stated in paragraph 49 above, rectification in such circumstances is not such as to affect legal certainty.

59. Lastly, in so far as it is common ground that, in the case in the main proceedings, Incyte brought before the authority which granted the SPC an appeal for rectification of the duration of the SPC, it is not necessary to ascertain, in addition, whether that authority could be required to make such a rectification ex officio in the absence of such an appeal brought by the holder of the certificate.

60. In the light of the foregoing, the answer to the second question is that Article 18 of Regulation No 469/2009, read in the light of recital 17 and of Article 17(2) of Regulation No 1610/96, must be interpreted as meaning that, in a situation such as that set out in paragraph 44 above, the holder of an SPC may, under Article 18 of Regulation No 469/2009, bring an appeal for rectification of the duration stated in the SPC, provided that the SPC has not expired.

Costs

61. 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 (Second Chamber) hereby rules:

1. Article 18 du 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, read in the light of Article 17(2) of 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, must be interpreted as meaning that the date of the first authorisation to place the product on the market, as stated in an application for a supplementary protection certificate, on the basis of which the national authority competent for granting such a certificate calculated the duration of the certificate, is incorrect in a situation, such as that at issue in the main proceedings, where the date led to a method for calculating the duration of the certificate which does not comply with the requirements of Article 13(1) of Regulation No 469/2009, as interpreted by a subsequent judgment of the Court.

2. Article 18 of Regulation No 469/2009, read in the light of recital 17 and of Article 17(2) of Regulation No 1610/96, must be interpreted as meaning that, in a situation such as that set out in point 1 of this operative part, the holder of a supplementary protection certificate may, under Article 18 of Regulation No 469/2009, bring an appeal for rectification of the duration stated in the certificate, provided that that certificate has not expired.