Reports of Cases

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,

* Language of the case: German.

— 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]