Reports of Cases

ORDER OF THE COURT (Eighth Chamber)

16 July 2024 *

(Reference for a preliminary ruling – Article 99 of the Rules of Procedure of the Court of Justice – Medicinal product for human use – Supplementary protection certificate for medicinal products (SPC) – Regulation (EC) No 469/2009 – Conditions for granting – Article 3(d) – First marketing authorisation (MA) – Medicinal products containing the same active ingredient being granted several MAs – Withdrawal of the prior MA)

In Case C-181/24,

REQUEST for a preliminary ruling under Article 267 TFEU from the Fővárosi Törvényszék (Budapest High Court, Hungary), made by decision of 27 February 2024, received at the Court on 6 March 2024, in the proceedings

Genmab A/S,

intervening party:

Szellemi Tulajdon Nemzeti Hivatala,

THE COURT (Eighth Chamber),

composed of K. Jürimäe (Rapporteur), President of the Third Chamber, acting as President of the Eighth Chamber, N. Jääskinen and M. Gavalec, Judges,

Advocate General: M. Campos Sánchez-Bordona,

Registrar: A. Calot Escobar,

having decided, after hearing the Advocate General, to rule by reasoned order, pursuant to Article 99 of the Rules of Procedure of the Court of Justice,

makes the following

* Language of the case: Hungarian.

Order

1 This request for a preliminary ruling concerns the interpretation of Article 3(b) and (d) 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), as amended by Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 (OJ 2019 L 153, p. 1) ('Regulation No 469/2009').

2 The request has been made in the context of an application by Genmab A/S, a company established in Denmark, to reverse a decision of the Szellemi Tulajdon Nemzeti Hivatala (National Intellectual Property Office, Hungary) refusing to grant it a supplementary protection certificate ('the SPC') for a medicinal product marketed under the name 'Kesimpta'.

Legal context

European Union law

3 Recitals 3, 4 and 7 to 10 of Regulation No 469/2009 state as follows:

'(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the [European] 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 [(MA)] makes the period of effective protection under the patent insufficient to cover the investment put into the 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 [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 [MA] has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

(9) The duration of the protection granted by the [SPC] should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and [an SPC] should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains [MA] in the Community.

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the [SPC] cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained [MA] as a medicinal product.'

4 Article 1 of that regulation states:

'For the purposes of this Regulation, the following definitions shall apply:

(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) "product" means the active ingredient or combination of active ingredients of a medicinal product;

(c) "basic patent" means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of an [SPC];

…'

5 Article 2 of that regulation 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 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 [an SPC].'

6 Article 3 of that regulation states:

'[An SPC] 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 [MA] as a medicinal product has been granted in accordance with Directive [2001/83] or Directive [2001/82], as appropriate;

(c) the product has not already been the subject of [an SPC];

(d) the authorisation referred to in point (b) is the first [MA] as a medicinal product.'

7 Article 4 of Regulation No 469/2009 provides:

‘Within the limits of the protection conferred by the basic patent, the protection conferred by [an SPC] shall extend only to the product covered by the corresponding medicinal product [MA] and for any use of the product as a medicinal product that has been authorised before the expiry of the [SPC].’

8 Article 5(1) of that regulation provides:

‘Subject to the provisions of Article 4, the [SPC] shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.’

9 Article 7(1) of that regulation states:

‘The application for [an SPC] shall be lodged within six months of the date on which the [MA] referred to in Article 3(b) as a medicinal product was granted.’

10 Article 8(1)(a) of that regulation provides:

‘The application for [an SPC] shall contain:

(a) a request for the grant of [an SPC], 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 [MA], as referred to in Article 3(b) and, if this [MA] is not the first [MA] in the Community, the number and date of that [MA]’.

Hungarian law

11 Paragraph 22/A of a találmányok szabadalmi oltalmáról szóló 1995. évi XXXIII. törvény (Law No XXXIII of 1995 on patent protection of inventions) provides in subparagraphs 1 and 2 thereof:

‘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 subparagraph 1 are the subject matter of the specific legislation.’

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

12 Genmab is the holder of the European patent EP 328 4753, designating the Republic of Hungary. That patent, entitled ‘Human monoclonal antibodies against CD20 for the treatment of multiple sclerosis’ (‘the basic patent’), is currently in force in Hungary and covers, inter alia, the active ingredient ‘ofatumumab’.

13 Genmab marketed its first medicinal product, Arzerra, containing this active ingredient used in a therapy for untreated chronic lymphocytic leukaemia. On 21 April 2010, Genmab was granted an MA for that medicinal product ('the prior MA'). However, it withdrew that MA on 27 February 2019.

14 On 29 March 2021, Genmab was granted an MA for the medicinal product Kesimpta of which ofatumumab is also the active ingredient ('the subsequent MA'). That medicinal product is indicated for the treatment of relapsing-remitting multiple sclerosis.

15 On 7 July 2021, on the basis of the basic patent and the subsequent MA, Genmab applied to the National Intellectual Property Office for an SPC. That office rejected that application on the basis that the subsequent MA was not the first MA, as provided for in Article 3(d) of Regulation No 469/2009, for ofatumumab. Arzerra and Kesimpta had an identical active ingredient, namely ofatumumab, and the only difference between the two medicinal products lies in their respective therapeutic indications. Relying on the judgments of 21 March 2019, *Abraxis Bioscience* (C-443/17, 'the *Abraxis* judgment', EU:C:2019:238) and of 9 July 2020, *Santen* (C-673/18, 'the *Santen* judgment', EU:C:2020:531), the National Intellectual Property Office took the view that it is the identical nature of the active ingredients rather than the difference in therapeutic applications that is decisive for the purposes of Article 3(d) of Regulation No 469/2009 in identifying which is the first MA within the meaning of that provision. Accordingly, the prior MA should have been regarded as the first MA. It was irrelevant that it had been withdrawn and that it was no longer in force on the date when the application for an SPC was lodged, because the question as to when a given MA can be regarded as the first MA would depend only on the definition of the 'product'.

16 Genmab brought an appeal before the Fővárosi Törvényszék (Budapest High Court), the referring court, against the decision of the National Intellectual Property Office. That company submits that the first MA, within the meaning of Article 3(d) of Regulation No 469/2009, can only be an MA in force on the date of lodging the application for an SPC. The National Intellectual Property Office was therefore wrong to hold that the first MA for the product ofatumumab as a medicinal product, was the MA which had been granted for the medicinal product Arzerra because that MA was no longer in force on the date of lodging the application for the SPC. The *Abraxis* and *Santen* judgments are irrelevant, since neither address the question of the validity of the prior MA. Genmab submits, moreover, that in the cases that gave rise to those judgments, the MAs in question were in force.

17 Genmab refers to the English-language version of Article 3(b) and (d) of Regulation No 469/2009, which would make the granting of the SPC conditional on a valid and first MA on the day of lodging the application for that certificate. Such an interpretation is confirmed by the German- and French-language versions of those provisions. Genmab points out that in the present case, the subsequent MA was the first relevant MA, within the meaning of Article 3(d) of that regulation, since, at the date on which the application for the SPC was lodged, it was the only MA in force for the active ingredient ofatumumab, as a medicinal product, in Hungary.

18 The referring court essentially endorses Genmab's line of argument. It points out that the Court of Justice has previously been asked about cases in which the SPC applications in question concerned medicinal products containing the same active ingredient as another medicinal product which has a prior AM and which is only distinguished from that medicinal product by its therapeutic indications or by the composition of that active ingredient. However, in those cases, all the MAs were still currently valid. Accordingly, the Court had not yet addressed the question of which

MA must be regarded as the first MA for the product in question as a medicinal product, within the meaning of Article 3(b) and (d) of Regulation No 469/2009, where that product was already covered by a prior MA, but that MA has been withdrawn.

19 While noting that the Hungarian-language version of the wording of Article 3(b) of Regulation No 469/2009 does not contain the equivalent of the English-language term 'valid', the referring court is nevertheless of the view that a teleological interpretation of that provision suggests that only the speciality medicinal products containing the active ingredient in question which are actually on the market on the date on which the application for an SPC is lodged must be taken into consideration. That interpretation follows from paragraph 55 of the *Santen* judgment, according to which the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product.

20 That being the case, in view of the diametrically opposed views held by Genmab and the National Intellectual Property Office, the referring court is uncertain as to the correct interpretation of the concept of 'first MA for the product'.

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

'Must Article 3(b) and (d) of [Regulation No 469/2009] be interpreted as meaning that [an MA] predating the [MA] appearing in the application for [an SPC] and referring to the same product must be regarded as the first [MA] for the purposes of that regulation, even where that prior [MA] was withdrawn prior to the submission of the application for the [SPC]?'

Consideration of the question referred

22 In accordance with Article 99 of its Rules of Procedure, the Court may at any time, on a proposal from the Judge-Rapporteur and after hearing the Advocate General, decide to rule by reasoned order where the answer to a question referred to the Court for a preliminary ruling may be clearly deduced from existing case-law or where the answer to such a question admits of no reasonable doubt.

23 It is appropriate to apply that provision in the present case.

24 By its single question, the referring court asks, in essence, whether Article 3(d) of Regulation No 469/2009 must be interpreted as precluding the MA submitted in support of an application for an SPC for a product from being regarded as the first MA, within the meaning of that provision, if a prior MA was granted for that same product but was withdrawn before the application for the SPC was submitted.

25 In that regard, it must be noted that the wording of Article 3(d) of Regulation No 469/2009, the context in which that provision is set, the objectives pursued by the EU legislature and the legislative history of that regulation all indicate that the condition laid down in that provision is based on an objective chronological criterion under which the first MA for the product as a

medicinal product, within the meaning of that provision, refers to the MA which was granted on the earliest date for that product in the Member State concerned, regardless of whether or not that MA is still in force.

26 First, the wording of that provision states that the SPC is to be granted if, in the Member State in which the application is submitted, the MA granted for the product for which the SPC is sought is the first MA for the product as a medicinal product. It is not however apparent from that wording that that first MA must be the first MA only among those in force on the date of lodging the application for an SPC. On the contrary, that wording clearly indicates that account must be taken in that regard of all the MAs which have been granted for the product in question in the Member State in which the SPC application in question was lodged.

27 Second, a contextual analysis of Article 3(d) of Regulation No 469/2009 leads to the same conclusion. It is apparent from Article 3 of that regulation that it sets out four independent and cumulative conditions which cannot be merged.

28 In that respect, Article 3(b) of that regulation requires that the product, as a medicinal product, had been granted a 'valid' MA. Article 3(d) of Regulation No 469/2009 refers to Article 3(b) only in order to identify the MA which must satisfy the additional and independent condition which it sets out therein. Accordingly, under Article 3(d), account must be taken of all the MAs granted for that product before the date of lodging the application for an SPC. If, of all those MAs, the first MA of them is the MA that satisfies the condition laid down in point (b), then the condition provided in point (d) is also satisfied.

29 A contrary interpretation of Article 3(d) of Regulation No 469/2009 to the effect that only MAs in force on that date should be taken into account, would amount to confusing the two conditions by merging the concept of 'MA' with the concept of a 'valid MA'.

30 The latter interpretation must also be rejected in the light of Article 8 of Regulation No 469/2009, which explains in detail the content of the application for an SPC. According to that article, that application is to contain the number and date of the MA referred to in Article 3(b) of that regulation and, if it is not the first MA for the product in question, the number and date of that first MA. If only the MAs in force were to be taken into account in order to determine which is the first MA for the product in question, Article 8 of that regulation would have required that such information also be provided. However, no justification is sought in order to determine whether the MAs in question are still valid, which reflects the fact that the condition laid down in Article 3(d) of that regulation is based on an objective chronological criterion.

31 Third, the legislative history of that provision confirms the interpretation set out in paragraph 25 of the present order. Paragraphs 35 and 36 of the Explanatory Memorandum of 11 April 1990 to the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final) explain that it occurs very often that the same product is successfully granted several MAs, in particular each time a modification is made affecting the pharmaceutical form, dose, composition or indications. Nevertheless, it is the first MA for the product in the Member State in which the application is presented that is taken into account for the purposes of the proposal for a regulation, in particular for calculating the period of six months which the holder of the basic patent has to submit an SPC application. Thus, although the same product may be the subject of several

patents and several MAs in one and the same Member State, the EU legislature decided that an SPC will only be granted for that product on the basis of a single patent and a single MA, namely the first chronologically granted for that Member State.

32 Fourth, the analysis of the objectives pursued by the EU legislature is entirely consistent with that strict interpretation of Article 3(d) of Regulation No 469/2009. In that regard, the Court held that that legislature intended, by establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a medicinal product, but to protect only research leading to the first MA of an active ingredient as a medicinal product (see, to that effect, judgments of *Abraxis*, paragraph 37, and *Santen*, paragraph 55). That objective would be undermined if only the MAs in force were taken into account in order to determine the first MA for a given product. It would be sufficient to withdraw a prior MA in order to be granted an SPC for the latest marketed version of the product in question, which would allow pharmaceutical laboratories to choose which version of the product to favour. That would turn the objective criterion laid down by that provision into a subjective criterion that would depend on the choice of laboratories, which clearly does not correspond to the choice of the EU legislature.

33 In the light of the foregoing, the answer to the question referred is that Article 3(d) of Regulation No 469/2009 must be interpreted as precluding the MA submitted in support of an application for an SPC for a product from being regarded as the first MA, within the meaning of that provision, if a prior MA was granted for that same product but was withdrawn before the application for the SPC was submitted.

Costs

34 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring 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 orders:

Article 3(d) 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, as amended by Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019

must be interpreted as precluding the marketing authorisation submitted in support of an application for a supplementary protection certificate for a product from being regarded as the first marketing authorisation, within the meaning of that provision, if a prior marketing authorisation was granted for that same product but was withdrawn before the application for the supplementary protection certification was submitted.

[Signatures]