European Court of Justice, 3 September 2009, AHP v BIE

PATENT LAW

SPC to two or more holders of basic patents for the same product

- **Grant of an SPC is possible to the holder of a basic patent for a product for which one or more SPCs have already been granted to one or more holders of one or more other basic patents**

Having regard to all the foregoing considerations, the answer to the questions referred is that Article 3(c) of Regulation No 1768/92, considered in the light of the second sentence of Article 3(2) of Regulation No 1610/96, must be interpreted as not precluding the grant of an SPC to the holder of a basic patent for a product for which, at the time the SPC application is submitted, one or more SPCs have already been granted to one or more holders of one or more other basic patents.

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European Court of Justice, 3 September 2009

(A. Rosas, J. Klučka, U. Lõhmus, P. Lindh and A. Arabadjiev)

JUDGMENT OF THE COURT (Third Chamber)

3 September 2009 (*)

(Patent law – Proprietary medicinal products – Regulations (EEC) No 1768/92 and (EC) No 1610/96 – Supplementary protection certificate for medicinal products – Conditions for granting certificates to two or more holders of basic patents for the same product – Clarification on the existence of pending applications)

In Case C-482/07,

REFERENCE for a preliminary ruling under Article 234 EC from the Rechtbank 's-Gravenhage (Netherlands), made by decision of 22 October 2007, received at the Court on 2 November 2007, in the proceedings

AHP Manufacturing BV

v

Bureau voor de Industriële Eigendom,

THE COURT (Third Chamber),

composed of A. Rosas, President of Chamber, J. Klučka, U. Lõhmus (Rapporteur), P. Lindh and A. Arabadjiev, Judges,

Advocate General: Y. Bot,

Registrar: R. Şereş, Administrator,

having regard to the written procedure and further to the hearing on 12 February 2009,

after considering the observations submitted on behalf of:

– AHP Manufacturing BV, by K.A.J. Bisschop, advocaat,

– the Bureau voor de Industriële Eigendom, by N.O.M Rethmeier, acting as Agent,

– the Netherlands Government, by C. Wissels, Y. de Vries and M. de Mol, acting as Agents,

– the Greek Government, by V. Kondolaimos and S. Charitaki, acting as Agents,

– the United Kingdom Government, by Z. Bryanston-Cross, acting as Agent, and S. Malynicz and G. Peretz, Barristers,

– the Commission of the European Communities, by H. Krämer and A. Nijenhuis, acting as Agents,

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

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 3(c) 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) and Article 3(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).

2 The reference has been made in proceedings between AHP Manufacturing BV ('AHP') and the Bureau voor de Industriële Eigendom (the Industrial Property Office, 'BIE') regarding a decision of the BIE refusing to grant AHP a supplementary protection certificate ('SPC').

Legal context

3 The first to fourth and sixth to ninth recitals in the preamble to Regulation No 1768/92 state:

'… pharmaceutical research plays a decisive role in the continuing improvement in public health;

… 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;

… 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;

… this situation leads to a lack of protection which penalises pharmaceutical research;

…

… 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 establishment and the functioning of the internal market;

… therefore, the creation 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 marketing authorisation has been granted is necessary; …
…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 exclusiv[it]y from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community;
…all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account; … for this purpose, the certificate cannot be granted for a period exceeding five years; …'

4 Article 3 of Regulation No 1768/92, which sets out the conditions for obtaining an SPC, provides:
'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 [Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ English Special Edition 1965-1966(I), p. 24)] or [Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ 1981 L 317, p. 1)] as appropriate;
(c) the product has not already been the subject of a certificate;
(d) the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product.'

5 Article 6 of that regulation specifies that the SPC is to be granted to the holder of the basic patent or his successor in title.

6 As provided in Article 7 of Regulation No 1768/92:
'1. 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.
2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.'

7 According to Article 9(1) of that regulation, the application for an SPC is to be lodged with the competent industrial property office of the Member State which granted the basic patent and in which the authorisation to place the product concerned on the market was obtained, unless another authority is designated.

8 Article 13 of that regulation states:
'1. 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.
2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.'

9 Recital 17 in the preamble to Regulation No 1610/96 reads as follows:
'… 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 … Regulation (EEC) No 1768/92'.

10 Article 3(2) of Regulation No 1610/96 provides:
'The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.'

11 In accordance with Article 21 thereof, Regulation No 1610/96 entered into force six months after its publication, on 8 August 1996, in the Official Journal of the European Communities, that is to say on 8 February 1997.

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

12 On 3 February 2000 the Commission granted for the first time an authorisation to place on the market the medicinal product Enbrel, the active ingredient of which is the compound etanercept.

13 On 4 and 6 October 2000 and 30 January 2001, three SPCs for etanercept were granted in respect of the Netherlands, to Immunex Corporation, Hoechst AG and General Hospital Corporation, and Abbott GmbH & Co KG respectively. The basic patents for etanercept had been granted to those undertakings between 1994 and 1998. The three SPCs expire on 1 February 2015.

14 Following an application lodged by F. Hoffmann-La Roche AG ('Hoffmann'), a European patent for TNF (tumor necrosis factor) binding proteins was granted to that undertaking. The grant of that patent was published on 2 April 2003.

15 On 2 July 2003, Hoffmann lodged with BIE in respect of the Netherlands an application for the grant of an SPC for Enbrel (etanercept). That application was based on Hoffmann's European patent and the above-mentioned marketing authorisation. By decision of 22 December 2003, BIE refused that application. On 2 February 2004, Hoffmann objected to that decision.

16 By transfer noted in the Netherlands patent register on 24 March 2005, Hoffmann ceded its rights in that patent to AHP.

17 On 16 June 2006, BIE declared Hoffmann's objection to be unfounded and confirmed its decision of 22 December 2003.

18 It is apparent from the order for reference that, in so doing, BIE based its decision on a strict textual interpretation of Article 3(c) of Regulation No 1768/92, in conjunction with Article 3(2) of Regulation No 1610/96, and held that, since other SPCs for etanercept had already been granted, the relevant applications were no longer pending, within the meaning of Article 3(2), at the time Hoffmann's application was lodged. Therefore, that application should be refused.

19 On 26 July 2006, AHP appealed against the BIE decision to the Rechtbank 's-Gravenhage, which has decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'1. Does [Regulation No 1768/92], and more specifically Article 3(c) thereof, preclude the grant of [an SPC] to the holder of a basic patent for a product for which, at the time of the submission of the application for [an SPC], one or more [SPCs] have already been granted to one or more holders of one or more other basic patents?

2. Does [Regulation No 1610/96], and more specifically recital 17 and the second sentence of Article 3(2) thereof, give rise to a different answer to Question 1?

3. When answering the previous questions, is it relevant whether the most recent application submitted, like the previous application or applications, is submitted within the period prescribed by Article 7(1) of [Regulation No 1768/92] or that prescribed by Article 7(2) of [Regulation No 1768/92]?

4. When answering the previous questions, is it relevant whether the period of protection afforded by the grant of [an SPC] pursuant to Article 13 of [Regulation No 1768/92] expires at the same time as, or at a later time than, under one or more [SPCs] already granted for the product concerned?

5. When answering the previous questions, is it relevant that [Regulation No 1768/92] does not specify the period within which the competent authority, as referred to in Article 9(1) of that regulation, must process the application for [an SPC] and ultimately grant [an SPC], as a result of which a difference in the speed with which the authorities concerned in the Member States process applications may lead to differences between them as to the possibility of [an SPC] being granted?'

The questions referred for a preliminary ruling

20 By its questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 3(c) of Regulation No 1768/92, considered in the light of the second sentence of Article 3(2) of Regulation No 1610/96, must be interpreted as precluding the grant of an SPC to the holder of a basic patent for a product for which, at the time the SPC application is submitted, one or more SPCs have already been granted to one or more holders of one or more other basic patents.

21 Under Article 3(c) of Regulation No 1768/92, in conjunction with Article 6 thereof, an SPC is to be granted to the holder of the basic patent or his successor in title where, in the Member State in which the SPC application is submitted and at the date of that application, the product protected by the patent has not already been the subject of an SPC.

22 In that respect, the Court held at paragraph 28 of **Case C-181/95 Biogen [1997] ECR I-357** that, where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of an SPC, although only one SPC may be granted for each basic patent.

23 That statement by the Court corresponds to the provisions of Regulation No 1610/96 which, although it was adopted before the date of delivery of the Biogen judgment, entered into force after that date. The second sentence of Article 3(2) of that Regulation provides for the possibility of granting one SPC for a product to each of two or more holders of different basic patents for that product. As set out in recital 17 in the preamble to that regulation, the detailed rules in Article 3(2) thereof, in particular, are also valid, mutatis mutandis, for the interpretation of Article 3 of Regulation No 1768/92 (C-431/04 Massachusetts Institute of Technology [2006] ECR I-4089, paragraph 24).

24 However, the second sentence of Article 3(2) of Regulation No 1610/96 refers expressly to such a grant only where the SPC applications emanating from the patent holders are pending. The question thus arises as to whether the wording of that provision precludes the grant of an SPC for a product for which, at the time the SPC application is submitted by the holder of a basic patent, one or more SPCs have already been granted to one or more holders of one or more other basic patents.

25 In that respect, it should be pointed out that the first sentence of Article 3(2) precludes the grant, to the holder of more than one patent for the same product, of more than one SPC for that product. However, the second sentence of Article 3(2) allows such a grant to two or more holders of different patents for the same product. It is thus apparent that the special condition for the grant of two or more SPCs for the same product is that the relevant applications emanate from different holders of basic patents. The second sentence of Article 3(2) does not require, on the other hand, that the applications be pending at the same time. Moreover, the word 'pending' does not feature in the Italian language version of Regulation No 1610/96, according to which those applications must merely have been submitted ('[t]uttavia, se sono state introdotte due o più domande …').

26 It is apparent from the findings in the preceding paragraph that the simultaneity of the applications in question cannot be considered an essential condition for the grant referred to in the second sentence of Article 3(2) of Regulation No 1610/96.

27 Next, the Court observes that the second sentence of Article 3(2) of Regulation No 1610/96 must be interpreted not solely on the basis of its wording, but also in the light of the overall scheme and objectives of the system of which it is a part (see, by analogy, **Case C-292/00 Davidoff [2003] ECR I-389, paragraph 24**).

28 As regards the overall scheme of Regulation No 1768/92, it should be noted that Article 7 thereof pro-

vides that an SPC application is to be lodged within six months of the date on which the authorisation referred to in Article 3(b) of that regulation to place the product on the market was granted or, where the authorisation is granted before the basic patent is granted, of the date on which the patent is granted. Furthermore, point 46 of the Explanatory Memorandum to the Proposal for a Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final) states that those time-limits were designed to respect, first, the interests of the patent holder and, second, those of third parties wishing to know as early as possible whether or not the product in question will be protected by an SPC.

29 The refusal of an SPC application submitted within the periods prescribed by Article 7, on the ground that another application relating to the same product had already been granted and for that reason was no longer pending, would effectively deprive the later applicant of the benefit of those periods, which are one of the elements of the system established by Regulation No 1768/92.

30 Regarding the objectives of Regulation No 1768/92, firstly, it must be noted that the fundamental objective of the Regulation, as set out in the first and second recitals in the preamble thereto, is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health (**Case C-392/97 Farmitalia [1999] ECR I-5553, paragraph 19**). In that regard, the third and fourth recitals in the preamble give as a reason for the adoption of the Regulation the fact that the period of effective protection under the patent is insufficient to cover the investment put into the pharmaceutical research. Regulation No 1768/92 thus seeks to make up for that insufficiency by creating an SPC for medicinal products. It seeks, in addition, to confer supplementary protection on the holders of national or European patents, without instituting any preferential ranking amongst them (Biogen, paragraphs 26 and 27).

31 If there are two or more holders of patents for the same product, who all make an SPC application to the competent industrial property office of the Member State in question within the periods laid down in Article 7 of Regulation No 1768/92, making the grant of an SPC subject to the condition that those applications be pending would risk denying to one or more of those holders the benefit of the supplementary protection allowing them better to cover the investment which they have put into the research, with the result that preferential ranking would be instituted amongst the holders.

32 If such a condition existed, the grant of an SPC could depend on an event which was uncertain and, as a rule, outside the control of the applicant, namely the date of the office's decision on the grant of one or more SPCs. Accordingly, once a positive decision had been taken with regard to one or more SPC applications for the same product, those applications would no longer be pending, so that another SPC application, whether it had been lodged before or after that decision or even prior to the lodging of the applications which are the subject of the decision, would have to be refused.

33 Such a solution would thus risk considerably reducing the possibility, provided for in Article 3(2) of Regulation No 1610/96, for two or more holders of different patents for the same product to obtain an SPC for that product.

34 Furthermore, the possibility expressly provided for in Article 7(2) of Regulation No 1768/92 for the holder of a basic patent to lodge an SPC application within six months of the date on which that patent is granted, where the patent is granted after the authorisation to place the product on the market, is such as to protect that holder against the possible duration of the procedure for granting such a patent, which the applicant can influence to only a limited extent. The refusal to grant that holder an SPC on the ground that, as in the main proceedings, other SPCs have already been granted to other holders of patents, the grant of which, before the marketing authorisation, allowed them to use the period prescribed in Article 7(1) of the Regulation, would deprive him of that protection, effectively placing him at a disadvantage compared with those other holders.

35 Second, Regulation No 1768/92, which was adopted on the basis of Article 100a of the EEC Treaty (subsequently Article 100a of the EC Treaty, and now, after amendment, Article 95 EC), establishes, as is apparent from the sixth and seventh recitals in the preamble thereto, a uniform solution at Community 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 Community and thus directly affect the establishment and the functioning of the internal market (see Case C-350/92 Spain v Council [1995] ECR I-1985, paragraphs 34 and 35, and Case C-127/00 Hässle [2003] ECR I-14781, paragraph 37).

36 Differences in the protection given in the Community to one and the same medicinal product would give rise to a fragmentation of the market, whereby the medicinal product would still be protected in some national markets but no longer protected in others (see Spain v Council, paragraph 36).

37 Since the Regulation does not specify any time-limit, from the lodging of an SPC application, for a decision on that application to be taken by the competent office referred to in Article 9(1), such time-limits may vary significantly between the Member States in accordance with their national legislation or the practice of their authorities. In that connection, AHP points out that, in the Netherlands, the competent office must, pursuant to Article 3:18(1) of the General Law on administrative law (Algemene wet bestuursrecht), take a decision on granting an SPC as quickly as possible, and not later than six months after receiving the application, whereas in certain other Member States the competent

office does not begin to assess SPC applications until the relevant basic patents are about to expire.

38 Clearly the shorter the time taken to make such a decision in a Member State, the less likely it is that two or more SPC applications for the same product will be pending, within the meaning of Article 3(2) of Regulation No 1610/96, in that State. Consequently, restricting the grant of such applications lodged by different holders of the basic patents concerned to cases where they are pending could lead to the protection of a pharmaceutical product varying between the Member States, a situation which would be duly likely to create obstacles to the free movement of medicinal products within the Community and thus affect the establishment and the functioning of the internal market.

39 Thirdly, apart from the objective of adequate protection to encourage research, Regulation No 1768/92 recognises, as is apparent from the ninth recital in its preamble, the necessity, in a sector as complex as the pharmaceutical sector, to take into account all the interests at stake, including those of public health (see Spain v Council, paragraph 38). For that purpose, the SPC may not be granted for a period exceeding five years. Similarly, the eighth recital in the preamble states that the holder of both a patent and an SPC should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

40 By reason of, first, the methods for calculating the duration of the SPC provided for in Article 13 of Regulation No 1768/92 and, second, the duration of the patent of 20 years from the date on which the application was lodged, the grant of an SPC may not cause those maximum protection periods to be exceeded. Therefore, it is not at all necessary, in order to achieve the balance between the different interests envisaged by that regulation, to refuse such a grant on the ground that one or more SPCs have already been granted to other holders of basic patents for the same product.

41 In that regard, it is of no consequence that the expiry date of the SPC applied for coincides with that of the one or more SPCs already granted provided that the protection period under each SPC was calculated according to the rules set out by Article 13 of Regulation No 1768/92.

42 In addition, point 36 of the Explanatory Memorandum to the Proposal for a Regulation, cited at paragraph 28 of the present judgment, states that the purpose of Article 3(c) of Regulation No 1768/92 is to avoid the same product being the subject of a number of successive SPCs, so that the overall duration of protection for one and the same medicinal product could be exceeded. For the reasons set out in the previous two paragraphs, a number of SPC applications emanating from different holders of basic patents for the product concerned, whether they are pending at the same time or not, cannot lead to a period of exclusive rights exceeding 15 years from the grant of the first authorisation to place that product on the market in the Community.

43 Having regard to all the foregoing considerations, the answer to the questions referred is that Article 3(c) of Regulation No 1768/92, considered in the light of the second sentence of Article 3(2) of Regulation No 1610/96, must be interpreted as not precluding the grant of an SPC to the holder of a basic patent for a product for which, at the time the SPC application is submitted, one or more SPCs have already been granted to one or more holders of one or more other basic patents.

Costs

44 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 (Third Chamber) hereby rules:

Article 3(c) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, considered in the light of the second sentence of Article 3(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 not precluding the grant of a supplementary protection certificate to the holder of a basic patent for a product for which, at the time the certificate application is submitted, one or more certificates have already been granted to one or more holders of one or more other basic patents.