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# JUDGMENT OF THE COURT (Second Chamber)

8 December 2011

(Intellectual and industrial property – Patents – Regulation (EEC) No 1768/92 – Article 13 – Supplementary protection certificate for medicinal products – Possibility of granting that certificate where the period that has elapsed between the date of the lodging of the basic patent application and the first marketing authorisation in the European Union is less than five years – Regulation (EC) No 1901/2006 – Article 36 – Extension of the duration of the supplementary protection certificate)

In Case C-125/10,

REFERENCE for a preliminary ruling under Article 267 TFEU from the Bundespatentgericht (Germany), made by decision of 28 January 2010, received at the Court on 9 March 2010, in the proceedings

Merck Sharp & Dohme Corp., formerly Merck & Co. Inc.,

v

Deutsches Patent- und Markenamt,

THE COURT (Second Chamber),

composed of J.N. Cunha Rodrigues, President of the Chamber, U. Lõhmus (Rapporteur), A. Rosas, A. Ó Caoimh and A. Arabadjiev, Judges,

Advocate General: Y. Bot,

Registrar: K. Malacek, Administrator,

having regard to the written procedure and further to the hearing on 4 May 2011,

after considering the observations submitted on behalf of:

– Merck Sharp & Dohme Corp., formerly Merck & Co. Inc., by M. Heinemann, M. Gundt, A. Rollins and A. von Falck, Rechtsanwälte,

– the French Government, by G. de Bergues, S. Menez and R. Loosli-Surrans, acting as Agents,

– the Lithuanian Government, by D. Kriaučiūnas and V. Balčiūnaitė, acting as Agents,



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– the Hungarian Government, by M. Ficsor, M. Fehér and Z. Tóth, acting as Agents,

– the Portuguese Government, by L. Inez Fernandes and P.A. Antunes, acting as Agents,

– the United Kingdom Government, by H. Walker, acting as Agent,

– the European Commission, by G. Braun and F.W. Bulst, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 9 June 2011,

gives the following

Judgment

1 This reference 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 (Codified version) (OJ 2009 L 152, p. 1).

2 The reference has been made in proceedings between Merck Sharp & Dohme Corp., formerly Merck & Co. Inc ('Merck'), and Deutsches Patent- und Markenamt (German Patent and Trade Marks Office) in relation to the latter's refusal to grant a supplementary protection certificate ('SPC') for the pharmaceutical substance sitagliptin.

Legal context

*Regulation (EEC) No 1768/92*

3 The first and second recitals in the preamble to 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), as amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (OJ 2006 L 378, p. 1, 'Regulation No 1768/92') are drafted as follows:

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

Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe



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unless they are covered by favourable rules that provide for sufficient protection [to] encourage such research'.

4 The third to fifth recitals to Regulation No 1768/92 state that the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place that medicinal product on the market (the 'marketing authorisation') makes the period of effective protection under the patent insufficient to cover the investment put into the research, which penalises pharmaceutical research and creates the risk of research centres relocating outside the Member States.

5 The eighth and ninth recitals to Regulation No 1768/92 state:

'Whereas the duration of the protection granted by the [SPC] should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a[n] [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;

Whereas 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; whereas, for this purpose, the [SPC] cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained [marketing authorisation] as a medicinal product'.

6 Under Article 3 of Regulation No 1768/92, entitled 'Conditions for obtaining a[n] [SPC]':

'A[n] [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 [marketing authorisation] 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 proprietary medicinal products (OJ, English Special Edition 1965 – 1966, p.24)), as amended by Council Directive 89/341/EEC of 3 May 1989 (OJ 1989 L 142, p. 11)] 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 1989 L 317, p. 1), as amended by Council Directive 90/676/EEC Of 13 December 1990 (OJ 1990 L 373, p. 15)], as appropriate …;

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



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

7 Article 7(1) of Regulation No 1768/92 provides that 'the application for a[n] [SPC] shall be lodged within six months of the date on which the [marketing authorisation] … as a medicinal product was granted'.

8 Article 8 of Regulation No 1768/92 sets out the information which the application for an SPC must contain. It provides, in particular, in Article 8(1)(d)(i), that, where the application for an SPC includes a request for an extension of the duration, the application must include a copy of the statement indicating compliance with a paediatric investigation plan as referred to in Article 36 of Regulation No 1901/2006.

9 Article 10 of Regulation No 1768/92, which sets out the conditions for the grant of the SPC or the rejection of the application for an SPC, provides at paragraphs 1 and 2:

'1. Where the application for a[n] [SPC] and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the [SPC].

2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a[n] [SPC] if the application or the product to which it relates does not meet the conditions laid down in this Regulation.'

10 Article 13 of Regulation No 1768/92, entitled 'Duration of the [SPC]', is worded as follows:

'1. The [SPC] 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 [marketing authorisation] in the Community, reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the [SPC] may not exceed five years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.'

11 Article 14(a) of Regulation No 1768/92 provides that the SPC shall lapse 'at the end of the period provided for in Article 13'.



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12 Regulation No 469/2009, codifying and repealing Regulation No 1768/92, entered into force on 6 July 2009. Article 13 thereof is worded in identical terms to Article 13 of Regulation No 1768/92. Nevertheless, taking account of the facts of the dispute in the main proceedings, Regulation No 1768/92 remains applicable thereto.

*Regulation No 1901/2006*

13 Recitals 26 and 27 in the preamble to Regulation No 1901/2006 state:

‘(26) For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in product information, a reward should be granted in the form of a 6-month extension of the [SPC] created by Council Regulation (EEC) No 1768/92 …

(27) An application for an extension of the duration of the [SPC] pursuant to this Regulation should only be admissible where a[n] [SPC] is granted pursuant to Regulation (EEC) No 1768/92.’

14 Under Article 36(1) and (4) of Regulation No 1901/2006:

‘1. Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or [SPC] shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92 [(“the paediatric extension”)].

The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

…

4. Paragraphs 1, 2 and 3 shall apply to products that are protected by a[n] [SPC] under Regulation (EEC) No 1768/92, or under a patent which qualifies for the granting of the [SPC]. … ’

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



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15 Merck is the owner of a European patent covering dipeptidylpeptidase inhibitors for the treatment or prevention of diabetes. That basic patent, also valid in the Federal Republic of Germany, was applied for on 5 July 2002.

16 On 14 September 2007, Merck applied to the Deutsches Patent- und Markenamt for the grant of an SPC for the pharmaceutical substance sitagliptin covered by that patent, where appropriate in the form of a pharmaceutically acceptable salt, in particular for sitagliptin phosphate monohydrate. It gave 21 March 2007 as the date of the first marketing authorisation in the European Union ('EU') and the Federal Republic of Germany, which is the date on which the European authorisation was issued for the medicinal product containing sitagliptine phosphate monohydrate. That medicinal product is marketed in the Federal Republic of Germany under the brand name Januvia.

17 That application was rejected by decision of 1 July 2008 on the ground that a period of only four years, eight months and sixteen days had elapsed between the date on which the application for a basic patent was lodged and the date on which the first marketing authorisation was issued, so that calculating the length of the SPC would have resulted, pursuant to Article 13(1) of Regulation No 1768/92, in a negative duration of three months and fourteen days.

18 Merck brought an action against the decision before the Bundespatentgericht. It submits that all the conditions required for the grant of an SPC are fulfilled in this case and the duration of the SPC is not one of those conditions.

19 Merck submits that even if the SPC cannot result in a positive duration, it can nevertheless have a zero or negative duration. The reason for its application for the SPC is that it wishes to be able to request, at a later date, an extension of the SPC. A paediatric investigation plan was authorised, to that effect, by the competent authority on 27 March 2009 and the studies prescribed in that plan must be completed by 2017.

20 The national court questions whether the entry into force of Regulation No 1901/2006 providing a reward in the form of a paediatric extension of six months alters the approach adopted until now according to which the delivery of the SPC is only possible where five years have elapsed between the patent application and the first marketing authorisation of the medicinal product in question in the EU. It is relevant to know whether, following the entering into force of that regulation, SPCs must be delivered for a negative or zero duration.

21 Thus, the national court indicated that it considered it necessary to request the Court to interpret Article 13(1) of Regulation No 469/2009.

22 In those circumstances, the Bundespatentgericht decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:



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'Can an [SPC] for medicinal products be granted if the period of time between the filing of the application for the basic patent and the date of the first [marketing authorisation] in the Community is shorter than five years?'

Consideration of the question referred for a preliminary ruling

23 As a preliminary point, it must be noted that, in its reference for a preliminary ruling, the national court refers to Regulation No 469/2009, codifying and repealing Regulation No 1768/92.

24 However, as Regulation No 469/2009 entered into force on 6 July 2009, that is after the adoption of the decision challenged in the main proceedings, Regulation No 1768/92 remains applicable to that decision.

25 Moreover, even if the duration of the paediatric extension is provided for by Article 13(3) of Regulation No 1768/92, the conditions of its application are established by Article 36 of Regulation No 1901/2006. Therefore, it is in light of those two regulations that the question posed by the national court must be answered.

26 Thus, by its question, the national court asks, in essence, whether Article 13 of Regulation No 1768/92, read in conjunction with Article 36 of Regulation No 1901/2006, must be interpreted as meaning that an SPC may be granted for medicinal products where the period that has elapsed between the date on which the application for a basic patent was lodged and the date of the first marketing authorisation in the EU is less than five years.

27 Having regard to the content of the reference for a preliminary ruling, that court also wishes to know whether, in the event of an affirmative response to that question, the extension for a period of six months provided for in Article 36 of Regulation No 1901/2006 must begin to run before the expiry date of the patent, that is on the date established by assigning a negative value to the SPC, or whether the duration of the SPC must be rounded to zero and the extension made to run from the expiry date of the patent.

28 It should be noted at the outset that Article 13(1) of Regulation No 1768/92 provides that the SPC takes 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 marketing authorisation in the EU, reduced by a period of five years. Nothing in the wording of that provision or in any other provision of that regulation suggests that it necessarily precludes an SPC of negative duration.

29 Article 13 of Regulation No 1768/92 must therefore be interpreted not solely on the basis of its wording, but also in consideration of the overall scheme and objectives of the system of which it is a part (see, to that effect, Case C-127/00



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*Hässle* [2003] ECR I-14781, paragraph 55 and Case C-482/07 *AHP Manufacturing* [2009] ECR I-7295, paragraph 27).

30 As regards, firstly, the overall scheme of Regulation No 1768/92, it must be noted that Article 10 thereof provides that, where the application for an SPC and the product to which it relates meet the conditions laid down by that regulation, the competent authority shall grant the SPC. It must be noted that the positive duration of the SPC does not figure among the basic conditions for obtaining such a certificate, set out in Article 3 of Regulation No 1768/92, or among the procedural conditions, referred to in Articles 7 to 9 thereof.

31 Regarding, secondly, the objectives of Regulation No 1768/92, it must be recalled that the fundamental objective of that 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 (see, to that effect, *AHP Manufacturing*, cited above, paragraph 30).

32 In that regard, the third and fourth recitals in the preamble give as a reason for the adoption of that regulation the fact that the period of effective protection under the patent is insufficient to cover the investment put into pharmaceutical research, taking into account the period that elapses between the lodging of a patent application for a new medicinal product and the grant of the marketing authorisation for it (see, to that effect, *AHP Manufacturing*, cited above, paragraph 30).

33 Regulation No 1768/92 thus seeks to make up for that insufficiency by creating an SPC for medicinal products. As is apparent from the ninth recital, the regulation acknowledges, in addition to that objective, the need, in a sector as complex and sensitive as the pharmaceutical sector, to take into account all the interests at stake, including public health, by ensuring that the monopoly on exploitation thus guaranteed does not exceed that which is necessary to cover the investment and does not unduly delay the moment when the product in question comes into the public domain (see, to that effect, *AHP Manufacturing*, cited above, paragraphs 30 and 39).

34 As for Regulation No 1901/2006, which amended, inter alia, Article 13 of Regulation No 1768/92, in its original version, it must be noted that, as is apparent from recital 26 thereto, its aim is to grant a reward for the effort involved in evaluating the paediatric effects of the medicinal product in question, by awarding a six-month extension of the SPC to the holder of the basic patent who conducted all the research proposed in the paediatric investigation plan approved for the medicinal product in question.



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35 Admittedly, while an SPC of negative or zero duration serves no purpose of itself, the fact remains that, since the adoption of Regulation No 1901/2006, such an SPC may be of use to the holder of the basic patent wishing to obtain the paediatric extension. Article 13(3) of Regulation No 1768/92 provides for the possibility of extending the duration of the SPC by six months, as calculated in accordance with Article 13(1), and allows, consequently, for the extension of the 15-year period of exclusivity set out in the eighth recital in the preamble to Regulation No 1768/92.

36 As follows from recital 27 of Regulation No 1901/2006 and from Article 13(3) of Regulation No 1768/92 read in conjunction with Article 36(1) of Regulation No 1901/2006, the grant of the paediatric extension is possible only if an SPC is delivered pursuant to Regulation No 1768/92.

37 Thus, if the SPC application had to be refused because the calculation provided for in Article 13(1) of Regulation No 1768/92 results in a negative or zero duration, the holder of the basic patent could not obtain an extension of protection conferred by such a patent, even if it conducted all the studies according to the approved paediatric investigation plan, under Article 36 of Regulation No 1901/2006. Such a refusal would be liable to adversely impact on the useful effect of Regulation No 1901/2006 and might jeopardise the objectives of that regulation, namely the compensation of effort made to evaluate the paediatric effects of the medicinal product at issue.

38 Consequently, it must be held that it follows from Regulation No 1768/92 read in conjunction with Regulation No 1901/2006 that the SPC and the paediatric extension together confer on the holder of the basic patent an exclusive right of a maximum duration of 15 years and 6 months from the date of the grant of the first marketing authorisation for the medicinal product in question in the EU.

39 It follows from that maximum duration that a paediatric extension is of use if the negative duration of an SPC is not more than six months. In other words, the objective of Regulation No 1901/2006 is achieved where the holder of the basic patent obtained its first marketing authorisation for the medicinal product in question in the EU during a period between four and a half and five years after the basic patent application. Therefore, an SPC can be granted where less than five years have elapsed between the date of the application for a basic patent and the date of the first marketing authorisation.

40 It follows that the grant of an SPC cannot be refused by reason only of the fact that the duration determined in accordance with the calculation rules laid down in Article 13(1) of Regulation No 1768/92 is not positive.

41 As to the question concerning the time at which the paediatric extension of six months must begin to run, it must be held that, in the case where the period that



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has elapsed between the date on which the application for a basic patent was lodged and the date of the first marketing authorisation in the EU is less than five years, the starting point for that extension cannot be established as the expiry date of the basic patent, so that the duration of that certificate be considered to be equal to zero. Such an approach would be contrary to the calculation rules laid down in Article 13(1) of Regulation No 1768/92, in so far as that provision provides that the duration of an SPC corresponds to the period which elapsed between the date on which the application for the basic patent was lodged and the date of the first marketing authorisation in the Community, reduced by a period of five years.

42 Therefore, where the duration of an SPC is negative, it cannot be rounded to zero. The period of the paediatric extension provided for by Regulation No 1901/2006 starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between lodging the patent application and obtaining the first marketing authorisation.

43 It is only in the case where the period between lodging the basic patent application and the date of the first marketing authorisation in the EU for the medicinal product in question is exactly five years that an SPC can have a duration equal to zero and that the starting point of the paediatric extension of six months is concurrent with the expiry date of the basic patent.

44 In the circumstances of the case in the main proceedings, the SPC and the paediatric extension would together confer on the holder of the basic patent a period of protection of 2 months and 16 days that takes effect at the end of the lawful term of the basic patent. Therefore, the grant of an SPC of negative duration in this case allows the objective of Regulation No 1901/2006 to be attained.

45 It follows from all of the foregoing that the answer to the question asked is that Article 13 of Regulation No 1768/92, read in conjunction with Article 36 of Regulation No 1901/2006, must be interpreted as meaning that medicinal products can be the object of the grant of an SPC where the period that has elapsed between the date of lodging the basic patent application and the first marketing authorisation in the EU is less than five years. In such a case, the period of the paediatric extension provided for by the latter regulation starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between the lodging of the patent application and the grant of the first marketing authorisation.

Costs

46 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



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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:

Article 13 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, as amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006, read in conjunction with Article 36 of Regulation No 1901/2006, must be interpreted as meaning that medicinal products can be the object of the grant of a supplementary protection certificate where the period that has elapsed between the date of lodging the basic patent application and the first marketing authorisation in the European Union is less than five years. In such a case, the period of the paediatric extension provided for by the latter regulation starts to run from the date determined by deducting from the patent expiry date the difference between five years and the duration of the period which elapsed between the lodging of the patent application and the grant of the first marketing authorisation.

[Signatures]

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* Language of the case: German.



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