Court of Justice EU, 8 December 2011, Merck v Patentamt

PATENT LAW – SPC

SPC can be granted if less than five years have elapsed between the first market authorization and the date of the basic patent application

- **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.**

Purpose of SPC of negative or zero duration: paediatric extension

- **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.

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Court of Justice EU, 8 December 2011
(Cunha Rodrigues, President of the Chamber, U. Lõhmus (Rapporteur), A. Rosas, A. Ó Caoimh and A. Arabadjiev)
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,
– 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 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];

(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'.

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

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:

'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 peri-

od 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 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.

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 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 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]

* Language of the case: German.

Opinion of Advocate General Yves Bot

delivered on 9 June 2011 (2)

Case C‑125/10

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

v

Deutsches Patent- und Markenamt

(Reference for a preliminary ruling from the Bundespatentgericht (Germany))

(Intellectual and industrial property – Patents – Regulation (EEC) No 1768/92 – Article 13(1) – Supplementary protection certificate for medicinal products – Conditions of grant – Regulation (EC) No 1901/2006 – Article 36 – Extending the duration of the supplementary protection certificate – Possibility of granting that certificate where the period that elapses between the filing of an application for a basic patent and the date of the first authorisation to place the product on the market in the Community is less than five years)

1. In the present preliminary ruling proceedings, the Court is asked to specify what consequences the adoption of Regulation (EC) No 1901/2006 of the European Parliament and of the Council (3) has on the conditions

for granting a supplementary protection certificate ('SPC') intended to extend the exclusive right to exploit a medicinal product conferred by a patent.

2. The development of a medicinal product requires long and costly research. In order to enable pharmaceutical laboratories to make a return on the investment needed for such research and, therefore, to promote that research, the Member States provided, in their domestic law or, by way of agreement, at European level, (4) that medicinal products could be granted a patent intended to guarantee for the patent holder an exclusive right to exploit those products for a specific period. (5)

3. However, the marketing of a medicinal product in a Member State is subject to the prior grant of a marketing authorisation ('MA') issued either by the competent authority of that State (6) or, since the entry into force of Council Regulation (EEC) No 2309/93, (7) by the European Community. (8)

4. The period that elapses between the filing of a patent application and the grant of an MA can be relatively long. Whereas a patent for a medicinal product must be applied for very early in order to avoid any risk of disclosure or the completion of parallel research, the grant of an MA may take several years on account of the research that has to be carried out to verify the effectiveness, safety and quality of the product. (9)

5. This therefore reduces by the same period the effective duration of the monopoly on exploitation conferred by the patent.

6. In order to mitigate that disadvantage in a uniform manner in the Member States, the Community legislature, in Council Regulation (EEC) No 1768/92, (10) made it possible for pharmaceutical laboratories to obtain an SPC which, on the expiry of the basic patent, confers on its holder the same rights as those attached to the patent for a period intended to offset the duration of the procedure for obtaining the MA where this exceeds the normal estimated period of five years.

7. Thus, Article 13 of Regulation No 1768/92 provides that the SPC is to take effect at the end of the lawful term of the patent for a period equal to the period which elapsed between the date on which the patent application was lodged and the date of the first MA in the Community reduced by a period of five years, but may not last longer than five years from the date on which it takes effect.

8. The Paediatric Regulation, for its part, was prompted by the finding that many medicinal products were being placed on the market without having undergone proper studies into their paediatric effects, which meant that they could not be used as an effective and safe treatment for children.

9. The Community legislature therefore provided in that regulation that, unless it had been granted a waiver, a medicinal product could not obtain an MA until it after had undergone studies to determine whether and how it could be used in the paediatric population.

10. In return for the completion of those additional studies, the Community legislature provided in the Paediatric Regulation that the duration of the SPC was to be extended by six months.

11. In this case, the Court is asked whether and to what extent an economic operator is eligible for that six-month extension where less than five years have elapsed between the application for a patent and the date on which the MA was granted.

12. The question, in other words, is whether an SPC may be granted with a negative or zero duration so as to make the six-month extension run either from the starting point of the negative duration, that is to say before the date on which the basic patent expires, or, if such a negative duration is to be rounded up to zero, from the date on which the basic patent expires.

13. In this Opinion, I shall say that there is no clear answer to the question referred in the content and scheme of Regulation No 1768/92 and the Paediatric Regulation and that the answer must therefore be inferred from the objectives which they pursue.

14. I shall explain that the purpose of Regulation No 1768/92 is to guarantee for the patent holder a period of exclusive exploitation of no more than 15 years from the grant of the MA and that the aim of the Paediatric Regulation is to extend by six months the SPC granted for that purpose. I shall submit that, taken together, those two regulations have the effect of guaranteeing for the patent holder a period of exclusive exploitation of 15 years and 6 months from the grant of the MA.

15. Consequently, I shall propose that the Court should find that a patent holder is eligible for the six-month extension established by the Paediatric Regulation where less than five years have elapsed between the application for a patent and the date on which the MA was granted, and that that extension must begin to run from the date determined by applying the negative value of the SPC to the date of expiry of the patent.

I – Legal context

16. In its order for reference, the Bundespatentgericht (Germany) refers to Regulation (EC) No 469/2009 of the European Parliament and of the Council, (11) which reproduces the content of Regulation No 1768/92 without amending its substance. However, Regulation No 469/2009 did not enter into force until 6 July 2009, in other words after the adoption of the decision under appeal in the main case. The applicable regulation is therefore Regulation No 1768/92.

A – Regulation No 1768/92

17. 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 the 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, which penalises that research and creates the risk of research centres relocating outside the Member States.

18. The eight 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 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;
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 authorisation to be placed on the market as a medicinal product'.

19. Article 3 of Regulation No 1768/92 is entitled 'Conditions for obtaining a[n SPC]'. It reads as follows:

'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 authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65 ... or Directive 81/851/CEE, [(12)] as appropriate;
(c)
the product has not already been the subject of a[n SPC];
(d)
the authorisation referred to in (b) is the first authorisation to place the product on the market as a medicinal product.'

20. Under Articles 4 and 5 of Regulation No 1768/92, the protection conferred by the SPC applies only to the product covered by the MA for the corresponding medicinal product and includes the same rights as those conferred by the basic patent.

21. Article 7(1) of Regulation No 1768/92 provides that the application for an SPC is to be lodged within six months of the date on which the authorisation to place the product on the market as a medicinal product was granted. Paragraph 3 of the same article provides that the application for an extension of the duration may be made when lodging the application for an SPC or when the application for the SPC is pending and the appropriate requirements of Article 8(1) of Regulation No 1768/92 are fulfilled. According to Article 7(4) of the same regulation, the application for an extension of the duration of an SPC already granted is to be lodged not later than two years before the expiry of the SPC.

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

23. Article 10 of Regulation No 1768/92, entitled 'Grant of the certificate or rejection of the application', states:

'1. Where the application for an [SPC] and the product to which it relates meet the conditions laid down in this Regulation, the [competent] authority shall grant the [SPC].
2. The [competent] authority ... shall, subject to paragraph 3, reject the application for an [SPC] if the application or the product to which it relates does not meet the conditions laid down in this Regulation.
...'

24. Article 13 of Regulation No 1768/92, entitled 'Duration of the [SPC]', provides:

'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 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 [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 the [Paediatric] Regulation applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.'

25. Article 14(a) of Regulation No 1768/92 states that the SPC is to lapse 'at the end of the period provided for in Article 13 [of that regulation]'.

B – The Paediatric Regulation

26. Recitals 26 to 28 to the Paediatric Regulation 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 ... Regulation ... No 1768/92.
(27)
An application for an extension of the duration of the [SPC] pursuant to this Regulation should only be admissible where an [SPC] is granted pursuant to Regulation ... No 1768/92.
(28)
Because the reward is for conducting studies in the paediatric population and not for demonstrating that a product is safe and effective in the paediatric population, the reward should be granted even when a paediatric indication is not authorised. However, to improve the information available on the use of medicinal products in the paediatric population, relevant information on use in paediatric populations should be included in authorised product information.'

27. Article 36 of the Paediatric Regulation is worded as follows:

'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 ... No 1768/92.
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 an [SPC] under Regulation ... No 1768/92, or under a patent which qualifies for the granting of the [SPC]. ...
...'

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

28. Merck Sharp & Dohme Corp., formerly Merck & Co. ('Merck'), is the owner of a European patent covering dipeptidylpeptidase inhibitors for the treatment or prevention of diabetes. That patent was applied for on 5 July 2002.

29. On 14 September 2007, Merck applied to the Deutsches Patent- und Markenamt (German Patent and Trade Mark Office) 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 as the date of the first MA in the European Union and the Federal Republic of Germany 21 March 2007, the date on which European authorisation was issued for the medicinal product under the brand name Januvia, which contains the active ingredient sitagliptin phosphate monohydrate.

30. 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 of the filing of the basic patent and the date of issue of the first MA, so that calculating the length of the SPC would have given a negative duration of three months and fourteen days.

31. Merck brought an action against that decision before the Bundespatentgericht.

32. It submits that duration is not one of the conditions governing the grant of an SPC, that the SPC must be granted to it because it fulfils all the conditions required for that purpose and that the grant of the SPC is necessary to enable it subsequently to apply for an extension of that SPC.

33. Merck points out that a paediatric investigation plan was authorised by the competent authority on 27 March 2009 and that the studies prescribed in that plan must be completed by 2017.

34. It argues that it should be granted an SPC with a negative or zero duration so as to make the six-month extension provided for by the Paediatric Regulation run either from 21 March 2022 or from the date of expiry of the basic patent, 5 July 2022.

35. The referring court states that, until the Paediatric Regulation was adopted, it was accepted that an SPC could be granted only where a period of five years had elapsed between the application for a patent and the grant of the first MA for the medicinal product in question. It raises the question whether, following the entry into force of that regulation, a different interpretation should be adopted and SPCs with a negative or zero duration should be granted.

36. The referring court states, first, that neither the Paediatric Regulation nor Regulation No 469/2009 expressly provided for the possibility of granting such SPCs and that that solution would run counter to the normal meaning of the word 'duration' in Article 13 of Regulation No 469/2009.

37. It states, secondly, that Article 13 does not form part of the conditions for granting an SPC and that granting an SPC with a negative or zero duration would be consistent with the objective pursued by the Paediatric Regulation. It points out that, if that interpretation were to prevail, it would also be necessary to clarify the starting point of the extension of the SPC. There would thus be a need to ascertain whether the six-month period must begin to run before the date of expiry of the patent, on the date established by assigning a negative value to the SPC, or whether that value must be rounded up to zero and the six-month period made to run from the date of expiry of the patent.

38. The referring court points out in this regard that the situation of the appellant in the main proceedings has revealed the existence of different practices in the Member States. Thus, it states, the competent authorities of the Republic of Bulgaria, the Kingdom of the Netherlands and the United Kingdom of Great Britain and Northern Ireland granted the appellant an SPC with a negative duration, while the competent authorities of the Hellenic Republic granted it one with a zero duration. Similarly, in Estonia and Latvia, the decisions refusing to grant an SPC were annulled by the boards of appeal.

39. The referring court states that, in the light of those considerations, it considered it necessary to ask the Court for an interpretation of Article 13(1) of Regulation No 469/2009. The Bundespatentgericht refers the following question for a preliminary ruling:

'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 first authorisation [MA] in the Community is shorter than five years?'

III – My analysis

40. The referring court has set out very clearly the matter at issue in these preliminary ruling proceedings. It must determine whether the appellant in the main proceedings is entitled to obtain an SPC for the product in question when only four years, eight months and sixteen days, that is to say, less than five years, elapsed between the date of filing of the basic patent and the date of issue of the first MA.

41. That question arises because the Paediatric Regulation makes the grant of the six-month extension of the SPC dependent on the grant of that SPC and because, under Regulation No 1768/92, the duration of that SPC is equal to the period that elapsed between the date on which the application for a patent was lodged and the

date of the first MA, reduced by five years. The question, therefore, is whether the grant of the extension provided for by the Paediatric Regulation must be made subject to the condition that the patent holder should be able to obtain an SPC with a positive duration.

42. If that question is answered in the affirmative, the appellant will not therefore be eligible for any extension of the exclusive rights conferred on it by its patent. If, on the other hand, the answer to that question is in the negative, it is also necessary to clarify the starting point of the six-month period.

43. It must after all be made clear whether the six-month period would have to run from the date determined on the basis of the negative value of the SPC or, by rounding up that value to zero, from the date of expiry of the patent, that is to say, in the present case, 5 July 2022.

44. In the former case, the six-month period would have to run from 21 March 2022, (13) so that the exclusive rights conferred on the appellant in the main proceedings by the basic patent would be extended by two months and sixteen days after the date on which the patent would ordinarily have expired, that is to say until 21 September 2022.

45. If that solution were adopted, this would mean that the basic patent holder would be eligible for the six-month extension provided for by the Paediatric Regulation only if the period that elapsed between the date of the patent application and the date on which the first MA was granted exceeds four years and six months.

46. In the latter case, the exclusive rights enjoyed by the appellant in the main proceedings would be extended until 5 January 2023. If that solution were adopted, this would mean that the patent holder would always be eligible for the extension provided for by the Paediatric Regulation for the full six-month period, irrespective of the period which had elapsed between the date of the patent application and the date when the first MA was granted.

47. In order to be able to answer those questions, the referring court is asking, in essence, whether and to what extent Regulation No 1768/92, read in the light of the Paediatric Regulation, must be interpreted as meaning that medicinal products can be granted an SPC where the period that elapsed between the filing of the application for a basic patent and the date of the first MA in the Community is less than five years.

48. The parties intervening before the Court have adopted opposing positions.

49. Thus, the Hungarian and United Kingdom Governments, like the appellant in the main proceedings, have asked the Court to answer the question referred in the affirmative and have also stated that the six-month period should begin to run from the ‘negative’ expiry date of the SPC.

50. The French, Lithuanian and Portuguese Governments and the European Commission, on the other hand, have submitted that the question under examination should be answered in the negative, on a number of grounds based on the wording of the relevant provisions, the scheme of which they form part and the objectives which they pursue.

51. As regards, first of all, the wording of the relevant provisions, the Commission points out that, under Article 13(1) of Regulation No 1768/92, the SPC ‘shall take effect at the end of the lawful term of the basic patent’ and that, under Article 13(2) of that regulation, the duration of such an SPC may not exceed five years from the date on which it takes effect, so that the SPC must necessarily have a positive duration. The French Government also considers that an SPC with a zero or negative duration is incapable of producing such an effect and is therefore devoid of any purpose.

52. To the same effect, the Portuguese Government argues that Article 13(3) of Regulation No 1768/92 provides for the six-month extension of the SPC under Article 36 of the Paediatric Regulation, which implies that the SPC has a period of validity that can be extended.

53. For its part, the Lithuanian Government maintains, with respect to the conditions for granting the SPC, that those laid down in Articles 3, 7 and 8 of Regulation No 1768/92 are not exclusive and that there is no obligation to grant that SPC if those conditions are met. Moreover, it submits, Article 11 of that regulation imposes an obligation to state the duration of the SPC, which means that its duration must be calculated before it is granted.

54. Furthermore, the Commission points out that none of the amendments made to Regulation No 1768/92 by the Paediatric Regulation supports the view that the condition relating to the five-year period has been removed. On the other hand, recital 27 to the Paediatric Regulation shows that the reward in the form of a six-month extension forms part of the existing SPC system and can be granted only if an SPC has been granted under Regulation No 1768/92. That reward is therefore ancillary in nature.

55. With regard, next, to the scheme of which the relevant provisions form part, the French Government and the Commission take the view that a schematic interpretation of Regulation No 1768/92 cannot call in question the assessment that an SPC must have a positive duration in so far as that regulation contains no indication that an SPC might have a negative duration.

56. What is more, the Lithuanian and Portuguese Governments do not consider it possible to draw a convincing argument from the position of Articles 10, 11 and 13 of that regulation or to infer from it that the application for an SPC must be assessed in several stages.

57. With regard, finally, to the objectives of Regulation No 1768/92, the French and Lithuanian Governments and the Commission submit that the aim of that regulation is to offset not the entire duration of the procedure for granting an MA but only that part of the procedure that exceeds five years, in order to ensure a balance between the interests at stake.

58. Consequently, in the view of the French and Lithuanian Governments, if the duration of the period between the patent application and the first MA authorisation were less than five years, the SPC, if granted,

would never enter into force. Similarly, if that were the case, it would be possible to receive income from the sale of the medicinal product for more than 15 years after the date of filing of the patent application and therefore to cover the investment put into the research.

59. The Lithuanian Government states in this regard that the converse solution would give create a distortion of competition inasmuch as the patent holder would be accorded a long period of protection.

60. I am not persuaded by those arguments. On the contrary, an analysis of the scheme of Regulation No 1768/92 and the Paediatric Regulation and in particular of their objectives inclines me towards the proposition put forward by the appellant in the main proceedings and the Hungarian and United Kingdom Governments to the effect that it must be possible to grant an SPC where less than five years have elapsed between the patent application and the date on which the first MA was granted. I too consider, like those governments, that the six-month extension must begin to run not from the date on which the patent expires but from the date on which the SPC takes effect, as determined by applying the negative value of the duration of the SPC to the date of expiry.

61. My position is based on the following considerations.

62. The first point to be made is that there is quite clearly no ready answer to the question under examination in the provisions of Regulation No 1768/92 and the Paediatric Regulation. None of the provisions of those regulations states explicitly whether or not the grant of an SPC with a positive duration is a necessary condition for granting the six-month extension provided for in the Paediatric Regulation. In accordance with the case-law, the answer to that question must therefore be inferred from the scheme established by those regulations and from the objectives which they pursue. (14)

63. Significantly, in my opinion, an examination of the scheme of Regulation No 1768/92 and the Medicines Regulation shows that the duration of the SPC is not one of the conditions for granting the six-month extension established by the Paediatric Regulation which are set out in Articles 7 and 8 of that regulation. The duration of the SPC is mentioned only in Article 36 of that regulation, which, it will be recalled, provides merely that, where an application under Article 7 or 8 of the Paediatric Regulation includes the results of the studies conducted in compliance with an agreed paediatric investigation plan, the holder of a patent or an SPC is to be entitled to a six-month extension of the period referred to in Article 13 of Regulation No 1768/92.

64. Similarly, an examination of the scheme of Regulation No 1768/92 shows that duration is not one of the substantive conditions, listed in Article 3 of that regulation, or formal conditions, laid down in Articles 7 to 9 of that regulation, governing the grant of the SPC. The rules relating to the duration of the SPC, set out in Article 13 of Regulation No 1768/92, also appear after the provisions of that regulation relating to the grant or rejection of [the application for] the SPC, contained in Article 10.

65. Consequently, the positive duration of the SPC cannot be regarded as a condition for granting the SPC that is explicitly required by Regulation No 1768/92. It follows that recital 27 to the Paediatric Regulation does not serve as a decisive lesson for the purposes of this case to the effect that an application for extension must be admissible only where an SPC has been granted within the meaning of Regulation No 1768/92.

66. Although, as the referring court pointed out, the grant of an SPC with a zero or negative duration was not conceivable before the entry into force of the Paediatric Regulation, the grant of such an SPC was precluded, in my view, not by any actual legal prohibition but by reasons of common sense relating to the fact that such an SPC was devoid of any purpose.

67. After all, up until that regulation was adopted, the only purpose of an SPC was to extend the exclusive rights conferred by the basic patent on its holder, which meant, self-evidently, that the SPC must have a positive duration and, therefore, taking into account the detailed calculation rules laid down in Article 13(1) of Regulation No 1768/92, that more than five years must have elapsed between the patent application and the date on which the first MA was granted.

68. Since the entry into force of the Paediatric Regulation, however, that has no longer been the case because the grant of the SPC is also a condition of eligibility for an additional six-month extension, and because – the matter at issue in this case – that extension may be applicable and cause the exclusive rights of the patent holder to continue in being for a given time, even though the duration of the SPC is zero or negative.

69. Previous practice cannot therefore be relied on for the purpose of answering the question referred and, at this stage of the analysis, it must be assumed, in my opinion, that the scheme of Regulation No 1768/92 and the Paediatric Regulation does not preclude an SPC from being granted where less than five years have elapsed between the patent application and the date on which the first MA was granted.

70. Since an examination of the scheme of those regulations leaves the question under examination open, the answer must be found in the objectives pursued by those regulations. I shall now argue that, in my view, those objectives provide clear justification for an affirmative answer to the question referred.

71. As I have already stated, the purpose of Regulation No 1768/92 is to compensate for the loss of entitlement to exclusive exploitation rights during the period required for the grant of the first MA where that period exceeds five years. It also serves to protect the interests of the consumers and health systems of the Member States by ensuring that the monopoly on exploitation so guaranteed does not exceed what appeared to be necessary to cover the investment and does not unduly delay the moment when the product in question comes into the public domain.

72. To that end, the Community legislature provided that the patent holder could be granted an SPC of a duration equivalent to the period that elapsed between the patent application and the date on which the first MA was granted, reduced by five years, although the duration of the SPC itself could not exceed five years.
73. As the eighth recital to Regulation No 1768/92 states, the Community legislature intended that regulation to have the effect of guaranteeing for the patent holder a monopoly on exploitation of no more than 15 years from the time when the first MA is granted for the medicinal product in question.
74. As for the Paediatric Regulation, its aim, as stated in recital 26 to that regulation, is to grant a reward in the form of a six-month extension of the SPC to laboratories which have conducted all the research recommended in the paediatric investigation plan established for the product in question.
75. That regulation is therefore intended to offset by means of a six-month period of additional exclusivity the cost and constraints resulting from the obligation to subject medicinal products to additional studies to assess their paediatric effects.
76. An examination of the objectives pursued by the two regulations taken together shows that the Community legislature intended the holder of a basic patent to be able to exercise a monopoly on exploitation for a total period of 15 years and 6 months, not just 15 years, as maintained by the Commission. Thus, where more than 5 years have elapsed between the patent application and the grant of the first MA, the cumulative effect of Regulation No 1768/92 and the Paediatric Regulation is to grant the patent holder a monopoly of 15 years and 6 months.
77. To accept the proposition, as the French, Lithuanian and Portuguese Governments and the Commission do, that the extension provided for by the Paediatric Regulation is not applicable where less than five years have elapsed between the patent application and date on which the first MA was granted, on the ground that, in those circumstances, the person concerned enjoyed a 15-year monopoly on exploitation, is therefore to deprive that regulation of much of its effectiveness.
78. That argument is also questionable, in my view, because it produces disproportionate results. After all, the difference between obtaining its MA five years and one day after its application for a basic patent and obtaining it exactly five years thereafter would determine whether the patent holder qualified for an extension of its exclusive rights by a period of six months or for no extension at all.
79. Such a disparity in treatment because of a difference of a mere 24 hours is, in my opinion, genuinely excessive. Nor is it in conformity with the SPC system established by Regulation No 1768/92, under which the five-year period referred to in Article 13(2) of that regulation is not an irreducible period but a limit designed to ensure that the patent holder will be able to exercise a monopoly on exploitation for no more than 15 years from the first MA.
80. Implementation of the extension provided for by the Paediatric Regulation must therefore, as I see it, obey the same logic and mean that the combined application of Regulation No 1768/92 and the Paediatric Regulation has the effect of guaranteeing for the patent holder a monopoly on exploitation of 15 years and 6 months.
81. Moreover, the argument put forward by the French, Lithuanian and Portuguese Governments and the Commission has a further disadvantage. The importance of the economic consequences that might result, if that argument were upheld, from a mere 24-hour difference in the date when an MA is granted might prompt pharmaceutical laboratories to delay the date on which the MA is obtained, which would be at odds with the protection of public health. After all, as recital 4 to the Paediatric Regulation points out, that general interest requires that a medicinal product be put on the market so that it can be used to treat patients as soon as possible.
82. The objectives of Regulation No 1768/92 and the Paediatric Regulation call, in my opinion, for an affirmative answer to the question referred. They also allow the following clarifications to be made as regards the starting point for the six-month extension where less than five years have elapsed between the patent application and the date on which the first MA was granted.
83. For the reasons that I have just outlined, the duration of the SPC, where less than five years elapsed between the patent application and the date on which the first MA was granted, cannot be 'rounded up to zero' to make the six-month period run systematically from the date of expiry of the patent. The purpose of the Paediatric Regulation, read in conjunction with that of Regulation No 1768/92, is, as I have stated, to guarantee for the basic patent holder a monopoly on exploitation starting on the date of the first MA and lasting for a maximum total duration of 15 years and 6 months. Its aim is not to extend the expiry date of all patents by a period of six months.
84. Such a systematic extension would jeopardise the balance, sought by the Community legislature, between covering the costs of the research necessary to develop medicinal products, on the one hand, and the economic interests of consumers and national social security systems, on the other, since it might lead to monopolies on exploitation being conferred for longer than the limit of 15 years and 6 months.
85. It might also lead to the unequal treatment of economic operators, since the combined application of Regulation No 1768/92 and the Paediatric Regulation would no longer have the effect of making the monopoly on exploitation exercised by basic patent holders subject to the same maximum duration.
86. I therefore propose that the Court's answer to the question referred should be that Regulation No 1768/92, read in the light of the Paediatric Regulation, must be interpreted as meaning that medicinal products can be granted an SPC where the period that elapses between the filing of the application for the basic patent

and the date of the first authorisation to place the product on the market in the Community is less than five years. In that event, the six-month period provided for by the Paediatric Regulation begins to run from the date determined by deducting from the date of expiry the difference between five years and the duration of the period that elapsed between the filing of the patent application and the grant of the first MA.

IV – Conclusion

87. In light of the foregoing considerations, I propose that the question referred by the Bundespatentgericht should be answered as follows:

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 and read in the light of Regulation No 1901/2006, must be interpreted as meaning that medicinal products can be granted a supplementary protection certificate where the period that elapses between the filing of the application for the basic patent and the date of the first authorisation to place the product on the market in the European Community is less than five years.

In that event, the six-month period provided for by Regulation No 1901/2006 begins to run from the date determined by deducting from the date of expiry the difference between five years and the duration of the period that elapsed between the filing of the patent application and the grant of the first marketing authorisation.

2 Original language: French.

3 Regulation of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directives 2001/20/EC and 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2006 L 378, p. 1) (‘the Paediatric Regulation’).

4 The Convention on the Grant of European Patents was signed in Munich on 5 October 1973 and it entered into force on 7 October 1977.

5 Pursuant to Article 63 of that convention, the term of the European patent is 20 years as from the date of filing of the application.

6 See Article 3 of 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. 20) and Article 6 of 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).

7 Regulation of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1).

8 –
See Article 3 of Regulation No 2309/93.

9 –
See Chemtob-Concé, M.-C., ‘Le certificat complémentaire de protection: un instrument devenu insuffisant pour assurer la rentabilité de l’innovation pharmaceutique’, Gazette du Palais, October 2008, No 283, p. 42.

10 Regulation of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), as amended by the Paediatric Regulation (‘Regulation No 1768/92’).

11 Regulation of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

12 Council Directive 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).

13 In other words, the date on which the patent would ordinarily have expired, 5 July 2022, reduced by three months and fourteen days, that is to say the length of the period that elapsed between the patent application on 5 July 2002 and the date of the first MA on 21 March 2007, reduced by five years.

14 For an example of an interpretation of a provision of the initial version of Regulation No 1768/92 arrived at by viewing it within its context and by reference to its spirit and purpose, see Case C‑127/00 Hässle [2003] ECR I‑14781, paragraph 55.