JUDGMENT OF THE COURT

21 December 2017*

(*Regulation (EEC) No 1768/92 – Medicinal products – Supplementary protection certificate – Certificate of negative duration*)

In Case E-5/17,

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by the Supreme Court of Iceland (*Hæstiréttur Íslands*), in a case pending before it between

Merck Sharp & Dohme Corp.

and

The Icelandic Patent Office (*Einkaleyfastofan*)

concerning the interpretation of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products,

THE COURT,

composed of: Carl Baudenbacher, President, Per Christiansen (Judge-Rapporteur), and Páll Hreinsson, Judges,

Registrar: Gunnar Selvik,

having considered the written observations submitted on behalf of:

– Merck Sharp & Dohme Corp. ("the appellant"), represented by Jóna Björk Helgadóttir, Supreme Court Attorney;

* Language of the request: Icelandic.

– the Icelandic Patent Office ("the respondent"), represented by Óskar Thorarensen, Supreme Court Attorney, Office of the Attorney General (Civil Affairs), acting as Agent;

– the Norwegian Government, represented by Marius Emberland, Advocate, Attorney General of Civil Affairs, and Carsten Anker and Ingunn Skille Jansen, Senior Advisers, Ministry of Foreign Affairs, acting as Agents;

– the EFTA Surveillance Authority ("ESA"), represented by Carsten Zatschler, Ingibjörg Ólöf Vilhjálmsdóttir, and Michael Sánchez Rydelski, members of its Department of Legal & Executive Affairs, acting as Agents; and

– the European Commission ("the Commission"), represented by Julie Samnadda and Nicola Yerrell, members of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

having heard oral argument of the appellant, represented by Jóna Björk Helgadóttir and Geneviève Michaux, Attorney; the respondent, represented by Óskar Thorarensen; the Norwegian Government, represented by Marius Emberland; ESA, represented by Ingibjörg Ólöf Vilhjálmsdóttir; and the Commission, represented by Lorna Armati, member of its Legal Service, acting as Agent, at the hearing on 14 November 2017,

gives the following

Judgment

I Legal background

EEA law

1 Article 65(2) of the Agreement on the European Economic Area ("the EEA Agreement" or "EEA") reads:

> *Protocol 28 and Annex XVII contain specific provisions and arrangements concerning intellectual, industrial and commercial property, which, unless otherwise specified, shall apply to all products and services.*

2 Article 103 EEA reads:

> *1. If a decision of the EEA Joint Committee can be binding on a Contracting Party only after the fulfilment of constitutional requirements, the decision shall, if a date is contained therein, enter into force on that date, provided that the Contracting Party concerned has notified the other Contracting Parties by that date that the constitutional requirements have been fulfilled.*
>
> *In the absence of such a notification by that date, the decision shall enter into force on the first day of the second month following the last notification.*
>
> *2. If upon the expiry of a period of six months after the decision of the EEA Joint Committee such a notification has not taken place, the decision of the EEA Joint Committee shall be applied provisionally pending the fulfilment of the constitutional requirements unless a Contracting Party notifies that such a provisional application cannot take place. In the latter case, or if a Contracting Party notifies the non-ratification of a decision of the EEA Joint Committee, the suspension provided for in Article 102(5) shall take effect one month after such a notification but in no event earlier than the date on which the corresponding EC act is implemented in the Community.*

3 Joint Committee Decision No 7/94 of 21 March 1994 (OJ 1994 L 160, p. 1, and EEA Supplement 1994 No 17, p. 1), which entered into force on 1 July 1994, incorporated 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) ("the SPC Regulation") into the EEA Agreement by inserting it as point 6 in Annex XVII (Intellectual property) to the Agreement. The SPC Regulation provides for the granting of a supplementary protection certificate (SPC) for a medicinal product covered by a basic patent, for a period of up to five years after the expiry of the basic patent.

4 The SPC Regulation was amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2006 L 378, p. 1, and EEA Supplement 2017 No 31, p. 521) ("the Paediatric Regulation"). The Paediatric Regulation provides for the granting of a six-month extension of the duration of the SPC for a medicinal product for paediatric use ("paediatric extension"). Subsequently, the SPC Regulation was repealed by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1, and EEA Supplement 2017 No 31, p. 542) ("the new SPC Regulation"). The new SPC Regulation essentially reproduces the provisions of the SPC Regulation, as amended by the Paediatric Regulation.

5 Joint Committee Decision No 92/2017 of 5 May 2017 prescribes the incorporation of the Paediatric Regulation into the EEA Agreement by inserting it as point 15zr in Annex II (Technical regulations, standards, testing and certification) to the Agreement. By the same decision, the new SPC Regulation is intended to replace the SPC Regulation in point 6 in Annex XVII to the EEA Agreement. Article 4 of the Joint Committee Decision provides that the decision shall enter into force on 6 May 2017, provided that all the notifications under Article 103(1) of the EEA Agreement have been made. Constitutional requirements were indicated by Iceland and Norway. On 11 September 2017, Norway notified that the constitutional requirements had been fulfilled. At the oral hearing, the respondent informed the Court that on 27 October 2017, Iceland submitted a notification under Article 103(2) EEA, stating that the fulfilment of constitutional requirements could not take place within the prescribed six-month period, expiring on 5 November 2017. Upon a question from the bench, the respondent confirmed that the notification stated that provisional application could not take place.

6 The second, third and the seventh to ninth recitals in the preamble to the SPC Regulation read:

> *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;*
>
> *Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization 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;*
>
> *...*
>
> *Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;*
>
> *Whereas the duration of the protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusively from the time the medicinal product in question first obtains authorization 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 certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product;

7 Article 3 of the SPC Regulation reads:

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate; ...

(c) the product has not already been the subject of a certificate;

(d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.

8 Article 7 of the SPC Regulation reads:

1. The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3(b) to place the product on the market as a medicinal product was granted.

2. Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

9 Article 8 of the SPC Regulation reads:

1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;
(ii) if he has appointed a representative, the name and address of the representative;
(iii) the number of the basic patent and the title of the invention;
(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) and, if this authorization is

not the first authorization for placing the product on the market in the Community, the number and date of that authorization;

(b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;

(c) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.

2. Member States may provide that a fee is to be payable upon application for a certificate.

10 Article 9 of the SPC Regulation reads:

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

2. Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:

(a) the name and address of the applicant;
(b) the number of the basic patent;
(c) the title of the invention;
(d) the number and date of the authorization to place the product on the market, referred to in Article 3(b), and the product identified in that authorization;
(e) where relevant, the number and date of the first authorization to place the product on the market in the Community.

11 Article 10 of the SPC Regulation reads:

1. Where the application for a certificate 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 certificate.

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

3. *Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.*

4. *If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.*

5. *Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.*

12 Article 13 of the SPC Regulation reads:

1. *The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years.*

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

National law

13 The SPC Regulation is incorporated into Icelandic law by virtue of Article 65a of the Patent Act No 17/1991 (*lög nr. 17/1991 um einkaleyfi*), as amended by Act No 36/1996. Article 65a states that the SPC Regulation accompanies and is considered part of the Patent Act and shall have the force of law in Iceland.

II Facts and procedure

14 The appellant is the holder of Icelandic Patent No 2218, concerning "Beta-amino tetrahydroimidazo (1, 2-a) pyrazines and tetrahydrotrioazolo (4, 3-a) pyrazines as dipeptidyl peptidase inhibitors for the treatment or prevention of diabetes". The application for that patent was filed on 5 July 2002.

15 On 21 March 2007, the appellant was granted a marketing authorisation throughout the European Union ("EU") for the medicinal product Januvia (Sitagliptin) for the improvement of the glycaemic control for adult patients with type 2 diabetes. The Icelandic

authorities granted a corresponding marketing authorisation for Iceland, applicable from the same date as the EU authorisation.

16 On 19 September 2007, the appellant filed an application for an SPC with the Icelandic Patent Office on the basis of the Icelandic patent. The period between the application date of the basic patent (5 July 2002) and the grant of the first marketing authorisation (21 March 2007) was less than five years. The calculation rules in Article 13 of the SPC Regulation provide for a reduction of five years in the period at issue. An SPC in the present case would therefore have a negative duration of 106 days. In its application, the appellant referred to the Paediatric Regulation and stated that the intention behind applying for a negative SPC in Iceland was to allow for an application for a paediatric extension at a later stage.

17 However, on 3 April 2009, the respondent, the Icelandic Patent Office, rejected the application on the basis that the duration of the SPC would be negative. The respondent considered it incompatible with the purpose of the Patent Act and the SPC Regulation to grant an SPC with a negative duration. Furthermore, the respondent stated that the Paediatric Regulation was not relevant since it had neither been incorporated into the EEA Agreement nor into Icelandic law.

18 The appellant filed a complaint against the respondent's decision with the Board of Appeal for Industrial Intellectual Property Rights (*Áfrýjunarnefnd hugverkaréttinda á sviði iðnaðar*) ("the Board of Appeal"). At the request of the appellant, the Board of Appeal deferred its examination until the delivery of judgment by the Court of Justice of the European Union ("ECJ") in a case deemed similar by the appellant.

19 By a judgment of 8 December 2011 in *Merck Sharp & Dohme*, C-125/10, EU:C:2011:812, the ECJ concluded that Article 13 of the SPC Regulation, as amended by and read in conjunction with the Paediatric Regulation, must be interpreted as meaning that medicinal products can be the object of the grant of an SPC even when the duration of the SPC is negative.

20 By a decision of 9 September 2015, the Board of Appeal upheld the respondent's decision of 3 April 2009. The appellant then brought the decision of the Board of Appeal to Reykjavík District Court (*Héraðsdómur Reykjavíkur*), seeking the annulment of the decision and recognition of the fact that the respondent is obliged to issue an SPC as requested. However, by a judgment of 13 April 2016, the District Court rejected the appellant's claims.

21 On 12 July 2016, the District Court's judgment was appealed to the Supreme Court of Iceland. On 12 June 2017, the Supreme Court decided to seek an advisory opinion from the Court. The request was sent by letter of 15 June 2017, and registered at the Court that same day.

22 In the order for reference, the Supreme Court observes that, according to the ECJ's judgment in *Merck Sharp & Dohme*, there is nothing in the SPC Regulation preventing the issuing of an SPC of negative duration. On the other hand, the ECJ interpreted the SPC Regulation with reference to the Paediatric Regulation. Neither the Paediatric Regulation nor the new SPC Regulation have been incorporated into the EEA Agreement, and they do not have the force of law in Iceland. On that basis, the Supreme Court has asked the following question:

> *In light of the fact that [the Paediatric Regulation] and [the new SPC Regulation] have not been incorporated into the [EEA Agreement], can a[n] [SPC] under [the SPC Regulation] be issued for a medicinal product if the period which has 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 [EEA] is less than five years?*

23 Reference is made to the Report for the Hearing for a fuller account of the legal framework, the facts, the procedure, and the written observations submitted to the Court, which are mentioned or discussed hereinafter only insofar as is necessary for the reasoning of the Court.

III Answer of the Court

Observations submitted to the Court

24 The *appellant* submits that, in using the term "shall", Article 10 of the SPC Regulation requires national patent offices to grant an SPC in cases where all the conditions of the SPC Regulation are met, without any discretionary power. A positive duration of the term of the SPC is not among the substantive or procedural conditions found in Article 3 and Articles 7 to 9, respectively, of the SPC Regulation (reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraph 30, and the opinion of Advocate General Bot in that case, EU:C:2011:377, points 64 to 66). The application fulfils all the conditions and the appellant is therefore entitled to an SPC, regardless of the fact that the duration will be negative.

25 The appellant contends that, in determining the duration of the SPC, neither Article 13 nor any other provision of the SPC Regulation expressly or even implicitly prevents national patent offices from granting SPCs with a negative duration (reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraph 28). Moreover, a negative SPC does not infringe Article 13 of the SPC Regulation as it neither takes effect before the expiration of the basic patent nor extends the maximum period of protection of fifteen years.

26 In the appellant's view, Article 13 of the SPC Regulation should be interpreted independently from the Paediatric Regulation. The SPC Regulation is in itself a sufficient legal basis to allow SPCs with a negative duration. Although negative SPCs had no purpose at the time of adoption of the SPC Regulation, there is nothing to suggest that negative SPCs would be invalid if granted. The Paediatric Regulation did not amend the rules on SPCs, it simply added rules on paediatric extensions. By doing so, the Paediatric Regulation gave a purpose to negative SPCs but it did not trigger their validity.

27 The appellant argues that the forthcoming incorporation of the Paediatric Regulation in the EEA Agreement and its subsequent transposition into Icelandic law gave the appellant a reason to apply for an SPC, as it is a prerequisite for a paediatric extension. The respondent should have granted the negative SPC, as it could not reasonably exclude that such an SPC would have a purpose in the future. Having regard to Article 3 EEA, the respondent should not have rejected the appellant's application for an SPC since it could encroach upon individual rights under EEA law. Refusing to grant a negative SPC to the appellant and thereby denying compensation for the paediatric studies conducted as required by the Paediatric Regulation, would unfairly tip the balance struck in that regulation between investments and incentives. The unfairness is further strengthened by the fact that the granting of a negative SPC would cause no harm to any third party.

28 At the hearing, the appellant stated that it is in the interest of the health of children to have an SPC extension, as this provides an incentive for conducting paediatric research. A paediatric extension can, however, only be granted if an SPC exists. Therefore, in the view of the appellant, it is in the interests of children to have a negative SPC issued. If a negative SPC is not issued, then no extension can be granted and there is no incentive to conduct the relevant research.

29 The *respondent* submits that the SPC Regulation cannot be interpreted in isolation to mean that an SPC of negative duration may be issued under Article 13. Moreover, given the provisions on the entry into force of the Paediatric Regulation, the respondent questions whether a paediatric extension could be applied for or granted even in the EU before the entry into force of the Paediatric Regulation on 26 January 2009. The respondent's refusal in 2009 to grant a negative SPC, as well as the Board of Appeal's rejection in 2015 of the appellant's complaint, are in accordance with the applicable EEA law.

30 The respondent acknowledges that Article 13 of the SPC Regulation does not mention a positive duration of the SPC as a condition, as also noted by the ECJ in *Merck Sharp & Dohme*. However, the ECJ held that the provisions of the SPC Regulation must be interpreted in light of the overall scheme and objectives of the system of which they are a part (reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraphs 28 to 33, and to the judgments in *Hässle*, C-127/00, EU:C:2003:661, paragraph 55, 56 and 61, and *AHP Manufacturing*, C-482/07, EU:C:2009:501, paragraphs 30 and 35). One of the objectives of the SPC Regulation, as reflected in the eighth and ninth recitals in its

preamble, is to balance all the interests at stake in the pharmaceutical sector. Therefore, Article 13 provides that an SPC may not be granted for a period exceeding five years, and the exclusivity afforded may not exceed an overall maximum of fifteen years.

31 The respondent observes that the overall scheme and system of protection of industrial property in the EU encompasses the Paediatric Regulation. In the respondent's view, it is clear from the ECJ's judgment and the Advocate General's opinion in *Merck Sharp & Dohme* that they interpreted Article 13 of the SPC Regulation in conjunction with Article 36 of the Paediatric Regulation. Read together, these provisions conferred an exclusivity period of a maximum of fifteen years and six months, and therefore an SPC could not be refused by reason only of the fact that it is of negative duration (reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraphs 25, 37, 39 and 40, and the opinion of Advocate General Bot in that case, points 67 to 70).

32 The respondent draws attention to the fact that the Paediatric Regulation was not part of the EEA Agreement at the time of the processing of the SPC application in Iceland. In its view, it was thus not part of the overall scheme and objectives of the system in the EEA at that time. The application for a negative SPC was therefore correctly rejected by the respondent and the Board of Appeal.

33 The respondent submits that neither the principles of homogeneity and loyalty nor any other general principle of EEA law supports an interpretation of Article 13 of the SPC Regulation to the effect that it incorporates rules that have not been made part of the EEA Agreement. Therefore, pending the entry into force of Joint Committee Decision No 92/2017, the Paediatric Regulation cannot be relied upon, neither to support a particular interpretation of the SPC Regulation nor in an assessment of the overall scheme of which the SPC Regulation forms part.

34 The respondent submits further that individuals or economic operators cannot have any legitimate expectations under the EEA Agreement related to rules that have not been incorporated. On the contrary, it would undermine the principle of legal certainty and legitimate expectations if national authorities or the Court were to apply in their reasoning provisions of EU law that have not been incorporated in the EEA Agreement. A lack of swift incorporation cannot be remedied by the Court adopting a progressive interpretation of EEA law.

35 Upon a question from the bench as to the relevance of public health considerations in general and the availability of paediatric medicine, more specifically whether a progressive or a conservative interpretation of the SPC Regulation would be preferable in this regard, the respondent maintains that the answer is not clear since it involves different interests that need to be balanced. On the one hand, pharmaceutical companies should be rewarded for the efforts they put into research. This is the rationale behind the old and the new SPC Regulations. However, on the other hand, the question also raises competition issues: the

sole right of patent holders results in their exclusive control of access to the relevant medicine, which usually leads to higher prices on the market. Conversely, prices of medicine are commonly lower when the exclusive right expires. The market, or, in this case, children, are thus not deprived of the medicine in question. It is only the pharmaceutical company that may be deprived of compensation.

36 The *Norwegian Government* submits that the ECJ's finding in *Merck Sharp & Dohme* allowing for the granting of a negative SPC was based on a joint reading of the SPC Regulation and the Paediatric Regulation. No clear conclusions were set out with respect to whether the SPC Regulation alone would provide a legal basis for issuing a negative SPC. In the Norwegian Government's view, a joint reading cannot be applied in the EEA context until the Paediatric Regulation has been incorporated into the EEA Agreement. Such a reading cannot be justified by the principle of homogeneity. Hence, pending such incorporation, the question of whether a negative SPC can be issued must be determined solely on the basis of the SPC Regulation.

37 The Norwegian Government observes that the ECJ in *Merck Sharp & Dohme* found nothing in the wording of the SPC Regulation to suggest that negative SPCs are necessarily precluded. The positive duration of an SPC is not among the conditions for obtaining it. While a negative SPC serves no purpose in itself, it may be of interest to the holder of the SPC if a possibility of extension exists or will be introduced in the future (reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraphs 28, 30 and 35).

38 In view of the uncertainty attached to the interpretation of the SPC Regulation and the exceptional situation in the case at hand, where the appellant's interest in an SPC will not materialise until the patent expires, the Norwegian Government submits that it may be reasonable to regard negative SPCs as not necessarily precluded under the SPC Regulation, even if the SPC serves no purpose in the EFTA States until after the incorporation of the Paediatric Regulation.

39 *ESA* submits that Article 13 of the SPC Regulation can be interpreted independently from the Paediatric Regulation. In *Merck Sharp & Dohme*, the ECJ found that nothing in the wording of Article 13 or any other provision of the SPC Regulation suggests that it necessarily precludes a negative SPC (reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraph 28). This interpretation of the SPC Regulation is on its own sufficient as a basis for the conclusion that negative SPCs are permitted. Furthermore, a positive duration is not among the conditions for obtaining an SPC (reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraph 30) and Article 10 of the SPC Regulation states that an SPC shall be granted where the conditions are met. The SPC Regulation therefore necessarily envisages the issuing of SPCs of zero or negative duration.

40 ESA submits that the question of whether an SPC of negative or zero duration serves a purpose is irrelevant for determining whether it can be issued. This is also supported by the

ECJ in *Merck Sharp & Dohme*, where the answer was formulated to apply to all SPCs of zero or negative duration, rather than only to SPCs with a negative duration of less than six months.

41 ESA contends that, in light of the fundamental aims of the EEA Agreement, Article 13 of the SPC Regulation should receive the same interpretation within the EFTA States as in the EU, irrespective of the specific reasoning underpinning the particular interpretation. In any event, a national authority that has a choice between several interpretations should opt for the interpretation that is most closely aligned with the interpretation followed in the EU.

42 In ESA's view, Article 3 EEA obliges the EEA States to refrain from taking measures liable to compromise seriously the result prescribed by an EU legal act where it is clear that the act will be incorporated into the EEA Agreement and made part of the internal legal order of the EFTA States. It is therefore incumbent on national authorities not to jeopardise the possibility under the Paediatric Regulation of obtaining a paediatric extension by refusing to grant negative SPCs. Furthermore, ESA states that, due to the principle of conform interpretation, the national court is bound to interpret the SPC Regulation in line with the Paediatric Regulation.

43 The *Commission* observes that the question of whether an SPC can be granted with a zero or negative duration did not arise before the introduction of the paediatric extension, as there was simply no use for a negative SPC before that point in time. This amendment, introduced by the Paediatric Regulation, gave negative SPCs a purpose and therefore triggered applications for such SPCs.

44 The Commission submits that the reasoning contained in *Merck Sharp & Dohme* was based primarily on an analysis of the SPC Regulation as such (reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraphs 28, 30 and 40). In its view, there is nothing to suggest that this reasoning should be affected by the existence or absence of the paediatric extension. The fact that an SPC of negative or zero duration will have no practical use in the EFTA States prior to the incorporation of the Paediatric Regulation in EEA law, does not change the underlying legal analysis of the basic conditions for entitlement to an SPC. Even if the benefit of a negative SPC may only materialise later in time via the paediatric extension, it is itself of value precisely because it grants access to that additional protection. At the hearing, the Commission argued that the ECJ in *Merck Sharp & Dohme* did not limit its conclusion to negative SPCs that may have a useful effect, which means that negative SPCs may be granted regardless of whether the negative duration is shorter or longer than six months.

Findings of the Court

Preliminary remarks

45 By its question, the national court asks, in essence, whether an SPC of negative duration may be granted pursuant to the SPC Regulation. An SPC of negative duration refers to an SPC for a medicinal product where the period that has elapsed between the date on which the basic patent application was lodged and the date of the first marketing authorisation in the EEA is less than five years.

46 The possibility of applying for an SPC has been available in the EEA since the incorporation of the SPC Regulation into the EEA Agreement in 1994. The SPC Regulation is intended to provide an adequate period of effective protection of a basic patent by permitting the holder to enjoy an additional period of exclusivity after the expiry of that patent. This protection is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first marketing authorisation in the EEA was granted (see Case E-16/14 *Pharmaq* [2015] EFTA Ct. Rep. 212, paragraph 50).

47 In this regard, the Court notes, that pursuant to the first recital in the preamble to the SPC Regulation, pharmaceutical research plays a decisive role in the continuing improvement in public health. Furthermore, pursuant to the ninth recital in the preamble to the SPC Regulation, all the interests at stake, including those of public health should be taken into account. Accordingly, it must be recalled that the fundamental objective of the SPC Regulation, is to ensure sufficient protection to encourage pharmaceutical research (compare *Merck Sharp & Dohme*, cited above, paragraph 31).

48 In 2006, the Paediatric Regulation was adopted in the EU. That regulation amended the SPC Regulation and made the paediatric extension possible. This extension entails an additional period of protection of six months for an existing SPC.

49 Joint Committee Decision No 92/2017, which incorporates both the Paediatric Regulation and the new SPC Regulation has not entered into force. In any case, the contested decision of the Board of Appeal was already adopted on 9 September 2015. The question raised by the referring court must thus be answered on the basis of EEA law as it stood at that point in time (compare *Merck Sharp & Dohme*, cited above, paragraphs 23 and 24).

Duration of SPCs under the SPC Regulation

50 There are no provisions in the SPC Regulation explicitly regulating an SPC of negative duration. Article 13(1) lays down the rules on the duration of the certificate. The provision states that the duration shall equal the period between the date of the application for the basic patent and the date of the first marketing authorisation reduced by a period of five

years. Nothing in the wording of that provision, or in any other provision of the SPC Regulation, suggests that it precludes an SPC of negative duration (compare *Merck Sharp & Dohme*, cited above, paragraph 28).

51 Furthermore, Article 3 of the SPC Regulation sets out the conditions for obtaining a certificate. That provision does not contain a requirement for the positive duration of an SPC. Similarly, there is no such requirement in the procedural conditions laid down in Articles 7 to 9. Consequently, there is nothing in the overall scheme of the SPC Regulation indicating that the positive duration of an SPC is a prerequisite for obtaining such a certificate (compare *Merck Sharp & Dohme*, cited above, paragraph 30).

52 Moreover, Article 10(1) of the SPC Regulation states that where the application for an SPC and the product to which it relates meet the conditions listed in the SPC Regulation, the competent authority shall grant the certificate. More specifically, Article 10(2) to (5), which regulate the basis on which an application should be rejected, do not list a negative duration among the reasons for refusal. The SPC Regulation thereby not only allows for the issuing of a negative SPC, it requires the competent authorities in the EEA to issue an SPC where the conditions for granting the certificate are fulfilled.

53 The Court therefore finds that the grant of an SPC of negative duration is permissible under the SPC Regulation and that a competent authority cannot reject an application merely because an SPC's duration is not positive.

54 It may be added that this conclusion is consistent with the objective of the SPC Regulation of striking a balance between all the interests at stake in the pharmaceutical sector. It follows from the eighth recital in the preamble to the SPC Regulation that the duration of an SPC should be such as to provide adequate effective protection. For that purpose, the holder of a basic patent and an SPC should enjoy an overall maximum of fifteen years of protection from the time of the first marketing authorisation. Furthermore, Article 13(2) of the SPC Regulation states that the SPC cannot be granted for a period exceeding five years. An SPC of negative duration does not exceed either of these limitations.

55 The answer to the question referred must be that the SPC Regulation permits the issuing of a supplementary protection certificate where the period that has elapsed between the date on which the basic patent application was lodged and the date of the first marketing authorisation in the EEA is less than five years. This result is not affected by the fact that the Joint Committee Decision incorporating the Paediatric Regulation and the new SPC Regulation into the EEA Agreement has not entered into force.

IV Costs

56 The costs incurred by the Norwegian Government, ESA and the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are a step

in the proceedings pending before the national court, any decision on costs for the parties to those proceedings is a matter for that court.

On those grounds,

THE COURT

in answer to the question referred to it by the Supreme Court of Iceland (*Hæstiréttur Íslands*) hereby gives the following Advisory Opinion:

> **Regulation (EEC) No 1768/92 permits the issuing of a supplementary protection certificate where the period that has elapsed between the date on which the basic patent application was lodged and the date of the first marketing authorisation in the EEA is less than five years. This result is not affected by the fact that the Joint Committee Decision incorporating Regulation (EC) No 1901/2006 and Regulation (EC) No 469/2009 into the EEA Agreement has not entered into force.**

Carl Baudenbacher Per Christiansen Páll Hreinsson

Delivered in open court in Luxembourg on 21 December 2017.

Gunnar Selvik
Registrar

Carl Baudenbacher
President