REPORT FOR THE HEARING

in Case E-5/17

REQUEST to the Court pursuant to 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 concerning the creation of a supplementary protection certificate for medicinal products.

I Introduction

1. By a letter of 15 June 2017, registered at the Court on 19 June 2017, the Supreme Court of Iceland (*Hæstiréttur Íslands*) made a request for an advisory opinion in a case pending before it between Merck Sharp & Dohme Corp. ("the appellant") and the Icelandic Patent Office ("IPO" or "the respondent").

2. The case before the referring court concerns the question whether Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1) ("the SPC Regulation") permits the issuing of a supplementary protection certificate ("SPC") when the period 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 would entail that the duration of the certificate would be negative.

II Legal background

EEA law

3. 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.

4. Article 103 of the EEA Agreement 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

5. 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 the SPC Regulation in the EEA Agreement by inserting it as point 6 in Annex XVII to the Agreement. The SPC Regulation provides for the granting of an 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.

6. In the European Union, 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.

7. Joint Committee Decision No 92/2017 of 5 May 2017 incorporates the Paediatric Regulation into the EEA Agreement by inserting it as point 15zr in Annex II to the Agreement. By the same decision, the new SPC Regulation replaces 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 have been indicated by Iceland and Norway. The six month period, referred to in Article 103(2) EEA, will expire on 5 November 2017.

8. The third and the seventh to ninth recitals in the preamble to the SPC Regulation read:

> *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;*

9. Article 3 of the SPC Regulation reads:

> *Conditions for obtaining a certificate*
>
> *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.

10. Articles 7 to 9 of the SPC Regulation contain requirements concerning the content and the lodging of the application for an SPC. The Paediatric Regulation amends these provisions to accommodate for the application of a paediatric extension.

11. Article 10(1) of the SPC Regulation reads:

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.

12. The Paediatric Regulation adds a sixth paragraph to Article 10 of the SPC Regulation, stating that inter alia the first paragraph of that article shall apply mutatis mutandis to the application for an extension of the duration.

13. Article 13 of the SPC Regulation reads:

Duration of the certificate

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.

14. The Paediatric Regulation adds the following paragraph to Article 13 of the SPC Regulation:

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.

15. Article 36(1) of the Paediatric Regulation reads:

> *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 [the SPC Regulation]*.

16. According to Article 36(4) of the Paediatric Regulation, the first paragraph of that article shall apply to products that are protected by an SPC under the SPC Regulation, or under a patent which qualifies for the granting of the SPC.

National law

17. The SPC Regulation is incorporated into Icelandic law by virtue of Article 65a of the Patents Act No 17/1991 (*lög 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 Patents Act and shall have the force of law in Iceland.

III Facts and procedure

18. The appellant, Merck Sharp & Dohme Corp., 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, and the application was granted on 15 March 2007.

19. On 21 March 2007, the appellant was granted a marketing authorisation throughout the European Union for the medicinal product Januvia (Sitagliptin) for the improvement of the glycaemic control for adult patients with type 2 diabetes. A corresponding marketing authorisation was subsequently issued in Iceland.

20. On 19 September 2007, the appellant filed an application for an SPC on the basis of Icelandic Patent No 2218. 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. Due to the calculation rules in Article 13 of the SPC Regulation, which prescribes for a reduction of five years in the period at issue, any SPC granted would 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 was to allow for an application for a paediatric extension at a later stage.

21. On 3 April 2009, the respondent, the Icelandic Patent Office, rejected the application for an SPC on the basis that the duration of the SPC would be negative. It was considered incompatible with the purpose of the Patents Act and the SPC Regulation to grant an SPC with a negative duration. The respondent stated that the Paediatric Regulation was not

relevant since it had neither been incorporated into the EEA Agreement nor into Icelandic law.

22. 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 examination by the Board of Appeal was deferred until the delivery of the judgment by the Court of Justice of the European Union ("ECJ") in a case deemed similar by the appellant.

23. 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 would be negative.

24. By a decision of 9 September 2015, the Board of Appeal upheld the respondent's decision of 3 April 2009.

25. The appellant brought the decision of the Board of Appeal to Reykjavík District Court (*Héraðsdómur Reykjavíkur*), seeking the annulment of the decision and a recognition 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.

26. On 12 July 2016, the appellant appealed the District Court's judgment 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 on 19 June 2017.

27. 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 issue 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 has 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?**

IV Written observations

28. In accordance with Article 20 of the Statute of the Court and Article 97 of the Rules of Procedure, written observations have been received from:

- the appellant, represented by Jóna Björk Helgadóttir, Supreme Court Attorney;
- 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.

V Summary of the arguments submitted

The appellant

29. 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. Article 3 contains the substantive conditions, whereas the procedural conditions are found in Articles 7 to 9. A positive duration of the term of the SPC is not among those conditions.[1] The appellant's application fulfils all the conditions and is therefore entitled to an SPC, regardless of the fact that the duration will be negative.

30. The appellant contends that, in determining the duration of the SPC, neither Article 13 nor any other provision of the SPC Regulation does expressly or even implicitly prevent national patent offices from granting SPCs with a negative duration.[2] Moreover, a negative SPC does not infringe Article 13 of the SPC Regulation as it does not take effect before the expiration of the basic patent and does not afford more than the maximum of 15 years of protection.

---

1 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.

2 Reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraph 28.

31. In the appellant's view, Article 13 of the SPC Regulation should be interpreted independently from the Paediatric Regulation. The SPC Regulation is 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.[3] 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.

32. 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 adopted the negative decision since it could encroach upon individual rights under EEA law. The appellant notes that in October 2016, that is before the transposition of the Paediatric Regulation into Norwegian law, the Norwegian Industrial Property Office ("NIPO") formally informed the appellant that its application for a negative SPC for Januvia in Norway fulfilled the requirements. Moreover, several national patent offices in the EU granted a negative SPC even before the ECJ's ruling in *Merck Sharp & Dohme*.

33. The appellant submits that it has been diligently conducting the clinical studies included in the paediatric investigation plan for Sitagliptin for several years. Yet it is denied a paediatric extension in Iceland since it does not hold an Icelandic SPC to be extended. Pharmaceutical companies should not suffer adverse consequences for the delay in incorporating the Paediatric Regulation in the EEA Agreement. Refusing to grant a negative SPC to the appellant and thereby denying compensation for the paediatric studies conducted on Januvia, would unfairly tip the balance struck in the Paediatric 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.

34. The appellant proposes that the Court should give the following answer to the question referred:

> *A[n] [SPC] under [the SPC Regulation] can 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, irrespective of whether [the Paediatric Regulation] and [the new SPC Regulation] have been incorporated into the [EEA Agreement]*.

---

[3] Reference is made to the Commission's Record of the Meeting of National Experts held on 3 February 1995.

The respondent

35. The respondent submits that the SPC Regulation cannot be interpreted in isolation to mean that an SPC of a negative duration can 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 before 26 January 2009 even in the EU. 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 applicable EEA law. The respondent argues that the same approach has been taken in Norway by NIPO.

36. 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 it is a part.[4] 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.

37. 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 interpret Article 13 of the SPC Regulation in conjunction with Article 36 of the Paediatric Regulation. Read in conjunction, these provisions conferred an exclusivity period of maximum 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.[5]

38. The respondent draws attention to the fact that the Paediatric Regulation was not part of the EEA Agreement at the time of 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 the time. The application for a negative SPC was therefore correctly rejected by the respondent and the Board of Appeal. The respondent further maintains that, even if the Paediatric Regulation had been applicable, the appellant has not substantiated that the conditions for a paediatric extension would be fulfilled.

39. 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

---

[4] Reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraphs 28 to 33. Reference is furthermore made to the judgments in *Hässle*, C-127/00, EU:C:2003:661, paragraph 55 and *AHP Manufacturing*, C-482/07, EU:C:2009:501, paragraphs 56 to 61.

[5] Reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraphs 25, 37, 39 and 40, and Advocate General Bot's opinion in that case, points 67 to 70.

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.

40. 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.

41. The respondent proposes that the Court should give the following answer to the question referred:

> *In light of the fact that [the Paediatric Regulation] and [the new SPC Regulation] have not yet been fully incorporated into the EEA Agreement and had not been incorporated at the time of the application in 2007 nor the time of the decisions of the Icelandic authorities, and in light of the objectives of [the SPC Regulation] and the overall scheme and objectives of the system of which it is a part under the EEA Agreement, Article 13 of the [SPC] Regulation is to be interpreted to mean that a[n] [SPC] for a medicinal product of a negative duration (when 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) cannot be issued by the competent national authorities in circumstances such as those in the case.*

The Norwegian Government

42. The Norwegian Government notes that two applications for a negative SPC are pending before NIPO, of which one concerns the appellant and is parallel to the application that was rejected by the respondent. The application was filed in 2007. Since 2009, it has been expected that the Paediatric Regulation would, at some point, be incorporated in the EEA Agreement. The proceedings before NIPO were therefore stayed awaiting further developments. In October 2016, when a draft Joint Committee decision had been approved at EFTA Subcommittee level and submitted to the EU, NIPO notified the appellant that the conditions for issuing a negative SPC were considered to be fulfilled. However, the application was left pending until the entry into force of the legislation giving the Paediatric Regulation and the new SPC Regulation the force of law in Norway. That legislation entered into force 1 September 2017.

43. The Norwegian Government submits that the ECJ's finding in *Merck Sharp & Dohme* that a negative SPC could be granted, 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.

44. In the Norwegian Government's view, there can be no question of applying a joint reading 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 whether a negative SPC can be issued must be determined solely on the basis of the SPC Regulation.

45. The Norwegian Government observes that the ECJ in *Merck Sharp & Dohme* found nothing in the wording of the SPC Regulation suggesting that negative SPCs are necessarily precluded under the SPC Regulation. 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.[6]

46. 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.

47. The Norwegian Government proposes that the Court should give the following answer to the question referred:

> *Under [the SPC Regulation], the grant of a[n] [SPC] for a medicinal product is in exceptional circumstances not precluded 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 authorization to place the product on the market in the [EEA] is less than five years.*

ESA

48. 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.[7] This could, on its own, have served as the basis for the conclusion that negative SPCs are permitted. Furthermore, as a positive duration is not

---

[6] Reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraphs 28, 30 and 35.

[7] Ibid., paragraph 28.

among the conditions for obtaining an SPC,[8] the SPC Regulation necessarily envisages the issuing of SPCs of zero or negative duration.

49. ESA submits that the question 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 of a negative duration of less than six months.

50. 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.

51. In ESA's view, these considerations become of even greater force once it is clear that the provisions of EU law at issue will be incorporated into the EEA Agreement and made part of the internal legal order of the EFTA States. An analogy may be made to the situation in the EU after the adoption of a directive. Although the Member States are not obliged to adopt any measures before the end of the period prescribed for transposition of the directive, they must refrain from taking measures liable seriously to compromise the result prescribed by the directive.[9] Reference is also made to Article 3 EEA. It is therefore incumbent on national authorities not to jeopardise the possibility of obtaining a paediatric extension by refusing to issue negative SPCs.

52. Finally, ESA refers to the principle of conform interpretation, which arises on the day the respective legal act is made part of the EEA Agreement.[10] In ESA's view, this is in no way affected by the fact that constitutional requirements were invoked, which merely delays the binding effect of Joint Committee Decision No 92/2017. Therefore, ESA submits that, as matters already stand, the national court is in any event bound to interpret the SPC Regulation in line with the Paediatric Regulation.

53. ESA proposes that the Court should give the following answer to the question referred:

> *Article 13 of [the SPC Regulation] must be interpreted as meaning that medicinal products can be the object of the grant of a[n] [SPC] where the period that has*

---

8 Ibid., paragraph 30.

9 Reference is made to the judgment in *Inter-Environnement Wallonie*, C-129/96, EU:C:1997:628, paragraph 45.

10 Reference is made to Case E-3/15 *Liechtensteinische Gesellschaft für Umweltschutz* [2015] EFTA Ct. Rep. 512, paragraph 74.

elapsed between the date of lodging the basic patent application and the first marketing authorisation in the [EEA] is less than five years.

The Commission

54. The Commission observes that the question 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.

55. The Commission submits that the reasoning contained in *Merck Sharp & Dohme* was based primarily on an analysis of the SPC Regulation as such.[11] 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 can only materialise later in time via the paediatric extension, it is itself of value precisely because it grants access to that additional protection.

56. The Commission proposes that the Court should give the following answer to the question referred:

[The SPC Regulation] should be interpreted as meaning that a medicinal product 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 EEA is less than five years.

Per Christiansen
Judge-Rapporteur

[11] Reference is made to the judgment in *Merck Sharp & Dohme*, cited above, paragraphs 28, 30 and 40.