JUDGMENT OF THE COURT

9 April 2015*

(Veterinary medicinal products – Supplementary protection certificate – Regulation (EEC) No 1768/92 – Concept of "first authorisation to place a product on the market" in the European Economic Area – Active ingredient)

In Case E-16/14,

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 Oslo tingrett (Oslo District Court), in the case between

Pharmaq AS

and

Intervet International BV,

concerning the interpretation of Articles 2, 3 and 4 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, and Páll Hreinsson (Judge-Rapporteur), Judges,

Registrar: Gunnar Selvik,

having considered the written observations submitted on behalf of:

- Pharmaq AS ("the Plaintiff" or "Pharmaq"), represented by Lars Erik Steinkjer, advokat, on behalf of Gunnar Meyer, advokat, and Ida Gjessing, advokat;

- Intervet International BV ("the Defendant" or "Intervet"), represented by Kristine Schei, advokat, and Eirik W. Raanes, advokat;

∗ Language of the request: Norwegian

- the Government of the United Kingdom, represented by Julia Kraehling, the Cabinet Office European Law Division, Treasury Solicitor's Department, acting as Agent, and by Nicholas Saunders, Barrister;

- the EFTA Surveillance Authority ("ESA"), represented by Xavier Lewis, Director, and Auður Ýr Steinarsdóttir, Officer, Department of Legal & Executive Affairs, acting as Agents;

- the European Commission ("the Commission"), represented by Friedrich Wenzel Bulst and Julie Samnadda, members of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

having heard oral argument of the Plaintiff, represented by Ida Gjessing and Penny Gilbert, Advocate; the Defendant, represented by Eirik W. Raanes and Geneviève Michaux, Attorney; ESA, represented by Xavier Lewis and Auður Ýr Steinarsdóttir, and the Commission, represented by Julie Samnadda and Friedrich Wenzel Bulst,

gives the following

Judgment

I Legal background

EEA law

1 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") is, with certain adaptations, made part of the EEA Agreement by EEA Joint Committee Decision No 7/1994 of 21 March 1994 amending Protocol 47 and certain Annexes to the EEA Agreement (OJ 1994 L 160, p. 1), under point 6 of Annex XVII to the Agreement. In the European Union ("EU"), the SPC Regulation has been repealed and replaced 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). As the EEA Joint Committee has not yet incorporated Regulation (EC) No 469/2009 into the EEA Agreement, the SPC Regulation remains applicable in the EFTA pillar. However, the relevant provisions of the two regulations are substantially identical.

2 The preamble to the SPC Regulation contains the following recitals:

> *[2] 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;

[3] 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;

...

[5] Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;

…

[7] 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 authorisation has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;

[8] 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 exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community;

[9] Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should 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;

3 Article 1 of the SPC Regulation sets out the relevant definitions, including the following terms:

(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be

administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

(c) 'basic patent' means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

...

4 Article 2 of the SPC Regulation provides as follows:

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 65/65/EEC or Directive 81/851/EEC may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

5 Article 3 of the SPC Regulation reads as follows:

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

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

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with 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 authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

6 Article 4 of the SPC Regulation provides as follows:

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

7 Article 7(1) of the SPC Regulation provides as follows:

> *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.*

8 Article 13 of the SPC Regulation provides as follows:

> *1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.*
>
> *2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.*

9 Article 15(1) of the SPC Regulation states that:

> *The certificate shall be invalid if*
>
> *(a) it was granted contrary to the provisions of Article 3;*
>
> *(b) the basic patent has lapsed before its lawful term expires;*
>
> *(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.*

10 Article 7 of the EEA Agreement provides as follows:

> *Acts referred to or contained in the Annexes to this Agreement or in decisions of the EEA Joint Committee shall be binding upon the Contracting Parties and be, or be made, part of their internal legal order* ...

11 Article 23 of the EEA Agreement provides for specific provisions and arrangements including:

> *(a) Protocol 12 and Annex II in relation to technical regulations, standards, testing and certification; ...*

12 Article 65(2) of the EEA Agreement provides that:

> *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.*

13 It follows from point 8 of Protocol 1 to the EEA Agreement that for the purposes of the EEA Agreement, Articles 2 and 13 of the SPC Regulation are to be read as if the references to "the Community" were replaced by "the EEA".

14 Point 6 of Annex XVII to the EEA Agreement provides that Article 3(b) of the SPC Regulation, for the purposes of the EEA Agreement, shall be read with the following adaptation:

> *a valid authorisation 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; for the purpose of this subparagraph and the Articles which refer to it, an authorization to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC as appropriate.*

15 Points 15p and 15zb of Chapter XIII of Annex II to the EEA Agreement refer, respectively, to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1) ("Directive 2001/82") and to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1). Directive 2001/82 replaces Directive 81/851/EEC. Consequently, when the SPC Regulation refers to authorisations pursuant to Directive 81/851/EEC, this must be read as a reference to Directive 2001/82 as regards products authorised under that directive.

16 Article 5(1) of Directive 2001/82, as amended, provides the following as regards marketing authorisations for veterinary medicinal products:

> *No veterinary medicinal product may be placed on the market of a Member State unless a marketing authorisation has been granted by the competent authorities of that Member State in accordance with this Directive or a marketing authorisation has been granted in accordance with Regulation (EC) No 726/2004.*
>
> *When a veterinary medicinal product has been granted an initial authorisation in accordance with the first subparagraph, any additional species, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions, shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 13(1).*

17 The first paragraph of Article 8 of Directive 2001/82, as amended, provides:

> *In the event of serious epizootic diseases, Member States may provisionally allow the use of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the Commission of the detailed conditions of use.*

18 Article 26(3) of Directive 2001/82 reads as follows:

> *In exceptional circumstances, and following consultation with the applicant, the authorisation may be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning the safety of the veterinary medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken. Such authorisations may be granted only for objective, verifiable reasons. Continuation of the authorisation shall be linked to the annual reassessment of these conditions.*

National law

19 In Norway, Directive 2001/82 has been implemented by the Medicines Act of 4 December 1992 No 132 (*lov 4. desember 1992 nr. 132 om legemidler*) and the Medicines Regulation of 18 December 2009 No 1839 (*forskrift 18. desember 2009 nr. 1839 om legemidler*).

20 The individual provisions that allow for the supply of medicinal products without marketing authorisation following an application from a physician, dentist, veterinarian or fish health biologist are laid down in Sections 2-5 to 2-7 of the Medicines Regulation. In the case of medicinal products for aquatic animals, the applicable provision is Section 2-7 (Section 2-6 if the applicant is a veterinarian).

21 Section 2-7 provides for authorisations known as "special approval exemptions" on application from a fish health biologist. Such authorisations exempt the medicinal product from the requirement for a marketing authorisation. The provision reads as follows:

> *The State Medicines Agency may, on application from a fish health biologist stating the grounds and subject to the applicant being personally liable, grant exemption from the requirement for marketing authorisation. Exemption can be granted for medicinal products to be dispensed in one's own practice to aquatic animals, with the exception of aquatic mammals, which are under the applicant's supervision. Exemption can be granted for a certain quantity or for a limited period of time of maximum one year.*
>
> *Exemption pursuant to the first paragraph for medicinal products for use in foodstuff-producing animals may only be granted for medicinal*

products that have been granted marketing authorisation in at least one EEA State and that contain active ingredients the use of which is permitted pursuant to Regulation (EC) No 470/2009; see also Regulation (EU) No 37/2010 and the Norwegian Regulation of 30 May 2012 No 512 concerning limit values for pharmacological residue in foodstuffs of animal origin. This does not, however, apply to animal vaccines.

In the case of serious epidemic diseases, the State Medicines Agency may also grant exemption for medicinal products without marketing authorisation in any EEA State, if no suitable medicinal product with marketing authorisation is available.

22 Under Section 13-3 of the Medicines Regulation, advertising of medicinal products supplied under a special approval exemption is not permitted.

23 The first paragraph of Section 62a of the Patents Act No 9 of 15 December 1967 (*lov 15. desember 1967 nr. 9 om patenter*) implements the SPC Regulation as follows:

Annex XVII, item 6, to the Agreement establishing the European Economic Area [Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products with adaptations to the EEA Agreement] including the amendments and additions provided in Protocol 1 of the Agreement and elsewhere in the Agreement shall apply as statutory provisions.

II Facts and pre-litigation procedure

24 The case before Oslo tingrett concerns the validity and scope of a supplementary protection certificate ("SPC") granted to the Defendant in January 2014 pursuant to the relevant Norwegian legislation.

25 The parties to the proceedings are two companies, both of which have developed a vaccine against viral pancreatic disease ("PD") in salmonid fish. The Plaintiff's vaccine is based on a virus strain isolated from PD-infected salmon in Norwegian waters. That strain is the third, that is SAV-3, out of the six strains of Salmonid Alpha Virus ("SAV 1-6").

26 The Defendant has developed a vaccine based on an inactive virus, which is deposited in the European Collection of Cell Cultures with deposit no V94090731. The deposited strain is isolated from PD-infected salmon in Ireland. That virus strain is referred to as SAV-1. The vaccine has been awarded a European patent, as well as patents in the United Kingdom and Norway.

27 In a previous patent dispute between the parties, Norwegian courts have found that the Defendant's Norwegian patent covers any virus strain that causes PD in salmon, and that the Plaintiff's vaccine strain falls within the scope of the Defendant's patent.

28 During the years 2003 to 2011, the Defendant sold its vaccine, Norvax Compact PD, and delivered it to fish farmers in Norway under "special approval exemptions" under Section 2-7 of the Medicines Regulation. The Defendant supplied the vaccine in Ireland under a corresponding scheme known as AR16 licences. Such licences are issued pursuant to Regulation 16 of the European Communities (Animal Remedies) Regulations 2007 (Irish Statutory Instrument No 144/2007). Part III of that statutory instrument, which includes Regulation 16, is headed "Exceptional authorisation".

29 In 2005, the Defendant was granted a provisional marketing authorisation in the United Kingdom for a vaccine to combat PD in salmonid fish based on such a virus under the trademark Norvax Compact PD ("Norvax"). Eventually, the Defendant obtained a marketing authorisation in the United Kingdom on 10 August 2011 and in Norway on 18 August 2011, both for a period of five years.

30 The Defendant applied for an SPC in Norway on the basis of its Norwegian marketing authorisation. In accordance with that application, an SPC was granted to the Defendant in January 2014 for:

> *Salmonid pancreatic disease virus that, when injected intraperitoneally at a titre of 103.5 TCID50 into Atlantic salmon post-smolts held in sea water at 14°C causes the fish to develop symptoms of pancreatic disease, wherein*
>
> *a) said virus is the virus strain as deposited at ECACC under Deposit number V94090731 or closely related strains which share similar genotypic and/or phenotypic characteristics to said deposited virus strain and*
>
> *b) said virus reacts serologically with convalescent anti-FPDV antiserum or antiserum raised against the deposited virus strain V94090731 and*
>
> *c) said virus is in an inactive form.*

31 In the Norwegian SPC, the provisional marketing authorisation granted in the United Kingdom in 2005 is regarded as the first marketing authorisation in the EEA. Therefore, the validity of the SPC has been fixed until 2020, in accordance with Article 13(1) of the SPC Regulation. As it appears that the Norwegian basic patent expires in 2015, this gives about five years of supplementary protection.

32 By its action before Oslo tingrett, the Plaintiff seeks a declaration that the SPC is invalid or, alternatively, that the scope of protection is deemed not to include the Plaintiff's vaccine.

33 By a ruling of 27 May 2014, Oslo tingrett decided to seek an Advisory Opinion from the Court on the interpretation of Articles 2, 3 and 4 of the SPC Regulation.

34 By a letter of 16 June 2014, Oslo tingrett submitted the following questions to the Court:

1. *Concerning Article 2 of the SPC Regulation, has a product been placed on the market as a medicinal product in the EEA before it has been granted marketing authorisation in accordance with the procedure for administrative authorisation laid down in Directive 81/851/EEC (or Directive 2001/82/EC) when delivery of the product has taken place in accordance with*

   (i) "special approval exemptions" granted by the State Medicines Agency to veterinarians and fish health biologists pursuant to Section 3-6 or 3-7 of the Norwegian Regulation of 22 December 1999, alternatively Sections 2-6 or 2-7 of the Norwegian Regulation of 18 December 2009, or

   (ii) what are known as "AR 16 licences" granted by the Irish Department of Agriculture, Food and the Marine pursuant to the Irish Statutory Instrument No 144/2007 European Communities (Animal Remedies) Regulations 2007 part III "Exceptional authorisation", point 16?

2. *If question 1 is answered in the affirmative, is such a product outside the scope of the SPC Regulation and is an SPC granted on the basis of such a product therefore invalid?*

3. *Concerning the interpretation of Article 2 of the SPC Regulation, should a marketing authorisation granted for a veterinary medicinal product pursuant to Article 26(3) of Directive 2001/82 be deemed to constitute an administrative authorisation pursuant to Directive 81/851 (or Directive 2001/82) within the meaning of Article 2?*

4.

   (a) Do special approval exemptions pursuant to Section 3-6 or 3-7 of the Norwegian Medicines Regulations of 1999 (FOR-199-12-22-1559) or Section 2-6 or 2-7 of the Norwegian Medicines Regulations of 2009 (FOR-2009-12-18-1839) constitute valid authorisation to place the product on the market as a medicinal product within the meaning of Article 3(b)?

   (b) Do special approval exemptions pursuant to Section 3-6 or 3-7 of the Norwegian Medicines Regulations of 1999 (FOR-199-12-22-1559) or Section 2-6 or 2-7 of the Norwegian Medicines Regulations of 2009 (FOR-2009-12-18-1839) constitute a first authorisation to place the product on the market as a medicinal product in Norway within the meaning of Article 3(d)?

5. *When the medicinal product is a virus vaccine, can the scope of protection under the SPC cover not only the specific strain of the virus that is included in the medicinal product and covered by the basic patent, but also other strains of the virus that are covered by the basic patent?*

   In answering this question, is it of significance whether

(a) such other strains have an equivalent therapeutic effect to the virus strain included in the medicinal product or whether the therapeutic effect is not immediately equivalent?

(b) a medicinal product based on such other strain will have to be the subject of a separate marketing authorisation with requirements for documentation of safety and effect?

6. If an SPC has been granted with a product definition that is not strictly limited to the specific strain of the virus authorised to be placed on the market as a medicinal product,

(a) will such an SPC be valid, or

(b) will the SPC be valid; such, however, that the scope of protection pursuant to Article 4 does not extend beyond the specific virus strain authorised to be placed on the market as a medicinal product?

35 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 Questions 1 to 4

36 The essential element of Questions 1, 2 and 4 from Oslo tingrett is whether the existence of the "special approval exemptions" or licences granted by the Norwegian and Irish authorities is sufficient to preclude the grant of an SPC for Norvax, on the basis that the vaccine has already been "placed on the market as a medicinal product" between 2003 and 2011 within the meaning of Article 2 of the SPC Regulation by virtue of the special approval exemptions and licences in question.

37 The third question seeks to establish whether a marketing authorisation issued pursuant to Article 26(3) of Directive 2001/82 constitutes a marketing authorisation within the meaning of Article 2 of the SPC Regulation. As all these questions essentially relate to the interpretation of Article 2 of the SPC Regulation, it is appropriate to address them together.

Observations submitted to the Court

38 The Plaintiff argues that any product placed on the market before receiving a marketing authorisation falls outside the scope of the SPC Regulation – and is not eligible for an SPC – because the patent holder has not suffered any loss of its period of exclusivity. In support of this claim, the Plaintiff submits that the Defendant has already sold substantial volumes of Norvax to its customers, since 2003, on the basis of the Norwegian special approval exemptions and Irish AR16 licences and, since 2005, on the basis of a UK provisional marketing authorisation. None of these include the efficacy and safety testing required for

marketing authorisations pursuant to Directive 2001/82. The Plaintiff argues that the limitations involved under the Norwegian special approval exemptions did not affect the Defendant's ability to commercially exploit Norvax or to advertise it, as the Defendant was able to satisfy market demand even before the grant of the marketing authorisation in 2011 without suffering any loss of exclusivity.

39 This position is essentially supported by ESA, which argues that, if a product has been placed on the market in the EEA before a marketing authorisation is granted pursuant to the relevant directives, the product does not fall within the scope of Article 2 of the SPC Regulation and cannot be the subject of such a certificate. Consequently, if such a certificate is nonetheless granted, it must be deemed invalid. ESA submits that it goes against the purpose of the SPC Regulation to compensate the Defendant with an SPC for a delay in the placing of its vaccine on the market, when the Defendant has in fact been able to exploit its product commercially since the vaccine was first delivered on the market in 2003.

40 Having regard to the special approval exemption granted to the Defendant in Norway during the years from 2003 to 2011 and the AR16 licences in Ireland from 2003, ESA contends that the vaccine must be deemed to have been placed on the market in Norway and Ireland in 2003, that is before obtaining a marketing authorisation.

41 In the view of the Defendant, on the other hand, in order to be eligible for an SPC under Article 2 of the SPC Regulation, the decisive factor is not that the medicinal product is granted a marketing authorisation but that the medicinal product is subject to a marketing authorisation procedure, namely that the company invests in pharmaceutical research. The Defendant argues that the commercial exploitation of the medicinal product starts with the marketing authorisation, irrespective of the volume supplied or the revenues generated under the national exemption provided by the Norwegian special approval exemption.

42 This position is essentially supported by the Commission. It argues that making a product available under a licence pursuant to Article 8 of Directive 2001/82 does not constitute, for the purposes of Article 2 of the SPC Regulation, placement on the market prior to an administrative authorisation procedure.

43 Moreover, it is common ground between the Defendant, the Government of the United Kingdom and the Commission that disqualification of a product from the benefit of an SPC due to the granting of a licence would deter patent holders from making their products available in the crisis situation envisaged, inter alia, in the first paragraph of Article 8 of Directive 2001/82. This would undermine the public health considerations underlying the SPC Regulation.

44 As regards the effect of a provisional marketing authorisation issued under Article 26(3) of Directive 2001/82, the Plaintiff argues that such a measure does not constitute a marketing authorisation for the purposes of Article 2 of the SPC Regulation. Hence, all sales based on special approval exemptions and/or AR16

licences, irrespective of a provisional marketing authorisation being issued in the UK, must be regarded, for the purposes of Article 2 of the SPC Regulation, as having taken place before a marketing authorisation was obtained.

45 ESA essentially supports this position. It submits that, under Article 26(3) of Directive 2001/82, the product is not required to undergo safety and efficacy testing which, in ESA's view, is a necessary part of the procedure if it is to be regarded as an administrative authorisation.

46 Furthermore, the Plaintiff contends that the composition of the product subject to the UK provisional marketing authorisation differed in various elements, including its potency, from the final product approved with the full marketing authorisation. Thus, the Defendant cannot be regarded as having satisfied the requirement of safety and efficacy studies prior to obtaining the UK provisional marketing authorisation. For this reason, the UK provisional marketing authorisation cannot qualify as a marketing authorisation granted in accordance with Directive 2001/82 and hence the product lies outside of the scope of the SPC Regulation.

47 The Defendant contends that, pursuant to the case law of the Court of Justice of the European Union, a marketing authorisation must be defined as an unconditional right to place a medicinal product on the market immediately. In the Defendant's view, the provisional marketing authorisation granted under exceptional circumstances in the UK, based on national provisions transposing Article 26(3) of Directive 2001/82, constitutes a marketing authorisation for the purposes of that directive, as it is subject to some but not all requirements concerning safety and efficacy data and allows the holder to place and sell the medicinal product on the market immediately without any specific restriction.

48 In this regard, the Defendant argues that since it follows from case law that post-marketing conditions, such as those imposed in marketing authorisations under exceptional circumstances, are not relevant, a marketing authorisation granted in exceptional circumstances pursuant to Article 26(3) of Directive 2001/82 equals a marketing authorisation in every respect, provided that it meets all relevant substantive and procedural requirements set out in Directive 2001/82.

49 The Commission essentially agrees with the Defendant. It submits that the marketing authorisation granted pursuant to Article 26(3) of Directive 2001/82 grants an immediate and unconditional right to place the product on the market (albeit on a restricted market). However, at the same time, the applicant is obliged to introduce specific procedures relating to the medicinal product. Thus, a marketing authorisation granted under Article 26(3) of Directive 2001/82 constitutes a marketing authorisation within the meaning of Article 5(1) of the same Directive and therefore must be treated as such in the context of all provisions of the SPC Regulation.

Findings of the Court

50 It is apparent from the third and eighth recitals in the preamble thereto that 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 (compare, to that effect, Case C-631/13 *Forsgren*, judgment of 15 January 2015, published electronically, paragraph 33 and case law cited).

51 Directive 2001/82 provides for a harmonisation in the EEA of national authorisation procedures for veterinary medicinal products. Moreover, the SPC Regulation provides for a uniform solution at EEA level by creating an SPC which may be obtained for the holder of a national or European patent under the same conditions in each EEA State (compare Case C-322/10 *Medeva* [2011] ECR I-12051, paragraph 24). However, a marketing authorisation pursuant to Directive 2001/82 and an SPC on the basis of the SPC Regulation are only effective in the EEA State in which the marketing authorisation and the SPC is granted. Therefore, a separate marketing authorisation and potentially an SPC must be obtained in each EEA State in which a manufacturer wishes to place his product on the market and acquire the extended protection provided by an SPC (compare, to that effect, Case C-110/95 *Yamanouchi* [1997] ECR I-3251, paragraphs 24 and 26).

52 The first marketing authorisation in the EEA for a veterinary medicinal product is nevertheless relevant for the calculation of the duration of the SPC pursuant to Article 13(1) of the SPC Regulation. This applies regardless of the EEA State in which the SPC is granted. That provision ensures that the effective exclusivity period under the patent and the SPC never exceeds a total of 15 years calculated from the time the first marketing authorisation was granted in the EEA. Furthermore, it ensures that an SPC for a medicinal product comes to an end at the same moment in all EEA States where the SPC has been obtained, thereby providing for a certain degree of uniformity throughout the EEA in line with the fifth recital in the preamble to the SPC Regulation.

53 In order to give an answer which will be of use to the national court, it is necessary to consider, first, whether a product, such as Norvax at issue in the main proceedings, comes within the scope of the SPC Regulation, as defined in its Article 2. Then, the Court will address the interpretation of the conditions for obtaining an SPC pursuant to Article 3 of that regulation.

54 According to Article 2 of the SPC Regulation, any product protected by a patent in the territory of an EEA State and subject, prior to being placed on the market as a veterinary medicinal product, to an administrative authorisation procedure as

laid down in Directive 2001/82, may be the subject of an SPC under the terms and conditions provided for in the SPC Regulation.

55 It follows from Article 3(b) of the SPC Regulation and from Article 5(1) of Directive 2001/82 that the administrative authorisation procedure in question is the one referred to in Title III of Directive 2001/82 for obtaining a marketing authorisation. That procedure includes testing the safety and efficacy of the medicinal product, the results of which must accompany the application for marketing authorisation, in accordance with Article 12(3) of Directive 2001/82 (compare, to that effect, Case C-195/09 *Synthon* [2011] ECR I-7011, paragraph 43).

56 Accordingly, pursuant to Article 2 of the SPC Regulation, a product protected by a valid patent in the territory of the EEA State concerned is eligible for an SPC only if, before being placed on the EEA market as a veterinary medicinal product, it obtained a marketing authorisation pursuant to an administrative authorisation procedure as laid down in Directive 2001/82, including in particular safety and efficacy testing (compare Case C-617/12 *Astrazeneca*, order of 14 November 2013, published electronically, paragraph 47 and case law cited). This authorisation procedure includes authorisations granted in exceptional circumstances pursuant to Article 26(3) of Directive 2001/82, also set out in Title III of the Directive, which are made subject to a requirement for the applicant to introduce specific procedures, in particular concerning the safety of the veterinary medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken (see, for comparison, Annex I to Directive 2001/82, Title III, point 6).

57 In contrast, the supply of a medicinal product on the basis of the first paragraph of Article 8 of Directive 2001/82, according to which, in the event of serious epizootic diseases, EEA States may provisionally allow the use of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product, does not constitute an administrative authorisation procedure as specified in Article 2 of the SPC Regulation.

58 It must be kept in mind that the first paragraph of Article 8 constitutes an exemption to the authorisation scheme set out in Title III of Directive 2001/82. Thus, a provisional permission granted under the first paragraph of Article 8 does not require the same safety and efficacy testing as the procedure preceding a marketing authorisation and does not entitle the producer to market the product but only to supply it, to the extent necessary to combat the disease in question. Consequently, such supply does not generally constitute a placement on the market as a veterinary medicinal product for the purposes of Article 2 of the SPC Regulation.

59 In the present case, the parties disagree whether the Defendant was enabled in fact to place the product on the market under the “special approval exemptions” in Norway and “AR16 licences” in Ireland to an extent which is comparable to that under a marketing authorisation pursuant to Directive 2001/82. This conflict

arose, as the Defendant was allegedly able to supply its product from 2003 to 2011 in significant quantities.

60 Given the restrictions on the supply of a medicinal product under the first paragraph of Article 8 of Directive 2001/82, a permission granted on the basis of national provisions correctly implementing the first paragraph of Article 8 of Directive 2001/82 does not entail placement on the market within the meaning of Article 2 of the SPC Regulation. Whether the permissions granted in the present case are based on the first paragraph of Article 8 or Article 26(3) of Directive 2001/82 depends essentially on the assessment of facts in the national proceedings, which is a matter for the national court. Nevertheless, the Court notes that the national competent authorities must ensure that any exemption granted under the first paragraph of Article 8 of Directive 2001/82 remains limited to the provisional supply in the event of serious epizootic diseases and in the absence of a suitable medicinal product.

61 The Court will now proceed to assess the conditions for obtaining an SPC. Under Article 3 of the SPC Regulation, the grant of an SPC is subject to four cumulative conditions. An SPC can only be granted if, in the EEA State in which the application is submitted, the product is, first, protected by a basic patent in force at the date of the application and, second, has not already been the subject of an SPC. Third, that product must have been granted a marketing authorisation as a veterinary medicinal product which is still valid, in accordance with Directive 2001/82. Finally, that authorisation must be the first in relation to that product as a veterinary medicinal product (compare Case C-577/13 *Actavis Group*, judgment of 12 March 2015, published electronically, paragraph 27).

62 The questions from the national court relate to the conditions specified in points (b) and (d) of Article 3 of the SPC Regulation requiring that a valid, first authorisation to place the product on the market as a veterinary medicinal product has been granted in accordance with Directive 2001/82.

63 In paragraphs 54 to 60 of this judgment, the Court has indicated what may constitute a marketing authorisation pursuant to Directive 2001/82 for the purposes of Article 2 of the SPC Regulation. These findings equally apply to Article 3(b) and (d) of the SPC Regulation. Consequently, a marketing authorisation granted in an EEA State pursuant to an administrative authorisation procedure as laid down in Directive 2001/82 constitutes a valid authorisation to place the veterinary medicinal product on the market within the meaning of Article 3(b) of the SPC Regulation. If no previous authorisation to place the veterinary medicinal product on the market has been granted in that EEA State, the marketing authorisation in question also constitutes the first authorisation to place the veterinary medicinal product on the market within the meaning of Article 3(d) of the SPC Regulation.

64 As a provisional permission to supply a veterinary medicinal product on the basis of the first paragraph of Article 8 of Directive 2001/82 does not qualify as an administrative authorisation procedure for the purposes of Article 2 of the SPC

Regulation, it may also not be considered an authorisation to place the product on the market within the meaning of Article 3(b) and (d) of the SPC Regulation.

65 In these circumstances, the answer to Questions 1 to 4 must be that, under the SPC Regulation, an SPC for a veterinary medicinal product may be granted in an EEA State on the basis of a marketing authorisation obtained in that State pursuant to the administrative authorisation procedure set out in Title III of Directive 2001/82, including the procedure for authorisation in exceptional circumstances under Article 26(3) of that directive. Such a marketing authorisation constitutes a valid authorisation and, where appropriate, may also constitute the first authorisation to place the product on the market as a veterinary medicinal product within the meaning of Article 3(b) and (d) of the SPC Regulation.

66 Permissions granted on the basis of the first paragraph of Article 8 of Directive 2001/82 do not constitute marketing authorisations within the meaning of the SPC Regulation. That derogating provision strictly limits the use of the measures permitted under it, stating that it applies only in the event of serious epizootic diseases, in the absence of suitable medicinal products and after informing ESA of the detailed conditions of use.

67 The determination of whether "special approval exemptions" or "AR16 licences", granted respectively by Norwegian and Irish authorities from 2003 to 2011, and the provisional marketing authorisation granted in the United Kingdom in 2005 were issued pursuant to national provisions implementing the first paragraph of Article 8 or Article 26(3) of Directive 2001/82 depends essentially on the assessment of the facts in the national proceedings, which is a matter for the national court.

IV Questions 5 and 6

68 In the present case the marketing authorisation and the SPC concern a virus vaccine. Oslo tingrett asks if the SPC will protect not only the specific strain of the virus included in the vaccine and covered by the basic patent, but also other strains of the virus that are covered by the basic patent. The national court also asks whether it is relevant if vaccines based on other strains of the virus have an equivalent therapeutic effect and are subject to a separate marketing authorisation. Furthermore, the referring court asks to what extent an SPC is valid if it is not strictly limited to the specific strain of the virus covered by the marketing authorisation.

Observations submitted to the Court

69 The Plaintiff argues that, pursuant to Article 4 of the SPC Regulation, the scope of an SPC extends only to the product covered by the authorisation to place the corresponding medicinal product on the market. The Plaintiff argues that this provision must be applied strictly and construed to the effect that when the

medicinal product is a virus vaccine, the scope of protection of the SPC only covers the specific strain of the virus that is the active ingredient in the medicinal product and covered by the marketing authorisation on which the SPC is based.

70 In the Plaintiff's view, the scope of protection of the SPC which is the subject of the national proceedings cannot be extended to cover strains of the virus other than that included in the medicinal product and covered by the basic patent. As the product definition specified in the SPC purports to cover more virus strains than the actual product authorised to be placed on the market, the SPC in question is in breach of Article 4 of the SPC Regulation.

71 In this regard, the Plaintiff contends that "therapeutic equivalence" is irrelevant. Moreover, it argues that the requirement to conduct separate safety and efficacy studies and to obtain a separate marketing authorisation has a significant bearing on the answer, as it confirms that, unlike simple chemical derivatives of an already authorised active substance, related vaccines are nonetheless different products and are not generally considered to have the same therapeutic effect.

72 The Defendant argues that the SPC only ensures an effective protection under the SPC Regulation if it covers not only the specific form of the active ingredient contained in the authorised medicinal product, but also the other forms of that active ingredient which are covered by the basic patent and that are therapeutically equivalent to the specific form contained in the authorised medicinal product. In this regard, the Defendant submits that the principles set out by the Court of Justice of the European Union in Case C-392/97 *Farmitalia Carlo Erba Srl* [1999] ECR I-5451 should apply also to biological substances, because the SPC Regulation does not distinguish between chemical and biological active ingredients. Hence, it affords an effective protection to biological substances, which would not be provided if SPCs for viruses were limited to a specific strain of the virus.

73 The Defendant submits that an SPC granted for both the specific strain of the virus contained in the authorised vaccine and strains other than that specific strain would be valid. However, the scope of protection should be limited to the specific strain of the virus contained in the authorised vaccine.

74 ESA contends that the protection provided by an SPC is limited to the product that is covered by the marketing authorisation. According to ESA, an SPC cannot be granted for other products which are covered by the basic patent and not the marketing authorisation on which the SPC is based. Consequently, if a product requires an alternative marketing authorisation of its own, it is not included within the scope of the protection of an SPC granted on the basis of a different marketing authorisation.

75 ESA distinguishes the circumstances of the case at hand from those in *Farmitalia*. In that case it was held that the SPC at issue should be capable of covering the active ingredient as such and also its various derived forms. In the case at hand, however, the Plaintiff claims that its vaccine contains an active

ingredient different to that contained in the Defendant's vaccine and that the two vaccines are not therapeutically equivalent.

76 ESA submits that an SPC that has been granted with a product definition not strictly limited to the specific strain of the virus authorised to be placed on the market as a medicinal product must be deemed valid only insofar as the product definition is the same as in the marketing authorisation on which it is based.

77 In the Commission's view, what is at issue is whether the allegedly infringing product, not mentioned in the marketing authorisation, but – according to the assumption of the referring court – covered by the patent, consists of the same active ingredient as the authorised one.

78 The Commission argues that in the absence of therapeutic equivalence, a marketing authorisation cannot by definition extend to a virus strain it does not mention. On the other hand, where an allegedly infringing strain is marketable under the marketing authorisation covering the patented strain and is a therapeutic equivalent to the latter, the allegedly infringing strain is clearly covered by that marketing authorisation for the purposes of Article 4 of the SPC Regulation.

Findings of the Court

79 The parties to the main proceedings disagree on the extent to which the scope of the SPC in question covers products other than the specific vaccine strain referred to in the Norwegian marketing authorisation granted in 2011. In particular, it is disputed whether the SAV-1 and SAV-3 strain of the SPD virus are two forms of the same active ingredients or two separate ingredients, as well as whether the two products constitute therapeutic equivalents.

80 Article 4 of the SPC Regulation states that an SPC can be granted only to the product which has been the subject of a marketing authorisation.

81 The term product is defined in Article 1(b) of the SPC Regulation as "the active ingredient or combination of active ingredients of a medicinal product". When determining the scope of an SPC, the decisive question is therefore what active ingredient is included in the marketing authorisation on which the SPC is based. Although the term active ingredient is not defined in the SPC Regulation, it appears to be generally accepted in pharmacology that the term does not cover substances forming part of a medicinal product which do not have an effect of their own (compare *Forsgren*, cited above, paragraph 23).

82 That interpretation has subsequently been reproduced, in essence, by Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ 2011 L 174, p. 74) referred to in point 15q of Chapter XIII of Annex II to the EEA Agreement.

83 Directive 2011/62/EU amended Article 1 of Directive 2001/83/EC to the effect that the term active substance — which must be understood as meaning active ingredient — is defined therein as "any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis" (compare *Forsgren*, cited above, paragraph 24 and case law cited).

84 It follows that the term "active ingredient", for the purposes of applying the SPC Regulation, concerns substances producing a pharmacological, immunological or metabolic action of their own.

85 Article 4 of the SPC Regulation entails that the use of a medicinal product which has not been authorised by the marketing authorisation may not be covered by an SPC. Consequently, an active ingredient whose therapeutic effects do not fall within the therapeutic indications for which a marketing authorisation was granted may not give rise to the grant of an SPC (compare, to that effect, *Forsgren*, cited above, paragraph 35 and case law cited).

86 In that regard, the protection conferred on a medicinal product by an SPC may be relied upon in order to oppose the marketing of another medicinal product containing the same active ingredient with a therapeutic effect falling within the same therapeutic indication (compare, *mutatis mutandis*, *Forsgren*, cited above, paragraph 36 and case law cited). Otherwise, it would be possible for medicinal products which were, in principle, therapeutically equivalent to that protected by the SPC to compete with the latter. Such a result would frustrate the purpose of the SPC Regulation, which is to ensure the holder of the basic patent of exclusivity on the market during a given period extending beyond the period of validity of the basic patent (compare, to that effect, *Farmitalia*, cited above, paragraph 18).

87 A marketing authorisation cannot extend to a virus strain it does not mention, unless its therapeutic effects fall within the therapeutic indications for which the marketing authorisation was granted. In this context, it is immaterial whether, in order to be marketed, the allegedly infringing strain would require a marketing authorisation.

88 In the present case, the product definition in the SPC granted to the Defendant in January 2014 covers the specific strain of the SPD virus as described in paragraph 30 above. The SPC is based on the Norwegian marketing authorisation obtained in 2011. That marketing authorisation has been granted for "Salmonid pancreatic disease (SPD) virus strain F93-125, > 70% RRP". It thus follows from Article 4 of the SPC Regulation that the SPC granted to the Defendant allows it to prevent the marketing of medicinal products containing "Salmonid pancreatic disease (SPD) virus strain F93-125, > 70% RRP".

89 It follows from the considerations set out in paragraphs 81 to 87 of this judgment that the Defendant may prevent the Plaintiff from marketing its vaccine, provided it contains the same active ingredient with a therapeutic effect that falls within the therapeutic indications for which the Defendant's marketing authorisation and subsequent SPC has been granted.

90 The determination of whether the virus strain in the Plaintiff's product (SAV-3 of the SPD virus) constitutes the same active ingredient with the same therapeutic indication as the vaccine for which the Defendant has been granted a marketing authorisation (SAV-1 of the SPD virus) is a matter of fact which is to be determined by the national court.

91 An SPC which is granted a wider scope than the product covered by the marketing authorisation is in breach of Article 4 of the SPC Regulation. Infringement of Article 4 is not included among the grounds of invalidity laid down in Article 15(1) of the SPC Regulation. Nevertheless, infringement of Article 4 may render an SPC invalid owing to the connection between that provision and Article 3 of the SPC Regulation (compare, to that effect, *Synthon*, cited above, paragraphs 55 and 56). Consequently, an SPC will be invalid to the extent it goes beyond the product covered by the marketing authorisation on which the SPC is based.

92 In light of the above, the answer to the fifth and sixth questions must be that, pursuant to Article 4 of the SPC Regulation, the scope of protection conferred by an SPC extends to a specific strain of a virus covered by the basic patent, but not referred to in the marketing authorisation for a virus vaccine relied on for the purposes of Article 3(b) of the SPC Regulation, only if the specific strain constitutes the same active ingredient as the authorised medicinal product and has therapeutic effects falling within the therapeutic indications for which the marketing authorisation was granted. It is not relevant whether a medicinal product based on such other strain would require a separate marketing authorisation. The appreciation of such elements is a matter of fact which is to be determined by the national court.

93 An SPC is invalid to the extent it is granted a wider scope than that set out in the relevant marketing authorisation.

V Costs

94 The costs incurred by the Government of the United Kingdom, 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 Oslo tingrett, 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 questions referred to it by Oslo tingrett hereby gives the following Advisory Opinion:

1. **Under Regulation (EEC) No 1768/92, a supplementary protection certificate for a veterinary medicinal product may be granted in an EEA State on the basis of a marketing authorisation granted in that State pursuant to the administrative authorisation procedure set out in Title III of Directive 2001/82/EC, including the procedure for authorisation in exceptional circumstances under Article 26(3) of that directive. Such a marketing authorisation constitutes a valid authorisation and, where appropriate, may also constitute the first authorisation to place the product on the market as a veterinary medicinal product within the meaning of Article 3(b) and (d) of Regulation (EEC) No 1768/92.**

   Permissions granted on the basis of the first paragraph of Article 8 of Directive 2001/82/EC do not constitute a marketing authorisation within the meaning of Regulation (EEC) No 1768/92. That derogating provision strictly limits the use of the measures permitted under it, stating that it applies only in the event of serious epizootic diseases, in the absence of suitable medicinal products and after informing the EFTA Surveillance Authority of the detailed conditions of use.

   The determination of whether "special approval exemptions" or "AR 16 licences", granted respectively by Norwegian and Irish authorities between 2003 and 2011, and the provisional marketing authorisation granted in the United Kingdom in 2005 were issued pursuant to national provisions implementing the first paragraph of Article 8 or Article 26(3) of Directive 2001/82/EC depends essentially on the assessment of the facts in the national proceedings, which is a matter for the national court.

2. **Pursuant to Article 4 of Regulation (EEC) No 1768/92, the scope of protection conferred by a supplementary protection certificate extends to a specific strain of a virus covered by the basic patent, but not referred to in the marketing authorisation for a virus vaccine relied on for the purposes of Article 3(b) of Regulation (EEC) No 1768/92, only if the specific strain constitutes the same active ingredient as the authorised medicinal product and has therapeutic effects falling within the therapeutic indications for which the marketing authorisation was granted. It is not relevant whether a medicinal product based on such other strain would require a separate marketing authorisation. The appreciation of**

such elements is a matter of fact which is to be determined by the national court.

A supplementary protection certificate is invalid to the extent it is granted a wider scope than that set out in the relevant marketing authorisation.

Carl Baudenbacher Per Christiansen Páll Hreinsson

Delivered in open court in Luxembourg on 9 April 2015.

Gunnar Selvik
Registrar

Carl Baudenbacher
President