REPORT FOR THE HEARING
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 of

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 SPC Regulation").[1]

I Introduction

1. Under EEA law, a patent holder cannot place a medicinal product on the market and commercially exploit it unless a marketing authorisation has been granted under the relevant legislation. As the date on which a marketing authorisation is obtained can differ from the date on which a patent is granted, the grant of a supplementary protection certificate ("SPC") is intended to ensure an extra period of protection for patent holders, so as to offset the time and investment required to obtain the marketing authorisation. The scope and procedure relating to SPCs are laid down in Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products.

2. By a letter of 17 July 2014, registered at the EFTA Court on 23 July 2014, Oslo tingrett (Oslo District Court) made a request for an Advisory Opinion in a case pending before it between Pharmaq AS ("the Plaintiff") and Intervet International BV ("the Defendant").

3. The case before Oslo tingrett concerns the validity of an SPC granted in January 2014 to the Defendant pursuant to the Norwegian Patents Act.[2] The Plaintiff

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[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, as incorporated into the EEA Agreement at Annex XVII point 6.

[2] Lov om patenter (Patentloven) Law No 9 of 15 December 1967. Entry into force of last amending act: 1 July 2013. Unofficial translation available at: http://www.patentstyret.no/en/For-Experts/Patents-Expert/Legal-texts/The-Norwegian-Patents-Act/#Capter9a.

seeks a declaration that the SPC granted to the Defendant is invalid or, in the alternative, limiting the scope of said SPC so as not to include the Plaintiff's vaccine.

II Legal background

EEA law

4. The first European legislation on SPCs was the SPC Regulation (Regulation (EEC) No 1768/92).

5. In the EU, Regulation (EEC) No 1768/92 has been repealed and replaced by Regulation (EC) No 469/2009. However, in the EFTA pillar, Regulation (EEC) No 1768/92 still remains applicable as the EEA Joint Committee has not yet incorporated Regulation (EC) No 469/2009 into the EEA Agreement.

6. 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;*
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> *...*
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> *(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;*
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> *(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 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community;*
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> *(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;*

7. 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;

...

8. 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.

9. 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.

10. 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.

11. 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.

...

12. 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.

13. 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 ...

14. 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; ...

15. 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.

16. Point 8 of Protocol 1 to the EEA Agreement provides that whenever the acts referred to in the Annexes to the EEA Agreement:

... contain references to the territory of the Community or of the 'common market' the references shall for the purposes of the Agreement be understood to be references to the territories of the Contracting Parties as defined in Article 126 of the Agreement.

17. It follows therefore 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".

18. Point 6 of Annex XVII to the EEA Agreement, as amended by Annex 15 to Decision 7/94 of the EEA Joint Committee,[3] refers to Regulation (EEC) No 1768/92. It also 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.*

19. Chapter XIII of Annex II to the EEA Agreement, as amended by EEA Joint Committee Decisions Nos 82/2002 and 61/2009, refers to Directive 2001/82 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1) and Regulation (EC) No 726/2004 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).

20. Article 5(1) of Directive 2001/82, as amended, provides the following as regards marketing authorisations:

> *1. 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).*

21. Article 8(1) of Directive 2001/82 reads as follows:

> *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.*

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

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[3] Decision of the EEA Joint Committee No 7/94 of 21 March 1994 amending Protocol 47 and certain Annexes to the EEA Agreement, OJ 1994 L 160, p. 1.

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

23. In Norway, Directive 2001/82/EC has been implemented by the Medicines Act of 4 December 1992 No 132[4] and the Medicines Regulation of 18 December 2009 No 1839.[5]

24. 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).

25. 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.

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4 Lov om legemidler (Legemiddelloven), LOV-1992-12-04-132.

5 Forskrift om legemidler (Legemiddelforskriften), FOR-2009-12-18-1839.

26. Under Section 13-3 of the Medicines Regulation, advertising of medicinal products supplied under a special approval exemption is not permitted. However, the Norwegian State Medicine Agency has granted dispensations from said Section 13-3 of the Medicines Regulation thereby permitting advertisement with respect to sales under special approval exemptions for the aquaculture industry.

27. Finally, Chapter 9(a) of the Norwegian Patents Act, Act No 9 of 15 December 1967, that implements the SPC Regulation contains two provisions on the "Prolonged Term of Protection for Medicinal Products". These read as follows:

> *Section 62a.*
>
> *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.*
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> *Applications for a supplementary protection certificate shall be filed with the Norwegian Industrial Property Office. The applicant shall pay the prescribed fee.*
>
> *In the case of protection certificates, the prescribed fees shall be paid for every fee year starting after the end of the patent term. In other respects the same rules apply to these annual fees as to the annual fees for patents. Further provisions concern applications for protection certificates and the processing and examination thereof, concerning the registration of protection certificates, concerning appeals against decisions and concerning the obligation of the applicant or the holder to have a representative in this country, etc. shall be laid down by the King.*
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> *The penal provisions of sections 57 and 62 shall apply correspondingly to protection certificates.*
>
> *Section 62b.*
>
> *EEA Agreement Annex XVII item 6a (Regulation (EC) No 1610/96 of the European Parliament and the Council concerning the creation of a supplementary protection certificate for plant protection products) applies as law with the amendments and additions made by Protocol 1 to the agreement and the agreement as a whole.*
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> *Section 62a second to fifth paragraph applies correspondingly.*

III Facts and procedure

28. As was set out above, the case before Oslo tingrett concerns the validity and scope of an SPC granted to the Defendant in January 2014 pursuant to the relevant Norwegian legislation.

29. 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, in the present case referred to as virus strain ALV 405. Such strain belongs to one of the six subtypes of Salmonid Alpha Virus ("SAV"), SAV 3.

30. The Defendant developed a vaccine based on an inactive virus, which was deposited in the European Collection of Cell Cultures with deposit no V94090731, and which is referred to as virus strain F93-125. The virus strain belongs to one of the six subtypes of SAV, i.e. SAV 1.

31. 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 Article 2-7 of the Medicines Regulation, which, together with the Medicines Act, is based on Directive 2001/82/EC. 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".

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

33. The Defendant applied for an SPC on the basis of its Norwegian marketing authorisation No 10-7431 granted in 2011. In accordance with that application, an SPC was granted to the Defendant in January 2014, pursuant to Chapter 9(a) of the Norwegian Patents Act 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*
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> *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.*

34. Norwegian courts have found that the Plaintiff's vaccine strain falls within the scope of Claim 1 in the Defendant's basic patent.

35. By its action, the Plaintiff seeks a declaration that the Norwegian SPC 2011024 is invalid and, alternatively, that the scope of protection is deemed not to include the Plaintiff's vaccine.

36. 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.

37. The following questions were submitted 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 the same?

(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?

IV Written observations

38. Pursuant to Article 20 of the Statute of the Court and Article 97 of the Rules of Procedure, written observations have been received from:

- the Plaintiff, represented by advokat Lars Erik Steinkjer, on behalf of Gunnar Meyer advokat, and Ida Gjessing, advokat;

- the Defendant, represented by advokat Kristine Schei and advokat Eirik W Raanes;

- the Government of the United Kingdom, represented by Julia Kraehling of 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.

V Summary of the pleas and arguments submitted

The first question

The Plaintiff

39. In the Plaintiff's view, by its first question, the referring court asks whether a product has been placed on the market before being granted a marketing authorisation when deliveries of the product concerned were made under Norwegian special approval exemptions or Irish AR16 licences.

40. According to the Plaintiff,[6] the purpose of the SPC regime is to promote investment in research by ensuring "adequate effective protection", i.e. a sufficient period of effective protection, through the compensation of the loss of exclusivity as a result of the time required to obtain a marketing authorisation, with the duration of the period of effective protection being set at an overall maximum of 15 years.

41. The Plaintiff emphasises that, according to Article 2 of the SPC Regulation and the case law of the Court of Justice of the European Union ("the Court of Justice"),[7] 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.

42. The Plaintiff contends that the Defendant has been selling the vaccine to its customers since 2003, pursuant to special approval exemptions and AR16 licences, neither of which required the submission of extensive safety and efficacy data. In the UK, sales took place from 2009 according to a UK provisional marketing authorisation granted in 2005, which equally did not require the submission of extensive safety and efficacy data. Hence, the product has to be considered as having been placed on the market before obtaining a marketing authorisation.

43. The Plaintiff submits that, having regard to the case law of the Court of Justice,[8] the concept of the market for the purpose of Article 2 of the SPC Regulation is the Community market and, as a consequence, all sales by the Defendant of the vaccine in any State within the EEA are relevant to establishing whether the product has been placed on the market before obtaining a marketing authorisation. The Plaintiff contends further that all such sales by the Defendant took place, under the exclusivity granted by the patent and, in addition, that those sales had a substantial volume.

44. The Plaintiff argues that, for the reasons set out above, the Defendant did not lose any period of exclusivity and, thus, grant of the SPC is contrary to Article 2 of the SPC Regulation and to the ruling in *Synthon*. Moreover, this wrongful grant of the

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6 Reference is made to recitals 2, 3, 8 and 9 of the SPC Regulation and Case C-493/12 *Eli Lilly and Company Ltd* v *Human Genome Sciences Inc.*, judgment of 12 December 2013, published electronically, paragraph 41.

7 Reference is made to Case C-195/09 *Synthon BV* v *Merz Pharma GmbH & Co. KGaA* [2011] ECR I-7011, paragraphs 47 and 51.

8 Reference is made to *Synthon*, paragraphs 38 to 42, cited above, as applied in Case C-427/09 *Generics (UK) Ltd* v *Synaptech Inc.* [2011] ECR I-7099, paragraph 33.

SPC entails that (i) the Defendant will enjoy seventeen years of exclusivity after placing the product on the market[9] and (ii) the rationale of the SPC Regulation is undermined, as research and competitiveness in the pharmaceutical market is discouraged and not promoted. The Plaintiff submits that, in keeping with the reasoning of the Court of Justice in *Synthon* and *Generics*,[10] a product must be regarded as "placed on the market as a medicinal product" in the Community (or EEA) prior to obtaining a full marketing authorisation in accordance with the procedure laid down in Directive 81/851 (now Directive 2001/82) in circumstances where it is placed on the market pursuant to special approval exemptions, AR16 licences and/or provisional marketing authorisations, as they permit substantial sales, in particular, without the product undergoing the requisite safety and efficacy testing under that Directive.

45. The Plaintiff argues also that the factors relied on by the Defendant to contradict such view are ultimately irrelevant. First, the Defendant's ability to disseminate information concerning Norvax or, perhaps more importantly, to commercially exploit the product prior to obtaining the 2011 marketing authorisation has not, in fact, been significantly restricted by any general prohibition against advertising the product, pursuant to the provisions relating to special approval exemptions.[11]

46. Second, the Plaintiff submits that the grant of special approval exemptions permitted the Defendant to place its product on the market and to satisfy market demand even prior to the grant of the 2011 marketing authorisation. Moreover, in practice, the grant of Irish AR16 licences directly to the Defendant allowed the Defendant to import and supply its vaccine. Hence, ultimately, it is irrelevant that the special approval exemptions were granted to veterinarians and fish health biologists and not to the Defendant directly.

47. Third, according to the Plaintiff, the argument that the special approval exemptions were granted because of a medical need for a PD vaccine cannot change the fact that the Defendant has not suffered any loss in relation to the period of exclusivity that the SPC Regulation endeavours to compensate, given the *de facto* early access to the market enjoyed by the Defendant. Moreover, the Plaintiff continues, having regard to the rulings of the Court of Justice in *Synthon* and *Generics*, the nature of the Norwegian and Irish legal instrument allowing the Defendant to sell Norvax between 2003 and 2011 does not alter the fact that the Defendant placed the product on the market before obtaining a full marketing authorisation in accordance with Directive 2001/82.

48. The Plaintiff also contends that, in the opposition filed on 14 January 2014 against the Plaintiff's Norwegian patent No 333 242 and in its submissions filed on 1 October 2008, the Defendant itself acknowledged that its product was commercially

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[9] That is two years longer than the overall maximum of fifteen years provided for by the SPC Regulation.

[10] Reference is made to *Synthon*, as applied in *Generics*, both cited above.

[11] The Plaintiff supports its statement by reference to Case C-617/12 *AstraZeneca AB* v *Comptroller General of Patents*, order of 14 November 2013, published electronically, paragraphs 56 and 57.

available and fully meeting market demand prior to the grant of the 2011 marketing authorisation and also prior to the grant of the UK provisional marketing authorisation in 2005. Consequently, there is no good reason to conclude that the product was not placed on the market before obtaining a marketing authorisation. As a result, the Plaintiff submits that the Defendant's Norvax vaccine does not fulfil the criteria laid down in Article 2 of the SPC Regulation and thus falls outside the Regulation's scope.

49. Furthermore, the Plaintiff considers that since the supply of vaccine did not take place in the framework of compassionate use programmes or named patients supplies, an affirmative answer to the first question would have no impact on such programmes. It submits that EU legislation concerning those programmes (Article 83 of Regulation (EC) No 726/2004 for compassionate use programmes and Article 5 of Directive 2001/83 for named patients supply programmes) is applicable only to products for human use and that, in turn, veterinary products cannot benefit from compassionate use programmes or programmes for named patients supplies.

50. The Plaintiff also notes that the supply of human medicinal products in the context of named patients supplies has already been found by the Court of Justice to constitute placement on the market.[12] As regards the supply of immunological veterinary medical products, the Plaintiff submits that the analogue provision, Article 8 of Directive 2001/82, prior to amendment in 2004, enabled EEA States to provisionally allow a product's use in the absence of a suitable medicinal product and after informing the Commission of the conditions of use.

51. The Plaintiff concludes that the Court should answer the first question in the affirmative, but does not propose any specific wording for the Court's answer.

The Defendant

52. In the Defendant's view, the first question concerns whether the supply of a medicinal product under a national regime of exemptions,[13] such as the special approval exemption in Norway or the AR16 licence in Ireland, constitutes placement on the market for the purposes of Article 2 of the SPC Regulation.

53. The Defendant emphasises that, under Article 2 of the SPC Regulation, a product protected by a national patent is eligible for an SPC if it is subject to an administrative authorisation procedure under Directive 2001/82 before being placed on the EEA market. The Defendant argues that, according to the case law of the Court of Justice, a product is not placed on the market as a result of supply under a national regime of exemption, but only as a result of supply under a marketing authorisation.

54. The Defendant contends that under the SPC Regulation, an SPC must be granted upon meeting the substantive conditions set out in Article 3 and the procedural conditions in Articles 7 and 8, provided that the placement on the market did not

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[12] Ibid., paragraph 57.

[13] The Defendant refers to the special approval exemption in Norway and to the AR16 licence in Ireland as "national regime of exemptions" or "national exemption regime".

precede the grant of the marketing authorisation in accordance with Directive 2001/82. It notes that Article 2 of the SPC Regulation does not permit patent offices to make a discretionary assessment whether to grant an SPC having regard to such criteria as "volume supplied" or "revenues generated". In the Defendant's view, a discretion of that kind would most likely lead to different thresholds for grant of an SPC and different interpretations of the criterion in different EEA States, in turn resulting in (i) legal uncertainty as to eligibility for an SPC in the different EEA States, (ii) fragmentation of the harmonised market under the SPC Regulation, (iii) patients seeking treatment in EEA States with higher thresholds, thus disrupting national healthcare systems and (iv) public health being less protected in cases of serious contagious diseases, due to patent holders refusing to supply the medicinal products in order to keep the SPC. Therefore the supply of a medicinal product under a national regime of exemption does not constitute placement on the market prior to an administrative authorisation, regardless of the volume of products supplied, or the revenues generated, under the national exemption regime. Furthermore, the Defendant contends that any other interpretation would be detrimental to the efforts of the Commission and of health authorities to promote early access to innovative drugs and to concerns of legal certainty and of fairness.

55. In absence of a legal definition, the Defendant argues that the term "place on the market" in Article 2 of the SPC Regulation must be interpreted in light of the fact that the marketing authorisation requirement under pharmaceutical law is the cornerstone of that Regulation. Moreover, this interpretation must take into account the objective of the Regulation to compensate for the delay in the commercial exploitation of an invention and so help recoup the investment in pharmaceutical research.[14] In this context, a product may only be considered as placed on the market as a medicinal product upon the grant of a marketing authorisation for the medicinal product concerned.

56. The Defendant submits that such interpretation is confirmed by the case law[15] of the Court of Justice which expressly links the commercial exploitation of the invention to the grant of the marketing authorisation. Furthermore, it is argued that the term "place on the market", often used together with the term "authorisation", should receive a uniform interpretation[16] throughout the Regulation.

57. The Defendant submits that such conclusion is consistent with the pharmaceutical *acquis*[17] according to which a medicinal product is placed on the

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[14] Reference is made to *Eli Lilly*, paragraphs 41 and 42, cited above; Case C-443/12 *Actavis Group PTC EHF and Actavis UK Ltd* v *Sanofi*, judgment of 12 December 2013, published electronically, paragraph 41; and Case C-130/11 *Neurim Pharmaceuticals (1991) Ltd* v *Comptroller-General of Patents* judgment of 19 July 2012, published electronically, paragraphs 22 and 23. See also Case C-11/13 *Bayer CropScience AG* v *Deutsches Patent- und Markenamt*, judgment of 19 June 2014, published electronically, paragraph 39.

[15] Reference is made to *AstraZeneca*, cited above, paragraph 42, and Case C-210/12 *Sumitomo Chemical Co. Ltd* v *Deutsches Patent- und Markenamt*, judgment of 17 October 2013, paragraph 59.

[16] Reference is made to Case C-127/00 *Hässle AB* v *Ratiopharm GmbH* [2003] ECR I-14781, paragraphs 53 to 59.

[17] The phrase "placing on the market" in Article 4(1) of Directive 81/851, as amended by Article 1(4) of Directive 90/676, was replaced with "marketing" in Article 7 of Directive 2001/82.

market only when it is granted a marketing authorisation and is considered actually to have been placed on the market upon release in the distribution chain. Furthermore, under what is known as the "sunset clause", the authorised product must actually be placed on the market within three years of the grant of the marketing authorisation, otherwise this becomes invalid.

58. The Defendant argues that, under the case law of the Court of Justice, 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. Furthermore, the Defendant submits (i) that the supplies or sales of products under national exemption regimes, which are not harmonised, cannot be compared with commercial exploitation under a marketing authorisation and, in turn, they cannot justify ineligibility for an SPC, and (ii) that a company, when it begins the supply under a national exemption regime, cannot know the duration of the health crisis or the volumes that will ultimately be supplied. The Defendant considers that, for the purposes of Article 13 of the SPC Regulation, the cut-off date for the calculation of the term of the SPC is the date of the first marketing authorisation in the EEA (and not the first marketing authorisation in the country concerned)[18] as this is the moment in which commercial exploitation is supposed to begin.

59. Moreover, the Defendant submits that the supply of a medicinal product under a national exemption depends primarily on the characteristics (duration, spread, contagiousness) of the health crisis concerned and that in the case at hand, without any initiative on its part, it was required by the Norwegian Medicines Authority (NoMA) and the Department of Agriculture, Food and the Marine (DAFM) to supply the experimental vaccine under a national exemption in order to counter the spread of PD. The Defendant contends that the grant of national exemptions did not allow it to exploit commercially the vaccine. Had that been the case, all Norwegian fish farms would have made use of the vaccine.

60. The Defendant argues that to consider a medicinal product as placed on the market on the occasion of its supply under national exemption regimes would be (i) detrimental to public health, (ii) undermine the Commission's policy of early access to medicinal products and (iii) call into question the validity of many SPCs. The Defendant notes that the Norwegian special approval exemptions and the Irish AR16 licences are based on exemptions from the marketing authorisation requirement provided by Directive 2001/82 to cover cases of health crisis or to allow for compassionate use. The Defendant notes also that Article 5 of Directive 2001/83 allows Member States, for the purpose of compassionate use on humans, to exempt the supply of medicinal products from the marketing authorisation requirement and constitutes the EU legal basis for "early access schemes". Moreover, it notes that Articles 7 to 11 of Directive 2001/82 do not use the term "place on the market", but merely that of "supply". According to the Defendant, the case law of the Court of Justice has established that national exemptions can be justified only for the purposes of the protection of public health, i.e. where one or more patients (humans or animals) are in therapeutic need of an experimental medicinal product. In the Defendant's view,

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[18] Reference is made to *Synthon* and *Generics*, both cited above.

insofar as the same exceptions from marketing authorisation apply to both medicinal products for human use and veterinary medicinal products, a ruling on the eligibility for an SPC of a product for veterinary use would also apply to medicinal products for human use, which are regularly supplied to many patients in Europe before the grant of a marketing authorisation.

61. In the Defendant's view, companies would be reluctant or unwilling to supply non-authorised medicinal products (for animal and human use) if such supplies were to deprive them of their right to SPC protection and such outcome would (i) be detrimental to animal and human patients, deprived of a needed therapy, (ii) be at odds with the principle set out in recital 10 in the preamble to the SPC Regulation that "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", and (iii) undermine efforts by the Commission and national health authorities to promote early access to innovative medicinal products prior to the grant of the marketing authorisation. In this regard, the Defendant stresses the findings of the Court of Justice whereby the protection of public health must prevail over financial considerations.[19]

62. The Defendant contends that it would be unfair to deprive a pharmaceutical company of the right to an SPC due to its consent to supply an experimental medicinal product in order to address a health crisis. To underline the unfairness involved the Defendant points to the fact that mandatory safety and efficacy testing is required by pharmaceutical law in order to obtain a marketing authorisation,[20] testing which in some EEA States is a condition for the application of the national exemption regime. Moreover, such an interpretation would lead to undesirable legal uncertainty regarding the validity of many SPCs granted to a product previously made available under a national exemption scheme.

63. Furthermore, the Defendant argues that, if a product supplied under a national exemption, and before the grant of a marketing authorisation, were to be considered as "placed on the market", a competitor of the SPC holder might arrange for the import into the EEA State of the medicinal product, authorised outside of the EEA, but not yet provided with a marketing authorisation in the EEA, with the consequence that such "placing on the market" in one EEA State, although outside of the control of the company, could deprive it of eligibility for an SPC.[21] The Defendant concludes that such interpretation of the notion of "placing on the market" would lead to legal uncertainty as to eligibility for an SPC and, in light of *AHP Manufacturing*,[22] would undermine the objective of the SPC Regulation.

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[19] Reference is made to Joined Cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan GmbH and Others* v *Commission* [2002] ECR II-4945 and, on appeal, Case C-39/03 P *Commission* v *Artegodan GmbH and Others* [2003] ECR I-7885.

[20] The Defendant avers that it conducted more than 160 tests over a period of more than 15 years in order to obtain a full marketing authorisation in 2011 (Exhibit 2).

[21] Reference is made to *Synthon* and *Generics*, both cited above.

[22] Reference is made to *AHP Manufacturing*, cited above, paragraphs 32 and 33.

64. The Defendant submits that the "exclusivity" resulting from being the sole medicinal product available to treat patients is very different from the exclusivity resulting from a legal mechanism such as a patent or SPC. It argues that these two different forms of "exclusivity" cannot be added together to conclude that, for the purposes of Article 13 of the SPC Regulation, the product will be protected for more than 15 years.[23]

65. In the view of the Defendant, 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, i.e. that the company invests in pharmaceutical research. The actual grant of a marketing authorisation is only decisive for Article 3 of the SPC Regulation (grant of an SPC). Consequently, the Defendant argues that were – contrary to its argument – the supply of a medicinal product under a national exemption to be considered placement on the market, the product would remain eligible for an SPC all the same if the product was subject to a marketing authorisation procedure before the occurrence of such supply. The Defendant stresses that in the present case it filed for a marketing authorisation on 6 May 2003, i.e. before the grant of national exemptions in Norway and Ireland, and before it started to supply the experimental vaccine to Norwegian or Irish veterinarians.

66. The Defendant concludes that the product remains eligible for an SPC if the medicinal product was the subject of a marketing authorisation procedure in accordance with Directive 2001/82 before it was supplied under a national exemption regime, whether or not that marketing authorisation procedure led to a marketing authorisation for the medicinal product. Therefore, even if the supply of the product under a national exemption were to be considered placement on the market, such product would remain eligible if it was the subject of a marketing authorisation procedure in accordance with Directive 2001/82 before such supply occurred.

67. Therefore, the Defendant proposes the following answer to the first question:

> *A product has not been placed on the market as a medicinal product in the EEA before being the subject of an administrative authorisation procedure 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.*

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[23] Reference is made to Case C-555/13 *Merck Canada* v *Accord Healthcare and Others*, judgment of 13 February 2014, published electronically.

The Government of the United Kingdom

68. The Government of the United Kingdom submits some general observations on the importance of restricting the Court's decision to veterinary medicinal products and not extending it to the human medicines regime, in particular, should the Court answer the first two questions in the affirmative. It stresses that although the present case concerns only the veterinary regime under Directive 2001/82, the request for an opinion refers also to the human medicinal products regime by analogy.[24]

69. The Government of the United Kingdom argues that although the overriding objective of both Directives 2001/82 and 2001/83 is to safeguard public health[25] there are substantial differences in the regulatory regime that each provides. Whereas Article 10 of Directive 2001/82 sets out provisions which apply where there is no authorised medicinal product for a condition and Article 26(3) of Directive 2001/82 provides provisions in relation to an authorisation in exceptional circumstances, these must be distinguished from Article 2 and Articles 5(1) and 6(1) of Directive 2001/83.

70. The United Kingdom Government stresses that although Article 5(2) of Directive 2001/83 is rarely applied in practice it is in fact of topical relevance, given the threat of Ebola and the availability of unauthorized drugs to control that disease. As regards Article 5(1) of Directive 2001/83, it observes that this provision is frequently used as it permits the supply of an unlicensed medicine where no licensed medicine can meet a particular patient's special needs.[26] Moreover, it may be necessary to maintain stocks of such medicines in order to ensure their availability for patients in response to unpredictable medical needs and also for repeat provision.

71. According to the United Kingdom Government, it is very important that an impractical, theoretical approach is not taken to the notion of "placing on the market" under the SPC Regulation which could have unintended consequences for the current operation of the supply chain in respect of human medicines and greatly harm patient care in many EEA Member States.

72. The United Kingdom highlights that the judgment in this case could have far-reaching consequences for the medicines regime, due to the interaction of the SPC and regulatory regimes. It cites, for example, the judgment in *Synthon*[27] in which the Court of Justice held that Article 2 of the SPC Regulation should be interpreted as meaning that a product placed on the market as a medicinal product for human use in the Community, not in accordance with Directive 65/65, is not within the scope of the SPC Regulation.

73. The United Kingdom Government observes that a judgment in the current case that could be interpreted to mean that a human medicine lawfully made available

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[24] Reference is made to pages 13 and 14 of the request and the case law cited on page 14.

[25] Reference is made to recital 2 in the preamble of each Directive.

[26] Reference is made to Case C-185/10 *Commission* v *Poland*, judgment of 29 March 2012, published electronically.

[27] Reference is made to *Synthon*, cited above.

under Article 5 of Directive 2001/83 was placed on the market would, in line with *Synthon*, entail that such products would be outside the scope of Article 2 of the SPC Regulation. Alternatively, there is the possibility that any SPC term would be reduced as it would be based on the date of distribution of the product under Article 5 of Directive 2001/83.

74. In the view of the United Kingdom Government, either of these scenarios could lead to pharmaceutical companies withdrawing the availability of products supplied under Article 5 of Directive 2001/83 due to the inability to obtain SPCs for such products. This would not only go against the stated aims of the SPC regime as set out in the recitals to the SPC Regulation, but would also cause significant hardship to patients with unmet medical needs including those suffering from chronic or terminal conditions for whom no alternative authorised treatment exists. Furthermore, it would create very substantial risks that pharmaceutical companies would be reluctant to provide access under Article 5 of Directive 2001/83 to medicines in circumstances where those medicines are urgently needed in the circumstances of a threatened epidemic.

The EFTA Surveillance Authority ("ESA")

75. According to ESA, the first three questions ask whether the Defendant's vaccine should be considered to have been "placed on the market" within the meaning of Article 2 of the SPC Regulation.

76. ESA observes that the Court of Justice has already held that if a product has been placed on the market in the EEA before 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 and, consequently, that if such a certificate is nonetheless granted, it must be deemed invalid. Moreover, it would be contrary to the objective of the SPC Regulation, if an SPC, which amounts to an extension of exclusivity, could be granted for a product that has already been sold on the Community market as a medicinal product before being subject to an administrative authorisation procedure as laid down in Directive 65/65 (now Directive 200l/83), including safety and efficacy testing.

77. In light of *Synthon* and *Generics*[28] and recital 8 in the preamble to the SPC Regulation, 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. Therefore, having regard to the special approval exemption granted to the Defendant in Norway during the years 2003 to 2011 and the AR16 licences in Ireland from 2003, the vaccine must be deemed to have been placed on the market in Norway and Ireland in 2003.

78. ESA proposes that the first question should be answered as follows:

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[28] Reference is made to *Synthon*, cited above, paragraphs 47, 50 and 53 to 57, and *Generics*, cited above, paragraphs 33 to 36.

A product has been placed on the market as a medicinal product in the EEA in accordance with Article 2 of the SPC Regulation before it has been granted marketing authorisation in accordance with Directive 2001/82 when delivery of the product has taken place in accordance with "special approval exemptions" granted under Norwegian law or "AR16 licences" granted in Ireland, as in the particular circumstances described in the Request for an advisory opinion.

The European Commission

79. The Commission notes that the first question addresses the issue whether, during the period 2003 to 2011, Norvax Compact PD was already "placed on the market as a medicinal product" within the meaning of Article 2 of the SPC Regulation by virtue of the Norwegian special approval exemptions and the Irish AR16 licences.

80. The Commission argues that the purpose of the SPC Regulation is to offset the time required to obtain a full marketing authorisation for a medicinal product in consideration of the long and demanding testing requirements.[29] Moreover, the Commission stresses the absence of any reason to offset any such delay where the product has been made available without such testing. The Commission notes that only a full marketing authorisation[30] under Article 5(1) of Directive 2001/82 can be invoked for the purposes of satisfying Article 3(b) of the SPC Regulation.

81. The Commission refers to the judgment of the Court of Justice in *Sumitomo*[31], which concerned the interpretation of Article 3(1)(b) and Article 7(1) of Regulation (EC) No 1610/96[32] ("the Plant SPC Regulation" establishing an SPC regime for plant protection products), due to the similar purpose of that regulation.

82. According to the Commission, licences[33] are altogether different from full marketing authorisations, as they are issued under a decision pursuant to Article 8 of Directive 2001/82 which allows for a medicinal product to be made available by way of derogation from Article 5(1) of Directive 2001/82 and before obtaining a full marketing authorisation. In the absence of a fully authorised product and after informing the Commission of the detailed conditions of use, Article 8 of Directive 2001/82 allows EEA States to provisionally permit the use of immunological medicinal products without a full marketing authorisation. In addition, so the Commission argues, Article 26(3) of Directive 2001/82 provides for the possibility to grant a marketing authorisation "in exceptional circumstances".

83. The Commission argues that it does not have all the information at its disposal to make a complete assessment of the exact basis in Directive 2001/82 for the

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[29] Reference is made to *Synthon*, cited above.

[30] The Commission refers to the marketing authorisations under Article 5(1) of Directive 2001/82 as "full marketing authorisations".

[31] Reference is made to *Sumitomo*, cited above.

[32] Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, OJ 1996 L 198, p. 30.

[33] The Commission refers to the special approval exemptions and the AR licences collectively as "licences".

derogations provided for in Norwegian and Irish law. Nevertheless, in its view, this does not preclude an assessment by the Commission of derogations of this nature under Directive 2001/82 and their relevance to the proper interpretation of Articles 2 to 4 of the SPC Regulation. It considers that the Irish AR16 licences appear to have been granted on the basis of a national rule implementing the first paragraph of Article 8 of Directive 2001/82. In contrast, in the case of the Norwegian special approval exemptions under section 2-7 of the Norwegian Medicines Regulation, it is less clear whether these are based on Article 8(1) or Article 26(3) of Directive 2001/82.

84. In the Commission's view, a literal interpretation of Article 2 of the SPC Regulation suggests that the obtaining of a licence for a medicinal product does not take the product outside the scope of the SPC Regulation, given that the licences do not give full market access, but cover only provisional use during a serious epizootic disease or for a particular condition in the absence of another authorised product.

85. Furthermore, according to the Commission, the *Synthon* line of cases should be distinguished from the present situation, as in the *Synthon* situation the product had been given full market access prior to receiving full market authorisation under the Union's pharmaceutical *acquis* and therefore was rightly disqualified from relying on a subsequent full marketing authorisation under Union law. Moreover, to disqualify 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 and would undermine the public health considerations underlying the SPC Regulation.

86. Distinguishing the *Synthon* line of cases, the Commission contends that the making available of a product under a licence does not constitute, for the purposes of Article 2 of the SPC Regulation, placement on the market prior to an administrative authorisation procedure. Therefore, the Commission proposes a reply to the first question which also includes replies to the second question and part (b) of the fourth question. It reads as follows:

> *Articles 2, 3(d) and 13(1) of the SPC Regulation should be interpreted to the effect that they do not preclude the granting of an SPC on the basis of a marketing authorisation granted subsequent to safety and efficacy testing in accordance with Directive 2001/82 where this marketing authorisation is preceded by a licence, based on Article 8 subparagraph 1 of Directive 2001/82, provided that the period, if any, during which that licence gives the medicinal product in question essentially full market access is not compensated for when the duration of the SPC is determined. Whether there has been full market access under the licence is a question of fact to be assessed by the national court.*

The second question

The Plaintiff

87. If the first question is answered in the affirmative, the Plaintiff considers that the second question concerns whether such a product, placed on the market before obtaining a marketing authorisation, is outside of the scope of the SPC Regulation and, in turn, whether an SPC granted to such product is invalid.

88. The Plaintiff notes that, according to Article 15 of the SPC Regulation, the grant of an SPC in violation of Article 3 of the SPC Regulation constitutes a ground of invalidity. Moreover, it contends that the list of grounds set out in Article 15 of the SPC Regulation is not-exhaustive.[34] It stresses further that, since the concept of "product" in Article 3 of the SPC Regulation refers necessarily to a product within the scope of the SPC Regulation, as defined in Article 2 of that regulation, to issue an SPC for a product outside the Regulation's scope disregards the meaning of "product" and, accordingly, such an SPC granted in breach of Article 2 of the Regulation is invalid.

89. The Plaintiff concludes that the Court should answer the second question in the affirmative. If an SPC is granted despite that product having been placed on the market, then such a product falls outside the scope of the SPC regulation. Therefore a supplementary protection certificate (SPC) granted on that basis is invalid.

The Defendant

90. According to the Defendant, the second question is not relevant as the first question must be answered in the negative. In any event, the second question has already been answered by the Court of Justice in *Synthon*, where it held that an SPC granted for a product outside the scope of Regulation No 1768/92, as that scope is defined in Article 2 of that regulation, is invalid.[35] Therefore, should, contrary to its submissions, the first question be answered in the affirmative, the Defendant contends that the second question should be answered as follows:

> *Such a product is outside the scope of the SPC Regulation and the SPC granted on the basis of such a product is therefore invalid.*

The Government of the United Kingdom

91. The United Kingdom refers to its submissions already set out with regard to the first question.

The EFTA Surveillance Authority

92. ESA submits that as the exemptions provided for in Norwegian and Irish law and granted to the product do not constitute an administrative authorisation (requiring

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[34] Reference is made to *Synthon*, cited above.

[35] Ibid., paragraphs 52 to 57.

safety and efficacy studies) pursuant to Directive 2001/82, the product falls outside the scope of the SPC Regulation. In these circumstances, it contends that an SPC granted in breach of Article 2 of the SPC Regulation should be deemed invalid, since the list of invalidity grounds specified in Article 15 of the SPC Regulation has been held not to be exhaustive.[36]

93. ESA proposes that the Court should answer the second question as follows:

> *Such a product falls outside the scope of the SPC Regulation and therefore an SPC granted on the basis of it is invalid.*

The European Commission

94. The Commission argues that making the product available through licences does not constitute placement on the market prior to a full marketing authorisation so that a patent holder may still rely on a subsequent full marketing authorisation for an SPC application. The Commission proposes a reply to the second question which also includes replies to the first question and part (b) of the fourth question.

The third question

The Plaintiff

95. In the view of the Plaintiff, by its third question, the national court essentially asks whether a marketing authorisation granted for a veterinary medicinal product pursuant to Article 26(3) of Directive 2001/82 should be deemed to constitute, for the purposes of Article 2 of the SPC Regulation, an administrative authorisation pursuant to Directive 81/851 (or Directive 2001/82).

96. The Plaintiff notes that the Defendant relied on its UK marketing authorisation Vm 01708/4551, granted on 10 August 2011, as the first marketing authorisation granted for the Norvax vaccine in the EEA and submits that, with a view to ensuring a uniform interpretation of the notion of marketing authorisation throughout the SPC Regulation, the UK marketing authorisation must also constitute the relevant marketing authorisation for the purposes of Article 2 of the SPC Regulation. According to the Plaintiff, the Defendant has apparently changed position in this regard and now relies on the earlier UK provisional marketing authorisation granted on 6 May 2005 as the relevant marketing authorisation for the purposes of Article 2 of the SPC Regulation, so as to curtail the period of relevant pre-authorisation sales of the vaccine.

97. In the Plaintiff's view, irrespective of the answer to the third question, the considerable sales of the vaccine between 2003 and 2005 predate even the UK provisional marketing authorisation granted in 2005, and therefore entail the placement of the product on the market before obtaining a marketing authorisation for

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[36] Reference is made to *Synthon*, cited above, paragraphs 55 to 56.

the purposes of Article 2 of the SPC Regulation. Consequently, it concludes that the SPC granted to the Defendant is invalid.

98. Furthermore, the Plaintiff contends that the Defendant's arguments based on a supposed analogy concerning the interplay of UK provisional marketing authorisations and Article 2 of the SPC Regulation, on the one hand, and the *Hogan Lovells* case in the context of an SPC for a plant protection product, on the other, are ultimately mistaken.[37] These arguments, which concern the impact of the grant of a provisional marketing authorisation on Article 3(1)(b) and Article 13 of the Plant SPC Regulation, are misplaced for several reasons. First, whereas Article 13 of the Plant SPC Regulation, as interpreted by the Court of Justice in *Hogan Lovells*,[38] envisages the grant of provisional marketing authorisations that do not render invalid a future SPC with regard to the same product, no similar treatment for provisional marketing authorisations is provided in Article 13 of the SPC Regulation. Furthermore, nor is Article 13(3) of the Plant SPC Regulation included in the list of provisions set out in recital 17 of the Plant SPC Regulation which are to be used in interpreting the SPC Regulation.

99. Second, the Plaintiff contends that the requirements set out under Article 4(1)(b) to (f) of Directive 91/414 to obtain a provisional marketing authorisation for a plant protection product are exactly the same as those to be satisfied to obtain a full marketing authorisation. In contrast, Article 26(3) of Directive 2001/82 provides simply that "in exceptional circumstances, and following consultation with the applicant, an authorisation may be granted subject to certain specific obligations, and subject to annual review, including: the carrying out of further studies following the granting of authorization, [and] the notification of adverse reactions to the veterinary medicinal product. These exceptional decisions may only be adopted for objective and verifiable reasons."

100. Third, the Plaintiff contends that since the composition of the product subject to the UK provisional marketing authorisation differed in various elements, including its concentration, i.e. its potency, from the final product approved with the full marketing authorisation, 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.[39]

101. The Plaintiff argues that an authorisation issued on the basis Article 26(3) of Directive 2001/82 does not constitute a marketing authorisation for the purposes of Article 2 of the SPC Regulation and hence all sales based on special approval exemptions and/or AR16 licenses, irrespective of a provisional marketing authorisation being issued in the UK, must be regarded, for the purposes of Article 2

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[37] Reference is made to Case C-229/09 *Hogan Lovells International LLP* v *Bayer CropScience AG* [2010] ECR I-11335.

[38] Reference is made to *Hogan Lovells*, paragraphs 53 and 54.

[39] Reference is made to *Synthon* and *Generics*, both cited above.

of the SPC Regulation, as having taken place before a marketing authorisation was obtained. In the light of the above, the Plaintiff concludes that the third question should be answered in the negative as follows:

> *A marketing authorisation granted for a veterinary medicinal product pursuant to Article 26(3) Directive 2001/82 should not be deemed to constitute an administrative authorisation pursuant to Directive 81/851 (or Directive 2001/82) within the meaning of Article 2 of the SPC Regulation.*

The Defendant

102. The Defendant argues that, by its third question, the referring court seeks to establish whether the UK provisional market authorisation is the first market authorisation in the EEA (for the purposes of Article 13 of the SPC Regulation) and hence whether the date of the UK provisional market authorisation is the cut-off date in relation to the criterion (irrelevant in the Defendant's view) of volume of products supplied, or revenues generated, under the national exemption. In the Defendant's view, the UK provisional marketing authorisation, granted in exceptional circumstances, constitutes a marketing authorisation for the purposes of Directive 2001/82 because the UK provisional marketing authorisation is based on UK provisions transposing Article 26(3) of Directive 2001/82.

103. The Defendant submits that, according to the case law of the Court of Justice, the notion of "authorisation to place on the market" has to be interpreted in a uniform manner throughout the SPC Regulation.[40] Moreover, a marketing authorisation is regarded as granted in accordance with Directive 2001/82 if the safety and efficacy tests are conducted as prescribed in that Directive.[41] In the context of medicinal products for human use, the Court of Justice summarised its position by stating that, for the purpose of granting an SPC on the basis of what is now Regulation No 469/2009, only a product which is protected by a basic patent that is valid in the territory of the EEA State in which an SPC application was submitted and which has obtained a marketing authorisation after being subject, as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83 or Regulation No 726/2004, including safety and efficacy testing in accordance with the requirements of Directive 2001/83, may be the subject of an SPC.[42]

104. The Defendant submits that the specific type of marketing authorisation, commonly known as "marketing authorisation under exceptional circumstances", provided for under Article 26(3) of Directive 2001/82 does not require all the safety and efficacy data that is necessary for a full marketing authorisation. Moreover, such an authorisation may only be granted for "objective and verifiable reasons", and in "exceptional circumstances". In addition, this kind of authorisation is subject to further conditions, which must be re assessed annually.

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40 Reference is made to *Hässle*, cited above, paragraphs 53 to 58.

41 Reference is made to *Synthon*, cited above, paragraphs 47 to 49.

42 Reference is made to *AstraZeneca*, cited above.

105. The Defendant contends further that, as the Court of Justice has defined a marketing authorisation as an unconditional right to place a medicinal product on the market immediately and specified that post-marketing conditions (such as those imposed in marketing authorisations under exceptional circumstances) are not relevant,[43] 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.

106. The Defendant argues that, in the UK, Article 26(3) of Directive 2001/82 was transposed through what are known as "provisional marketing authorisations",[44] which are subject to some but not all requirements concerning safety and efficacy data and which allow the holder to place and sell the medicinal product on the market immediately without any specific restriction. The Defendant observes that the UK Patent Office refused to grant an SPC on the basis of the full marketing authorisation granted in the UK in 2011, because the Defendant had already obtained a provisional marketing authorisation in 2005 on the basis of a dossier that contains safety and efficacy data resulting from several tests already conducted by the Defendant.

107. The Defendant proposes the following answer to the third question:

> *A marketing authorisation granted for a veterinary medicinal product pursuant to Article 26(3) of Directive 2001/82 constitutes an administrative authorisation pursuant to Directive 81/851 (or Directive 2001/82) within the meaning of Article 2.*

The Government of the United Kingdom

108. The United Kingdom did not submit observations in relation to the third question.

The EFTA Surveillance Authority

109. ESA submits that a marketing authorisation granted on the basis of Article 26(3) of Directive 2001/82 does not constitute an administrative authorisation. It points out that, under this provision, it is not required that the product undergoes the safety and efficacy testing which is a necessary part of the procedure if it is to be regarded as an administrative authorisation.[45]

110. Moreover, ESA submits that the solution adopted in *Hogan Lovells*[46] cannot be applied to the current case, since the SPC Regulation does not have a similar provision

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[43] Reference is made to Case C-385/08 *Commission* v *Poland* [2010] ECR I-178, paragraphs 64 and 65.

[44] Reference is made to Veterinary Medicines Guidance, paragraph 66, Note No 1 - Controls of Veterinary Medicines, VMD, July 2013.

[45] Reference is made to *Synthon*, cited above, paragraph 47, and *Generics*, cited above, paragraph 34.

[46] Reference is made to *Hogan Lovells*, cited above, where the Court of Justice concluded that Article 3(1)(b) of the Plant SPC Regulation did not preclude the grant of an SPC for a plant protection product where a provisional marketing authorization had been granted.

to Article 13(3) of the Plant SPC Regulation, which makes it possible to take account of a provisional marketing authorisation, if it is followed by a definitive authorisation.

111. In light of the above, ESA proposes the following answer to the third question:

> *A marketing authorisation granted for a veterinary medicinal product pursuant to Article 26(3) of Directive 2001/82 does not constitute an administrative authorisation pursuant to Directive 2001/82 within the meaning of Article 2 of the SPC Regulation.*

The European Commission

112. In the Commission's view, there is no basis for the third question. According to the Commission, the referring court does not explain which of the various licences it has in mind or if it is referring to the full marketing authorisation for the purposes of implementation of Article 26(3) of Directive 2001/82. It asserts that Article 26(3) of Directive 2001/82 provides for the possibility to grant a marketing authorisation "under exceptional circumstances". In light of the dossier requirements specified in Annex I to Directive 2001/82 (Title III, point 6), the Commission contends that Article 26(3) of that Directive is intended to cover situations where the applicant is unable to provide comprehensive data on efficacy and safety under normal conditions of use, but where nevertheless a positive benefit-risk balance can be established.

113. In the Commission's view, 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), but, at the same time, the applicant is obliged to introduce specific procedures relating to the medicinal product.

114. The Commission argues that the marketing authorisation granted under the provisions cited is a marketing authorisation within the meaning of Article 5(1) of Directive 2001/82 and therefore must be treated as such in the context of all provisions of the SPC Regulation. Therefore, no reply to the third question is offered.

The fourth question

The Plaintiff

115. According to the Plaintiff, the referring court is essentially asking whether Norwegian special approval exemptions constitute valid marketing authorisations within the meaning of Article 3(b) of the SPC Regulation (Question 4(a)) and first marketing authorisations within the meaning of Article 3(d) of the SPC Regulation (Question 4(b)).

116. Were the Court to find that the Norvax vaccine meets the requirements of Article 2 of the SPC Regulation, the Plaintiff contends that the special approval exemptions constitute the first valid marketing authorisations for the purposes of Article 3(b) and (d) of the SPC Regulation. The Plaintiff submits that Article 3(b) of the SPC Regulation, as applicable in the EEA in accordance with Decision No 10/95

of the EEA Joint Committee, envisages different types of authorisations, issued in the EU as well as in the EFTA States, to place a particular product on the market, It contends that this is consistent with the purpose of the SPC Regulation which is to establish a single uniform system of supplementary protection and a uniform period of exclusivity throughout the EEA. Moreover, in keeping with the judgment in *AstraZeneca*,[47] the requirement specified in Article 3 of the SPC Regulation is satisfied by any authorisation enabling the holder to legally commercialise the product, irrespective of the other characteristics of the authorisation.

117. The Plaintiff stresses that although the wording of Article 8 of Directive 2001/82 refers to the possibility for EEA States to provisionally allow the use of the product without a marketing authorisation, the special approval exemption, i.e. the way Norway implemented Article 8 of Directive 2001/82, achieves the same effect and, in practice, constitutes a provisional allowance to place the product on the market. It contends further that, in effect, the Defendant was allowed to place its vaccine on the market and exploit it, benefiting also from an exemption, granted by NoMA, from the advertising prohibition. The Plaintiff asserts that the Defendant has failed to demonstrate any real difference between the Norwegian special approval exemption and the UK provisional marketing authorisation, both as regards the requirements for data on safety and efficacy, or with respect to their commercial exploitation, whereas the turnover and period of sales demonstrate that most of the vaccine's commercialisation occurred under the Norwegian special approval exemption and not under the UK provisional marketing authorisation.

118. The Plaintiff infers that the special approval exemptions amount to an authorisation to place Norvax on the market, granted in accordance with the laws of Norway as an EFTA State, thus satisfying Article 3(b) of the SPC Regulation, as amended by Decision No 10/95. Moreover, it follows from Article 3(b) of the SPC Regulation that a marketing authorisation granted under the national legislation of an EFTA State must be treated as a marketing authorisation granted in accordance with Directive 81/851 (now Directive 2001/82). Consequently, it argues that the Norwegian special approval exemption constitutes a marketing authorisation for the purposes of Article 3(b) of the SPC Regulation and, as such, it also constitutes the first marketing authorisation for the purposes of Article 3(d) of the SPC Regulation. As a result, the SPC granted to the Defendant is invalid as it is not based on the first marketing authorisation for the product.

119. Were the Court to find that the special approval exemptions do not satisfy Article 3(b) of SPC Regulation, the Plaintiff submits that the notions of "marketing authorisation" in Article 3(b) and (d) of the SPC Regulation do not necessarily coincide and that a broad interpretation of Article 3(d) is required in the present circumstances to ensure that the basic objectives of the SPC Regulation are safeguarded. In its view, it would clearly contradict the objectives of the SPC Regulation to allow for a period of exclusive commercial exploitation which extends beyond a total of 15 years.

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[47] Reference is made to *AstraZeneca*, cited above, paragraph 53.

120. The Plaintiff proposes the following answer to the fourth question:

> *The SPC is not valid as it was based on the 2011 marketing authorisation, which is not "the first authorisation to place the product on the market" in Norway as required by Article 3(d) of SPC Regulation.*

The Defendant

121. In the view of the Defendant, an authorisation granted under a national exemption regime does not qualify as an "authorisation to place the product on the market" under Article 3(b) of SPC Regulation because, according to settled case law of the Court of Justice, only a marketing authorisation granted in accordance with Directive 2001/82 qualifies as such. In contrast, a national exemption is, by its very nature, a derogation from the general requirement for an authorisation to place the product on the market as set out in Directive 2001/82. Moreover, the authorisation granted under the national regime is not granted on the basis of safety and efficacy testing as required by Directive 2001/82.

122. According to the Defendant, the additional reference to "national law" contained in Article 3(b)[48] of the Norwegian law on SPCs for medicinal products does not mean that any and all national grants relating to a medicinal product are valid authorisations for the purposes of that provision. Like the SPC Regulation, the Norwegian provision uses the term "authorisation to place the product on the market", which in turn refers to a marketing authorisation.[49] The Defendant argues that a different interpretation would lead to a fragmented internal market, impede the free movement of goods and lead to legal uncertainty.[50]

123. The Defendant proposes the following answer to the fourth question:

> *a) 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) do not constitute valid authorisations to place the product on the market as a medicinal product within the meaning of Article 3(b).*
>
> *b) 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) do not constitute first authorisations to place the product on the market as a medicinal product in Norway within the meaning of Article 3(d).*

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[48] The translation of the Defendant: "*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. With respect to this provision and the articles referring to it, an authorisation to place the product on the market granted in accordance with the national legislation of the EFTA state, shall be regarded as an authorisation granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC as appropriate.*"

[49] Reference is made to *Hässle*, cited above.

[50] Reference is made to *Hässle*, cited above, paragraph 60.

The Government of the United Kingdom

124. The United Kingdom did not submit observations in relation to the fourth question.

The EFTA Surveillance Authority

125. ESA argues that the Defendant's vaccine falls outside the scope of the SPC Regulation. Were the Court to conclude otherwise, ESA submits that the primary purpose of the SPC Regulation is to encourage pharmaceutical research and to ensure that pharmaceutical companies benefit from a secure exclusive use of their patent over a sufficient period of time. The marketing authorisation is one element to take into account in such exercise.

126. However, ESA does not consider that such an authorisation must necessarily comply with Directive 2001/82 or Regulation (EC) No 726/2004.[51] Provided that the authorisation is issued in accordance with the national legislation of the EEA State concerned, what is crucial, as Advocate General Ruiz-Jarabo Colomer explained in his Opinion in *Novartis*, is the date on which the product was first lawfully put on the market in the EEA.[52]

127. In the EEA, medicinal products can be placed on a national market by application of the centralised procedure (as provided for in Regulation (EC) No 726/2004), the decentralised procedure (as provided for in national authorisation procedures) or in accordance with the mutual recognition procedure. Under this regulatory framework, medicines are treated differently to other goods which can freely be marketed in the EEA once they have been lawfully marketed in one of the EEA States.[53]

128. According to ESA, it follows from the wording of the adaptations to Article 3(b) of the SPC Regulation that an authorisation to place a product on the market which is granted in accordance with national rules of an EFTA State must, for the purposes of Article 3(b) of the SPC Regulation and of the other provisions referring to it, be treated as an authorisation granted under Directive 2001/82.[54] This wording seems to recognise that the national rules of the EFTA States may provide for different types of authorisations to place a product on the market.

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[51] Reference is made to Joined Cases C-207/03 and C-252/03 *Novartis AG, University College London and Institute of Microbiology and Epidemiology* v *Comptroller-General of Patents, Designs and Trade Marks for the United Kingdom (C-207/03) and Ministre de l'Économie* v *Millennium Pharmaceuticals Inc.* [2005] ECR I-3209.

[52] Reference is made to the Opinion of Advocate General Ruiz-Jarabo Colomer in *Novartis* v *Comptroller-General of Patents*, cited above, point 49: "the decisive factor is the date on which that use commences, namely the date from which the drug can be lawfully marketed in a part of the EEA, regardless of where, and regardless of the enabling document".

[53] Reference is made to *Novartis* v *Comptroller-General of Patents*, cited above, paragraph 32, and the Opinion of Advocate General Ruiz-Jarabo Colomer in the same case, point 43.

[54] Joint Committee Decision No 7/94 provides that Article 3(b) of the SPC Regulation should, for the purposes of the EEA Agreement, be read with certain adaptations to be inserted in Article 3(b).

129. In ESA's view, the special approval exemption granted to the Defendant's vaccine in Norway from 2003 to 2011 must be deemed to constitute the first valid authorisation to place the product on the market. As a consequence, the marketing authorisation of August 2011, on which the application for an SPC was based, cannot constitute the first authorisation. Hence, ESA submits that the SPC granted to the Defendant in Norway should be deemed invalid under Article 15(1)(a) of the SPC Regulation.

130. ESA therefore proposes the following answer to the fourth question:

> *Special approval exemptions pursuant to Norwegian rules constitute a valid authorisation to place a product on the market as a medicinal product within the meaning of Article 3(b) of the SPC Regulation. Consequently, such exemptions can constitute a first authorisation to place a product on the market as a medicinal product in Norway within the meaning of Article 3(d) of the SPC Regulation. The SPC granted to the Defendant in January 2014 should be deemed invalid under Article 15(1)(a) of the SPC Regulation.*

The European Commission

131. The Commission contends that part (a) of the fourth question is irrelevant. According to the Commission, the Defendant applied for an SPC on the basis of marketing authorisation No 10-7431 and not on the basis of the licences, which do not constitute full marketing authorisation for the purposes of Article 3(b) of the SPC Regulation.

132. The Commission submits that the licence cannot be relied upon neither for the purposes of Article 3(b) of the SPC Regulation nor for those of Article 3(d) of the SPC Regulation, which entails that the licence cannot be regarded as a first full marketing authorisation.[55] According to the Commission, to interpret Article 3(d) of the SPC Regulation differently would frustrate the purposive interpretation of Article 2 of the SPC Regulation it advocates (set out above).

133. Furthermore, as regards part (b) of the fourth question, the Commission considers that, while licences issued on the basis of the first paragraph of Article 8 of Directive 2001/82 should, *de iure*, generally not give full market access, they may, under certain circumstances, do so in fact, such as in the case where the entire demand is satisfied under the licence. In that situation, full market access achieved on such basis should be relevant for the purposes of Article 13(1) of the SPC Regulation. This entails that an SPC should not be granted where it leads to a term of effective protection which exceeds the maximum of 15 years envisaged by the SPC Regulation. The Commission submits that it is a question of fact – to be assessed by the national court – whether or not a licence gives access in fact to the full demand for a product during the period of its validity.

134. The Commission proposes a single answer to Questions 1, 2 and 4(b).

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[55] Reference is made to *Sumitomo*, cited above, paragraph 35.

The fifth question

The Plaintiff

135. The Plaintiff submits that, by the fifth question, the referring court asks in essence whether, in the context of a virus vaccine, the scope of protection under the SPC can 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.

136. 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 notes that the objectives of the SPC Regulation, i.e. ensuring sufficient protection to encourage research, preventing the fragmentation of the EEA pharmaceutical market and balancing the interests at stake, including those of public health, require that the scope of protection granted by an SPC be limited to the product and, more precisely, to the active ingredient authorised to be placed on the market as a medicinal product.[56]

137. The Plaintiff contends that, while the case bears similarities to the *Farmitalia* case,[57] the two cases should be distinguished. *Farmitalia* concerned minor chemical modifications or "derivatives" of the same active ingredient (i.e. salt forms of the same underlying small molecule compound), whereas the current case concerns two different active ingredients, not merely different "forms" of the same active ingredient. Furthermore, in its view, a different virus strain is for regulatory purposes considered a different biological product, i.e. a different active substance, requiring an independent marketing authorisation based upon a full dossier regulatory submission. Applying these principles to the facts of the present case, it should be clear that the Plaintiff's product is not a simple salt, ester or other chemical derivative of the Defendant's product (as was the case in *Farmitalia*), but is a complex biological medicinal product constituting not only a different virus strain to the Defendant's product but also a different sub-type of virus.

138. The Plaintiff argues that it is required by the Norwegian Medicines Agency to conduct the same kinds of comprehensive safety, efficacy and quality tests on its vaccine as the Defendant did to obtain the marketing authorisation MT No 10-7431. Unlike other biological products for which there may be a reference product pursuant to Article 13(4) of Directive 2001/82, the veterinary medicinal product at issue here is a vaccine produced by conventional methods and hence will not be a similar biological medicinal product to another vaccine based on a different virus strain. In such circumstances, it is not sufficient for the Plaintiff's product to demonstrate mere "bioequivalence" to an existing (reference) product (specifically, to Norvax) to obtain regulatory approval. Moreover, the Court of Justice's concerns in *Farmitalia* regarding

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[56] Reference is made to *AHP Manufacturing*, cited above, paragraphs 33 to 39, recital 9 in the preamble to the SPC Regulation and paragraphs 9, 13, 20, 39 of the Explanatory Memorandum to the proposal for Council Regulation of 11 April 1990 (COM(90) 101 final).

[57] Reference is made to Case C-392/97 *Farmitalia Carlo Erba Srl* [1999] ECR I-5451.

the ease of market entry of competing medicinal products do not apply in the case of vaccines and other complex biological molecules. The Plaintiff concludes that Article 4 of the SPC Regulation must be applied strictly such that any SPC should extend only to the particular product covered by the authorisation to place the corresponding medicinal product on the market. Such conclusion – the Plaintiff argues – is consistent with the practice of national intellectual property offices to grant SPCs that are strictly limited to the authorised medicinal product, even though they are based on a broad patent claim.

139. The Plaintiff submits that the product definition in the Defendant's SPC is contrary to the SPC grant practice of national industrial property offices and that such broad product definition would also be wholly inconsistent and unjustified as a matter of SPC law leading to unwarranted uncertainty across the entire life sciences industry in Europe.

140. In light of the above, the Plaintiff proposes that the Court should answer the fifth question in the negative, since, given that the product definition in the SPC purports to cover all virus strains claimed in claims 1 and 4 of the patent and not the actual product authorised to be placed on the market, the SPC is in breach of Article 4 of the SPC Regulation. As regards sub-question (a), the Plaintiff contends that "therapeutic equivalence" is irrelevant. As regards sub-question (b), it contends that the requirement to conduct separate safety and efficacy studies and obtain a separate marketing authorisation is a significant factor for 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. Article 4 of the SPC regulation is to be 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.

The Defendant

141. The Defendant emphasises that the dispute concerns the concept of "product" with regard to the scope of protection afforded by the SPC and argues that, in light of Article 4 of the SPC Regulation, the mere fact that other strains of the virus are also covered by the basic patent is not sufficient to determine whether those other strains fall within the scope of protection of the SPC and thereby to address the issue raised by the parties. Moreover, it contends that the English translation of sub-question (a) is mistaken in referring to a "not immediately equivalent therapeutic effect". The correct translation of the original Norwegian wording is simply "equivalent therapeutic effect". In the Defendant's view, the fifth question has been mistranslated and should be formulated in English as follows:

> *When the medicinal product is a virus vaccine, can the scope of protection afforded by the SPC cover not only the specific strain of the virus that is contained in the authorised medicinal product and is covered by the basic patent, but also other strains of the virus that are covered by the basic patent and are therapeutically equivalent to the specific strain?*

In answering this question, is it of significance whether a medicinal product based on such other strains will have to be the subject of a separate marketing authorisation with requirements for documentation of safety and effect?

142. In the Defendant's view, the fifth question raises the question whether the "product" protected by the SPC is limited to the specific strain of the virus contained in the authorised vaccine and, if not, what are the criteria to determine the scope of protection afforded by an SPC. The Defendant relies on *Farmitalia*,[58] where it was held that the SPC only ensures an effective protection – and thereby meets the objective of 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.

143. The Defendant argues that the principles set out by the Court of Justice in *Farmitalia*[59] should apply also to biological substances, because the SPC Regulation does not distinguish between chemical and biological active ingredients and 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.

144. In the Defendant's view, this interpretation is the only one that gives any value to SPCs for complex biological substances, including vaccines, because SPCs would be totally worthless were they to cover only one specific biological substance in disregard of (even minor) differences in the chemical structure of complex biological substances. The Defendant stresses that vaccines contain biological substances, the characteristics of which are different to the characteristics of other chemical substances. Nonetheless, it contends that those differences do not undermine the conclusion above, because they are only relevant as regards the evidence of therapeutic equivalence between two substances and this specific issue of evidence has not been referred to the Court.

145. Finally, the Defendant argues that the regulatory route used, or to be used, for the authorisation of a vaccine containing a new strain of the virus is not relevant for determining the scope of protection afforded by an SPC, because the Court of Justice has ruled that pharmaceutical rules are not relevant for the interpretation of the SPC Regulation. Moreover, a new strain may be authorised by a line extension or a new marketing authorisation, depending on the facts and on the company's choice of procedure.

146. Therefore, the Defendant proposes the following answer to the fifth question:

When the medicinal product is a virus vaccine, the scope of protection afforded by the SPC covers not only the specific strain of the virus which is contained in the authorised medicinal product and is covered by the basic patent, but also

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58 Reference is made to *Farmitalia*, cited above.

59 Reference is made to *Farmitalia*, cited above.

the other strains of the virus which are covered by the basic patent and are therapeutically equivalent to the specific strain of the virus.

In answering this question, it is not relevant whether a vaccine based on such other strain can be the subject of a separate marketing authorisation under pharmaceutical law.

The Government of the United Kingdom

147. The United Kingdom did not submit any observations in relation to the fifth question.

The EFTA Surveillance Authority

148. In ESA's view, the final two questions seek to establish whether, in the case of a virus-based vaccine, the SPC protection can be extended to more than the specific virus strain covered by the marketing authorisation.

149. ESA notes that the parties disagree on the extent to which the SPC protection can include more than the specific vaccine strain referred to in the marketing authorisation, granted in 2011, and on which the SPC is based.

150. It observes that, in the present case, the product definition in the SPC granted covers the specific strain of the SPD virus (inactive) included in Norvax Compact PD and other virus strains with which "(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".

151. These are strains covered by Claim 1 in the basic patent. ESA observes that, according to the referring court, in a previous patent dispute between the parties, it has been conclusively and finally determined that the Plaintiff's vaccine strain falls within the scope of Claim 1 in the basic patent.[60]

152. Based on the wording of Article 4 and recital 9[61] in the preamble to the SPC Regulation, ESA submits that the protection provided by an SPC is limited to the "product" that is covered by the marketing authorisation. ESA emphasises that such conclusion is strengthened by the European Commission's Explanatory Memorandum.[62]

153. Hence, 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

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[60] See pages 8 to 9 of the Request for an advisory opinion.

[61] " ... the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product."

[62] In the European Commission's Explanatory Memorandum of 11 April 1990, paragraph 9 reads: "The certificate confers the same protection as the basic patent, but only protects the product covered by the authorization ...". Similarly, paragraph 13 reads "The certificate does not protect the expired patent in its entirety. It protects only the product authorized to be placed on the market. ...". In addition, ESA refers to paragraphs 20 and 39 of that document.

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.

154. ESA distinguishes the circumstances of the case at hand from those in *Farmitalia*.[63] In that case, the Court of Justice held that the SPC at issue should be capable of covering the active ingredient as such and also its various derived forms such as salts and esters.[64] 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.[65]

155. Furthermore, according to ESA, it is clear from the request for an advisory opinion that the virus strains on which the two vaccines are based consist of two different subtypes.[66] However, in its view, it is for the national court to determine, on the basis of the evidence produced by the parties, whether the vaccines can be considered to be therapeutically equivalent.

156. ESA proposes that the fifth question should be answered as follows:

> *a) When the medicinal product is a virus vaccine, the scope of protection under the SPC only covers the specific strain of the virus that is included in the medicinal product and covered by the marketing authorisation on which the SPC is based, provided that it does not have an equivalent therapeutic effect to other strains of the virus that are covered by the basic patent.*
>
> *b) 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. If a product must be subject to a different marketing authorisation, it is not covered by the scope of the protection of an SPC which has been granted on the basis of a different marketing authorisation.*

The European Commission

157. On the Commission's reading of the request, the referring court appears to assume that use of a strain of the virus subtype SAV 3 would, under Norwegian law, infringe a patent on a strain of subtype SAV 1 and closely related strains which share similar genotypic and/or phenotypic characteristics of the latter. The Commission argues that the question whether that assumption is correct is not a matter of interpretation of the SPC Regulation but of Norwegian patent law.

158. The Commission stresses that in *Farmitalia* the Court of Justice established that an SPC covers "the actual medicinal product, as protected by the basic patent and one

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63 Reference is made to *Farmitalia*, cited above.

64 Ibid., paragraph 21.

65 See page 9 of the Request for an advisory opinion.

66 i.e. The virus strain on which Plaintiff's vaccine is based is of the subtype SAV 3, whereas the virus strain on which the Defendant's vaccine is based is of the subtype SAV 1.

of the possible forms of which is the subject-matter of a marketing authorisation",[67] and that "the certificate is capable of covering the active ingredient as such and also its various derived forms, such as salts and esters, as medicinal products, in so far as they are covered by the protection of the basic patent".[68]

159. The Commission observes that, according to the Court of Justice, the purpose of the SPC Regulation is to prevent medicinal products based on a different salt of the same active ingredient and, in principle, therapeutically equivalent to the product protected by an SPC from competing with the latter, as to allow this would frustrate the aim of the SPC which is to ensure the patent holder of exclusivity for a period extending beyond the period of validity of the basic patent.[69] 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.

160. According to the Commission, 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.[70]

161. The Commission argues that whether or not a strain of a virus of a certain subtype is identical to a strain of a different subtype is a question of fact, which is for the national court to determine.

162. The Commission proposes that the fifth and sixth questions should be answered jointly as follows:

> *Article 4 of the SPC Regulation should be interpreted to the effect that the scope of protection conferred by a supplementary protection certificate extends to a specific strain of a virus covered by the basis patent but not referred to in the marketing authorization 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. A supplementary protection certificate is invalid to the extent that it is granted a wider scope.*

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67 Reference is made to *Farmitalia*, paragraph 19.

68 Ibid., paragraph 21.

69 Ibid., paragraph 18.

70 Reference is made to Case C-574/11 *Novartis AG* v *Actavis Deutschland GmbH & Co. KG and Actavis Ltd*, order of 9 February 2012, paragraph 20, and *Neurim Pharmaceuticals*, cited above, paragraph 33.

The sixth question

The Plaintiff

163. In relation to part (a) of the sixth question, the Plaintiff argues that the Court must hold that in these circumstances an SPC will be invalid (i) for breach of Article 4 of the SPC Regulation, in accordance with the principle laid down in *Synthon*,[71] and (ii) for breach of Article 15(1)(a) of the SPC Regulation. On this latter point, the Plaintiff argues that the SPC was not granted in respect of a product as specified in Article 3(b) of the SPC Regulation, as there is a mismatch between the "product" as defined in the SPC and the product authorised to be placed on the market as a medicinal product within the meaning of Article 3(b) of that Regulation.

164. In relation to part (b) of the sixth question, if the SPC is held valid, the Plaintiff argues that the answer should be in the affirmative, since the scope of protection does not extend beyond the specific virus strain authorised to be placed on the market as a medicinal product. If an SPC has been granted with a product definition that is not strictly limited to the specific virus strain authorised to be placed on the market as a medicinal product, then such an SPC will be invalid.

The Defendant

165. The Defendant argues that the sixth question is irrelevant on the grounds that an SPC is not granted for the specific strain of the virus contained in the authorised vaccine. Nevertheless, in the event that the Court considers the question relevant, 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. Therefore, in the opinion of the Defendant, the answer to the sixth question should be as follows:

> *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, such an SPC is valid but its scope of protection is determined by the specific strain of the virus contained in the authorised vaccine.*

The Government of the United Kingdom

166. The United Kingdom did not submit observations in relation to the sixth question.

The EFTA Surveillance Authority

167. In light of its submissions on the fifth question, and insofar as an SPC is found to fulfil the requirements specified in Articles 2 and 3 of the SPC Regulation, ESA

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[71] Reference is made to *Synthon*, cited above, paragraphs 52 to 57.

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.

168. ESA proposes that the sixth question should be answered as follows:

> *An SPC which has been granted within 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, must be deemed valid only insofar as the product definition is the same as in the marketing authorisation on which it is based.*

The European Commission

169. The Commission submits that an SPC that does not meet the requirements for the identity of the active ingredient and therapeutic equivalence amounts to an SPC for a product outside the scope of the SPC Regulation. Such an SPC disregards the meaning of "product" in Article 3 of the SPC Regulation and must therefore be regarded as invalid pursuant to Article 15(1)(a) of the SPC Regulation[72] to the extent that it is granted a wider scope.

170. The Commission has proposed a joint reply to the fifth and sixth questions.

Páll Hreinsson

Judge-Rapporteur

[72] Reference is made to *Synthon*, cited above, paragraph 59.