Intellectual Property Office

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COUNCIL REGULATION (EC) 469/2009
CONCERNING THE CREATION OF A
SUPPLEMENTARY PROTECTION CERTIFICATE
FOR MEDICINAL PRODUCTS

APPLICANT	Boehringer Ingelheim Vetmedica GmbH
ISSUE	Whether application for supplementary protection certificate SPC/GB20/032 meets the requirements of Articles 3(c) and 3(d) of the SPC Regulation
HEARING OFFICER	Dr Rowena Dinham

DECISION

Background

1 This decision relates to the issue of whether the SPC application, SPC/GB20/032 ("the application"), meets the requirements of Articles 3(c) and 3(d) of Council Regulation (EC) No 469/2009[1] ("the SPC Regulation"), filed in the name of Boehringer Ingelheim Vetmedica GmbH ("the applicant").

2 The application was filed on 24 June 2020 and relies on basic patent EP(UK) 2934479 which has a filing date of 18 December 2013, and on centralised European marketing authorisation EU/2/19/249, covering the medicinal product Aservo® EquiHaler®[2]. The marketing authorisation for Aservo Equihaler was granted following Commission Implementing Decision C(2020)578 of 28 January 2020.

3 The product that is the subject of the application is identified on the associated form SP1 as "Ciclesonide or a pharmaceutically acceptable salt thereof".

The Basic Patent

4 The basic patent, EP(UK) 2934479, entitled "Ciclesonide for the treatment of airway disease in horses", was filed on 18 December 2013, with an earliest priority date of 21 December 2012, and was granted on 19 September 2018. The expiry date of the

[1] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificates for medicinal products; see CELEX Document 32009R0469; published in the Official Journal of the European Union L 152 16/6/2009. Whilst this is an EU instrument, it is now retained EU law and has not materially changed since Brexit. Any relevant changes will be highlighted.

[2] Both Aservo® and Equihaler® are Registered Trade Marks in the UK. For brevity the medicinal product will be referred to as "Aservo Equihaler" for the remainder of the decision.

patent is 17 December 2033. There is a single independent claim, which reads as follows:

> *Ciclesonide or a pharmaceutically acceptable salt thereof or a composition comprising ciclesonide or a pharmaceutically acceptable salt thereof for the use in a method of treating an airway disease in equines, preferably horses.*

Other authorisations

5 There are earlier authorisations for ciclesonide, which were acknowledged by the applicant in the letter accompanying the filing of the application. In particular, UK authorisations PL 20141/0004-0012 of 16 April 2004 were granted for ciclesonide as Alvesco/Freathe/Amavio 40, 80 and 160 inhalers. Furthermore, a previous Supplementary Protection Certificate ("SPC") has been granted for ciclesonide as SPC/GB04/026, which was based on authorisations PL 20141/0004-0006. This earlier Certificate expired on 2 September 2016.

Issues to be decided

6 A decision on the papers has been requested by the applicant, and in this decision I will consider whether the application satisfies Articles 3(c) and 3(d). I shall only consider what the appropriate term for the SPC is with regard to Article 13 given the arguments presented if I determine that the requirements of Articles 3(c) and 3(d) are met.

The law[3]

7 The SPC Regulation allows the proprietor of a patent for a medicinal product to obtain an SPC for that product; the SPC provides a patent-like right extending the period of exclusivity for the product so as compensate the proprietor for the effective loss of patent term due to the need to obtain a marketing authorisation (MA) before the product can be marketed. The period of the extension is determined in relation to the dates of grant of the basic patent and the appropriate marketing authorisation, with a maximum period of five years following expiry of the basic patent.

8 Article 1 of the SPC Regulation defines various terms, of which Articles 1(a) to 1(d) are relevant to this decision and are reproduced below:

Article 1

Definitions

> *For the purposes of this Regulation, the following definitions apply:*
>
> *(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*

[3] For clarity and consistency throughout this decision, relevant EU legislation implemented prior to Brexit will be referred to in terms of their EU instruments if they are part of retained EU law. As indicated above, any relevant changes will be highlighted.

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 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;

(d) 'certificate' means the supplementary protection certificate;

(e) …

(h) "EEA authorisation" means an authorisation to place a medicinal product on the market which has effect in an EEA state in accordance with Directive 2001/83/EC or Directive 2001/82/EC;
…
(j) 'UK authorisation' means, in relation to a product, an authorisation to place that product on the market in the United Kingdom as a medicinal product granted or having effect as if granted in accordance with-
(i) Part 5 of the Human Medicines Regulations 2012; or
(ii) regulation 4(3) of, and Schedule 1 to, the Veterinary Medicines Regulations 2013.

9 Article 3 of the SPC Regulation (at the time of filing the application) concerns the conditions for obtaining an SPC; Article 3(d) makes it clear that a certificate cannot be obtained if the marketing authorisation to place the medicinal product including this product onto the market in the EU is not the first authorisation (my emphasis):

Article 3

Conditions for obtaining a certificate

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

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

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, 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*.[4]"

[4]For applications still pending as of 1 January 2021, a transitional form of Article 3(d) reads:

10 Relevant case law to these articles will be considered in the body of the decision.

The examiner's view

11 The examiner maintained his view throughout that the relevant case law is as set out in *Santen SAS v Directeur Général de l'Institut National de la Propriété Industrielle*, C-673/18 ("*Santen*"). He considered that *Santen* makes it clear that the approach adopted in the earlier decision of the CJEU in *Neurim*[5] is overturned, and that there is no need to take into account the limits of the protection of the basic patent. Therefore, in the present case, the product is deemed to be ciclesonide, and treatment of the airway of horses is not taken into account. As a consequence, he asserted that prior authorisations PL 20141/0004-0012 represent the first authorisations to place the product ciclesonide on the market in the United Kingdom for the purposes of Article 3(d) of Regulation 469/2009; the use of ciclesonide in the earlier authorisations being immaterial for the purposes of deciding the first authorisation as set out in Article 3(d). Furthermore, the examiner noted that *Santen* makes no reference to treating authorisations for human medicines differently to those for veterinary medicines. He further argued that had it been the intention of the CJEU to draw such a distinction then it seems highly unlikely that this point would not have been made abundantly clear.

12 Secondly, the examiner also asserted that the application also cannot be granted in view of Article 3(c), as ciclesonide has also been the subject of earlier certificate, SPC/GB04/026, for the same product, as noted above.

13 Thirdly the examiner pointed out that, even if incorrect as regards Article 3(d) and 3(c), and a certificate were subsequently granted, it would have zero term by virtue of the operation of Article 13(1) and having regard to the decision of the CJEU in *Pharmacia Italia SpA* (C-31/03)[6].

The applicant's view

14 The applicant summarised their position in their letter of 18 January 2024. Whilst they have not provided any arguments in response to the examiner's pre-hearing report, I am grateful for their structured argument in their earlier letter, focussing on what they consider to be five key points. I will summarise these points accordingly.

15 The applicant began by pointing out that the active ingredient ciclesonide obtained a marketing authorisation as a "**new active substance**" granted by the European Commission based on the assessment of the European Medicines Agency (EMA), in view of the lack of any prior *veterinary* authorisation for the product. In their opinion, this authorisation as a new active substance (i.e. a veterinary active substance rather than a human active substance) should be considered as the first approval of that active substance.

(d) the authorisation referred to in point (b) is the first UK authorisation to place the product on the market as a medicinal product

[5] *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* (C-130/11)

[6] Although the examiner further notes that this alone does not provide grounds for rejection under Article 10(2)

16 In particular, the applicant stated:

> "Boehringer Ingelheim Vetmedica GmbH was granted a marketing authorisation (MA) by the European Commission for the product containing the active product ciclesonide on 28 January 2020. In the assessment report for the product, the Committee for Medicinal Products for Veterinary Use (CVMP) noted that the active substance of Aservo® EquiHaler® is a *new active substance (NAS) not previously authorised for a veterinary product in the EU.*
>
> Following Brexit, the UK preserved, as part of UK law, the principles of EU law relating to veterinary products, including legislation and case law, as they stood on 31 December 2020 (per the European Union (Withdrawal) Act 2018). The UK regime is set out in the Veterinary Medicines Regulation 2013/2033, which initially implemented the relevant EU legislation into UK law, and has subsequently been amended to ensure the regime as at 31 December 2020 applies in the UK post Brexit. Consequent upon Brexit, as of 1 January 20[21], the centralised Aservo MA was automatically converted to an MA applicable in Great Britain (04491/5003). However, in accordance with the relevant provisions, no new assessment was conducted at this time, and the CVMP's assessment of the NAS status of ciclesonide in Aservo® EquiHaler® remains valid in the UK.
>
> …medicinal products that – like the product which is the subject of the present application – are not covered by the Annex to the Regulation – can only be authorized by the European Commission if they meet the requirements of Article 3(2) of the Regulation, which states as follows:
>
> > *"Any medicinal product not appearing in the Annex may be granted a marketing authorisation by the Community in accordance with the provisions of this Regulation, if:*
> >
> > (a) *The medicinal product contains **a new active substance** which, on the date of entry into force of this Regulation, was **not authorised in the Community**…"*
>
> Ciclesonide has been classified as a new active substance (NAS) by the EMA, as can be seen from the European Public Assessment Report (EPAR) – see page 4 paragraph 2, under the heading "Introduction" of which states as follows:
>
> > *"The eligibility to the centralised procedure was agreed upon by the CVMP on 15 March 2018 as Aservo® EquiHaler® contains **a new active substance (ciclesonide)**, which **was not authorised in the Community** on the date of entry into force of the Regulation."*
>
> The EPAR concludes as follows – see page 37, which states as follows:
>
> > "This product is **a new active substance** administered via an integrated novel inhaler."

Ciclesonide was therefore authorized in a veterinary product as a new active substance which was not previously authorized in the Community. As stated above, this status remains the case in the UK following the expiry of the Brexit transition period and no new assessment was conducted in the UK on the grant of the GB MA."

17 The applicant further argued that, with regard to the designation as a new active substance under Article 3(2)(a) of Regulation 726/2004[7,8], the EMA does not consider it relevant that a prior human authorisation had been granted for that product; when assessing whether an active substance has been approved, a distinction is made between veterinary medicinal product MAs and human medicinal product MAs. In this regard, they pointed out that a "new active substance" is not defined in legislation, and point to Commission guidance, Eudralex – Volume 6 – Notice to applicants and regulatory guidelines for medicinal products for veterinary use[9], and specifically chapter 1 on marketing authorisations, where Annex I defines a new active substance as:

> *"A new chemical, biological or radiopharmaceutical active substance*
>
> - *includes a chemical, biological or radiopharmaceutical active substance not previously authorised in a veterinary medicinal product in the European Union"*

18 The applicant then pointed to where the EMA expands on this guidance in the "*Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances for veterinary medical products*"[10] ("*the EMA reflection paper"*) in which the EMA clarifies the criteria that needs to be met in order for a veterinary MA to be considered to contain a NAS under EU law. This paper states:

> *"A chemical active substance that is not previously authorised in a medicinal product for* ***veterinary use*** *in the European…should be considered a NAS"*

19 They thus asserted, including by reference to the corresponding human medicinal reflection paper etc. that, when assessing whether an active substance has already been approved in the Community, a distinction is made between veterinary product MAs and human product MAs.

20 Secondly, the Applicant went on to argue that, although the phrase "new active substance" is not found in the SPC Regulation, the term "active ingredient" in the

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[7] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

[8] *Article 3 (2) Any medicinal product not appearing in the Annex may be granted a marketing authorisation by the Community in accordance with the provisions of this Regulation, if:*

(a) *the medicinal product contains a new active substance which, on the date of entry into force of this Regulation, was not authorised in the Community.*

[9] EudraLex - Volume 6 - European Commission

[10] Reflection paper on the chemical structure and properties criteria to be considered for the evaluation of New Active Substance (NAS) status of chemical substances for veterinary medical product; 8 December 2022; EMA/CVMP/QWP/3629/2016-Rev.1). The earlier 13 July 2017 version of this paper also contains equivalent wording to the Sections 1.2 and 2 text reproduced in this decision.

sense of "first marketing authorisation" of that active ingredient is to be construed in the Regulation in the same way as in EU medicinal and veterinary regulatory law. They considered that this was confirmed by the CJEU in *Forsgren* (C-631/13)[11]:

> *"23. "Product" is defined in Article 1(b) of Regulation No.469/2009 as 'the active ingredient or combination of active ingredients of a medicinal product'. However, the term 'active ingredient' is not defined in that regulation. That term appeared in Article 1(b) of Council Regulation (EEC) No1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p.1), which was repealed by Regulation No 469/2009, and a question relating to that provision has already been referred to the Court. The Court held on that occasion that it is generally accepted in pharmacology that the term 'active ingredient' does not cover substances forming part of a medicinal product which do not have an effect of their own on the human or animal body (see judgment in Massachusetts Institute of Technology, EU:C:2006:291, paragraph 18).*
>
> *24. That interpretation was subsequently reproduced, in essence, by the EU legislature. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 (OJ 2011 L 174, p.74) amended Article 1 of Directive 2001/83 to the effect that* ***the term 'active substance' – which must be understood as meaning 'active ingredient'*** *(judgment in Massachusetts Institute of Technology, EU:C:2006:291, paragraph 21) – is defined therein as 'any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis."*

21 They referred to paragraph 38 of *Forsgren*, which states that an approval procedure in which no trials or data on the therapeutic effects of an *excipient* in relation to the approved use of the MA have been included does not delay the economic exploitation of the basic patent (and so would be contrary to the aims of the SPC Regulation). Accordingly, they considered that the CJEU confirms that the term "valid authorization" within the meaning of Article 3(b) must also be interpreted in the light of EU pharmaceutical regulatory law, according to which it is the **therapeutic effect of the substance** in question **in connection with the medicinal product containing it** that is important. This, they suggested, also demonstrates that the term "active substance" in the context of Article 3 is to be understood exactly as it is understood in pharmaceutical regulatory law. Therefore, in the mind of the applicant, as the term "valid authorisation" or "first authorisation" in Article 3 of the SPC Regulation refers directly to the product, which in turn refers to the "active substance" of a medicinal product, this uniform understanding of the term "active substance" for the MA procedure and the SPC Regulation results in the uniform understanding of the term "authorisation". As such, a first authorisation as a "new active substance" within the meaning of Regulation 726/2004 must also be a first authorisation within the meaning of the SPC Regulation.

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[11] *Arne Forsgren v Österreichisches Patentamt* (C-631/13)

22 As the strict regulatory distinction between an authorisation as a veterinary medicinal product, or as a medicinal product for human use, also applies to the interpretation of Articles 3(b) and 3(d) of the SPC Regulation, the applicant concluded that ciclesonide as a new active substance of the authorised medicinal product Aservo Equihaler is also a new "product" within the meaning of Article 1(b) of the SPC Regulation, and the corresponding first MA in the Community for this veterinary medicinal product is also the first MA for this new product within the meaning of Articles 3(b) and 3(d) of the SPC Regulation.

23 In their third point, the applicant argued that the grant of an SPC for ciclesonide is in line with the objectives of the Regulation, in view of the fact that separate and independent clinical trials are required to demonstrate the safety and efficacy which led to the grant of the veterinary authorisation. In particular, the applicant noted that the wholly different regulatory frameworks of the veterinary and human medicinal systems mean that (their emphasis):

> "[c]linical studies to test the therapeutic efficacy of the veterinary product in animals, including dose-finding and pharmacokinetic studies, must naturally be carried out **regardless** of whether or not the active substance has already been approved as a human medicinal product. In addition, when testing the safety of a veterinary medicinal product, not only must the safety for the target animal species be tested via corresponding studies in animals, but independent studies are also required that prove the safety for humans when the veterinary medicinal product is administered, as well as studies that prove that the administration to animals does not cause any harm to the environment. This should be contrasted with the situation (as in *Santen*) where data from an existing human MA that demonstrates the safety of the human medicinal product **can** be used in the authorisation procedure for a **new human therapeutic indication** for that **previously** authorised **human** medicinal product".

24 Therefore, as the applicant could not rely on the clinical trials which led to the prior MA of a human medicinal product which also contains ciclesonide as an active ingredient, they were of the view that the granting of an SPC is in line with the SPC Regulation as it compensates the patent holder for the new studies required to demonstrate the safety and efficacy of the new veterinary medicinal product.

25 Fourthly, the applicant contended that *Santen* is not relevant to the situation where a first veterinary marketing authorisation follows an earlier marketing authorisation for use in humans. This is because they are granted under entirely different regulatory frameworks, and in the applicant's view, the wording of Article 3(b) "*a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/82/EC* ***or*** *Directive 2001/82/EC, as appropriate"* is intended to distinguish between human and veterinary MAs in regard to Article 3(b), and by extension to Article 3(d) also. In this regard, the applicant argued that Article 3(d) is based on the corresponding regulatory law for granting MAs and should be interpreted the same way; an active substance not previously authorised as a veterinary medicinal product under the veterinary medicines regulatory regime should be considered a new active substance even if already authorised for human use under the human medicines regulatory regime. They

concluded that the resulting veterinary MA is therefore the first authorisation within the meaning of Article 3(d).

26 Fifthly, the applicant argued that *Santen* only reverses *Neurim* to the extent that the scope of the basic patent should not be taken into account when considering Article 3(d), and so does not disqualify from SPC protection a product which has received a first veterinary authorisation even when a human authorisation has previously been granted. The applicant considered that guidance of the Manual of Patent Practice in this regard is incorrect in so far as it suggests that *Santen* entirely reversed *Neurim*.

27 In addition to the five points raised in their letter of 18 January 2024, the applicant argued (in their letter of 16 February 2023) in relation to the examiner's argument regarding Article 13(1) that the decision of the CJEU in *Pharmacia*[12] is not relevant to the present case. In their opinion, in that instance the basic patent claimed ergoline derivatives and their pharmaceutically acceptable salts *as such*, and so the patent protected the product regardless of its use as a human or veterinary product. Therefore, a marketing authorisation granted for any kind of medicinal product containing the ergoline derivative cabergoline allowed the patentee to make use of its product, and so no distinction was made as to whether the grant of the marketing authorisation followed the human Directive 2001/83/EC[13] or Directive 2001/82/EC[14]. In the applicant's view, if a patent protects a human medicinal product or a veterinary medicinal product, a valid marketing authorisation for placing the product on the market requires that the approval is obtained according to the appropriate directive (i.e. 2001/83/EC or 2001/82/EC respectively).

Analysis

28 The crux of the applicant's arguments appears to lie in what is considered to be a "new" active substance for the purposes of the SPC Regulation, and how the Regulation was intended to distinguish between veterinary and human uses of active substances which require the granting of MAs under different regulatory frameworks. They also question the extent to which the CJEU judgment in *Santen* "reverses" *Neurim*, such that it was not the intention of the CJEU in *Santen* that a prior MA for human use should be viewed as the first MA for the same active substance for veterinary use, and *vice versa*, because the MAs are granted under entirely different regulatory frameworks.

29 In their letter of 18 January 2024, the applicant went to some lengths to describe how the subject of their application is a "new active substance" not previously authorised in the EU (and now, for our purposes, the UK). They note that the term "new active substance" is not defined in legislation and instead they refer to the EMA reflection paper, highlighting the passage at the beginning of Section 2 which in its entirety states (my emphasis):

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[12] *Pharmacia Italia* C-31/03

[13] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

[14] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (Repealed by Regulation (EU) 2019/6 of 11 December 2018

> *"A chemical active substance that is* ***not previously authorised in a medicinal product for veterinary use*** *in the European Union* ***and that is from a chemical structure point of view not related to any other authorised substances*** *should be considered as a NAS. Such substance is considered to be new in itself, when the administration of the applied active substance would not expose animals to the same therapeutic moiety as already authorised active substance(s) in the European Union. If the chemical active substance is structurally related as a salt, ester, ether, isomer, mixture of isomers, complex or derivative of an already-approved active substance(s) in the European Union, it should be assessed whether it shares the same therapeutic moiety at the site of the biological activity as the already-approved active substance and if so whether it differ significantly in properties with regard to safety and/or efficacy.* ***Guidance is provided below to define the elements taken into account to qualify a salt, ester, ether, isomer, mixture of isomers, complex or derivative of an active substance as NAS in the context of the NAS status claim****".*

30 The applicant emphasises the point that a chemical substance not previously authorised in a veterinary medicinal product is viewed as a "new active substance" for the purposes of Regulation 2019/6[15], requiring a new veterinary medicinal product MA. They conclude that this veterinary medicinal product MA should be taken as the first approval of that (new) "active substance", regardless of whether the (new) "active substance" has previously been the subject of an MA as a human medicinal product, and vice versa.

31 Whilst the applicant does acknowledge that the term "new active substance" is not found in the SPC Regulation, they attempt to draw parallels between the definition of "new active substance" in the EMA reflection paper, and the term "active ingredient" as required by the SPC Regulation. Specifically, they argue that the term "new active substance" and "active ingredient" in the sense of the "first marketing authorisation" of that active ingredient are to be construed in exactly the same way in the SPC Regulation as they are in human and veterinary medicinal regulatory law. In this regard, they refer to the CJEU in *Forsgren*[16] as supporting their position.

32 Whilst the phrase "new active substance" is important from a regulatory point of view (e.g. in terms of the safety and efficacy testing required)[17], it does no more than tell us that the chemical substance is distinct from any previously authorised product under the relevant Regulation. Therefore, in the present case it would be distinct from any previously authorised *veterinary* product (even though the chemical substance had previously been authorised as a *human* product). However, this phrase is not used in the SPC Regulation, and I see nothing that suggests that the "active ingredient" (for the purpose of the first MA) is to be construed in the same way as the "new active substance" for the purposes of the veterinary or human

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[15] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. It is part of the post-Brexit retained EU law, with no amendments to date and sets out a regulatory framework for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and the use of veterinary medicinal products.

[16] See paragraphs [23] & [24] therein

[17] and the designation is advantageous to an applicant, not least because of the period of data exclusivity under Regulation 726/2004 Article 14 associated with this status for human use

medicinal product Regulations, or that any distinction is to be made between a veterinary or human MA for the purposes of the SPC Regulation. Article 1(b) of the SPC Regulation defines the product as "the active ingredient or combination of active ingredients of a medicinal product", and paragraph [28] of the Explanatory Memorandum further clarifies what is meant by the concept of "medicinal product". Again, there is no reference to the "active ingredient" in the SPC Regulation being synonymous with the "new active substance" used for human and veterinary medicine regulatory purposes.

33 In *Forsgren,* the CJEU considered what was meant by the term "active ingredient, and, in reference to *Massachusetts Institute of Technology* ("MIT"[18], concluded that "*the term 'active ingredient', for the purposes of applying [the SPC Regulation] concerns substances producing a pharmacological, immunological or metabolic action of their own*". This, the court stated, follows from the definition of an "active substance" in Directive 2011/62/EU[19], on the understanding that "active substance" is understood as meaning "active ingredient"[20]. However, this is in the context of defining the pharmacological, immunological etc. effects of that active substance and distinguishing it from a non-active substance, based upon how actives and non-actives are understood in pharmacology. The phrase "new active substance" as such, with all its associated context, is not considered in *Forsgren*, and therefore I do not see how this helps the applicant's position.

34 In the present case, the applicant does not appear to suggest that the ciclesonide in the Aservo Equihaler is a different chemical substance to that in the Alvesco etc. inhalers, and thus I can conclude that they are the same active substance and thus the same product. Ciclesonide's "new active substance status" under Regulation 2019/6 does not change this. Referring back to Article 1 of the SPC Regulation which, at the time of filing of the application, stated that an "*'EEA authorisation' means an authorisation to place a medicinal product on the market which has effect in an EEA state in accordance with Directive 2001/83/EC or Directive 2001/82/EC*", (i.e. either human and veterinary regulatory routes), and Article 3(d), which makes it clear that the consideration is "the authorisation (referred to in point (b)) is the **first authorisation** to place **the product** on the market as a medicinal product", it is clear that there is no qualification here. A marketing authorisation is one for a **product** under either the human medicinal product Directive or the veterinary medicinal product Directive. Furthermore, Article 3(d) merely refers to the first authorisation, without restriction, and that authorisation must relate to the **product**; in the present case that product would be ciclesonide.

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[18] Massachusetts Institute of Technology C-431/04

[19] Directive 2011/62/EU amended Directive 2001/83, with Article 1 amended as follows:

(a) the following points are inserted:

3a. Active substance:

Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.

3b. Excipient:

Any constituent of a medicinal product other than the active substance and the packaging material

[20] Again with reference to MIT, paragraph [21]

35 Nevertheless, the applicant goes on to argue that the grant of an SPC for ciclesonide for equine use is in line with the objectives of the SPC Regulation, due to the entirely separate and independent clinical trials needed in horses from those that formed the basis of the first human MA. I acknowledge that the SPC system is intended to balance relevant interests, including assisting in adequately compensating the patentee for the additional research required to commercialise their patent. However, as is clear from the Explanatory Memorandum, this balanced system not only takes into account encouragement of pharmaceutical research, but also other relevant interests and the need for a simple, transparent system. As Birss LJ noted in *Merck Serono* (albeit obiter)[21]

> "32. *Note that Art 3(d) is important because of its interaction with the term of the SPC. That term is calculated by reference to the date of the marketing authorisation named in the application for the certificate. If the company could use a second later marketing authorisation in its SPC application then even though it had been able to start selling the product at an earlier time- and thereby started to recoup its investment- it could still obtain a 5 year term for its SPC. It might be that the second marketing authorisation was a much better pharmaceutical formulation of the compound than the one in the first marketing authorisation but that does not justify ignoring the first marketing authorisation for the purposes of Art 3(d). This is an example of the kind of balancing of the policy objectives set by the terms of the SPC regulation".*

36 Birss LJ went on to agree with the opinion of Arnold J in *Abraxis*[22]*,* when offering his own answer to the questions the Court was referring to the CJEU:

> *"48. In referring the questions on Art 3(d) to the CJEU, Arnold J … observed that the Regulation was intended to provide a simple and predictable system that could be operated by the competent authorities of the Member States, and in particular the national patent offices, in a uniform manner. He also noted that the Regulation aims to balance the interests of patentees with those of other stakeholders. As Arnold J then said to achieve those objectives, it is necessary to have bright-line rules even if they sometimes deprive meritorious inventions of extended protection. I agree."*

37 In the present case, I have no doubt that the research required to ascertain the safety and efficacy of ciclesonide in horses was considerable. However, regardless of the merit of an application in terms of different sorts of research effort, the allowability of an application is to be determined on the basis of the law. As I have noted above, I see nothing in the SPC Regulation that suggests that a distinction should be made between MAs for human and veterinary medicinal products for the purposes of Article 3(d), even though these are viewed as distinct authorisations by the EMA (and correspondingly by the MHRA[23] and VMD[24] in the UK). This is despite the additional research that may be required in order to achieve a veterinary medicinal product authorisation for a previously authorised human medicinal product.

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[21] *Merck Serono S.A. v The Comptroller General of Patents, Trade Marks And Designs* [2025] EWCA Civ 45

[22] *Abraxis Bioscience LLC v Comptroller General of Patents* [2017] EWHC 14 (Pat)

[23] Medicines and Healthcare products Regulatory Agency

[24] Veterinary Medicines Directorate

38 Nevertheless, the applicant further argues that a distinction should be made between human and veterinary medicinal use for the purposes of Article 3(d) as a result of interpretation of the SPC Regulation in view of the relevant case law. They suggest that I should regard *Santen* as having only partially reversed *Neurim* and that *Santen* is not relevant to a situation where a first veterinary MA follows an earlier human MA. In considering the operative law, it is therefore appropriate to refer back to *Neurim*, where the first of the CJEU's rulings in that case was (my emphasis):

> *"Articles 3 and 4 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, in a case such as that in the main proceedings**, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted**, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate."*

39 Thus, the *Neurim* judgment makes explicit reference to a distinction between a first veterinary use and a later different application. This provides the context for the later decisions which pertain to it.

40 Turning now to *Santen*, a Grand Chamber decision, this judgment goes further than almost any other CJEU judgment in making explicit reference to the previous decision which is being addressed (i.e. *Neurim*). As the examiner noted, paragraph 53 of *Santen* states:

> *"53. It follows that, contrary to what the Court held in paragraph 27 of the judgment in Neurim, to define the concept of 'first [MA for the product] as a medicinal product' for the purpose of Article 3(d) of Regulation No 469/2009, there is no need to take into account the limits of the protection of the basic patent."*

41 It is in this context that the final ruling of the CJEU in *Santen* at paragraph 62 should be considered:

> *"Article 3(d) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application."*

42 The Grand Chamber, explicitly disagreeing with the previous CJEU ruling in *Neurim*, which itself made explicit mention of both human and veterinary use, did not choose to define any limitations on the nature of what constitutes the "different therapeutic application", despite otherwise going to some lengths to spell out the meaning of the relevant aspects of Articles 1 and 3.

43 The extent to which *Santen* reverses *Neurim* has been considered recently in the UK Courts. Therefore, it is appropriate to consider these two recent decisions of the Court of Appeal, *Newron*[25] and *Merck Serono*[21]. The applicant made reference to the *Merck Serono* proceedings, and I refer to *Newron* merely because this case is discussed at length in *Merck Serono* and the Court of Appeal's position post-*Merck Serono* is more readily elucidated by reference to both judgments.

44 In *Newron,* Birss LJ discussed what *Santen* teaches (see paragraphs 22 and 30):

> *"22. Finally in July 2020 what might be called orthodoxy was restored in Santen C-673/18. The CJEU there held that the definition of product in the SPC Regulation did not include the therapeutic application for which it might be used (see [43]) and went out of its way to expressly contradict (at [53]) what had been said about this in Neurim. At [44] of Santen the court said this:*
>
> > *"44. Under Article 4 of [the SPC Regulation], the protection conferred on the product by the SPC, although it extends only to the product covered by the MA, covers, on the other hand, any use of that product as a medicinal product which was authorised before the expiry of the SPC. It follows that the term 'product' within the meaning of Regulation 469/2009 is not dependent on the manner in which that product is used and that the intended use of the medicinal product does not constitute a decisive factor for the grant of an SPC (see, to that effect, judgment of 19 October 2004, Pharmacia Italia, C-31/03, EU:C:2004:641, paragraphs 19 and 20)."*
>
> *…*
> *30. While Newron's submission is understandable, in my judgment Medeva does not alter the law as I have found it to be from looking at the run of CJEU authority up to Santen. It was a broader, outcome driven teleological approach in Neurim itself which led to the difficulty in that case making it inconsistent with a run of previous authority. Santen concludes that the right approach to interpreting the SPC Regulation in the present context is a strict one when one is examining what counts as the product. Necessarily the decision also shows that while the purpose of the SPC Regulation is in turn to support the purpose of the patent system as a scheme for incentivising investment in research, nevertheless not all kinds of inventions, deserving of patents though they all may be, will be able to obtain an SPC."*

45 Thus, not only did the Court describe the CJEU's contradiction of the broader interpretation of the definition of "product" (for the purposes of the SPC Regulation) taken in *Neurim*, but it also provided its interpretation that Santen restored "orthodoxy" and that "the definition of product in the SPC Regulation did not include the therapeutic application for which it might be used"[26]. Whilst neither the CJEU in *Santen* or the Court of Appeal in either *Newron* or *Merck* explicitly refer to a human use or a veterinary use, I see nothing in these judgments that suggest that such a distinction should be made. Thus, I cannot agree with the applicant when they seek either to claim that *Neurim* is only partially overturned by *Santen*, or that the particular facts of this case allow for their MA to be interpreted as the first MA for the

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[25] *Newron Pharmaceuticals SPA v The Comptroller General of Patents, Trade Marks And Designs* [2024] EWCA Civ 128
[26] See paragraph [22] therein

purposes of Article 3(d). It is very clear to me from the Court of Appeal in *Newron,* that the definition of product is independent of use, and I cannot see how this does not include whether that use is for veterinary or human purposes. Therefore, an earlier MA for a product for human use must be considered to be the first MA for the purposes of Article 3(d), regardless of any later MA for that product, veterinary or otherwise.

46 In the most recent relevant Court of Appeal judgment, *Merck Serono*, Birss LJ, in the context of ascertaining whether the Court was bound by *Newron,* stated (my emphasis):

> *"13. With these principles in mind I will consider whether paragraph 4(2) of the statutory instrument applies to Newron. The facts in Newron concerned a patent for a combination of compounds including safinamide, levodopa and PDI, but a marketing authorisation for safinamide alone, albeit the marketing authorisation was said to describe using the compound safinamide with the other compounds in the combination. The argument in law concerned the distinction between what a product is and how it is to be used. The argument was that the marketing authorisation could be found to match the patent if one took the manner of use into account. The appellant argued that the Court and Hearing Officer below had taken the law to be that the manner of use was irrelevant. The appellant contended this was an error of law. Essentially the same CJEU cases which have been cited in the present appeal were cited. In particular Neurim was identified as an example of a decision by the CJEU in which the intended use could play a role in the analysis of the criteria for grant (see Newron paragraph 21)*
>
> ***but then Santen was also identified as overruling Neurim (see Newron paragraph 22), holding that the definition of the product is not dependent on the manner of use.*** *Then at paragraph 33 the judgment in Newron is as follows: Turning to the facts of this case and applying the law above, in my judgment the Hearing Officer and the judge were right in their conclusion that the product which this marketing authorisation authorises to be placed on the market as a medicinal product is safinamide. It is not a combination.*
>
> *14. In other words in Newron this court was presented with a choice, to follow Neurim (and another earlier CJEU case along similar lines Medeva v Comptroller Case C-322/10 [2012] RPC 25 which applied a broad teleological approach to combinations), or to follow Santen; and the decision which this court made was to follow Santen**. In my judgment therefore Newron is a decision which applies Santen** and it does so as part of the ratio decidendi. The fact that the specific aspect of the Regulation in issue in Newron was Art 3(b) whereas it is Art 3(d) which is in issue in the present case does not alter that conclusion. In the terms of R (Youngsam) v Parole Board [2019] EWCA Civ 229, the conclusion in Newron would be (much) weaker without the application of Santen. …*
>
> *15.* ***Therefore as a previous decision of this court Newron is binding*** *and paragraph 4(2) of the statutory instrument applies.* ***The appellant in this case invites us to depart from the very same retained EU case law which was***

applied in Newron. However under the 2018 Act that course is not open to this court."

47 I believe that the applicant in this case is in essence doing the very same thing, arguing that this retained case law, *Santen*, should be departed from. It was not open to the Court of Appeal to do so, and so as a lower-level tribunal I cannot depart from this settled legal position either.

48 Therefore, I am bound by *Santen* and accordingly must regard UK authorisations PL 20141/0004-0012 of 16 April 2004, and not the later marketing authorisation for Aservo Equihaler, as the first authorisation placing ciclesonide on the market under Article 3(d). Similarly, the product ciclesonide has also already been the subject of a certificate, SPC/GB04/026, and thus the application cannot meet the conditions of Article 3(c).

Conclusion

49 For the reasons given above, this application does not satisfy Article 3(d) of the SPC Regulation and therefore I am rejecting it for failing to meet the conditions laid down in the Regulation. In view of the existence of earlier certificate SPC/GB04/026 for the same product as the application, the application also does not satisfy the requirements of Article 3(c). I therefore refuse the SPC application under Article 10(2) of the SPC Regulation.

50 Having concluded that the application does not meet the requirements of Articles 3(c) and 3(d), I do not need to consider the issue of the term of the certificate under of Article 13.

Appeal

51 Any appeal must be lodged within 28 days after the date of this decision.

Dr Rowena Dinham

Patent Examination Group Head, acting for the Comptroller