Intellectual Property Office

BL O/0705/25

31 July 2025

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

APPLICANT LABORATORIAS LEON FARMA SA

ISSUE Whether application for supplementary protection certificate SPC/GB22/021 meets the requirements of Article 3(d) of the SPC Regulation

HEARING OFFICER Dr Rowena Dinham

DECISION

1 This decision relates to the issue of whether the supplementary protection certificate ("SPC") application SPC/GB22/021 ("the application") filed in the name of LABORATORIAS LEON FARMA SA ("the applicant"), meets the requirements of Article 3(d) of Council Regulation (EC) No 469/2009[1] ("the SPC Regulation")

2 The application was filed on 9 June 2022, relying upon basic patent EP(UK) 3632448 B1 ("the basic patent"), entitled "Pharmaceutical composition comprising drospirenone for use as a contraceptive"; and United Kingdom marketing authorisation ("MA") PL 44081/0005, granted on 1 March 2021. The MA relates to the medicinal product "Slynd[2]", which comprises the single active ingredient drospirenone, and form SP1, filed with the application, identifies the product as "drospirenone".

3 The examiner is of the opinion that the MA relied upon does not meet the requirements of Article 3(d) because there are two earlier MAs for drospirenone, both of which contain drospirenone, in combination with other active ingredients[3].

4 Following three rounds of correspondence, the applicant was unable to persuade the examiner on this issue, and so the matter came before me at a hearing on 30 April

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[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] Slynd is a Registered Trade Mark in the United Kingdom

[3] The prior authorisations referred to by the examiner are Angeliq (RTM), PL 00010/0518 of 11/12/07, which is a combination of drospirenone and estradiol (an oestrogen); and Yasmin (RTM), PL 00010/0571 of 27/04/10, which is a combination of drospirenone and ethinyl estradiol (an oestrogen)

2025. At the hearing, the applicant was represented by Mark Chacksfield KC instructed by Hoffman Eitle, and I was assisted by Senior Patent Examiner Mr Gareth Prothero.

5 In his skeleton arguments, Mr Chacksfield submitted that if it were to assist, as an auxiliary request, the applicant would be willing to amend the product description to "drospirenone (not containing any estrogen)". Following on from this, I asked Mr Chacksfield for his views on the relevance of the decision of the court in *Draco A.B.'s SPC Application* [1996] RPC 417. As this decision had not been previously considered, the applicant was given a further two weeks to provide comments on this issue, and I am grateful for Mr Chacksfield's submissions in this regard.

The issue to be decided

6 The issue to be decided is whether or not the MA relied upon for the product Slynd represents the first such authorisation under Article 3(d) of the SPC Regulation, to put the product, drospirenone, on the market in the United Kingdom, or whether the earlier authorisations cited by the examiner represent the first such authorisations. If the MA relied upon for the product Slynd is found to represent the first MA for the product drospirenone, then the application will meet the requirements of Article 3(d). I shall also consider the auxiliary request.

The basic patent

7 The basic patent, EP 3632448 B1, is entitled "Pharmaceutical composition comprising drospirenone for use as a contraceptive". It relates to the use of the synthetic progestogen drospirenone as a contraceptive, without the further presence of an oestrogen, which is stated to lead to advantages including reduced side-effects. The following passages are taken from the description, and explain the invention in more detail:

> *"[0002] Several contraceptives which comprise synthetic progestogens and no oestrogen are commercially available. These contraceptives called "progestogen-only contraceptives" encompass implants, uterine delivery systems and pills.*
>
> *[0003] Progestogen-only Pills (POPs) have the advantage of avoiding the combined administration of estrogens as compared to traditional contraceptive combined pills.*
>
> *[0004] However, POPs display several major drawbacks. Because of their low contraceptive reliability, POPs have to be taken each day at the same time without pill-free or placebo interval.*
>
> *[0005] The bleeding patterns for women who take POP may be also altered deeply as compared to the natural menstrual cycle, since amenorrhea or unscheduled bleeding or spotting may occur.*
>
> *[0006] It results that, in spite of their potential benefits, POPs are poorly used and are usually indicated for women who cannot tolerate estrogen, for women*

in post-partum period and for women who are breast-feeding (Amy, Tripathi, 2009, BMJ, 339, 563-568 ; Mandisk, 2008, Obstetric Medicine, 1,78-87).

[0007] Drospirenone (CAS: 67392-87-4 ; 6β, 7β,15β, 16β-dimethylen-3-oxo-17a-pregn4-ene-21,17-carbo-lactone) is a synthetic progestogen with a pharmacological profile very closely related to that of natural progesterone.

[0008] Drospirenone (or DRSP) is devoid of androgenic, glucocorticoid and antiglucocorticoid activity but does possess potent antimineralocorticoid and antiandrogenic properties. It was shown that oral daily doses of at least 3 mg of drospirenone are able to inhibit ovulation over a single treatment cycle of 21 days. The combination of 3 mg drospirenone/30 µg ethinylestradiol provides a reasonable contraceptive safety margin by inhibiting ovulation with a low frequency of follicular maturation (Rosenbaum et al., 2000, The European Journal of Contraception and Reproductive Health Care, 5,16-24).

[0009] Drospirenone (DRSP) is thus an appropriate progestin ingredient which may avoid the side-effects occurring with conventional synthetic progestogens such as weight gain and breast tension when combined with an estrogen for use as a contraceptive. DRSP is also likely to minimize fluid retention and to have neutral effects on metabolic and vascular risks (Blode et al., 2000, The European Journal of Contraception and Reproductive Health Care, 5, 256-264 ; Sitruk-Ware, 2006, Human Reproduction Update, 12, 169-178). It has been also reported that drospirenone may treat moderate acne because of its well-established antiandrogenic properties.

[0010] Drospirenone as a contraceptive ingredient is available only in oral combined pills such as those marketed under the name of Yasmin® (3 mg DRSP/30 µg ethinylestradiol), Yaz® (3 mg DRSP/ 20 µg ethinylestradiol) and Yasminelle® (3 mg DRSP/ 20 µg ethinylestradiol). These pills comprise ethinylestradiol which acts to increase the ovulation inhibitory effect of drospirenone and to ensure contraception and cycle stability.

[0011] The patent application WO2008031631 describes combined oral contraceptives in which drospirenone is used as a progestative agent and ethinylestradiol is replaced by the phytoestrogen 8-prenylnaringenin. These contraceptives may consist in modified release formulations of 8-prenylnaringenin and drospirenone which may continuously distribute the active ingredients for the gastro-intestinal transit time of generally 12h-16h.

[0012] The commercially available contraceptives Yasmin®, Yaz® and Yasminelle® comprise drospirenone in a micronized form which promotes its rapid dissolution in vitro and ensures its good oral bioavailability. It is also the case for Angeliq® which is a hormone replacement medicament combining drospirenone and estradiol.

[0013] However, such formulations are characterized by a high plasma concentration peak for drospirenone after oral intake.

[0014] High plasma concentrations are not preferred in patients treated with drospirenone because of a correlation between high C_{max} and certain

undesirable side effects as well as poor general tolerance when hormonal levels fluctuate too much each and every day.

[0015] There is still a need in the art for novel contraceptive kits and for novel pharmaceutical compositions comprising drospirenone."

8 Claim 1 of the basic patent is the only independent claim and is reproduced below:

"(1) A pharmaceutical composition comprising drospirenone for use as a contraceptive for a female patient in need thereof, wherein:

(a) a daily active dosage unit of said composition comprises an amount of drospirenone of about 2 mg to about 6 mg of drospirenone, one or more pharmaceutically-acceptable excipients, and does not contain any estrogen, and wherein said daily active dosage unit is to be administered under a dosing regimen which comprises administering said daily active dosage unit for 24 consecutive days followed by 4 consecutive days wherein no active dosage unit is administered to said patient; and wherein

(b) the dissolution rate of said daily active dosage unit is such that when subjected to an in vitro dissolution test according to the USP XXIII Paddle Method,

(i) no more than 50% of the drospirenone initially present in said daily active dosage unit is dissolved within 30 minutes, and

(ii) at least 50% of the drospirenone initially present in said daily active dosage unit is dissolved in a time range from 3 hours to 4 hours."

The relevant law

9 Article 1 of the SPC Regulation sets out the definitions of terms used, of which Articles 1(a) and (b) are reproduced below:

Article 1

Definitions

"For the purpose 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 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;"

…

10 Article 3 sets out the conditions for obtaining a certificate:

> ***Article 3***
>
> ***Conditions for obtaining a certificate***
>
> *(a) Where an application is submitted under Article 7, a certificate shall be granted if, at the date of submission of that application-the product is protected by a basic patent in force;*
>
> *(b) there is a valid UK, GB or NI authorisation to place the product on the market;*
>
> *(c) the product has not already been the subject of a certificate;*
>
> *(d) the authorisation referred to in point (b) is the first UK, GB or NI authorisation to place the product on the market as a medicinal product in the territory of the United Kingdom, the territory of England and Wales and Scotland or the territory of Northern Ireland as the case may be."*

11 Article 10 sets out the conditions for grant or reject of an application:

> ***Article 10***
>
> ***Grant of the certificate or rejection of the application for a certificate***
>
> *1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the comptroller shall grant the certificate.*
>
> *2. The comptroller shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which hit relates does not meet the conditions laid down in this Regulation or any prescribed fee is not paid.*
> *…*

The relevant case law

12 The following court decisions were referred to during the course of the correspondence between the examiner and the applicant, and at the hearing itself:

Case C-322/10 Medeva ("*Medeva*")[4]; Case C-422/10 Georgetown ("*Georgetown*")[5]

13 Medeva had filed five SPC applications with the Patent Office, seeking SPC protection for DTPa-IPV/HIB vaccines covering diphtheria, tetanus, whooping cough, poliomyelitis, and meningitis (*Haemophilus influenzae*).

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[4] Medeva BV v Comptroller General of Patents, Designs and Trade Marks; Case C-322/10; for full text of the decision, see ECLI identifier: ECLI:EU:C:2011:773; https://ipcuria.eu/case?reference=C-322/10.
[5] Georgetown University, University of Rochester, Loyola University of Chicago v Comptroller General of Patents, Designs and Trade Marks; Case C-422/10; for full text of the decision, see ECLI identifier: ECL!:EU:C:2011:776; https://ipcuria.eu/case?reference=C-422/10

14 With regard to four of these (SPC/GB09/015, SPC/GB09/016, SPC/GB09/017 and SPC/GB09/019), more active ingredients were specified in the applications for SPCs covering those ingredients than were identified in the wording of the claims of the basic patent. In refusing these applications, the Hearing Officer found that these were not protected by the basic patent within the meaning of Article 3(a) of the Regulation.

15 In the case of the remaining application (SPC/GB09/018), the Hearing Officer concluded, inter alia, that although the active components or ingredients identified in the patent were the same as those specified in the SPC application, namely the combination of pertactin and filamentous haemagglutinin, the MAs submitted in support of that application did not fulfil the conditions laid down in Article 3(b) of the Regulation, because they related to medicinal products containing nine active ingredients, that is to say vaccines which did not contain only the active components or ingredients specified in the SPC application and in the patent claims. All five applications were therefore refused[6]. This decision was appealed to the High Court, and then the Court of Appeal, which referred a number of questions to the European Court of Justice ("CJEU") for a preliminary ruling. Six questions were referred, which are listed below:

> *"1. Regulation No 469/2009 (the Regulation) recognises, amongst the other purposes identified in the recitals, the need for the grant of an SPC by each of the Member States of the Community to proprietors of national or European patents to be under the same conditions, as indicated in recitals 7 and 8. In the absence of Community harmonisation of patent law, what is meant in Article 3(a) of the Regulation by "the product is protected by a basic patent in force" and what are the criteria for deciding this?*
>
> *2. In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?*
>
> *3. In a case like the present one involving a multi-disease vaccine, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?*
>
> *4. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens "protected by a basic patent" if one antigen of the vaccine is "protected by the basic patent in force"?*
>
> *5. For the purposes of Article 3(a), is a multi-disease vaccine comprising multiple antigens "protected by a basic patent" if all antigens directed against one disease are "protected by the basic patent in force"?*

[6] Decision BL O/357/09, for full text see https://www.ipo.gov.uk/p-challenge-decision-results/p-challenge-decision-results-bl?BL_Number=O/357/09

6. Does the Regulation and, in particular, Article 3(b), permit the grant of a supplementary protection certificate for a single active ingredient or combination of active ingredients where:

(a) a basic patent in force protects the single active ingredient or combination of active ingredients within the meaning of Article 3(a) of the Regulation; and

(b) a medicinal product containing the single active ingredient or combination of active ingredients together with one or more other active ingredients is the subject of a valid authorisation granted in accordance with Directive 2001/83/EC or 2001/82/EC which is the first marketing authorisation that places the single active ingredient or combination of active ingredients on the market?"

16 In answering these questions, the CJEU ruled that[7]:

"1. Article 3(a) 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 precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate.

2. Article 3(b) of Regulation No 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a supplementary protection certificate contains not only that combination of the two active ingredients but also other active ingredients."

17 In the related *Georgetown* decision, a similar conclusion was reached[8]:

"Article 3(b) 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, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for an active ingredient specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the supplementary protection certificate application contains not only that active ingredient but also other active ingredients."

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[7] At paragraph [43]
[8] At paragraph [36]

Case C-443/12 Actavis ("*Actavis*")[9]

18 Sanofi was the proprietor of an SPC for the combination of ibersartan and hydroclorothiazide, used in the treatment of primary hypertension. Actavis challenged the validity of this SPC, arguing that it was contrary to Article 3(a), because the combination of active ingredients is not expressly specified or identified in the claims of the basic patent upon which it relied. It further argued that the SPC was invalid in light of Article 3(c), given that the product within the meaning of that provision had already been the subject of an initial SPC for ibersartan on its own.

19 The CJEU held[10] that:

> *"In circumstances such as those in the main proceedings, where, on the basis of a patent protecting an innovative active ingredient and a marketing authorisation for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained a supplementary protection certificate for that active ingredient entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients, Article 3(c) 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 precluding that patent holder from obtaining – on the basis of that same patent but a subsequent marketing authorisation for a different medicinal product containing that active ingredient in conjunction with another active ingredient which is not protected as such by the patent – a second supplementary protection certificate relating to that combination of active ingredients."*

Case C-673/18 Santen ("*Santen*")[11]

20 Santen applied for an SPC for "Ciclosporin for use in the treatment of keratitis"; however, this application was refused by l'Institut national de la propriété industrielle ("INPI"), on the grounds that an earlier MA had already been granted for ciclosporin, albeit for a different therapeutic indication. According to the INPI, the previous decision of the CJEU in *Neurim*[12], issued prior to the decision in *Santen*, did not preclude the grant of an SPC for a different application of the same product for which an MA had been granted, provided that the application was within the limits of the protection conferred by the basic patent relied on for the purposes of the application of the SPC. However, the INPI further argued that the concept of a "different therapeutic application" of the same product should be interpreted strictly, such that the MA being relied upon must relate to an indication within a new therapeutic field,

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[9] Actavis Group PTC EHF, Actavis UK Ltd v Sanofi; Case C-443/12; for full text of the decision, see ECLI identifier: ECLI:EU:C:2013:833; https://curia.europa.eu/juris/liste.jsf?language=en&jur=C,T,F&num=C-443/12&td=ALL

[10] At paragraph [45]

[11] Santen SAS v Directeur général de l'Institut national de la propriété industrielle; C-673/18; for full text of the decision, see ECLI identifier: ECLI:EU:C:2020:34; https://curia.europa.eu/juris/liste.jsf?&num=C-673/18

[12] Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents; C-130/11; ; for full text of the decision, see ECLI identifier: ECLI:EU:C:2012:268; https://curia.europa.eu/juris/liste.jsf?num=C-130/11&language=EN

in the sense of a new medical specialism, compared to the earlier MA. The INPI refused the application, and the Court d'Appel de Paris referred the matter to the CJEU, which held (in a decision of the Grand Chamber)[13]:

> *"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."*

Newron [2024] EWCA Civ 128 ("*Newron*")[14]

21 Newron applied for an SPC application for the product safinamide, in combination with levodopa and a PDI (where "PDI" stands for peripheral decarboxylase inhibitor), which was based on the medicinal product XADAGO[15], used in the treatment of patients with idiopathic Parkinson's Disease. This application was refused by the Intellectual Property Office under Article 3(b), because although protected by the basic patent in question, the authorisation on which the application was based related to safinamide only, and did not enable the marketing of safinamide in combination with levodopa or a PDI. This decision was subsequently upheld on appeal to the High Court.

22 In dismissing the further appeal, Birss LJ at the Court of Appeal held that:

> *"33. 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.*
>
> *34. I am quite sure both the Hearing Officer and the judge interpreted the marketing authorisation in this case correctly. The Commission decision itself only mentions Xadago-safinamide and first two sections of the SmPC which name the medicinal product and state its composition, identify simply Xadago as the name and the only active ingredient identified is safinamide. It is true that the only therapeutic indication mentioned in the relevant section of the SmPC is add-on therapy with Levodopa alone or in combination, but this mention of Levodopa is clearly an aspect of how the product safinamide is to be used. It is not an active ingredient in the medicinal product authorised by this marketing authorisation."*

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[13] At paragraph [62]

[14] Newron Pharmaceuticals S.p.A. v The Comptroller-General of Patents, Trade Marks and Designs; for the full decision, see https://www.bailii.org/ew/cases/EWCA/Civ/2024/128.html

[15] XADAGO is a Registered Trade Mark

Merck Serono [2025] EWCA Civ 45 ("*Merck*")[16]

23 Merck applied for an SPC for cladribine for treating multiple sclerosis in 2018, prior to Brexit, and also prior to the decision in *Santen*. The application was refused by a Hearing Officer at the Intellectual Property Office, on the basis that, owing to the subsequent decision in *Santen*, it was contrary to Article 3(d), cladribine having been the subject of two earlier marketing authorisations, both for use in the treatment of hairy cell leukaemia. The appeal was also refused at the Patents Court, which decision was subsequently appealed to the Court of Appeal, based on the sole ground that *Santen* had been wrongly decided, and that the Court of Appeal should depart from it. However, aside from the question of departure from *Santen*, the court also addressed the prior question as to whether it was open to the court to depart from *Santen* in the first place, given the decision of the same court in *Newron*.

24 On this latter point, it was noted that *Santen* and the CJEU cases prior to it form "assimilated case law", as a result of amendments made to the European Union (Withdrawal) Act 2018 by the Retained EU Law (Revocation and Reform) Act 2023. Under s.6(5) of the 2018 Act, the Supreme Court has the power to depart from a CJEU judgment like *Santen*, but only on the same basis as that court would depart from one of its own precedents, or one of the House of Lords. A similar power was extended to the Court of Appeal by a statutory instrument made under the powers of s.6(5A) of the 2018 Act[17]. According to this statutory instrument, the Court of Appeal is a "relevant court", and under paragraph 4(2), a relevant court is bound by assimilated EU case law, so far as there is post-transition case law which modifies or applies that retained EU case law, and which is binding on the relevant court.

25 The court then applied this to the situation with regards to *Newron*, and concluded that:

> *"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. There was a suggestion that Newron was per incuriam such that one of the Young v Bristol Aeroplane exceptions applied, on the basis that it was not argued in Newron that the court should depart from Santen. However irrespective of whether that is the correct approach to the scope of the per incuriam doctrine, Mr Baran, who appeared for the Comptroller in both Newron and in this case demonstrated that despite the*

[16] Merck Serono S.A. v Comptroller-General of Patents, Designs, and Trade Marks [2025] EWCA Civ 45; for full text of the decision, see https://www.judiciary.uk/wp-content/uploads/2025/01/Merck-Serono-v-Comptroller-General-of-Patents-Designs-and-Trade-Marks.pdf

[17] European Union (Withdrawal) Act 2018 (Relevant Court) (Retained EU Case Law) Regulations (SI 2020/1525)

fact that the appellant there did not invite the court to depart from Santen, the Comptroller's skeleton argument had nevertheless addressed the issue just in case, and made submissions why it would not be appropriate to depart in that case.

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."

26 The court found that not only was it bound by the previous decision of the same court in *Newron*, but it also concluded that, even if it were not so bound, it would in any case have held that *Santen* should not be departed from.

Cases C-119/22 and C-149/22 ("*Teva II*")[18]

27 This is a post IP completion day[19] decision of the CJEU, and at the hearing, Mr Chacksfield took me through a helpful summary as to the operation of the 2018 Withdrawal Act[20]. In this regard, I agree that, for the purposes of the application of EU case law by the IPO, decisions of the CJEU prior to IP completion day (31 December 2020), remain binding, unless overruled by subsequent UK decisions of the Court of Appeal or Supreme Court. Decisions of the CJEU after that date are persuasive, but not binding, unless contradicted by later decisions of the Court of Appeal or Supreme Court.

28 *Teva II* concerned two joined cases, in which similar issues arose. In the first, C-119/22, Merck had obtained an SPC in Finland for a product used in the treatment of diabetes, comprising sitagliptin and metformin. Teva brought an action for invalidity of the SPC before the markkinaoikeus (Market Court of Finland), on the basis that firstly, the product, within the meaning of Article 1(b) of the Regulation, was not protected as such by the basic patent, and that secondly, the SPC was in breach of Article 3(c), because an SPC had already been granted for sitagliptin on its own.

29 The second dispute was between Merck and Clonmel concerning the validity of an SPC obtained by Merck in Ireland for a product comprising ezetimibe and simvastatin. Here, the combination product was expressly mentioned in the claims of the basic patent.

30 Merck had already obtained an earlier SPC in respect of a product comprising ezetimibe on its own. The Court of Appeal in Ireland upheld the judgment of the Irish High Court that the SPC at issue did not satisfy the conditions of Articles 3(a) and 3(c), finding that, in order to ascertain whether a product actually falls under the 'invention covered by the basic patent', it is necessary to assess the scope of the

[18] Teva BV, Teva Finland Oy v Merk Sharp & Dohme LLC (C-119/22), and Merck Sharp & Dohme LLC v Clonmel Healthcare Limited (C-149/22)
[19] Implementation Period ("IP") completion day marked the end of the UK-EU transition period following Brexit
[20] And as I discussed in paragraph 24 of decision with regard to the decision of the Court of Appeal in *Merck*

invention covered by the basic patent. It concluded that the combination of ezetimibe and simvastatin did not fall under the invention of the basic patent.

31 In its judgment, the CJEU held that[21]:

> *"1. Article 3(c) 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 not precluding the grant of a supplementary protection certificate (SPC) for a product consisting of two active ingredients even if one of those two active ingredients has already been, alone, the subject of an earlier SPC and it is the only one to have been disclosed by the basic patent, whereas the other active ingredient was known at the filing date or priority date of that patent.*
>
> *2. Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that it does not suffice that a product is expressly mentioned in the claims of the basic patent in order for that product to be regarded as being protected by that patent, within the meaning of that provision. It is also necessary, in order to satisfy the condition laid down in that provision, that that product necessarily fall, from the point of view of a person skilled in the art, and in the light of the description and drawings of that patent, under the invention covered by that patent at the filing date or priority date.*
>
> *3. Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product consisting of two active ingredients (A+B) is protected by a basic patent, within the meaning of that provision, where A and B are expressly mentioned in the claims of that patent and the specification of that patent teaches that A may be used as a medicinal product for human use alone or in combination with B, which is an active ingredient in the public domain at the filing date or priority date of that patent, provided that the combination of those two active ingredients necessarily falls under the invention covered by the same patent."*

Draco's SPC Application ("*Draco*")[22]

32 Draco applied for an SPC for the product budesonide, relying on marketing authorisation PL 0017/0272; however, the Patent Office refused this application under Article 3(d) of Council Regulation (EEC) No. 1768/92, on the basis that there were two earlier authorisations for budesonide: Product Licence Nos. 0117/0113 and 0117/0128.

33 In order to overcome the objection, the applicant proposed to amend the product definition to "additive-free budesonide in the form of agglomerated micronised particles", based on the reasoning that in neither of two earlier prior authorisations was the budesonide additive-free, or micronised.

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[21] At paragraph [74]
[22] *Draco A.B.'s SPC Application* [1996] RPC 417

34 Lewis J[23] concluded that[24]:

> *"Having considered the matter, I find that I cannot accept Mr. Thorley's submission in this respect. Thus, both of the earlier product licences identify the surfactant sorbitan triooleate and three propellants as "other consistuents". In addition, it is apparent from Mr Kållstrand's evidence that it is only the gluco-corticosteroid budesonide which is the anti-asthma agent, the sole function of the propellant/surfactant mixture being to act as a carrier for delivering the steroid particles to the patient's lungs. There is no suggestion that either the propellant or the surfactant enhances the pharmacological properties of the budesonide in any way. Indeed, it is clear from the evidence, in particular exhibit GK3, that these additives are actually detrimental in that they cause adverse side effects such as cough and bronchoconstriction in some patients.*
>
> *In my view, the fact that the use of a propellant/surfactant mixture is necessary in the PL113 and PL128 inhalers for the delivery of the steroid budesonide does not make them "active ingredients" for the purposes of Article 1(b). I therefore find that the only "active ingredient" in these inhalers is the budesonide".*

Pearl Therapeutics ("Pearl")[25]

35 This is a decision of the Swedish Patent and Market Court of Appeal, a machine translation of which has been provided to me by the applicant.

36 Pearl Therapeutics applied for an SPC at the Swedish Patent and Registration Office for a product consisting of two active ingredients: glycopyrrolate and formoterol. Their application relied on the MA Bevespi[26], for use in the treatment of chronic obstructive pulmonary disease (COPD). The Patent and Registration Office, applying the approach taken *Medeva*, refused the application under Article 3(d), because although the product was covered by the MA Bevespi, it considered that it was not the first authorisation to put the product on the market in Sweden. In particular, an earlier authorisation (Trimbow[27]) had been granted, consisting of formoterol fumarate dihydrate, glycopyrronium, and also beclomethasone dipropionate.

37 In dismissing the appeal, the Patent and Market Court of Appeal held that, in order for the case to correspond to the circumstances in *Medeva*, it would be necessary for the Trimbow MA to include Pearl's combination for treating COPD, as well as other active ingredients with other therapeutic purposes; Trimbow only contains the three active ingredients in combination, which, following *Teva II*, is a different product from Pearl's, which comprises just two actives.

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[23] As he then was
[24] At page 431, lines 19 to 35.
[25] *Pearl Therapeutics Inc. v Patent and Registration Office*, SVEA HOVRÄTT, 2025, PMÄ 6595-24
[26] Bevespi is a Registered Trade Mark
[27] Trimbow is a Registered Trade Mark

Arguments and analysis

38 As a preliminary point, I think it is worth considering the reasoning behind the examiner's objection. In essence, it is based on the application of the approach of the CJEU in *Medeva*, which allows an SPC to be granted where the MA relied upon in support of the application is for a medicinal product that contains one or more other active ingredients, in addition to the those of the product for which protection is sought[28]. This approach is based on a teleological interpretation of the definition of the term 'product' under Article 1(b) of the SPC Regulation. It is the examiner's view that a consequence of this approach is that a product will not meet the requirement of Article 3(d) if the MA upon which it relies is not the first such authorisation to place that product on the market in the UK, in view of an earlier authorisation for the same active ingredient (or combination of active ingredients), in combination with one or more further active ingredients. Therefore, as the product drospirenone has already been the subject of earlier authorisations, including both Yasmin and Angeliq, in which it is combined with an oestrogen, the Slynd authorisation relied upon is therefore not the first to place the product on the market, as required by Article 3(d).

39 In setting out my decision, I will follow a similar structure as put forward by Mr Chacksfield at the hearing. In particular, I will firstly consider his argument that the decision in *Medeva*,is restricted only to multivalent vaccines, and so doesn't apply in the present instance. Secondly, I will go on to consider whether *Medeva* should be followed at all, or whether it has been overturned by the more recent decisions in *Santen*, *Newron*, *Merck* and *Teva II*. I will then consider the applicant's view that, even if *Medeva* is still considered relevant, a certificate should nevertheless be granted; and also the applicant's auxiliary request. Finally, I will look at the decision in *Pearl*, and also other policy considerations raised by Mr Chacksfield.

Is the decision in Medeva restricted to multivalent vaccines only?

40 In Mr Chacksfield's view, *Medeva* is not relevant to the present application because its decision is restricted only to products that are multivalent vaccines. In support of this, he pointed towards various passages of the Advocate General's (AG) opinion in *Medeva*, which illustrate their reasoning in applying a teleological interpretation of Article 1(b) instead of a literal one. In particular, he stressed that the reasoning behind the opinion is closely based on the factual issues that arise in respect of multivalent vaccine products, and referred, *inter alia*, to paragraphs [79] to [86] of the passages of the AG's opinion, reproduced below:

> *"79. Nevertheless, it is in my view clear that the result of the literal interpretation of Articles 1 to 3 of Regulation No 469/2009, according to which, in the case of medicinal products with multiple active ingredients only part of which is the subject-matter of a patent, no supplementary protection certificates can be granted, is not compatible with the objectives of Regulation No 469/2009.*
>
> *80. If no supplementary protection certificates could be granted in respect of medicinal products with multiple active ingredients only part of which is the subject-matter of a patent, that would actually have the result that, in all*

[28] See also the Manual of Patent Practice at paragraph SPM3.03

spheres in which the manufacturers of medicinal products found themselves obliged, for legal or practical reasons, to place patented active ingredients on the market in combination with other active ingredients in one medicinal product, an extension of the term of protection of the patented active ingredients in accordance with the requirements of Regulation No 469/2009 would not be possible.

81. The fact that such a result would not be compatible with the objectives of Regulation No 469/2009 can be unequivocally substantiated by the example of the development of active ingredients for vaccines with which we are concerned in this case.

82. The importance of vaccines for public health is difficult to overestimate. It is reflected inter alia in the observations of the European Commission's Directorate-General for Health and Consumers on the Commission's vaccination strategy. That directorate-general points out that vaccination offers people immunity to diseases and is unquestionably one of the most cost-effective public health measures available. It also stresses that the Commission has supported the introduction of vaccines against cervical cancer, and the vaccines Gardasil and Cervarix, which are at issue in Georgetown University and Others, are expressly mentioned.

83. In their written observations, Georgetown University, University of Rochester and Loyola University of Chicago and Medeva have all pointed out that national health authorities as well as patients have a particular interest in the development of multi-disease vaccines. The use of multi-disease vaccines makes it possible, in particular, to provide infants and young children with fast and complete protection by vaccination against a multitude of diseases by means of only a few vaccinations. That in turn means that vaccination schedules are better adhered to, inconvenience for patients is kept to a minimum and delays in the achievement of comprehensive protection provided by vaccination are avoided. Accordingly, vaccines are in many cases placed on the market only as multi-disease vaccines.

84. To support those arguments, those parties refer, on the one hand, to WHO Fact Sheet No 288 (2005) – Immunisation against diseases of public importance, which, under the heading 'Types of vaccines', points out that vaccines are frequently administered as combinations of antigens. In that context, Medeva further stresses that it has produced no vaccine containing only FHA and pertactin.

85. That argument put forward by the undertakings from the pharmaceutical research sector which are represented in the main proceedings is supported by several World Health Organisation publications. In its article 'Six common misconceptions about immunisation', the World Health Organisation points out, for example, that research is under way to find out how to combine more antigens in a single vaccine injection. The advantage of complete multi-disease vaccines lies in the fact that infants receive extensive protection by being vaccinated as early as possible. The reduction in the number of vaccinations also saves parents time and money and makes the vaccinations less traumatic for the child.

> *86. In that context, the referring court has also pointed out in Medeva that vaccine manufacturers are forced by countries' purchasing policies to produce large combinations of vaccines wherever possible. In the view of that court, the market is thus dictated by the State which insists that vaccines be combined where possible. In such circumstances, there may not be a market for patented vaccines which are provided on their own."*

41 Mr Chacksfield then pointed towards the AG's proposed solution, which is to adopt a teleological interpretation of the definition of the term product under Article 1(b), rather than a literal one, so as to achieve the objectives of the SPC Regulation. This is summarised at paragraph [110]:

> *"110. In the light of the above, a teleological interpretation of Regulation No 469/2009 leads to the conclusion that the definition of product in Article 1(b) of the regulation covers not only 'the' active ingredient or 'the' combination of active ingredients, but also 'an' active ingredient or 'a' combination of active ingredients of a medicinal product. Moreover, Article 3(a) of the regulation is to be interpreted to the effect that the product within the meaning of that provision must be the same as the product which forms the subject-matter of the basic patent within the meaning of Article 1(c) of the regulation."*

42 He also drew my attention to the following passage from the CJEU's subsequent decision:

> *"34. If the holder of such a basic patent relating to an innovative active ingredient or an innovative combination of active ingredients were to be refused a SPC on the ground that, in the commercial version of the medicinal product which places that active ingredient or that combination on the market for the first time, the active ingredient or the combination coexists in the medicinal product alongside other active ingredients or combinations which have other therapeutic purposes and may or may not be protected by another basic patent in force, the fundamental objective of Regulation No 469/2009, which is to ensure sufficient protection to encourage pharmaceutical research and play a decisive role in the continuing improvement in public health, could be undermined."*

43 In his view this is important because it highlights that the court is particularly concerned with protecting "innovative" products. I will deal with this point regarding innovative products in more detail below.

44 Having carefully considered Mr Chacksfield's submissions, while I agree that the AG was addressing a specific problem that arises with respect to multivalent vaccines, in my view the AG's opinion, and the decision of the court itself with regard to Article 3(b), are clearly generally applicable to all instances involving authorisations that include the active ingredient, or combination of ingredients of the product, in combination with other active ingredients.

45 In this regard, I particularly note that paragraph [80], quoted above, states that if no SPCs could be granted in respect of medicinal products with multiple active ingredients only part of which is the subject-matter of a patent, that would actually have the result that, "in all spheres" in which manufacturers of medicinal products

are obliged to place active ingredients on the market in combination with other active, an extension of the term in accordance with the SPC Regulation would not be possible. This suggests to me that the AG wasn't limiting their opinion just to vaccines.

46 In order to further illustrate this point, I have reproduced the second and third questions referred to the court below[29], and the AG's answers to them (emphasis added):

> "*2. In a case like the present one involving a medicinal product comprising more than one active ingredient, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?*
>
> *3. In a case like the present one involving a multi-disease vaccine, are there further or different criteria for determining whether or not "the product is protected by a basic patent" according to Article 3(a) of the Regulation and, if so, what are those further or different criteria?*

…

> *115. Against that background, the second and third questions are to be answered to the effect that, in the context of the assessment of an SPC application relating to a medicinal product with multiple active ingredients or to a multi-disease vaccine, there are no further or different criteria for determining whether a product within the meaning of Article 3(a) of Regulation No 469/2009 exists and whether that product is protected by a basic patent in force."*

47 It is particularly clear from the subtle difference between the second and third questions (highlighted above) that the court was not being asked to restrict its decision only to medicinal products that are multi-component vaccines. Furthermore, in answering these questions, the AG emphasises, by referring to medicinal products with multiple active ingredients and multi-disease vaccines in the alternative, that their opinion is not restricted to vaccines only.

48 I further note the analysis of the AG at paragraphs [118] to [121], which refer to medicinal products in general terms. They also make explicit reference to the effect of the teleological approach on Article 3(b), and foreshadow its corresponding effect on the operation of Article 3(d) (emphasis added):

> *"118. My above observations on the teleological interpretation of Regulation No 469/2009 have led me to the conclusion that the regulation is also intended to cover medicinal products in which the combination of active ingredients is not patented in its entirety but nevertheless includes a patented active ingredient or combination of active ingredients.*

[29] See paragraph [20]

119. For the purposes of the interpretation of Article 3(b) of Regulation No 469/2009, it follows from the foregoing that a valid marketing authorisation within the meaning of that provision may also exist where that authorisation under Directive 2001/83 or Directive 2001/82 relates to a medicinal product which also contains, together with the patented active ingredient or combination of active ingredients, one or more other active ingredients.

120. However, it should be pointed out in that connection that Article 3(b) of Regulation No 469/2009 must be read in conjunction with Article 3(d) and Article 7(1) of the regulation. Under Article 3(d), the authorisation referred to in point (b) of that provision is the first authorisation to place the product on the market as a medicinal product. Article 7 of the regulation provides, moreover, that the SPC application must be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted, or, where the authorisation to place the product on the market is granted before the basic patent is granted, within six months of the date on which the patent is granted.

121. It thus follows from the combined operation of those provisions that a manufacturer of medicinal products who places an active ingredient which is the subject-matter of a basic patent on the market in combination with other active ingredients in the form of a number of medicinal products with differing combinations of active ingredients must lodge the SPC application for the patented active ingredient within six months of the date on which the first authorisation to place the first medicinal product with the patented active ingredient on the market is granted in the Member State for which the application is made."

49 The same is true also for the conclusion reached by the CJEU itself at paragraph [34], quoted above, which is consistent with the opinion of the AG, and which also makes no mention of any restriction of its effect to vaccines only. The examiner's pre-hearing report also highlighted paragraphs [37] and [38] of the CJEU's decision, which also refer to the Explanatory Memorandum to the SPC Regulation[30] (emphasis added):

"37. The requirement in Regulation No 469/2009 that the 'product' must be covered, as a medicinal product, by a MA confirms that approach in that that requirement does not in itself rule out the possibility that the MA may cover other active ingredients contained in such a medicinal product. Moreover, in accordance with Article 4 of Regulation No 469/2009, a SPC is intended to protect the 'product' covered by the MA, not the medicinal product as such.

38. Furthermore, such a situation corresponds to that described at paragraphs 34 and 39 of the explanatory memorandum, in which the Commission of the European Communities stated, first, that the requirement that the product must have obtained a valid MA is met 'if the proprietary medicinal product containing it has been granted the [MA] concerned' and,

[30] Explanatory Memorandum to the Proposal for a Council Regulation (EEC) Concerning the Creation of a Supplementary protection Certificate for Medicinal Products, COM (90) 101 final – SYN 255

second, that in such a situation, 'where the product authorised consists of a combination of compound X and another active ingredient, only compound X will be protected by the certificate'."

50 The reference here to "compound X" is notable, and in my opinion this appears to be a clear indication of the general applicability of the decision across all medicinal products, and not simply limited to medicinal products that are vaccines.

51 A further point raised in Mr Chacksfield's skeleton arguments is that the CJEU's decision at paragraph 42 contains permissive language where it states that Article 3(b) "does not preclude" the granting of an SPC in the circumstances being considered, which reflects that the analysis is an exceptional one, applied to the context of multivalent vaccines. I am not convinced by this either. As was pointed out by the examiner in the pre-hearing report, such language appears to be in response to the way the referring questions were framed. I also note that very similar wording appears in other decisions of the CJEU, such as in those of *Neurim*[31] and *Forsgren*[32], and it is not clear to me why it should be viewed as placing any kind of limitation on any of these decisions. Therefore, while I accept that parts of the AG's opinion and the decision of the court itself refer to the particular problems encountered in the field of multivalent vaccines, which was necessary in the context of the facts of the case before them, it appears to me from the manner in which the referring questions were answered that the approach taken was intended to be applicable across all medicinal products comprising multiple active ingredients. Consequently, the decision of the CJEU in *Medeva* is not limited to multivalent vaccines only.

Do Santen, *Newron*, *Merck* and *Teva II overturn Medeva?*

52 Mr Chacksfield's second argument was that *Medeva* is no longer relevant in light of the judgments of the CJEU in *Santen* and *Teva II*[33], and the judgments of the UK Court of Appeal in *Newron and Merck.* At the hearing he pointed towards the following passages of *Newron* as providing a useful summary of the background to the decision in *Santen*, and in particular how the approach to Article 1(b) adopted by the CJEU has changed over time:

> *"20. The early cases are C-31/03 Pharmacia Italia SpA [2004] ECR I-10001; C-431/04 Massachusetts Institute of Technology [2006] ECR I-4089 and C-202/05 Yissum Research and Development Company of the Hebrew University of Jerusalem v. Comptroller-General of Patents [2007] ECR I-2839. Collectively these stand for the proposition that what a product amounts to is the active ingredient itself and it does not involve taking into account any formulation of the active ingredient into drug (such as excipients, physical form or the like) or the intended use for it. So in Yissum at [17] the CJEU held that the concept of product referred to in Article 1(b) "must be interpreted*

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[31] At paragraph [36]
[32] Arne Forsgren v Osterreichisches Patentamt; Case C-631/13; for full text of the decision, see ECLI identifier: ECLI:EU:C:2015:13; https://curia.europa.eu/juris/liste.jsf?language=en&jur=C,T,F&num=C-631/13&td=ALL, at paragraph [55]
[33] Although, as noted in paragraph 27 above, *Teva II* is a judgment delivered post-Brexit

strictly to mean 'active substance' or 'active ingredient'". The strictness there refers to the exclusion of other aspects such as formulation and use.

21. Next is Neurim Pharmaceuticals v Comptroller C-130/11 [2012] EPC 23. Here the CJEU (and Advocate General Trstenjak) followed a persuasive judgment of the Court of Appeal in the referring case by Jacob LJ giving the judgment of the court with Patten and Smith LJJ ([2011] EWCA Civ 228). That judgment proposed that contrary to the early CJEU cases, the use to which a product is put should be taken into account, in order to achieve the result of encouraging research into new uses for old ingredients. So in Neurim the CJEU held that the use could play a role in the analysis. Nevertheless a notable aspect of the CJEU's judgment in Neurim was that while it appeared to reverse the three early cases referred to above, it did not refer to them or explain the change. Later in this jurisdiction in Abraxis v Comptroller [2017] EWHC 14 (Pat) Arnold J at [32] – [38] noted these and other difficulties with the CJEU's judgment in Neurim.

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)."”

53 I have also reproduced below paragraphs [45] and [46] of the decision of the CJEU in *Santen*, which Mr Chacksfield submitted are of importance here (emphasis added):

“45 Such an interpretation is supported by an analysis of the origins of Regulation No 469/2009. Thus, paragraph 11 of the Explanatory Memorandum of 11 April 1990 to the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), which led to Regulation No 1768/92, itself repealed and replaced by Regulation No 469/2009, indicates that the term ‘product’ is understood to mean an active ingredient in the strict sense and that minor changes to the medicinal product such as a new dose, the use of a different salt or ester or even of a different pharmaceutical form will not lead to the issue of a new SPC (see, to that effect, judgments of 4 May 2006, Massachusetts Institute of Technology, C-431/04, EU:C:2006:291, paragraph 19, and of 21 March 2019, Abraxis Bioscience, C-443/17, EU:C:2019:238, paragraph 26).

> *46 That strict view of the term 'product' was given concrete form in Article 1(b) of Regulation No 469/2009, which defines that term by reference to an active ingredient or combination of active ingredients and not by reference to the therapeutic application of an active ingredient protected by the basic patent or a combination of active ingredients protected by that patent."*

54 Therefore, in *Santen*, the CJEU found that the term 'product' needs to be interpreted in its strict sense, and not by reference to its therapeutic application. In particular, Mr Chacksfield highlighted the importance of the last ten words of paragraph [46] of *Santen*. In his view, the reference to a combination of active ingredients should be considered as overruling the approach taken in *Medeva*.

55 However, in my opinion, Mr Chacksfield's interpretation of paragraph [46] of *Santen* is incorrect. What I believe paragraph [46] is saying is that the term product, as defined by Article 1(b), does not include a reference to therapeutic application, whether it is a single active ingredient product, or a product that is a combination of active ingredients. The last few words, therefore, are not making an explicit reference to the situation in *Medeva* concerning products that are a combination of active ingredients, which is what I understand Mr Chacksfield was suggesting.

56 Whilst both *Medeva* and *Santen* relate to the interpretation of Article 1(b), the considerations in *Santen* (concerning different therapeutic applications of products) are distinct from those in *Medeva* (concerning products that are a combination of active ingredients). Therefore, the reasons behind the teleological approach taken in *Medeva* are not the same as the reasons behind the teleological approach taken in *Neurim* (which the CJEU in *Santen* later disagreed with), and therefore in my opinion *Santen* does not necessarily overturn *Medeva*. In this regard, the approaches to Article 1(b) in each of these decisions do not appear to be mutually exclusive. For instance, according to *Medeva*, an SPC application for a product A+B could rely upon a marketing authorisation for the active ingredients A+B+C (for use in the treatment of condition Y), in order to satisfy the requirement of Article 3(b). However, if an earlier authorisation also existed for A+B+C (for treating condition Z), then according to *Santen* the application would not meet the requirement of Article 3(d).

57 Nevertheless, and as pointed out by Mr Chacksfield, Birss LJ did go on to make specific reference to *Medeva* at paragraphs [28] to [30] of *Newron*, reproduced below, which was in response to a point made by the appellant in that case:

> *"28. The final case to mention is the CJEU's decision and the Opinion of Advocate General Trstenjak in Medeva v Comptroller Case C-322/10 [2012] RPC 25. That case was decided in 2011, the year before Neurim in the CJEU. Medeva was concerned with vaccine compositions and in one respect (question 6) concerned a converse situation to the present case. There the patent protected a single ingredient or combination while the marketing authorisation authorised a product involving a combination including the patented ingredient or combination, but also requiring at least one further active ingredient. So if the patent protected active ingredients A+B the marketing authorisation authorised active ingredients A+B+C.*

29. Counsel for Newron focussed on the opinion of the AG and submitted that the view expressed there (particularly at [89]) was that a broad or teleological approach to the definition of product and to the effect of Art 3(b) should be taken in order to achieve the purposes of the SPC Regulation in the context of vaccines and the need to encourage multivalent vaccines. Therefore the SPC should not be precluded in that case. The CJEU itself did reach the same conclusion on the question referred. Its reasoning is inevitably more compressed but it is right to note that although the term "teleological" is not used by the court, the reasoning is essentially the same as that of the AG. The CJEU adopted an outcome driven approach determined by a view about what the purpose of the scheme was and that a result which did not lead to an SPC in that case would be undesirable and wrong.

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."

58 At the hearing, Mr Chacksfield considered that the intention of Birss LJ in the above passages from *Newron* was that the interpretation of Article 1(b) was a strict one and that it should not be approached on a teleological basis, and in Mr Chacksfield's opinion this explicitly overrules the reasoning which underlies the *Medeva* decision. However, whilst I agree with Mr Chacksfield that Birss LJ considers that the outcome driven teleological approach led to difficulties following the judgment of the CJEU in *Neurim,* I do not agree that this necessarily extends to overturning *Medeva*. Indeed, the statement of Birss LJ "….*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*" suggests to me that Birss LJ was discussing the issues that arose following the teleological approach taken in *Neurim* alone, even though he had earlier discussed the teleological approach taken in *Medeva*. In other words, whilst I agree that Birss LJ was dismissing the teleological reasoning behind the decision of the CJEU in *Neurim*, I do not see that this explicitly extends to the dismissal of the (different) teleological reasoning behind the decision of the CJEU in *Medeva*. I therefore have to conclude that *Medeva* remains binding upon me.

59 Turning now to *Merck*, which also discussed the teleological reasoning in *Neurim* and whether the court could depart from *Santen*. Notwithstanding the fact that Birss LJ concluded that departing from the judgment of the same court in *Newron* was not an option that was open to the court[34], he went on to conclude that even if that option were possible, it would not be right to depart from *Santen*. As such, *Newron* is

[34] Under the terms of the European Union (Withdrawal) Act 2018; see paragraphs [8]-[15] of *Merck*

binding in its conclusion on *Santen* (and the court agreed with its conclusion). With regards to *Medeva*, again there is very little mention of this case. At paragraph [14] of *Merck* Birss LJ states:

> "*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 24 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...*"

60 Whilst I note here that Birss LJ refers to *Medeva* as being along similar lines to *Neurim* in its application of a teleological approach, he goes no further than to say that the decision of the Court of Appeal in *Newron* was to follow *Santen*. As in *Newron*, there is no clear indication of whether the approach of the CJEU in relation to the specifics of the case in *Medeva* is incorrect. Therefore, again I cannot conclude that the Court of Appeal is dismissing the judgment of the CJEU in *Medeva,* and as such I cannot see why it would not remain binding on me.

61 Mr Chacksfield also submitted that the decision of the CJEU in *Teva II* is persuasive because its analysis relies on the strict definition of Article 1(b) applied in *Santen*. In particular, he directed me towards paragraphs [45] and [46] of the CJEU's decision:

> *"45. It follows from that strict definition, first, that whether two products are identical or different, in the framework of Regulation No 469/2009, depends only on the comparison of the active ingredient or ingredients which they contain, irrespective of their therapeutic applications. In particular, where, as in the cases in the main proceedings, one of the products to be compared is a combination of active ingredients (A+B), it must be regarded as being a different product from the product consisting of only one of the active ingredients comprising the aforementioned product (A or B).*
>
> *46. Second, it also follows that the concept of 'product', within the meaning of Article 1(b) of Regulation No 469/2009, cannot depend on the context in which it is relied on. On the contrary, the definition of 'product', set out like the other definitions in Article 1 of that regulation 'for the purposes' of the regulation taken as a whole, is identical for all the provisions of Regulation No 469/2009 in which that concept is used. In particular, that concept cannot have a different meaning and scope depending on whether it is interpreted in the context of Article 3(a) or Article 3(c) of that regulation."*

62 According to Mr Chacksfield, the approach in *Teva II* is that a product comprising ingredients A+B must be considered differently to a product that is just A or a product that is just B, and that this reasoning must be applied across all the limbs of Article 3. However, having concluded above that I am bound by the decision of the CJEU in *Medeva*, it follows that, by virtue of the operation of the Withdrawal Act 2018, to the extent that the approach to the interpretation of Article 1(b) taken in *Teva II* differs from that in *Medeva*, it cannot be taken into account for the purposes of my decision.

Even if Medeva remains good law, it actually supports grant

63 The applicant also argues that, even if *Medeva* is still considered binding, and not restricted solely to multivalent vaccines, then the application should nevertheless be granted. This is because, in the applicant's view, *Medeva* states that the product is restricted to that which is protected by the patent. With respect to the present application, the applicant argues that what the patent actually protects is drospirenone without an oestrogen, and that since each of the prior authorisations cited by the examiner contain drospirenone in combination with an oestrogen, they cannot be considered relevant for the purposes of Article 3(d) as they do not relate to the same product.

64 As Mr Chacksfield put it at the hearing: "*My case is that the definition of the term product is the same in (a), (b), (c) and (d). What that means is you identify from whichever bit of paper you are looking at, be it a patent, be it an MA or be it an SPC; you identify from that the product that is the subject matter of that thing"….. "When you are doing that, there is only one test for what is the product. When you look at that particular document, it is either the single active ingredient if there is only one, or it is all of the active ingredients if there is a plurality, and nothing else*". Mr Chacksfield also suggested at various points in the hearing that *Medeva* allows you to "read across" from Article 3(a) to Article 3(b). If I understand Mr Chacksfield's submission correctly, he is suggesting that it is a question of considering the basic patent and what it protects, and "reading across" to consider whether that product is the subject of the marketing authorisation under 3(b) and 3(d). He also suggested that the examiner's analysis is "a sort of halfway house approach", in that the product protected by the patent has been taken to be just drospirenone, which ignores the invention underlying the basic patent, which is drospirenone without an oestrogen. These are, in his opinion, two distinct inventions.

65 I acknowledge that *prima facie* there is a difference between drospirenone, and explicitly drospirenone without an oestrogen, and for the purposes of a patent these may be two distinct inventive concepts. However, I can find no direction in any part of the decision in *Medeva* that suggests that one should identify the *invention* protected by the basic patent and read that across to the *product* for the purposes of all limbs of Article 3. My understanding of what *Medeva* allows is that the "product" (i.e. the active ingredient) must be covered as a "medicinal product" by an MA, and that the MA may cover other active ingredients in that "medicinal product" [35]; the SPC covers the "product" (i.e. the active ingredient) covered by the MA, and not the "medicinal product" which contains the product with other actives. The CJEU goes on to confirm "product" is also that which is protected by the basic patent, as the purpose of the SPC is to confer the same rights as were conferred by the patent in relation to the "product" [36]. Therefore, my understanding of *Medeva* is that the "product" (or "active ingredient") has to be protected by the basic patent relied upon (and the CJEU has subsequently refined the tests to determine this), but the medicinal product of the MA may contain other active ingredients in addition to the "product" (or "active ingredient") for which the SPC application is sought (and which not necessarily protected by the basic patent).

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[35] See paragraph [37] of *Medeva*
[36] See paragraph [39] of *Medeva*

66 What Mr Chacksfield seems to suggest it is that, in the present case, you would read the claims of the basic patent (i.e. drospirenone without oestrogen), and from this read across to the MA in support of this as necessarily being for drospirenone without any oestrogen. This means that the earlier MAs for the medicinal products Yasmin and Angeliq, both of which contain drospirenone as the active ingredient but in combination with another active ingredient (in this case an oestrogen) are not considered to be an MA in support of the product/ active ingredient protected by the basic patent. However, in *Medeva* the claims of the basic patent protected just the two antigens (i.e. "active ingredients") from *Bordetella pertussis,* yet the MA relied upon in support of this contained these two active ingredients and several additional active ingredients. I acknowledge that the claims of the basic patent in *Medeva* did not explicitly exclude the presence of additional active ingredients, but it is clear from the specification itself that no other active ingredients are present in the composition (or form part of the invention). Nevertheless, the CJEU was satisfied that an MA that contained these two active ingredients from *Bordetella pertussis* as well as additional active ingredients was able to support an SPC application to protect these two actives from *Bordetella pertussis* only (which was in line with what was claimed in the corresponding patent). From my understanding of this approach, the active ingredient(s) defined by claims of the patent define the scope of protection conferred by SPC, and the MA must allow for that active ingredient(s) to be placed on the market as a medicinal product, whether or not that active ingredient(s) is present in the medicinal product in isolation or in combination with other active ingredient(s); any limitations of the product/ active ingredients conferred by the patent are not read across into the medicinal product authorised in the MA, beyond ensuring that the product/ active ingredients protected by the patent are present in that authorised medicinal product.

67 Applying this understanding to the present case, if it is possible for an SPC application for a product containing a single active ingredient (and relying on a patent claiming the same single active ingredient) to rely on an MA that contains that active ingredient in combination with one or more further active ingredients, as was the situation in *Medeva,* then in my opinion it stands to reason that it should be the first such authorisation that contains that active ingredient. If there is an earlier such authorisation, then Article 3(d) will not be met, and to find otherwise would appear to override this requirement. I would also point towards the comments of the AG in *Medeva* at paragraph [121] would appear to support this approach, where it states that (following the analysis given in the opinion) an applicant must lodge their SPC application within six months of the date of grant of the first authorisation to place the first medicinal product that contains the patented active ingredient, along with other active ingredients.

68 Furthermore, paragraph [38] of *Actavis*, highlighted by the examiner in the pre-hearing report, states that (emphasis added):

> *"38. Similarly, if, in circumstances such as those in the main proceedings, the medicinal product CoAprovel had obtained MA before Aprovel, which would have enabled its proprietor to obtain an SPC either, in the light of paragraph 34 of Medeva, for irbesartan alone, or for the irbesartan-hydrochlorothiazide combination, and MA had subsequently been obtained for Aprovel, that could*

not have secured a second SPC for irbesartan, in view of the condition laid down in Article 3(c) of Regulation No 469/2009."[37]

69 Although I accept that these comments are *obiter* as the decision itself concerned Article 3(c), *Medeva* is specifically referred to, and I think it nevertheless supports the approach that an earlier authorisation containing a product in combination with other active ingredients, can represent a valid authorisation to place that product on the market for the purposes of both Article 3(d) and Article 3(d). It is especially notable that in the situation described in this comment, the product is not a multivalent vaccine, and so the court clearly did not consider that its own prior decision was restricted in this manner.

70 Turning now to the present case, item (6) of form SP1 accompanying the application identifies the product as "drospirenone". Therefore, it is the product drospirenone that, quite reasonably, has been assessed by the examiner with respect to the requirements set out in each of Articles 3(a) to (d) of the SPC Regulation. In doing so, the examiner has been satisfied that the requirements of Articles 3(a), (b) and (c) have been met, but that Article 3(d) has not. In light of my reasoning above, and my understanding of *Medeva* as it currently stands, I agree with this. The MAs for both Yasmin and Angeliq are for a medicinal product that contains drospirenone as an "active ingredient"/ product, the SPC application is for the product "drospirenone" alone, and the basic patent is also for the product "drospirenone" (albeit without the presence of an oestrogen). As the MAs for both Yasmin and Angeliq authorise the product "drospirenone" to be placed on the market as part of their respective medicinal products, I cannot see how I can agree that the MA for Slynd is the first MA for the product "drospirenone".

The auxiliary request

71 Along with their skeleton arguments, the applicant indicated that, as an auxiliary request, they would be willing to amend the product description on form SP1 to "drospirenone (without any estrogen)". In their opinion this would better capture the product which is specifically the focus of the claims of the basic patent, and which is the specific medicinal product authorised as Slynd. However, the applicants acknowledge that they are not aware of any SPC that has been sought with a negative definition in this manner.

72 I agree that there is little guidance on the issue of products defined in negative terms. In *Draco*, the judge considered whether amendment of the product description from "budesonide" to "additive-free budesonide in the form of agglomerated micronised particles" would overcome the examiner's objection that the authorisation relied upon was not the first to put the product on the market, in view of two earlier authorisations for budesonide. In Mr Chacksfield's further submissions on this point, he notes that neither the Hearing Officer nor the judge in *Draco* appeared to consider the negative form of the definition of the product as being objectionable *per se*, and that although there was no explicit approval, this tacitly supports the applicant's approach.

[37] Aprovel and CoAprovel are Registered Trade Marks

73 However, although the allowability or otherwise of a negatively defined product put forward in *Draco* was ultimately not explicitly commented upon, in concluding that the amended description was not allowable, the judge found[38] "*… that the "active ingredient" – and hence the "product" as defined in Article 1(b) – is budesonide in each case, this active ingredient being used in a slightly different form in the Turbuhaler*". This is consistent with the conclusion that I have reached above, that no matter how it is defined, the product in the present instance is just drospirenone.

74 Therefore, having given this matter careful consideration, I do not agree that an SPC can be granted in respect of a product so-described either. This is because Article 1(b) defines the product in terms of "*the active ingredient or combination of active ingredients of a medicinal product"*. Even applying the approach taken in *Medeva*, whereby Article 1(b) is read as "an active ingredient or combination of active ingredients of a medicinal product", in my view it necessarily follows that the product can only be defined in terms of the active ingredient, or active ingredients, that are actually present. In other words, I see nothing in the case law or the SPC Regulation that suggests that Article 1(b) should allow for a product to be defined in terms of the presence of one active ingredient, in combination with the absence of another.

75 Furthermore, claim 1 of the basic patent specifies (emphasis added) "*A pharmaceutical composition comprising drospirenone for use as a contraceptive for a female patient in need thereof, wherein: (a) a daily active dosage unit of said composition comprises an amount of drospirenone …. and does not contain any estrogen…*". It seems to me that the definition proposed by the applicant in its auxiliary request is merely a description of the composition that contains the product: it isn't a definition of the product itself. In other words, the active ingredient, and therefore the product, remains drospirenone, and the MAs for Yasmin and Angeliq are still considered to authorise a medicinal product containing drospirenone. It follows that the auxiliary request does not satisfy the requirements of Article 3(d) either.

Pearl

76 As I have noted above, *Pearl* is a decision of the Swedish Court of Appeal. While I acknowledge that the facts correlate closely with those of the present application, I also note that the reasoning applied in this decision, according to the machine translation provided by the applicant, was based on that applied in *Teva II*, which, as I have discussed above, I cannot take into consideration. It therefore does not alter my conclusions.

Policy considerations

77 Mr Chacksfield also put forward arguments regarding policy considerations. In the view of the applicant, the purpose of the SPC Regulation is to ensure sufficient reward for the invention of new therapeutic products, which he said contrasts with inventions such as those in respect of new medical uses or excipients. In this regard, he noted that the basic patent was found to be novel and inventive by the Opposition Division of the EPO in view of the fact that the patent protects drospirenone with no oestrogen, whereas previously it had been thought

[38] At page 432, lines 16 to 19

drospirenone needed to be used in combination with an oestrogen. With regard to the AG's opinion and the CJEU's teleological approach in *Medeva,* he also noted that this had been driven by a need to give protection for "innovative products", so that a fundamental objective of the SPC Regulation wasn't undermined. Furthermore, it was argued that the examiner's approach has the effect that a whole class of inventions, i.e. those involving taking an active ingredient previously used as part of a combination and finding that it can be used alone, would be excluded from the SPC regime.

78 In my opinion, the references to "innovative products" in the CJEU's decision in *Medeva* were not intended to distinguish the type of invention at issue in that decision from other inventions. The award of an SPC involves no assessment as to the level of innovation of the basic patent. In my view, the Court was merely referring to the fact that the purpose of the SPC Regulation is to ensure sufficient protection to inventions in the field of medicines that are subject to regulatory approval. As was pointed out in the examiner's pre-hearing report, there is no automatic right of a patented invention to SPC protection, and as is pointed out at paragraph 11 of the Explanatory Memorandum, it was envisaged that the SPC Regulation does not involve granting a certificate for all medicinal products.

79 While I have some sympathy with the applicant in view of the fact that the invention of the basic patent matches with the active ingredient of the medicinal product Slynd, this does not overcome the fact that the requirements of the SPC Regulation, interpreted via the case law as I have assessed it, have not been met.

Conclusion

80 I consider that *Medeva* is of general application in that it is not restricted solely to multivalent vaccines, and furthermore has not been overturned by the subsequent decisions in *Santen*, *Newron* and *Merck*. I am therefore bound by its judgment. Furthermore, the reasoning applied by the CJEU in *Teva II* cannot be taken into consideration. I have further concluded that the product as defined in the auxiliary request is not allowable. As I consider that it does not meet the requirements of Article 3(d), I therefore reject the application under Article 10(2).

Appeal

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

Rowena Dinham

Patent Examination Group Head