Neutral Citation Number: [2026] EWHC 663 (Ch)

Appeal No: CH-2025-000249

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

ON APPEAL FROM

THE DECISION OF THE COMPTROLLER-GENERAL OF PATENTS
DATED 31 JULY 2025 (BL O/0705/25)

Royal Courts of Justice, Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 20 March 2026

Before :

RECORDER DOUGLAS CAMPBELL KC
Sitting as a Judge of the Patents Court

- -

Between :

LABORATORIOS LEON FARMA SA **Appellant**

-

and -

THE COMPTROLLER-GENERAL OF PATENTS

Respondent

- -

Mark Chacksfield KC (instructed by **Wiggin LLP**) for the **Appellant**
Stuart Baran (instructed by the **Treasury Solicitor**) for the **Respondent**

Hearing date: 5 March 2026

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APPROVED JUDGMENT

This judgment was handed down remotely at 10.30am on 20 March 2026 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

Recorder Douglas Campbell KC:

Introduction

1. This is another appeal about Article 3 of the SPC Regulation (Regulation EC 469/2009), which is assimilated EU law. In particular it is another appeal about the relevant "product" authorised by the marketing authorisation (MA) on which the applicant bases its SPC application.

2. In this case, the UKIPO accepts that Articles 3(a) to 3(c) of the SPC Regulation are satisfied by an application for an SPC made by Laboratorios Leon Farma SA ("Leon"), namely SPC/GB22/02. That SPC application relates to an oral contraceptive product for women called "Slynd" (or sometimes "Slinda"). Slynd contains as its active ingredient the compound drospirenone. It does not contain any other active ingredient, such as estrogen.

3. The fact that Slynd does not contain any estrogen is an important feature of Leon's basic patent in this case, EP (UK) 3 632 448. Claim 1 thereof reads in material part as follows, emphasis added:

> *A pharmaceutical composition formulated in a galenic form suitable for oral administration 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 about 3.5 mg to about 6 mg of **drospirenone**, one or more pharmaceutically acceptable excipients, **and does not contain any estrogen** …"*

4. The first authorisation for a medicinal product consisting of drospirenone only - ie without any estrogen - was the MA for Slynd itself, which was granted for the first time in Denmark in October 2019 and then in the UK in March 2021. However, there were prior MAs for medicinal products called Angeliq (PL 00010/0518 of 11/12/07) and Yasmin (PL 00010/0571 of 27/04/10), where Angeliq contained drospirenone and estradiol (an estrogen) and Yasmin contained drospirenone and ethinyl estradiol (another estrogen).

5. Leon argues that its SPC application complies with Article 3(d) of the Regulation since Slynd was *"the first authorisation to place the product on the market as a medicinal product"*, as required. The Hearing Officer, Dr Rowena Dinham, held that it did not so comply. She held that the CJEU decision in **Medeva** (C-322/10, EU:C: 2011:773) remained good law, and that pursuant to **Medeva** the previous MAs for Angeliq and Yasmin were both prior authorisations to place drospirenone on the market as a medicinal product. The question for me is whether she was right to so conclude.

6. Leon submits that the Hearing Officer was wrong to do so. Formally there are 8 Grounds of Appeal, but I can summarise the way in which the appeal was actually argued as follows:

a) The term "product" is to be construed strictly, and on that basis an MA placing "A+B" on the market is not an MA for placing "A" alone, or indeed "B" alone, on the market. See Grounds 2-4.

b) **Medeva** is at most a narrow exception to this approach which relates to multi-disease vaccines or other multi-therapeutic target medicinal products. It only applies to Art 3(b) of the Regulation and not to Art 3(d). **Medeva** is therefore an irrelevance to the case. See Ground 5(a)-(c).

c) In any event other UK and EU cases establish that **Medeva** is either limited or wrong. See Ground 5 (d)-(e). In Ground 5(f), Leon reserved its position to argue in a higher court that **Medeva** should not be followed or should be overruled, but I do not need to address this.

d) Ground 6 criticises the Hearing Officer for dismissing Leon's teleological arguments against applying **Medeva** and in favour of granting the SPC.

e) As an auxiliary request, Leon would be willing to amend the description of its product to *"drospirenone (not containing any estrogen)"* were that further to demonstrate the acceptability of its application. See Ground 7.

Grounds 1 and 8 are more generalised complaints which were not advanced independently of the other grounds and I will deal with Ground 6 (teleological arguments) in context below.

7. Counsel for the Comptroller supported the Hearing Officer's decision for the reasons she gave, which included rejection of the auxiliary request mentioned above. There was no Respondent's Notice.

8. In order to assess these arguments I will consider the SPC Regulation; **Medeva**; and the case law relied upon by both sides.

The SPC regulation

9. My attention was drawn to the recitals, in particular recitals (3)-(9), which indicate the purpose behind the Regulation's enactment. I will not set them out here but have borne them in mind.

10. Article 1 provides as follows:

Definitions

(1) For the purposes of this Regulation, the following definitions shall 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;*
>
> *(c) 'basic patent' means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate";…*

11. As Jacob J (as he then was) explained in **Draco's Application** [1996] RPC 417 at 438, the 'medicinal product' is the actual formulation authorised to be put on the market. Birss LJ pointed out in **Newron Pharmaceuticals v Comptroller** [2024] EWCA Civ 128 at [14] that the term is defined in the same way as in the underlying regulatory statutes. In this case it is not disputed that the relevant medicinal products are Slynd, Angeliq, and Yasmin.

12. Conversely the "product" is the active ingredient, or a combination thereof if there is more than one. In this case there is no dispute that the active ingredient is drospirenone. I will return to this below.

13. Article 3 of the Regulation provides as follows:

> *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 authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.*

14. The concept which links the four criteria in Art 3 together is "the product", as pointed out by Birss LJ in **Newron** at [15]. Birss LJ explained at [16] of the same case:

> *"It is manifest that the meaning of product cannot be different in these various limbs of art 3, and before us Newron did not contend otherwise".*

This is in any event binding upon me, but I respectfully agree. I can see no reason why the meaning of "product" should be different depending upon which part of Article 3 is being considered.

15. As Counsel for the Comptroller pointed out, the question under Article 3(a) is whether "the product" is protected by a patent in force, and "the product" is not the same as the claimed invention. The Hearing Officer drew a similar distinction between the product and the invention in the decision under appeal at [65].

16. For instance the claim may be a use, or second medical use, claim. If so, "the product" for purposes of the Regulation is not limited by any claimed therapeutic use. See **Santen** C-673/18, CJEU, at [39]-[53], a passage of the Grand Chamber's judgment which concludes as follows:

> *"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."*

17. As part of its argument on "product", Leon relied upon the EC Notice to Applicants, page 9, at point 3. However as the Comptroller pointed out, the passage relied upon refers (5 times) to "medicinal product" rather than to "product". I do not consider this further.

18. Article 10 of the Regulation makes it clear that the Regulation has no element of discretion. If the application meets the conditions laid down in the Regulation, the SPC shall be granted; if not, the application shall (subject to conditions not relevant here) be rejected.

19. The single most important matter on this appeal is to analyse what **Medeva** actually decided, and I will do that first.

What did Medeva decide?

20. The Hearing Officer dealt with **Medeva** and the related decision in **Georgetown** at paragraphs [13]-[17]; and then with Leon's submissions in relation thereto at [39]-[70]. I shall follow a similar structure, but bearing the arguments on this appeal in mind.

21. At one point it appeared that Leon intended to submit that **Medeva** was limited to the special case of multi-valent vaccines, as it had argued below (see [40] of the decision under appeal). However in the event Leon argued slightly differently. It said that while **Medeva** was still an *"exception to the standard approach"*, the exception also applied to other medicinal products containing active ingredients directed to different therapeutic applications.

22. The essential facts in **Medeva** did indeed relate to multivalent vaccines. The point was that Medeva's patent, EP 1 666 057, claimed a combination of two particular antigens as active ingredients in a vaccine for treating whooping cough. Medeva then filed a number of SPC applications, the material one of which relied upon the marketing authorisation of a vaccine which contained the two claimed antigens along with others.

23. The English Court of Appeal referred the following question, among others, to the CJEU:

> *(6) Does the Regulation and, in particular, Art.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 Art.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?' "*

It will be noted that the question is not restricted to polyvalent vaccines, nor to other medicinal products containing active ingredients directed to different therapeutic applications.

24. In support of its argument that **Medeva** was limited in the way suggested, Leon referred to the Advocate-General's opinion. In this opinion the Advocate-General began with what she called a "literal interpretation" of the Regulation, and concluded as follows:

> *74 It follows from my above observations that, as a general rule, on a literal interpretation of Regulation No.469/2009, there can be no question of a supplementary protection certificate being granted for a multi-disease vaccine in which the combination of active ingredients is only partly patented. I shall now examine below first whether such a conclusion is compatible with the aims of Regulation No.469/2009. Since, in my view, the answer to that must be in the negative, I shall then complement the literal interpretation of Arts.1 to 3 of Regulation No.469/2009 with a teleological interpretation."*

25. The Advocate-General explained why the "literal interpretation" of the Regulation was in her view incompatible with its aims at [80]-[81], to which I have added emphasis:

> *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 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*

26. This then led to her conclusion at [89]-[90], my emphasis:

> *89 In the light of my above observations, it appears to me to be necessary to interpret the definition of 'product' in Art.1(b) of Regulation No.469/2009 teleologically to the effect that the product within the meaning of the regulation includes 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.*

> *90 Such an interpretation also brings within the scope of Regulation No.469/2009 medicinal products in which the combination of active ingredients is only partly the subject-matter of a patent. It in fact allows an SPC application to designate the part of the combination of active ingredients which forms the subject-matter of a patent as the product within the meaning of Art.1(b). That patent can then automatically be classified as the basic patent within the meaning of Art.1(c) of that regulation, so that on that basis the conditions for obtaining the supplementary protection certificate as laid down in Art.3 of the regulation can be examined."*

27. It seems to me, as it seemed to the Hearing Officer, that the above observations are not limited as Leon suggests. On the contrary they apply to "all spheres" where a medicinal product is marketed with the patented active ingredient(s) along with other active ingredients, and multi-disease vaccines were just "the example" being considered in **Medeva** itself. I accept the Comptroller's submissions in this respect.

28. Leon stressed the reference to Article 1(c) in paragraph [90] and at paragraph [98] of the Opinion, but I do not see that anything turns on it. The product must be the same for purposes of Article 1(c) and Article 3.

29. It was common ground that in its judgment the CJEU agreed with AG Trstenjak, albeit in more compressed terms, although the parties differed as to what exactly had been agreed. In my judgment it is clear what was agreed. It is true that some of the CJEU's judgment is specific to multivalent vaccines and to medicinal products which have other therapeutic purposes (see e.g. paragraphs [33], [34]) but I accept the Comptroller's submission that the key paragraphs of the Court's judgment are not so limited. See eg paragraph [42], and paragraph (2) of the dispositif, as follows:

> *42 In view of the foregoing, the answer to Question 6 is that Art.3(b) of Regulation No.469/2009 must be interpreted as meaning that, provided the other requirements laid down in Art.3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a SPC 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 MA is submitted in support of the SPC application contains not only that combination of the two active ingredients but also other active ingredients…*
>
> *(2) Art.3(b) of Regulation No.469/2009 must be interpreted as meaning that, provided the other requirements laid down in Art.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 special protection certificate contains not only that combination of the two active ingredients but also other active ingredients."*

30. Leon emphasised the words "corresponding to that specified in the wording of the claims of the basic patent relied on" appearing in paragraph 2 of the dispositif, but I agree with the Comptroller that (1) this is simply a reference back to the requirements

of Article 3(a); and (2) this needs to be read in the light of the Grand Chamber's decision in **Santen**.

31. I was not referred to **Georgetown** in detail, but it was common ground that this merely restated the same principle as is identified in paragraph 2 of the dispositif in **Medeva**, in the situation where the relevant MA and SPC both contained only one active ingredient rather than a combination of two active ingredients.

32. If one applies the principle identified above to the facts of the present case, it is apparent that Article 3(d) has not been satisfied although each of Articles 3(a) to 3(c) has been. In particular:

    3(a) the product (drospirenone) is protected by a basic patent in force (namely EP(UK) no. 3 632 448);

    3(b) a valid authorisation to place the product (drospirenone) on the market as a medicinal product (Slynd) has been granted;

    3(c) the product (drospirenone) has not already been the subject of a certificate [although different products, namely drospirenone + ethinylestradiol, and drospirenone + estradiol have been];

    3(d) however, the Slynd authorisation was not the <u>first</u> authorisation to place the product (drospirenone) on the market as a medicinal product – the authorisations for both Angeliq and Yasmin satisfied that requirement.

33. I will expand on that last point. Of course drospirenone + ethinylestradiol ("A + B") is not the same product as drospirenone ("A"). However, since the MA for Angeliq contained drospirenone as an active ingredient, Art 3(b) *"did not preclude"* the UKIPO from granting an SPC on the basis of the Angeliq MA. Furthermore since Article 10 of the Regulation does not confer any discretion, *"did not preclude"* means that a notional SPC application based on the Angeliq MA rather than the Slynd MA would have complied with Art 3(b) of the Regulation. It follows that the Angeliq MA, not the Slynd MA, was the first authorisation to place the product (drospirenone) on the market <u>as a medicinal product.</u> It does not matter that the Angeliq MA contained other active ingredients as well. I specify Angeliq rather than Yasmin in this example since Angeliq was earlier, but nothing turns on this.

34. Returning to my summary of Leon's arguments, I agree (as for that matter the Comptroller agreed) that the term product has to be construed strictly. However for the reasons set out above I reject Leon's argument that an MA placing "A+B" on the market is not an MA for placing "A" alone, or indeed "B" alone, on the market.

35. Nor do I accept Leon's argument that **Medeva** only applies to Art 3(b) and not to Art 3(d). I can see no logical justification for having a different approach to Articles 3(b) and 3(d), and nor was any such justification suggested. It would be particularly odd if the word "product" had to be given the same meaning in each limb of Art 3, but the phrase "marketing authorisation" had to be given different meanings as between 3(b) and 3(d).

36. Although nothing turns on it I do not accept that **Medeva** is an "exception" in the sense suggested by Leon. To call **Medeva** an exception is halfway towards dismissing it, and I was not shown any case in which a court had referred to it as such. It is merely a legal rule, to be applied like any other.

37. I therefore dismiss Grounds 2-4 and 5(a)-(c). This brings me to the next stage of Leon's argument, namely that other UK and EU cases establish **Medeva** is either limited or wrong.

Is Medeva either limited or wrong?

38. When Leon submitted that **Medeva** was "limited", what Leon actually meant was that **Medeva** was limited to its precise facts, and as such could and should be ignored for any case (such as the present) which did not feature the precise same facts. I do not accept that argument, as explained above: it is clear to me that **Medeva** established a generally applicable principle. However the submission that **Medeva** is wrong requires more consideration.

39. In support of this submission Leon relied upon **Generics v Daiichi** [2009] EWCA Civ 646, [2009] RPC 23; **Astellas Pharma Inc v Comptroller General of Patents** [2009] EWHC 1916 (Pat); the decision of the Bundesgerichtshof in **Lundbeck**, Xa ZR 130/07; **Santen** C-673/18, CJEU; **Newron Pharmaceutical Spa v Comptroller General of Patents** [2024] EWCA Civ 128; **Merck Serono SA v Comptroller General of Patents** [2025] EWCA Civ 45; the decision of the CJEU in **Teva II** C-119/22 and C-149/22; and the Swedish Patent and Market Court of Appeal decision in **Pearl Therapeutics**, Case No: PMÄ 6595-24, 25 February 2025. Most of these cases are summarised in the decision under appeal, and since the Hearing Officer's summary was not criticised I will borrow part of it.

40. It will be apparent that Leon relies on a considerable amount of case law in support of this proposition. By way of example, the authorities bundle for this hearing contained over 800 pages. However Leon accepted that none of these cases actually said in terms that **Medeva** was wrong. Instead Leon argued that this conclusion could be reached as a matter of implication.

41. I start with **Generics v Daiichi**, which was not cited to the Hearing Officer below**.** This concerned whether Daiichi's SPC for levofloxacin was correctly granted given its earlier marketing authorisation for ofloxacin, which was a racemic combination of levofloxacin and the corresponding R(+) enantiomer. Jacob LJ (with whom Lloyd and Ward LJJ agreed) held that it was correctly granted, on the basis that a combination of two active ingredients in the racemate is not the same 'product' as the single levofloxacin enantiomer alone, see [57]-[58]:

> *[57] …What is the "product" of the 1990 authorisation? To my mind the answer is clear– it is the racemic mixture-ofloxacin as such. We now know the enantiomers within it have individual biological properties: levofloxacin is much the more active from the desired antimicrobial point of view but the R(+) enantiomer has some activity (more than nalidixic and pipemidic acids) in that regard. Both are active in the undesired, toxicological, respect too. In this respect it is the R(+) which has the greater activity. But the overall activity of the racemic mixture derives from both components.*

> *[58] In the Regulation "product" means "the active ingredient or combination of active ingredients" (Art.1(b)). Clearly that must be read with the words "as the case may be" at the end. If you have two active ingredients the "product" is the pair of them. And ofloxacin is a combination of significantly active ingredients. So it is that combination which was the subject of the 1990 and 1985 authorisations. The authorisation for levofloxacin was the first authorisation for that active ingredient alone."*

42. Leon submitted that **Daiichi** was still regarded as good law (see e.g. **Terrell** at 6-93 and 6-94; in the **CIPA Guide** at 128B-66, as well as in the **UKIPO's Manual of Patent Practice** at SPM 3.02) and that since **Daiichi** was Court of Appeal authority it remained binding upon me. The Comptroller correctly pointed out that **Daiichi** predates **Medeva**, and submitted that to the extent it is not consistent with **Medeva**, **Medeva** supersedes it. When I pressed the Comptroller on the latter point, the Comptroller was not prepared to accept that the result in **Daiichi** was wrong. The Comptroller did accept that the **Daiichi** judgment could not stand in its current form, but did not offer any alternative basis upon which it could be supported.

43. With great respect to the Court of Appeal in **Daiichi**, who did not have the advantage of the subsequent decision in **Medeva,** it seems to me that the reasoning, particularly in the last sentence of paragraph [58], is indeed inconsistent with **Medeva**. It remains true today that a product consisting of A+B is not the same as a product consisting of only A, or only B, which is the main point being discussed in paragraphs [57]-[58]. However following **Medeva** the earlier MA discussed in **Daiichi** would now be treated as an MA for placing "A" alone, or indeed "B" alone, on the market. Leon did not dispute that if this was my conclusion about what **Medeva** established, then **Medeva** (and not **Daiichi**) was binding upon me.

44. I do not think that the fact that **Daiichi** is still regarded as good law takes matters any further since it was not suggested to me that any of the sources mentioned actually considered whether its reasoning was consistent with **Medeva**.

45. I turn to **Astellas** and **Lundbeck**, neither of which was cited below either. Here I can be brief. The relevant passage of **Astellas** (paragraph [48]) also predates **Medeva**, is *obiter* and expressly relies upon paragraphs [57]-[58] of **Daiichi**. **Lundbeck** also predates **Medeva**, appears to apply the same logic as **Daiichi** to a similar set of facts (see [73] of **Lundbeck**), and is in any event a foreign decision. Neither takes matters any further.

46. The next group of cases relied upon consists of **Santen**, **Newron**, and **Merck**. These were cited to the Hearing Officer and are addressed in the decision under appeal at [20]-[26].

47. **Santen** was a CJEU reference concerning an attempt to seek an SPC for a new therapeutic use of an old active ingredient, ciclosporin. Ciclosporin had previously been known for use in *inter alia* the rejection of solid organ and bone marrow grafts, but the applicant had also discovered its utility in the treatment of keratitis. The focus of the debate concerned whether the earlier marketing authorisation (ie for the old therapeutic use) could be ignored for the purposes of Art. 3(d), having regard to the CJEU's earlier decision in **Neurim,** paragraph [27] of which was thought to have opened the door to allowing SPCs in such circumstances.

48. It will be seen from this summary that **Santen** relates to a different legal point, and to a different factual situation, from those with which I am concerned. The Grand Chamber's conclusion at [53], which I have already set out above, was that paragraph [27] of **Neurim** was wrong. This led to its conclusion at [62], as cited by the Hearing Officer below at [20] of the decision under appeal:

> *"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."*

49. It follows that **Santen** is not directly relevant, but each side sought to draw something else from it.

a) Leon relied on paragraph [46], emphasising that the definition of the "product" under Art 1(b) is a strict one. So it is, but nothing turns on that.

b) The Comptroller relied on the reference at [51], to paragraph [34] of Abraxis Bioscience v Comptroller-General of Patents, C-443/17 (**Abraxis),** as showing that the Grand Chamber positively approved of the reasoning in **Medeva**. This was because paragraph [35] of **Abraxis** not only refers back to paragraph [34] thereof, but cites paragraph [40] of **Medeva** with approval. This seems to me to be a roundabout way of showing that **Santen** specifically approved **Medeva**, but I agree that it is difficult to reconcile with the suggestion that **Santen** impliedly *overruled* **Medeva**.

c) The Comptroller relied on the express disapproval of **Neurim** at [53] as illustrating that when the CJEU wanted to overrule a case, it said so in terms. However I agree with Leon that sometimes the CJEU will simply depart from a previous case without expressly saying so: for instance, Leon mentioned the CJEU's cases about what was meant by the scope of protection under Art 3(a).

50. Leon relied upon the English Court of Appeal's approval of **Santen** in **Newron**. However the issue in **Newron** was essentially the same as in **Santen**, namely whether a therapeutic use could be considered when identifying the 'product'. The particular therapeutic use relied upon was "add-on therapy", namely the treatment of patients with idiopathic Parkinson's disease, and consisted of the use of the product safinamide in combination with levodopa and a PDI (peripheral decarboxylase inhibitor). The problem for the applicant was that the marketing authorisation relied upon only authorised safinamide, not upon any combination.

51. Leon pointed out that Birss LJ (with whom Moylan and Lewison LJJ agreed) discussed **Medeva** at [28]-[30] as follows, my emphasis:

> *28. The final case to mention is the CJEU's decision and the Opinion of Advocate General Trstenjak in Medeva BV 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."*

52. It will be seen that the Court of Appeal did not criticise **Medeva** itself: on the contrary, it held that **Medeva** did not alter the law. The criticism was instead of **Neurim** for adopting a "*broader, outcome driven teleological approach ... making it inconsistent with a run of previous authority".* I mention this because Leon also invited me to adopt a broader, outcome driven teleological approach if I considered that **Medeva** prevented the grant of an SPC in this case: see its Ground 6.

53. I also note paragraph [17] of **Newron** where Birss LJ said as follows:

> *"Counsel for the Comptroller also drew attention to the Explanatory Memorandum COM (90) 101 final, 1990 OJ C 114/10 which was promulgated by the European Commission. It is clear from this, and from the recitals to the SPC Regulation itself, that the overall scheme seeks to strike a balance between various interests at stake, including the interests of those carrying out pharmaceutical research, public health and generic manufacturers. However as Counsel for the Comptroller also submitted, the balance is itself struck by the terms of the SPC Regulation. It is not a balancing exercise which courts are invited to undertake on a case by case basis."*

54. Thus my task is to apply **Medeva**, not to undertake an *ad hoc* balancing exercise of my own or to perform my own teleological analysis (which in my view amounts to the same thing). I do not accept Leon's criticism of the Hearing Officer for dismissing the teleological arguments put forward in this case. Nor is it correct that she failed to address them, as was also submitted: she did do so, albeit briefly, at paras [77]-[79] of the decision under appeal.

55. The second underlined point in paragraph [30] of **Newron** is also important. The Comptroller did not, and does not, dispute that Leon had conducted valuable and important research. However, that is not the test. As the Comptroller submitted, even research considered worthy of a Nobel Prize would not for that reason alone satisfy the requirements of the SPC Regulation.

56. **Merck** is a decision of the English Court of Appeal, also relating to Article 3(d) of the Regulation, in which the issue was whether **Santen** had been wrongly decided. The Court held that its own previous decision in **Newron** to follow **Santen** was binding: see paragraphs [14]-[15], per Birss LJ, with whom Arnold and Lewison LJJ agreed: see [59], [79]-[88]. The high point of Leon's argument was the following underlined words appearing in paragraph [14]:

> *"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..."*

57. All that the underlined words say is that **Neurim** was *"along similar lines"* to **Medeva** insofar as **Medeva** applied a *"broad teleological approach to combinations*". This reference is understandable in context because Merck's argument for departing from **Santen** had expressly relied on *"the teleological reasoning of the CJEU in Neurim"*: see **Merck** at [6], and in particular [6(ii)]. Hence insofar as the Court of Appeal was rejecting anything about **Medeva**, it was the invitation for the Court of Appeal to apply a broad teleological approach of the type adopted therein. The Court of Appeal did not discuss, let alone reject, the aspect of **Medeva** which is relevant to the present case.

58. The most important case relied upon by Leon in this part of its argument was **Teva II**, which the Hearing Officer considered at [27]-[31]. As she noted this is a post IP Completion Day (31 December 2020) decision of the CJEU, which means that it is persuasive rather than binding. However given that it is a decision of the CJEU in relation to the SPC Regulation, which is retained EU law, it needs to be considered carefully.

59. **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 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. The second dispute (C-149/22) was between Merck and Clonmel concerning the validity of an SPC obtained by Merck in Ireland for a product comprising ezetimibe and simvastatin. In each case the debate was whether those products (i.e. the combinations) were protected by the respective basic patents under Art. 3(a) or not.

60. **Teva II** also referred to earlier decisions called **Actavis I** and **II**, but I was not taken to either of these. I was referred to both the Advocate-General's opinion and to the Court's judgment in **Teva II**, but in my view it is sufficient to refer only to the latter.

61. The CJEU had no difficulty in concluding that a product consisting of A+B is not the same as a product consisting of only A or B. See [45]:

> *"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 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)."*

62. Nor did the CJEU have any difficulty concluding that "product" must mean the same regardless of its context within the Regulation. See [46]:

> *"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."*

63. The paragraph particularly relied upon by Leon was that immediately following the above, at [47]:

> *"47 In the context of Article 3(c) of Regulation No 469/2009, that definition, as clarified in paragraphs 42 to 46 above, necessarily leads to the conclusion that an SPC application relating to a product consisting of two active ingredients (A+B) cannot be refused, under that provision, on the ground that a product, consisting of only active ingredient A or only active ingredient B, has already been the subject of an SPC at the date of application in the Member State in which that application is submitted."*

64. I do not see that this is inconsistent with **Medeva** either. **Medeva** established that an earlier MA placing "A+B" on the market is an MA for placing "A" alone, or indeed "B" alone, on the market. This paragraph of **Teva II** is actually referring to products, not to MAs or medicinal products, but in any event deals with the opposite situation to **Medeva**. **Teva II** establishes that if the earlier product only has A, or only has B, then it is not the same as the later product consisting of A+B.

65. Leon also relied upon paragraph [53], as follows (Leon's emphasis):

> *"53 It follows from the foregoing that where an SPC application relates to a product consisting of two active ingredients (A+B), it is irrelevant, with regard to the condition laid down in Article 3(c) of Regulation No 469/2009, that only one of the active ingredients comprising a product the subject of an SPC application has been disclosed by the basic patent. First, the considerations relating to the basic patent are assessed solely in the light of Article 3(a) of that regulation, and not in the light of Article 3(c) of that regulation, which refers to a separate condition. Second, the fact that only one of the active ingredients comprising the product at issue (A or B) has been disclosed in the basic patent cannot be taken into account in the definition of the product."*

This paragraph is in line with the focus of **Teva II**, which primarily concerned Arts 3(a) and 3(c), but I do not see that the underlined portions are particularly relevant for present purposes (ie for purposes of Arts 3(b), 3(d)). They do not relate to MAs, medicinal products, or to the principle identified in **Medeva**.

66. Next Leon relied upon the decision of the Swedish Patent and Market Court of Appeal in **Pearl**, of which only a machine translation was provided.

67. 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 for a product called Bevespi, for use in the treatment of chronic obstructive pulmonary disease (COPD). The Patent and Registration Office, applying the approach taken in **Medeva**, refused the application under Article 3(d) because although the product was covered by the Bevespi MA, it considered that it was not the first authorisation to put the product on the market in Sweden. In particular, an earlier authorisation for a product called Trimbow had been granted, consisting of formoterol fumarate dihydrate, glycopyrronium, and also beclomethasone dipropionate. In short the earlier MA (Trimbow) was for A+B+C and the later MA (Bevespi) was for A+B.

68. The relevant paragraph of the machine translation reads as follows:

> *"In the view of the Patent and Market Court of Appeal, the statement in paragraph 34 of Medeva does not support the view that a marketing authorization for a medicinal product containing only a combination product with a specific therapeutic indication, and no other active ingredients, is to be regarded as a valid marketing authorization for a product consisting of one or more, but not all, of the active ingredients in the marketing authorization. As the Patent and Market Court of Appeal has already noted, the examination in Actavis concerned two other articles (3 a and 3 c) than in the present case (3 b and 3 d), which is why caution must be exercised regarding the conclusions that can be drawn from what the Court of Justice of the European Union stated in paragraph 38 of Actavis - not least because the Court of Justice of the European Union in Teva Finland clarified that the conditions in Article 3 are to be assessed independently of each other. In addition, the circumstances in the present case are not identical to those in Actavis. In light of the above, the Patent and Market Court of Appeal considers that what is stated in Actavis, paragraph 38, not support the view that the marketing authorization for*

> *Trimbow is to be considered a valid marketing authorization for Pearl's product."*

69. As both sides accepted, this is a very brief discussion from which it is difficult to draw conclusions. For instance it is not clear to me why the Patent and Market Court of Appeal actually held the view that the statement in paragraph 34 of **Medeva** did not apply to the case before it, or the relevance of its reference to "*a specific therapeutic indication".* Nor is it clear whether the Court considered that **Teva II** (which is referred to as Teva Finland in the above extract) positively overruled **Medeva**. The most I can glean from it is that the Court considered it could distinguish **Medeva** on the facts.

70. Finally Leon relied upon the results of various cases across Europe (both involving its own patents and those of others, such as Pearl). It seemed to me that the most important of these results was that in Hungary, where Leon's equivalent SPC application was granted after (1) the Hungarian Patent Office raised objections under Art. 3(d) which are similar to those which were raised here, and (2) Leon filed a response to such objections which relied on arguments similar to those I have considered. However there does not appear to have been any reasoned decision in that case, so it is not clear to me whether (and if so, how) the Hungarian Patent Office concluded that its original objections had been properly addressed.

71. My conclusion is therefore that none of the cases relied upon by Leon as impliedly demonstrating that **Medeva** is either limited or wrong do so, any more than any of them does so expressly. I therefore dismiss Grounds 5(d)-(e) and also Ground 6.

The auxiliary request

72. As noted above the auxiliary request involves amending the description of Leon's product to *"drospirenone (not containing any estrogen)"*.

73. Whilst superficially attractive it seems to me, as it seemed to the Hearing Officer, that this does not make any difference. I do not accept, as Leon submitted, that amending the description in this way actually means that the SPC would be in respect of a different product. It is merely a different description of the same product. In particular "product A" is the same product as "product A not containing X"; or "product A not containing Y", etc rather than (as Leon submitted) these all being different products with different combinations of active ingredients. In this case, the product (ie the active ingredient) is still drospirenone for purposes of Articles 1 and 3 of the Regulation and the words "not containing any estrogen" do not refer to an active ingredient at all.

74. The analysis is then exactly the same as set out above. As the Hearing Officer put it at [76]:

> *"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."*

I therefore dismiss Ground 7.

75. This conclusion makes it unnecessary to decide whether an SPC can lawfully be granted with a negative definition in the first place. I will merely note that, as Leon pointed out, the Court in **Draco** was presented with a similar type of definition and did not appear to consider it objectionable per se.

Conclusion

76. In my view the Hearing Officer was essentially right for the reasons she gave, which I have supplemented with some reasons of my own. The appeal is therefore dismissed.