Neutral Citation Number: [2025] EWCA Civ 45

Case No: CA-2024-000545

IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT
Michael Tappin KC (sitting as a Deputy Judge of the High Court)

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 28/01/2025

Before :

LORD JUSTICE LEWISON
LORD JUSTICE ARNOLD
and
LORD JUSTICE BIRSS

- -

Between:

Merck Serono S.A.	**Appellant**
- and -	
The Comptroller-General of Patents, Designs, and Trade Marks	**Respondent**

- -
- -

Tom Mitcheson KC, Daniel Selmi (instructed by **EIP**) for the **Appellant**
Anna Edwards-Stuart KC, Stuart Baran (instructed by **Government Legal Department**) for the **Respondent**

Hearing dates: 11 December 2024

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Approved Judgment

This judgment was handed down remotely at 10.30am on 28/1/2025 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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Lord Justice Birss:

1. This appeal relates to the application by the appellant Merck for a supplementary protection certificate (SPC) for a pharmaceutical called cladribine. The application relies on a basic patent EP 1 827 461 which relates to the use of cladribine for treating multiple sclerosis, and a 2017 marketing authorisation for the medicinal product MAVENCLAD which contains cladribine as an active ingredient and is indicated for the treatment of highly active relapsing remitting multiple sclerosis. The problem is that the application has been held not to meet the requirements of the relevant provisions because of the existence of an earlier marketing authorisation for a medicinal product containing cladribine as an active ingredient, contrary to article 3(d) of the relevant Regulation ((EC) No. 469/2009). In fact there were two earlier marketing authorisations, one for a medicinal product called LEUSTAT issued in 1995 and another for a medicinal product called LETAK issued in 2004. Each of these authorisations are for a medicinal product containing cladribine as an active ingredient for the treatment of hairy cell leukaemia.

2. This is therefore another case raising the question of the relationship between patents for second medical uses of pharmaceutical products and the SPC regime, and the position of the CJEU judgment in *Neurim Pharmaceuticals v Comptroller* C-130/11 [2012] RPC 23.

3. A recent summary of the development of the CJEU cases on this topic was set out in February 2024 in *Newron Pharmaceuticals v The Comptroller* [2024] EWCA 1471 (Lewison, Moylan and Birss LJJ) at [19] – [22] of my judgment. I will come to the detail below, but briefly the position is as follows. By 2012 the effect of a series of CJEU decisions was that no certificate would be granted in a situation like the present one because the intended use of a product was irrelevant. That line of cases started with *Pharmacia Italia SpA* C-31/03 [2004] ECR I-10001 and included C-202/05 *Yissum Research and Development Company of the Hebrew University of Jerusalem v. Comptroller-General of* Patents [2007] ECR I-2839. Then in 2012 in *Neurim*, the CJEU changed tack and held that the law would permit a certificate in these circumstances, taking the intended use into account. Essentially the CJEU's reasoning was that this outcome was in accordance with the objectives of the Regulation and so the CJEU was applying what the Advocate-General in that case called a schematic-teleological interpretation. However in 2020 in *Santen* C-673/18 the Grand Chamber of the CJEU overruled *Neurim*, holding that this teleological approach was wrong and that the correct interpretation of the Regulation was such that no certificate would be granted in a case like the present one. Finally in 2024 this court in *Newron* applied *Santen* to the case before it, dismissing the appeal.

4. The present application was filed in 2018, before Brexit and also before *Santen*. The matter came to be decided by the Comptroller's Hearing Officer, Deputy Director Mary Taylor at a hearing in March 2023. In her decision (BL O/0484/23) of 26 May 2023 the Hearing Officer refused the application, essentially because she decided to follow *Santen*. A distinct issue before the Hearing Officer, and on appeal to the Patents Court (Michael Tappin KC sitting as a Deputy Judge of the High Court) was whether, at the time the development of MAVENCLAD took place, Merck had a legitimate expectation that it would be entitled to a certificate based on *Neurim* prior to it being overruled in *Santen*. That case failed before the Hearing Officer, the appeal was dismissed by Mr Tappin and no appeal to this court was sought on that ground.

5. The appeal to this court is based on a single ground. Merck contends that *Santen* is wrongly decided and that the Court of Appeal should depart from it. As well as the question of departure itself, there is a prior question whether it is open to this court to depart from *Santen* at all given *Newron*.

6. Merck's case on departure is that the teleological approach of *Neurim* is the right approach and that when this is taken, the result would be the grant of a certificate. It is not in dispute that if *Neurim* represents the law then Merck would be entitled to a certificate, and so the focus in this case is on departure from *Santen*. In summary Merck's case in favour of departing from *Santen* is as follows:

    i) There is a lack of cogency and consistency in CJEU case law in relation to Article 3(d).

    ii) The teleological reasoning of the CJEU in *Neurim* was careful and correct and should be followed, otherwise the SPC Regulation "will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose" [this is a quote from Jacob LJ in *Neurim*]. This teleological approach is supported by later judicial consideration, including in the UK, and by the position adopted by the UK Government in the *Abraxis* reference.

    iii) The CJEU's reasoning in *Santen* is regressive, overly literal, restrictive and conveys no practical benefit to the UK IPO or the public at large.

7. Before dealing with these aspects of the argument on departure, it is convenient to deal with the prior question first.

Could this court depart from Santen*?*

8. *Santen* and the CJEU cases prior to it are what was called "retained EU case law" in s6(7) of the European Union (Withdrawal) Act 2018 as enacted and are now called "assimilated EU case law" as a result of the amendments made to the 2018 Act by the Retained EU Law (Revocation and Reform) Act 2023. As Arnold LJ explained in *Industrial Cleaning Equipment (Southampton) Ltd v Intelligent Cleaning Equipment Holdings Co Ltd* [2023] EWCA Civ 1451 at [80], that means it continues to form part of domestic law after Brexit and continues to bind lower courts.

9. Under the terms of s6(5) of the 2018 Act the Supreme Court has 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, in accordance with the *Practice Statement (Judicial Precedent)* [1966] 1 WLR 1234. A similar power was extended to the Court of Appeal by a statutory instrument made under the powers in s6(5A) of the 2018 Act. By s6(4)(ba) of the 2018 Act a relevant court defined in such a statutory instrument is not bound by any assimilated EU case law so far as provided for in that statutory instrument.

10. The statutory instrument is the European Union (Withdrawal) Act 2018 (Relevant Court) (Retained EU Case Law) Regulations (SI 2020/1525). In its terms the Court of Appeal is a "relevant court" by paragraph 3(b). The position of relevant courts is provided for in paragraphs 4 and 5, as follows:

> 4(1) A relevant court is not bound by any retained EU case law except as provided in paragraph 2.
>
> (2) A relevant court is bound by retained 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.
>
> 5. In deciding whether to depart from any retained EU case law by virtue of section 6(4)(ba) of the 2018 Act and these Regulations, a relevant court must apply the same test as the Supreme Court would apply in deciding whether to depart from the case law of the Supreme Court.

11. The effect of these provisions is as follows. The principles to be applied by the Court of Appeal in deciding whether to depart from any retained EU case law are the same as those to be applied by the Supreme Court, in other words the 1966 *Practice Statement.* However that power is only available to the Court of Appeal if it is not bound by the retained EU case law, as provided for in paragraph 4. The Court of Appeal is only bound by retained EU case law if the circumstances in paragraph 4(2) apply, otherwise it is not bound (paragraph 4(1)). Paragraph 4(2) applies 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. Post-transition case law is defined in paragraph 2 of the statutory instrument as being "any principles laid down by, and any decisions of, a court or tribunal in the United Kingdom, as they have effect on or after IP completion day".

12. So for paragraph 4(2) to apply, there must be a decision of a court which modifies or applies that retained EU case law and that decision must itself be binding on the Court of Appeal. Therefore, for example, a prior decision of the High Court applying the retained EU case law would not prevent the Court of Appeal from exercising the power to depart. However if the relevant prior decision was a judgment of the Court of Appeal it would follow that since, subject to *Young v Bristol Aeroplane* [1944] KB 718 CA, the *ratio decidendi* of that prior decision would be binding on the subsequent Court of Appeal, then the power to depart would not be available to that subsequent Court of Appeal as long as the modification or application of the retained EU case law was part of that *ratio*. These conditions only apply to relevant courts and do not affect the Supreme Court's power to depart, which is not subject to the provisions in the statutory instrument.

13. With these principles in mind I will consider whether paragraph 4(2) of the statutory instrument applies to *Newron*. The facts in *Newron* concerned a patent for a combination of compounds including safinamide, levodopa and PDI, but a marketing authorisation for safinamide alone, albeit the marketing authorisation was said to describe using the compound safinamide with the other compounds in the combination. The argument in law concerned the distinction between what a product is and how it is to be used. The argument was that the marketing authorisation could be found to match the patent if one took the manner of use into account. The appellant argued that the Court and Hearing Officer below had taken the law to be that the manner of use was irrelevant. The appellant contended this was an error of law. Essentially the same CJEU cases which have been cited in the present appeal were cited. In particular *Neurim* was identified as an example of a decision by the CJEU in which the intended use could play a role in the analysis of the criteria for grant (see *Newron* paragraph 21)

but then *Santen* was also identified as overruling *Neurim* (see *Newron* paragraph 22), holding that the definition of the product is not dependent on the manner of use. Then at paragraph 33 the judgment in *Newron* is as follows:

> Turning to the facts of this case and applying the law above, in my judgment the Hearing Officer and the judge were right in their conclusion that the product which this marketing authorisation authorises to be placed on the market as a medicinal product is safinamide. It is not a combination.

14. In other words in *Newron* this court was presented with a choice, to follow *Neurim* (and another earlier CJEU case along similar lines *Medeva v Comptroller* Case C-322/10 [2012] RPC 25 which applied a broad teleological approach to combinations), or to follow *Santen*; and the decision which this court made was to follow *Santen*. In my judgment therefore *Newron* is a decision which applies *Santen* and it does so as part of the *ratio decidendi*. The fact that the specific aspect of the Regulation in issue in *Newron* was Art 3(b) whereas it is Art 3(d) which is in issue in the present case does not alter that conclusion. In the terms of *R (Youngsam) v Parole Board* [2019] EWCA Civ 229, the conclusion in *Newron* would be (much) weaker without the application of *Santen*. 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 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.

Would this court depart from Santen?

16. Even if it was open to the Court of Appeal to depart from *Santen*, I would not do so because I am not convinced it would be right to do so following the principles in the 1966 *Practice Statement*.

17. The application of the *Practice Statement* in the context of departing from retained EU case law under the 2018 Act arose in *Warner v TuneIn Radio* [2021] EWCA Civ 441 and in *Industrial Cleaning Equipment*, (see *Warner* paragraph 75 (Arnold LJ), paragraph 200 (Sir Geoffrey Vos MR) and *Industrial Cleaning Equipment* paragraph 81 (Arnold LJ) and paragraph 122 (Nugee LJ)). Both cases noted decisions of the Supreme Court to the effect that the court should not refuse to follow an earlier decision of that court or the House of Lords "merely because we would have decided it differently". More was required not least because of the desirability of certainty in the law. Nevertheless too rigid adherence to precedent may lead to injustice and hinder the proper development of the law. Overall the court will be very circumspect in applying the Practice Statement or, putting it another way, great caution is required.

18. In my judgment the starting point must be to examine the criticisms levelled at the assimilated EU case law, in this case *Santen*, to see if they are justified. If not then the application of the Practice Statement does not arise.

19. To address *Santen* in its proper context it is necessary to go into some detail, starting with a summary of the operation of the SPC system itself. The following summary is essentially the same as the one in paragraphs 2, 3 and 12-17 of *Newron*, with suitable modifications for this case.

20. SPCs are a form of patent term extension to compensate for lost time caused by the marketing authorisation regime applicable to pharmaceutical products and such like. The normal 20 year patent term starts when the patent is applied for, once the invention of the new drug as a treatment for a given disease has been made. However the law prevents the marketing of such a product as a medicine without authorisation, and the authorisation is only given on proof to the appropriate authority that the product is a safe and effective medicine for the disease concerned. That proof is only possible after extensive, costly and uncertain clinical trials have been completed to establish safety and efficacy. That takes time, and the result is that the patentee cannot begin to recoup its investment in research and development, by marketing the pharmaceutical, for some years later than would have been possible absent the marketing authorisation regime. Thus the SPC system will extend the relevant term for up to five years provided the various criteria are satisfied (see Recitals [3] to [8] of the Regulation and also *Draco's SPC Application* [1996] RPC 417 at 436).

21. To apply the criteria one needs to examine two relevant documents – the patent and the marketing authorisation. Put briefly, a critical requirement for an SPC to be granted is that the patent and the marketing authorisation must match. In the language of the SPC Regulation the product authorised to be placed on the market as a medicinal product by the relevant marketing authorisation must be the product protected by the relevant patent.

22. The SPC Regulation is an EU instrument but is now assimilated EU law, and has not materially changed since Brexit.

23. The relevant provisions of the Regulation are parts of Articles 1 and 3, as follows:

> Article 1 Definitions
>
> 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;

> […]
>
> Article 3 Conditions for obtaining a certificate
>
> A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
>
> (a) the product is protected by a basic patent in force;
>
> (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
>
> (c) the product has not already been the subject of a certificate;
>
> (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.
>
> Article 4 Subject-matter of protection
>
> Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.
>
> […]

24. To understand how the scheme works it helps to start from the medicinal product. That is defined in Art 1(a) of the SPC Regulation essentially as any substance or combination of substances presented for treating a disease. It is no accident that the definition is the same as the one used for medicinal product in the relevant marketing authorisation legislation. In other words, naturally enough, the scheme of the SPC Regulation starts with a concept taken from the marketing authorisation legislation.

25. Now one can see what a "product" is. Art 1(b) defines it as the active ingredient or combination of active ingredients of a medicinal product. Following from this one can apply Art 3, noting that the concept which links the four criteria in that article together is the product. At Art 3(a) the product must be protected by the patent, at 3(b) there must be a marketing authorisation to place the product on the market as a medicinal product, and so on in Art 3(c) and 3(d).

26. In *Newron* (at paragraph 16) I said it was manifest that the meaning of product cannot be different in these various limbs of Art 3, and noted that Newron did not contend otherwise. In the present case, although Merck does not accept this, one of the possible problems with the approach taken in *Neurim* might be to undermine that principle.

27. Finally at this introductory stage I mention the Explanatory Memorandum COM (90) 101 final, 1990 OJ C 114/10 which was promulgated by the European Commission as

part of the process leading up to the passing of the SPC Regulation in its original form. Merck places heavy reliance on passages in this document as identifying objectives of the SPC Regulation which are the basis for the teleological reasoning it advances. The particular point Merck makes is to note that the Explanatory Memorandum supports the idea of giving SPCs for patents on new therapeutic uses of known products.

28. It is true that this objective is something mentioned in the Explanatory Memorandum but the scheme as a whole has a number of other objectives too, including ensuring sufficient protection to encourage pharmaceutical research, taking account of all the interests at stake including those of public health, and the idea that the system is meant to be a simple transparent one for patent offices to administer.

29. With that background it may help to summarise how the scheme operates based on the law as it stands today, including *Santen*.

30. In what I will call a traditional case, the scheme works in this way. A new compound is discovered with potential utility to treat a particular disease. The compound is patented as a product. A marketing authorisation is obtained which permits the company to bring the compound to market in a suitable pharmaceutical formulation as a safe and effective medicine to treat a particular disease. Given the development and clinical trials required, this process takes 10 more years after filing the patent. The term of the SPC, i.e. the length of the extension of patent life, is calculated in accordance with Art 13 of the Regulation essentially by taking the time it took for the marketing authorisation to be granted after the patent was filed and subtracting 5 years. So in this case the SPC would be granted to last for 5 years (10 minus 5). That would result in a total of 15 years protection after the date of the marketing authorisation, which is the maximum allowed by the Regulation (subject to irrelevant exceptions).

31. In this example an SPC would be granted. In terms of the Regulation, the "medicinal product" is the compound as formulated in accordance with the marketing authorisation for treating the disease. The "product" is the active ingredient, i.e. the compound. Art 3(a) is satisfied because the product is protected by a basic patent. Art 3(b) is satisfied because the marketing authorisation is a valid authorisation to place the product on the market as a medicinal product. Art 3(c) is satisfied because there has been no other SPC granted for the product, i.e. the compound. Art 3(d) is satisfied because the marketing authorisation is the first authorisation to place the product on the market as a medicinal product.

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

33. Changing the example slightly, if at the outset the compound was already publicly known perhaps as a possible treatment for a disease but had never been authorised for

that disease, and the company discovered it had utility for a different disease, then the patent would be for the use of the compound to treat that different disease, in other words a second medical use patent. However this would make no difference to the analysis above. An SPC would still be available on the same basis for the same period. In other words there is nothing in the Regulation which prohibits relying on a second medical use patent as such.

34. However the problem for Merck is that the earlier use of the compound cladibrine has led to the grant of earlier marketing authorisations, but the age of those marketing authorisations means that if either of them were used as the basis for an SPC on cladibrine, the term would be zero. Merck's case is that in order to avoid this problem the use of the compound as authorised in the marketing authorisation ought to be taken into account. If it is then one can distinguish between the current marketing authorisation and the two earlier ones.

Pharmacia Italia

35. This is not a new problem in the SPC scheme. In *Pharmacia Italia* in 2005 the applicant's problem was the existence of an earlier marketing authorisation for the same active ingredient as the one on which the SPC application was based but for a different use. At that time the SPC scheme was relatively new and the issue was about how the transitional provisions operated but the problem was the same. The earlier marketing authorisation was for veterinary use of the compound whereas the SPC was sought based on a marketing authorisation for human use. The CJEU held that the earlier authorisation was a relevant authorisation for the product as medicinal product because the active ingredient was the same. The decisive factor was not the intended use (CJEU paragraph 20). In reaching this conclusion the court took into account Art 4 which provides that the protection conferred relates to any use of the product as a medicinal product that has been authorised and Art 1(b) which defines the "product" as the active ingredient of the medicinal product. For a fuller treatment of *Pharmacia Italia* and the cases I mention below up to and including *Neurim*, I refer to the review of these cases by Arnold J as he then was in *Abraxis Bioscience v The Comptroller* [2017] EWHC 14 (Pat) at paragraphs 20 to 38.

MIT

36. Briefly, the next relevant CJEU decision was C-431/04 *Massachusetts Institute of Technology* [2006] ECR I-4089 ("*MIT"*). Here the applicant had discovered a new way of delivering a known drug called carmustine to treat brain tumours by using a device which combined carmustine with a form of polymeric carrier material called polifeprosan. The applicant advanced two cases before the German Patent Office but both failed. One case was to seek an SPC for carmustine alone but that failed on Art 3(d) grounds because the applicant's marketing authorisation was not the first marketing authorisation for carmustine itself. The other case was to seek an SPC for the combination of carmustine and polifeprosan as the relevant product but that failed because the definition of product in Art 1(b) provides for a combination of active ingredients, and polifeprosan is not an active ingredient. Although polifeprosan's properties as a carrier were crucial to make the treatment work against brain tumours, that did not make it an active ingredient. Only the second case was taken forward and went to the CJEU. The CJEU held that the reference to a combination of active ingredients in Art 1(b) did not include a combination of two substances only one of

which has therapeutic effects of its own even if the other substance renders possible a pharmaceutical form which is necessary for therapeutic efficacy.

Yissum

37. Then in 2007 the CJEU dealt with the *Yissum* case by a reasoned order. The background is explained in Arnold J's judgment which led to the reference at [2004] EWHC 2880. The applicant had discovered a new use for a known compound calcitriol, in an ointment to treat psoriasis and the patent was for that use. The compound was already known for treating problems associated with kidney diseases and there were existing marketing authorisations for calcitriol in solution for injection or as an orally administered gelatine capsule.

38. Before the Hearing Officer (see Arnold J's judgment at paragraphs 10-14) the applicant's primary case was based on characterising the product as calcitriol. The applicant had argued that the references in the Regulation to "medicinal product" should be read as "relevant medicinal product" so that the skin disease authorisation was the first "relevant medicinal product" thereby satisfying Art 3(d). The concept of relevance was derived from the scope of the patent. So a relevant medicinal product was one within that scope. That was rejected on the ground that the terms product and medicinal product had to have the same meaning throughout the Regulation and in particular in Articles 1, 3 and 4. Therefore, since the earlier marketing authorisations were for the same product, i.e. the same active ingredient, the application on this basis failed on Art 3(d) grounds.

39. The alternative case before the Hearing Officer in the Patent Office was to define the product as the combination of calcitriol with the ointment. That failed too because the ointment was not an active ingredient.

40. Before Arnold J the applicant advanced a different primary case, arguing that the use could be part of the definition of product, so that the product as defined in the primary case was "calcitriol for the topical treatment of psoriasis". The alternative case based on the combination was also advanced, and Arnold J referred questions to the CJEU on both cases. On the primary case the question was whether the therapeutic application might play a role in the definition of product. The questions on the alternative case were subsequently withdrawn because the CJEU had by then decided *MIT* on the same issue. In relation to *Yissum* the CJEU decided that no hearing was necessary to resolve the question on the primary case because the answer could be deduced clearly from the decisions in *Pharmacia Italia* and *MIT*. The answer was that the concept of product cannot include the therapeutic use of the active ingredient. The concept of a product had to be confined to the active ingredient (*MIT*) and the intended use was not a decisive factor (*Pharmacia Italia*).

41. At this point the case law of the CJEU was consistent and coherent. It did not matter what sort of patent was used as the basis for an SPC, so in principle an SPC could be granted based on a compound patent, a second medical use patent or a patent for a combination of a compound with an excipient. The problem in the cases had been the existence of earlier marketing authorisations for the same active ingredient albeit being used in different circumstances.

Neurim

42. The next step was the decision of the Court of Appeal in *Neurim* in 2011. This was another second medical use case. The patent was for the use of the drug melatonin for the treatment of sleep disorders and a marketing authorisation for that human use had been granted in 2007. However there was an earlier marketing authorisation in 2001 for melatonin to be used in animals to improve reproductive performance. The applicant argued the same or a similar point about reading in the concept of "relevance" as mentioned already, submitting that the proper construction of Art 3(d) was that the marketing authorisation in Art 3(b) had to be the first relevant authorisation, whereas the old marketing authorisations were not relevant because they were for a different use, outside the scope of the patent. The Patent Office refused the SPC application on Art 3(d) grounds and that was upheld in the Patents Court by Arnold J, following the body of CJEU case law described above culminating in *Yissum*.

43. In *Neurim* the Court of Appeal decided to refer questions to the CJEU to resolve the issue. As I said in *Newron* (paragraph 21), in the Court of Appeal Jacob LJ giving the judgment of the court with Patten and Smith LJJ ([2011] EWCA Civ 228) provided a persuasive judgment 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. The means to achieve this was to read in the concept of relevance judged by reference to the scope of the patent. It is a persuasive case but given what happened it is also worth noting that while the judgment and the four questions did to some extent explore how a decision in Neurim's favour might fit in with the scheme of the Regulation as a whole, it did not go into the matter in depth and in particular did not try either to rationalise the earlier case law with the conclusion or suggest that some or all of those decisions should be overruled. A difficulty with "relevance" is that reading it in does not draw a line specific to particular case types. It would work for second medical use cases, which might be thought to have some merit, but it could also bring in others, of less obvious merit.

44. The CJEU in *Neurim* followed the invitation of the Court of Appeal and held that the use could play a role in the analysis. I put it at this level of generality because the scope of what the CJEU decided in *Neurim* is not clear. One example will do. The first question referred was framed specifically by reference to Art 3(d) and involved wider circumstances than the human/veterinary distinction, although that was mentioned in the third question. The CJEU reformulated the questions and in its dispositive paragraphs the first answer refers to Arts 3 and 4 in general and also appears to be focussed only on saying that an older marketing authorisation for veterinary use would not preclude an SPC based on a different application of the same product, although it is fair to point out that paragraph 25 of the CJEU's decision is more widely stated. The second dispositive paragraph is or appears to be based on the "relevance" approach although that word is not used.

45. It is also notable that although the Advocate General in *Neurim* identified two lines of CJEU cases on the conditions for grant of an SPC, one line supporting a broader interpretation (such as C-482/07 *AHP Manufacturing v Bureau voor de Industriele Eigendom* [2009] ECR I-7295) and another line supporting a narrower interpretation (such as C-195/09 *Synthon BV v Merz Pharma GmbH & Co KGaA* [2011] ECR I-7011 and C-427/09 *Generics (UK) Ltd v Synaptech Inc* [2011] ECR I-7099), there is no mention of *MIT* or *Yissum* at all in either the Advocate General's Opinion or the Court's

judgment and barely any reference to *Pharmacia Italia* (a footnote in in the AG's Opinion)

46. The CJEU decision in *Neurim* led to difficulties. Some of the most important are illustrated by what happened in *Abraxis* in 2017. There Arnold J referred further questions to the CJEU which only arose because of *Neurim*. That case was about a new formulation of an old active ingredient. The applicant had a patent and marketing authorisation for a known cancer drug paclitaxel formulated as albumin bound nanoparticles. It sought a SPC on that basis. In the Patent Office the Hearing Officer refused the application on Art 3(d) grounds because of the existence of an earlier marketing authorisation for the same active ingredient, paclitaxel, albeit formulated differently. The applicant contended that *Neurim* decided that Art 3(d) was to be interpreted as meaning that the authorisation in Art 3(b) was the first "relevant authorisation", i.e. the first authorisation within the scope of the basic patent. Although *Neurim* was about a second use, the same policy considerations could be said to apply to a new formulation and so on that basis the SPC should be granted. One can see the force of the argument based on *Neurim* in isolation but it is hard to reconcile that outcome with other CJEU decisions such as *MIT*, which provide that SPCs cannot be obtained for a new formulation of a known active ingredient.

47. Arnold J addressed all the cases mentioned above and after summarising *Neurim* at paragraphs 32 – 35 he set out the difficulties at paragraphs 37 – 38 as follows:

> 36. As I observed in *AstraZeneca AB v Comptroller-General of Patents, Trade Marks and Designs* [2012] EWHC 2840 (Pat), [2013] RPC 25 at [52]-[53], the Court's judgment in *Neurim* (although not the actual decision) is problematic for two reasons:
>
> 37. First, it appears that the Court was intending to depart from its decisions in *Pharmacia*, *MIT* and *Yissum*, and in particular the decisions in *Pharmacia* and *Yissum*. This is not clear, however, since it did not refer to those decisions. Thus one does not know if those decisions are to be regarded as having been overruled, or as qualified in some unspecified manner.
>
> 38. Secondly, it does not appear that the Court was intending to depart from its earlier judgments in *Synthon* and *Generics*, since it cited *Synthon* at [20]. It is not clear to me, however, how *Neurim* is to be reconciled with those decisions. The reasoning which the Court relied on in *Neurim*, namely that the research required to obtain a patent and marketing authorisation for a second medical use of an active ingredient justifies the grant of an SPC for the second medical use despite the fact that the same active ingredient has already been lawfully marketed as a medicinal product, seems to me to be equally applicable to *Generics* and *Synthon*, albeit that those cases did not concern Article 3(d). As noted above, Advocate General Trstenjak drew attention to this difficulty in her opinion, yet the Court proceeded as if there was no problem.

48. In referring the questions on Art 3(d) to the CJEU, Arnold J indicated at paragraph 63 that he would answer the questions in a manner which precluded the SPC based on a new formulation. He observed that the Regulation was intended to provide a simple and predictable system that could be operated by the competent authorities of the Member States, and in particular the national patent offices, in a uniform manner. He also noted that the Regulation aims to balance the interests of patentees with those of other stakeholders. As Arnold J then said to achieve those objectives, it is necessary to have bright-line rules even if they sometimes deprive meritorious inventions of extended protection. I agree.

49. The Advocate General's 2018 Opinion in *Abraxis* is instructive. In it AG Saugmandsgaard Øe puts *Neurim* into context, explaining the problems it caused. For example at paragraph 41 the AG refers to an independent study by the Max Planck Institute, commissioned by the Commission, which highlights the differing interpretations of the Regulation as between the Member States caused by *Neurim*. In a carefully reasoned opinion the AG's expressly preferred option is to abandon *Neurim* altogether, taking the view that neither the objectives of the Regulation nor the wording of Art 3(d) support it (paragraph 85). As an alternative the AG proposed limiting *Neurim* to cases involving the human/veterinary distinction (paragraph 105).

50. However the court took neither of those approaches. The CJEU expressed concern that to accept the approach suggested by Abraxis would risk legal uncertainty and inconsistencies (paragraph 39). The CJEU rejected the argument that it could be applied to cases of new formulation cases and sought to characterise *Neurim* as an exception to what it regarded as the generally appropriate narrow interpretation of Art 3(d).

Santen

51. The last judgment in this line of course is *Santen* itself. In that judgment the court decided that the narrow, pre-*Neurim*, approach to the interpretation of Art 3(d) was the right one both in terms of the wording of the Regulation (see paragraphs 38 to 53) and also by considering the objectives of the Regulation (see paragraphs 54 – 59), which include those identified in the Explanatory Memorandum. In addition to answering the question referred in a manner clearly contrary to *Neurim* (see below) the court also expressly overruled it (paragraph 53). The answer to the question referred was:

> 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.

Merck's criticisms of Santen

52. Merck suggests that there is lack of cogency and consistency in CJEU case law in relation to Article 3(d). In my judgment the real problem of a lack of cogency and consistency was the one caused by *Neurim*.

53. Merck also submits that the teleological reasoning of the CJEU in *Neurim* was careful and correct and should be followed, otherwise, as Jacob LJ put it, the Regulation will not achieve its objective for large areas of pharmaceutical research. However this is an unbalanced approach to the objectives of the Regulation. It takes no account of other objectives including public health and the competing interests of third parties. The run of cases explained above shows why things are not that simple.

54. Merck suggests that the teleological approach is supported by later judicial consideration, including in the UK, and by the position adopted by the UK Government in the *Abraxis* reference. In relation to the former, Merck referred to the observation of Arnold J in *Abraxis* at paragraph 36 (quoted above) that it was the judgment but not the actual decision in *Neurim* which was problematic and they also referred to my observation in *Newron* at paragraph 21 (quoted above) that the Court of Appeal in *Neurim* was persuasive. In my judgment neither of these statements provide firm support for Merck's case. At that time of *Abraxis, Neurim* represented EU law and there was no need then to criticise it in its application to second medical use cases. The problem with *Neurim* is and always has been the implications of whatever interpretation of the Regulation is made in order to achieve the objective of providing an SPC on those facts. What the cases show, taken as a whole, is that to achieve the potentially worthy policy objective a process of judicial interpretation of the Regulation cannot achieve that result without creating more uncertainties. The only way to achieve the result sought would be by legislation.

55. Merck is correct that in *Abraxis* the UK's submissions were that the *Neurim* interpretation only concerned cases of a new therapeutic use (see AG opinion at paragraph 89) and therefore did not extend to new formulations. However as the AG went on to observe at paragraph 90, that interpretation was at odds with the wording and objectives of the Regulation and the interested parties had not presented arguments capable of justifying the distinction.

56. Finally Merck criticises the reasoning of the CJEU in *Santen* itself as regressive, overly literal, restrictive and conveying no practical benefit to the UK IPO or the public at large. I have already explained why I do not accept that submission. The CJEU in *Santen* explicitly considered both the wording of the Regulation and its objectives. To the extent benefits to the Patent Office are relevant, part of the problem caused by *Neurim* was that the SPC scheme was made more difficult to administer when it was meant to be simple. In terms of public benefit, this has been dealt with already. Grant or refusal of an SPC in a given set of circumstances amounts to the extension or not of a patent monopoly as part of a scheme in the Regulation which balances objectives of support for innovation with the interests of public health.

57. Since I believe Merck's criticisms of *Santen* are unsound, there is no reason to depart from this aspect of retained EU case law. However I will add that even if there is some force in these points, I am far from convinced this would be a proper case to depart. *Santen* is a decision which brought to the scheme of the Regulation back into a measure of coherence, and substantially reduced the legal uncertainty caused by *Neurim*, albeit at the expense of applicants like *Neurim* themselves and Merck too. However the real

problem with *Neurim* was that it did not face up to the wholesale reorganisation of the way the Regulation would need to be interpreted in order to provide a consistent scheme in which cases like *Neurim* and Merck led to SPCs.

Conclusion

58. I would dismiss this appeal. I would also add that I agree with the judgments of Arnold LJ and Lewison LJ below, which I have had the advantage of reading in draft.

Lord Justice Arnold:

59. I agree that the appeal should be dismissed for the reasons given by Birss and Lewison LJJ. On the question of departure from *Santen*, I would add three brief points. First, the assimilated version of the SPC Regulation that applies in the UK post-Brexit has not relevantly been amended. It follows that it remains the will of Parliament that the legislation should continue to be harmonised with that of the EU. In those circumstances, the UK courts should continue to interpret the legislation in harmony with the Court of Justice unless convinced that the Court of Justice's interpretation is wrong (as in *ICE v ICE*). Secondly, there is no realistic prospect of the Court of Justice reversing its ruling in *Santen* (unlike the ruling in issue in *ICE v ICE*). Thirdly, Merck cited neither any academic criticism of *Santen* nor any decisions of any EU national courts supportive of its case.

Lord Justice Lewison:

60. I also agree with the judgment of Birss LJ. But the question of precedent is an important one; and I wish to add a judgment dealing principally with that question.

The issue and legal background

61. As Birss LJ has explained, the appeal arises out of a difference of approach taken to the grant of a supplementary protection certificate (an "SPC") in two decisions of the CJEU. In (Case C-130/11) *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* [2013] RPC 23 the Fourth Chamber of the CJEU decided that, in considering the definition of "product" in article 3 (b) of Regulation 1768/92, the definition could encompass a medicinal product exploiting a new use; and hence under article 3 (d) a marketing authorisation ("MA") for that product for that new use could be a first MA, even though that product already had an MA for a different therapeutic use. In so doing, it adopted what it described as a schematic-teleological approach rather than a literal approach. In the minds of many that decision had departed from a consistent line of previous case-law of the CJEU. In (Case C-443/17) *Abraxis Bioscience LLC v Comptroller-General of Patents* Advocate General Saugmandsgaard Øe pointed out a number of difficulties arising out of the decision in *Neurim*. He considered that the best way forward was to return to the literal interpretation of Article 3 (d).

62. The Fourth Chamber of the CJEU did not accept that advice in its entirety, but did try to narrow the effect of *Neurim*.

63. The issue returned to the CJEU in (C-673/18) *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*. The reference was made by the Paris Court of Appeal seeking clarification of the judgment in *Neurim*. In his opinion

Advocate General Pitruzzella took the view at [30] that *Neurim* had "circumvented" previous case law; and that that contradiction was perpetuated by subsequent decisions. The decision in *Abraxis* attempted to mitigate that contradiction. But at [33] he said that the court was required to make a clear choice either to reverse the judgment in *Neurim* or to "widen the fine mesh" of the concept of product. Because of the importance of the issue, the case was heard by the Grand Chamber. The court summarised the questions referred at [32] and commented at [34]:

> "The questions referred are thus based on the premiss, arising from the judgment in *Neurim*, that it is possible, in certain circumstances that, according to the referring court, are still to be defined, to obtain an SPC for a new therapeutic application of an active ingredient which has already been the subject of an MA prior to the MA on which the application for that SPC is based."

64. At [47] the court held:

> "It follows from the foregoing considerations that Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that the fact that an active ingredient, or a combination of active ingredients, is used for the purposes of a new therapeutic application does not confer on it the status of a distinct product where the same active ingredient, or the same combination of active ingredients, has been used for the purposes of a different, already known, therapeutic application."

65. It then went on to consider the concept of the first marketing authorisation for that product. It concluded at [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."

66. Finally the court said at [60]:

> "It follows from the foregoing that the premiss on which the referring court relies, mentioned in paragraph 34 above, must be disregarded and that an MA for a therapeutic application of a product cannot be regarded as the first MA for that product as a medicinal product, for the purpose of Article 3(d) of Regulation No 469/2009, where another MA was granted previously for a different therapeutic application of the same product. The fact that the most recent MA is the first MA to fall within the limits of the protection of the basic patent relied on in support of the SPC application cannot call that interpretation into question."

67. The premiss to which the court referred was the premiss that *Neurim* was good law, albeit narrowed in accordance with *Abraxis*. Thus, in accordance with the choice

presented to the court by the Advocate General, the Grand Chamber decided to reverse the judgment in *Neurim*.

68. This court gave judgment in *Newron Pharmaceuticals S.p.A. v The Comptroller General of Patents, Trademarks and Designs* [2024] EWCA Civ 128 on 15 February 2024. After a review of all the relevant decisions of the CJEU we held that *Neurim* was an outlier in the jurisprudence of the CJEU; and that in *Santen* the CJEU had gone out of its way to contradict what had been held in *Neurim*. In this appeal we are invited to depart from *Santen* and to apply *Neurim* instead. The reason given in the ground of appeal is that *Santen* was wrongly decided.

69. But in order for that ground of appeal to succeed, we must depart not only from retained EU law (i.e. *Santen*) but also from a previous decision of this court (i.e. *Newron*).

Departure from previous case law

70. Following the issue of the *Practice Statement (Judicial Precedent)* [1966] 1 WLR 1234 the House of Lords and now the Supreme Court has power to depart from previous decisions: *Austin v Southwark London Borough Council* [2011] 1 AC 355, para 25. But as the Practice Statement made clear, it was not intended to affect the use of precedent elsewhere than in the House of Lords.

71. Section 6 of the European Union (Withdrawal) Act 2018, as amended, relevantly provides:

> "(3) Any question as to the validity, meaning or effect of any assimilated law is to be decided, so far as that law is unmodified on or after IP completion day and so far as they are relevant to it—
>
> (a) in accordance with any assimilated case law ... , and
>
> (b) having regard (among other things) to the limits, immediately before IP completion day, of EU competences.
>
> (4) But—
>
> (a) the Supreme Court is not bound by any retained EU case law,
>
> (b) …
>
> (ba) a relevant court or relevant tribunal is not bound by any retained EU case law so far as is provided for by regulations under subsection (5A), and
>
> (c) no court or tribunal is bound by any retained domestic case law that it would not otherwise be bound by.
>
> (5) In deciding whether to depart from any retained EU case law by virtue of subsection (4)(a) or (b), the Supreme Court … must apply the same test as it would apply in deciding whether to depart from its own case law."

72. It is possible that section 6 of the 2018 Act may, in due course, be amended by section 6 of the Retained EU Law (Revocation and Reform) Act 2023, but that section is not yet in force. Moreover, the commencement order that was due to bring it into effect on 1 October 2024 has itself been revoked: Retained EU Law (Revocation and Reform) Act 2023 (Commencement No 2 and Saving Provisions) (Revocation) Regulations 2024.

73. Section 6 (5) of the 2018 Act lays down the test that must be applied by the Supreme Court in deciding whether to depart from retained (or assimilated) EU case law.

74. As section 6 (4) (ba) foreshadows regulations may be made under section 6 (5A) dealing with departure from EU assimilated law by lower courts. Those regulations may provide for (among other things):

> "(b) the extent to which, or circumstances in which, a relevant court or relevant tribunal is not to be bound by retained EU case law,
>
> (c) the test which a relevant court or relevant tribunal must apply in deciding whether to depart from any retained EU case law"

75. Article 3 of the European Union (Withdrawal) Act 2018 (Relevant Court) (Retained EU Case Law) Regulations 2020, made under section 6 (5A) of the 2018 Act, designates this court as a relevant court.

76. The test in section 6 (5) of the 2018 Act does not apply to decisions of a "relevant court" as defined by article 3. Article 4 of the 2020 Regulations provides:

> "(1) A relevant court is not bound by any retained EU case law except as provided in paragraph (2).
>
> (2) A relevant court is bound by retained 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."

77. Article 5 provides:

> "In deciding whether to depart from any retained EU case law by virtue of section 6(4)(ba) of the 2018 Act and these Regulations, a relevant court must apply the same test as the Supreme Court would apply in deciding whether to depart from the case law of the Supreme Court."

78. There is, in my judgment, a significant difference between article 4 (2) and article 5 of the 2020 Regulations which gives the power to depart from earlier decisions. Article 5 applies in the absence of any post-transition case law applying retained EU case law. That test deals with a case in which a relevant court is deciding whether to depart from retained EU case law in accordance with article 4 (1). In such a case a relevant court adopts the same test as the Supreme Court would adopt in departing from its own previous decisions. I would interpret the test as recognising that in such a case a relevant court may, adopting that test, depart from its own previous decisions. But article 4 (2) applies a different test where there is such post-transition case law which modifies or

applies retained EU case law. *Newron* is post-transition case law which applies *Santen*. The question, then, to my mind, is whether under domestic law we are bound by the decision in *Newron*.

Is this court bound by Newron?

79. Prima facie, we are bound by *Newron*, because (unlike the Supreme Court) this court is in principle bound by its own earlier decisions. The Explanatory Note accompanying the 2020 Regulations made it clear that they were not intended to alter the ordinary domestic rules of precedent.

80. There are recognised exceptions to this principle, which are collected in the well-known case of *Young v Bristol Aeroplanes Co Ltd* [1944] KB 718. That case decides that the Court of Appeal is bound to follow its own decisions and those of courts of co-ordinate jurisdiction, The only exceptions to this rule are: (1) The court is entitled and bound to decide which of two conflicting decisions of its own it will follow; (2) the court is bound to refuse to follow a decision of its own which, though not expressly overruled, cannot, in its opinion, stand with a decision of the House of Lords; (3) the court is not bound to follow a decision of its own if it is satisfied that the decision was given per incuriam. (I retain the Latin because the phrase has a particular legal meaning which is not easy to encapsulate in English. "By mistake" is inadequate). These limited exceptions to the binding nature of previous decisions of this court were reaffirmed "expressly, unequivocably and unanimously" by the House of Lords in *Davis v Johnson* [1979] AC 264, 328.

81. The second category has, however, been expanded, in a case about patentability, to a case which a decision of this court was inconsistent with a settled view of the law adopted by the Boards of Appeal of the European Patent Office: *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444, [2009] 1 WLR 1186 at [95].

82. It is plain, in my judgment, that neither exception (1) or (2) applies. Can it be said that *Newron* was decided per incuriam? At the heart of Merck's argument is the argument that *Santen* was wrong and that the approach in *Neurim* was right. If we were to exercise our power to depart from *Santen* we must inevitably hold that it was wrong; because if it was right then there is nothing on which the power of departure can bite. It is true that the precise point in issue in this appeal was not the point in *Newron*, and it is also true that in *Newron* the court was not asked to exercise its power to depart from retained (or assimilated) EU case law. But it did decide that *Santen* was correct and stated the law.

83. Contrary to the submissions of Mr Mitcheson KC, I consider that the approval and application of Santen was part of the ratio of *Newron*. That is most clearly seen at [22] ("orthodoxy was restored in *Santen*"); [30] ("*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 a product") and [33] ("applying the law above").

84. In my judgment, therefore, Merck must persuade us that *Newron* was decided per incuriam. This court gave consideration to the meaning of that expression in *Morelle Ltd v Wakeling* [1955] 2 QB 379. The judgment of the court states at 406:

> "As a general rule the only cases in which decisions should be held to have been given per incuriam are those of decisions given

> in ignorance or forgetfulness of some inconsistent statutory provision or of some authority binding on the court concerned: so that in such cases some part of the decision or some step in the reasoning on which it is based is found, on that account, to be demonstrably wrong."

85. They added:

> "In our judgment, acceptance of the Attorney-General's argument would necessarily involve the proposition that it is open to this court to disregard an earlier decision of its own or of a court of co-ordinate jurisdiction (at least in any case of significance or complexity) whenever it is made to appear that the court had not upon the earlier occasion had the benefit of the best argument that the researches and industry of counsel could provide. Such a proposition would, as it seems to us, open the way to numerous and costly attempts to re-open questions now held to be authoritatively decided."

86. Plainly there was no authority binding the court in *Newron* which would have *compelled* a different decision. The court in *Newron* was faced with a choice between *Neurim* and *Santen* both of which were decisions of the CJEU. Nor, in my judgment, was there an *inconsistent* statutory provision. The power to depart from retained EU law is not inconsistent with deciding what EU law was. In *Miliangos v George Frank (Textiles) Ltd* [1975] QB 487, 503 Lord Denning MR pointed out that "a case is not decided per incuriam because counsel have not cited all the relevant authorities or referred to this or that rule of court or statutory provision". Moreover, in *Duke v Reliance Systems Ltd* [1988] QB 108, 113 Lord Donaldson MR said:

> "I have always understood that the doctrine of per incuriam only applies where another division of this court has reached a decision in the absence of knowledge of a decision binding upon it or a statute, and that in either case it has to be shown that, had the court had this material, it *must* have reached a contrary decision. That is per incuriam. I do not understand the doctrine to extend to a case where, if different arguments had been placed before it or if different material had been placed before it, it *might* have reached a different conclusion. That appears to me to be the position at which we have arrived today." (Original emphasis)

87. In *Jazztel plc v HMRC* [2022] EWCA Civ 232, [2022] Ch 403 Singh LJ (with whom Newey LJ and Sir Launcelot Henderson agreed), having referred to *Duke*, said at [136]:

> "In my view, there is an important distinction in principle between a case in which an *argument* was not advanced on the earlier occasion and a case in which the *legal issue* was entirely different: see, by way of example, *R (Elias) v Secretary of State for Defence* [2006] 1 WLR 3213. In that case, there had been an earlier decision of the Court of Appeal in which a challenge to the very same scheme now under challenge had been rejected:

> see *R (Association of British Civilian Internees: Far East Region) v Secretary of State for Defence* [2003] QB 1397. That did not prevent the Court of Appeal from reconsidering the matter (and indeed deciding it in favour of the claimant) because there was an entirely new legal issue and a different ground of challenge advanced in *Elias*, which had not been raised in the earlier case. In the earlier case, the grounds of challenge were the conventional public law grounds of irrationality and breach of legitimate expectations; whereas, in *Elias*, the grounds arose under the Race Relations Act 1976. This was not therefore simply a case where different arguments were advanced which had not been made in the earlier case; the legal issues were themselves different." (Original emphasis)

88. In *Newron*, there was an argument which might have been deployed (but was not) that the court should have departed from *Santen* and preferred *Neurim*. But there was no prospect of the court exercising that power unless it had been persuaded that *Santen* was wrong. A decision that *Santen* was wrong is a necessary but not a sufficient reason to exercise the power to depart. So the same legal issue arises (in effect as a preliminary issue) in this appeal as arose in *Newron*. I am not persuaded that *Newron* was decided per incuriam. Moreover, if the court had considered exercising the power to depart from *Santen*, it would have required the court to undertake a careful analysis of the circumstances in which it would have been proper to exercise that power.

If we were not bound by Newron should we depart from Santen?

89. There are a number of points arising out of the jurisprudence on when the highest court considers that it is appropriate to depart from an earlier decision of that court.

90. First, the power to depart from a previous decision should not be invoked merely because the later court thinks that the earlier decision of that court was wrong: *Fitzleet Estates Ltd v Cherry* [1977] 1 WLR 1345; *Horton v Sadler* [2007] 1 AC 307; *Test Claimants in the FII Group Litigation v HMRC* [2020] UKSC 47, [2022] AC 1 at [245].

91. Second, the power should be more sparingly used where the point in issue is the interpretation of a statutory provision, rather than the scope of a principle of the common law. As Lord Reid put it in *Jones v Secretary of State for Social Services* [1972] AC 944, 966:

> "I would not seek to categorise cases in which it should or cases in which it should not be used. As time passes experience will supply some guide. But I would venture the opinion that the typical case for reconsidering an old decision is where some broad issue is involved, and that it should only be in rare cases that we should reconsider questions of construction of statutes or other documents. In very many cases it cannot be said positively that one construction is right and the other wrong. Construction so often depends on weighing one consideration against another. Much may depend on one's approach. If more attention is paid to meticulous examination of the language used in the statute the result may be different from that reached by paying more

> attention to the apparent object of the statute so as to adopt that meaning of the words under consideration which best accord with it."

92. The Supreme Court reiterated that point in *JTI Polska sp z oo v Jakubowski* [2024] AC 621 at [41]. The court added at [43]:

> " A previous decision on interpretation will not be departed from if it reflects a tenable view. "

93. Third, it is relevant to consider whether the earlier decision has been criticised by academics, judges or practitioners: *R v G* [2004] 1 AC 1034 at [34]. Equally relevant is whether the impugned decision has been followed elsewhere. Thus in *Peninsula Securities Ltd v Dunnes Stores (Bangor) Ltd* [2021] AC 1014 the Supreme Court departed from an earlier decision of the House of Lords on the question of what test should be applied to decide whether a covenant was void as being in restraint of trade. Lord Wilson said at [50]:

> "To adapt Lord Bingham's words, the objection to it is not just that the issue in the *Esso* case should have been resolved differently or the principle formulated differently there. Apart from the fact that even at the time Lord Wilberforce chose not to associate himself with it, the objections to the test are that it has no principled place within the doctrine; that it has been consistently criticised for over 50 years and, although in some quarters loyally applied, the reasoning behind it has, to the best of my knowledge, scarcely been defended; and that the common law has been limping between the continuing authority of the test in our jurisdiction and its rejection in Australia and in parts of Canada."

94. Fourth, where the provision in question concerns a legal instrument with international application, it is relevant to consider how that instrument has been interpreted in other jurisdictions. The approach to interpretation should, where possible, aim to produce a uniform interpretation applicable to all jurisdictions where the international instrument applies.

95. Fifth, it is relevant to consider whether there has been a relevant change in circumstances since the earlier decision. Changes in public policy are one such change: *Arthur JS Hall v Simons* [2002] 1 AC 615, 683, 688.

96. Sixth, it is relevant to consider whether the earlier decision defeats the purpose of the provision in question or has given rise to incoherence in the law: *Test Claimants in the FII Group Litigation v HMRC* [2020] UKSC 47, [2022] AC 1 at [250].

97. In my judgment, few, if any, of these factors apply to this case. Moreover, Birss LJ has now carried out a careful analysis of both the case-law and the policy underpinning the grant of an SPC; and I agree with that analysis.

98. Accordingly, even if we had not been bound by *Newron*, it would not have been appropriate to depart from the judgment of the CJEU in *Santen*.

Result

99. I do not consider that the appeal in this case falls into any of the exceptions to the basic principle that this court is bound by its previous decisions. In my judgment, therefore, this court is bound by *Newron* and must dismiss the appeal.