[2026] IEHC 617

THE HIGH COURT

[2026/2 SP]

IN THE MATTER OF AN APPEAL FROM A DECISION OF THE CONTROLLER OF INTELLECTUAL PROPERTY UNDER SECTION 96 OF THE PATENTS ACT, 1992, AS AMENDED, AS APPLIED TO DECISIONS TO GRANT OR REFUSE SUPPLEMENTARY PROTECTION CERTIFICATES BY ARTICLE 18 OF REGULATION (EC) NO. 469/2009 AND ARTICLE 11 OF EUROPEAN COMMUNITIES (SUPPLEMENTARY PROTECTION CERTIFICATE) REGULATIONS, 2008 (S.I. NO. 307 OF 2008)

BETWEEN

MERCK SERONO S.A.

PLAINTIFF

AND

THE CONTROLLER OF INTELLECTUAL PROPERTY

DEFENDANT

JUDGMENT of Mr. Justice Barry O'Donnell delivered on the 9th day of September, 2026

INTRODUCTION

1. This is a judgment on a statutory appeal brought by the plaintiff, Merck Serono S.A. (*Merck*), against a decision of the defendant, the Controller of Intellectual Property (*the*

Controller). The Controller refused Merck's application for a supplementary protection certificate *(SPC*) to extend the duration of protection for Mavenclad, a human medicinal product. Mavenclad is the subject of Irish patent number EP (IE) 1 827 461 B1 (*the Basic Patent*).

2. As framed by Merck, a central issue in the case is the question of whether and, if so, in what circumstances can an SPC be granted for a second medicinal use product. A second medicinal use product is one in which, in very general terms, the active ingredient already is known but the novelty in the product is the purpose limited process to which the active ingredient is applied. In this case, the situation is illustrated by the fact that, again in broad terms, Mavenclad is a product for the treatment of relapsing remitting multiple sclerosis (*RRMS*). The main active ingredient is a compound called *cladribine*, and its innovation relates to its dosage regimen. Cladribine was the active ingredient in another, earlier, product, Litak, which was produced by a different company. Litak is authorised for use in the treatment of hairy cell leukaemia. Litak was the subject of an earlier marketing authorisation and an earlier patent. The Basic Patent in this case therefore can be characterised as a second medicinal use patent: cladribine had been used previously in Litak, but the particular dosage regime for Mavenclad was the new invention or innovation.

3. The Controller decided that the SPC for Mavenclad had to be refused having regard to the provisions of Regulation EC 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (*the 2009 Regulation*) as interpreted by the CJEU in Case C-673/18 *Santen SAS v Directeur général de l'Institut national de la propriété industrielle* (*Santen*). Because cladribine was the active ingredient in Litak, which had been the subject of an earlier marketing authorisation (*MA*), the

Controller considered itself compelled to refuse the application for an SPC for Mavenclad on the basis of its interpretation of the CJEU decision in *Santen*.

4. Merck contends that the decision was incorrect and that it should obtain the SPC for Mavenclad. That was based on a number of arguments, most of which related to the interpretation of the *Santen* decision and the relevant provisions of the 2009 Regulation. Merck also argues that this court should refer a question to the CJEU in order to clarify what it submitted was an anomaly regarding the treatment of second medicinal use patents which arose from earlier CJEU caselaw that, it was argued, could not be reconciled in a satisfactory way with the *Santen* decision.

5. The court was greatly assisted by the careful and intelligent submissions made by the parties. In summary, for the reasons explained in this judgment, the court has concluded that the Controller was correct to refuse the application for the SPC; and that the decision in *Santen* and the reasons for that decision are sufficiently clear, such that the court is in a position to make a decision without the need to refer a question to the CJEU. The explanation for the decision ultimately could be set out in reasonably brief terms. This was because the court is satisfied that the *Santen* judgment's interpretation of relevant provisions of the 2009 Regulations provides clear answers to the questions presented. Very briefly, the course of the jurisprudence in the CJEU concerning SPCs had been clear prior to the decision in *Neurim*. *Santen* can be understood as a decision to overturn *Neurim* – or at least to significantly restrict its application – and return to the previous situation of clarity and predictability.

6. In this judgment I will briefly describe the background to the application for the SPC; address the standard of review; set out the materials that were before the Controller; describe the course of the application before the Controller; set out briefly the decision made by the Controller; and then describe the course of the caselaw. I will set out the course of the caselaw in some detail, as it is apparent to me that the decision in *Santen* was directed to clarifying issues that had arisen, particularly after the decision in *Neurim*. Finally, in the light of the analysis of the caselaw, I will explain why I consider that the appeal cannot succeed.

BACKGROUND

7. The Basic Patent is entitled "*Cladribine Regimen for Treating Multiple Sclerosis*" and is owned by Merck. It is subject to European patent EP 1 827 461 B1, which was applied for on the 20 December 2005, granted on the 29 February 2012, and expired on the 19 December 2025.

8. The dosage regimen protected by the Basic Patent comprises a pulsed administration of an oral cladribine pharmaceutical formulation to persons suffering from RRMS. Patients take a certain dose of the drug over a short period of time, followed by a hiatus in treatment, after which the drug is taken again. Claims 1 to 4 in the Basic Patent protect the cladribine pharmaceutical formulation for use according to the dosage regimen for which Mavenclad is authorised, as well as the use of cladribine for the preparation of a pharmaceutical formulation.

9. When cladribine is administered in accordance with the protected dosage regimen, it results in a decrease of the incidence of brain lesions linked to the physical symptoms of multiple sclerosis. It also results in the selective suppression of certain lymphocytes of the

autoimmune and pro-inflammatory immune cell set present in relapsing multiple sclerosis and a selective repopulation of immune cells that are less pro-inflammatory, and capable of inducing an immune-tolerance state closer to the immune homoeostasis of healthy individuals.

10. Mavenclad was authorised for supply under MA number EU 1/17/1212, which was granted on the 22 August 2017 – 12 years after the patent application. The plaintiff and Merck Europe BV are affiliated companies in the Merck group. The MA authorised the use of Mavenclad according to a regimen protected under the Basic Patent.

11. Separately, the ingredient, cladribine, had been authorised to be supplied for the treatment of hairy cell leukaemia under the name Litak by MA EU/1/04/275. The Basic Patent does not cover Litak, it only protects the invention comprised in the pulsed dosage regimen used for the treatment of persons suffering from multiple sclerosis.

12. On the 9 February 2018, Merck applied to the controller for an SPC in respect of "*Mavenclad-cladribine*". The plaintiff made the application on the basis of the Basic Patent and the MA. If granted, the SPC would have expired on the 19 December 2030.

13. In the decision of the 8 September 2025, the Controller refused the application in light of the Litak MA for cladribine on the basis that "…*the marketing authorisation presented in respect of the present Request for cladribine in accordance with the requirements of Article 3(b), is not the first such authorisation to place cladribine on the market.*" On that basis, the Controller held that the application did not accord with Article 3(d) of the 2009 Regulation.

14. In these proceedings, Merck has appealed the entirety of the decision with the exception of the part of the decision which found, on the basis of the evidence, that *"... cladribine, in the treatment of multiple sclerosis, is completely distinct from that of its treatment of hairy cell leukaemia, in terms of the pharmaceutical and metabolic effects by which it achieves its effect.*" As will be explained, that carve out from the decision was the subject of a separate argument which it was said would justify the grant of an SPC.

15. Accordingly, in these proceedings, Merck seeks an order discharging the Controller's decision and substituting therefor a decision granting the application for an SPC, and, insofar as is necessary for the just determination of the appeal, an order for the reference of a preliminary question for the CJEU pursuant to Article 267 of the TFEU in relation to the correct interpretation of the criteria of Article 3 of the 2009 Regulation in cases involving patented second medical use inventions.

16. In the special summons, Merck set out a series of grounds upon which it is alleged that the controller erred in refusing to grant the application. Those arguments and grounds, while set out extensively in the summons, will be dealt with below but effectively amounted to three basic assertions.

17. First, it was said that a strict literal construction of the word "*product*" in art. 3 of the 2009 Regulation to mean "*active ingredient*" does not work if products comprising patented second medical use inventions are eligible in principle for SPCs. In that regard, Merck argues, in summary, that the Controller relied upon dicta in *Santen* incorrectly, and that the decision in *Santen* does not provide a basis for a strict literal interpretation of Article 3(a) which would preclude the grant of certificates for second medical use patents as a matter of principle.

18. Second, the plaintiff argues that the construction of Art. 3 "*as being hidebound by a literal application of Article 1(b) of the Regulation*" directly contradicts a key principle of construction laid down by the CJEU in two cases; case C-121/17 *Teva UK Ltd v. Gilead Sciences Inc.*, and case C-149/22 *Merck Sharp & Dohme v. Clonmel Healthcare*. The argument here is that the *Gilead* and *Merck Sharp & Dohme* cases found that patent law – which remains a matter of national law as distinct from EU law – governs the identification of the subject matter protected by a basic patent under Article 3(a), which is the starting point of the application of the Article 3 criteria.

19. The third argument was that the fundamental premise of the Regulation was that the product authorised must correspond with the invention protected by the basic patent. In turn the rationale for compensating the patentee for time lost from patent protected exploitation of the invention only holds if the loss of time is down to the need to obtain marketing authorisation for that invention is also accounted for.

20. There was also an alternative argument to the effect that because of the distinct effect of the Mavenclad regime, it ought to have been granted authorisation on that basis alone. That argument was the reason that Merck sought to preserve one element in the Controller's decision.

21. The appeal was fully defended by the Controller, who argued that the relief should not be granted and that the decision in *Santen* provided a clear basis for resolving the question of whether the SPC should have been refused.

STANDARD OF REVIEW

22. The parties were agreed, and the court was satisfied, as to the standard of review that applies in an appeal of this type. The court is to engage in a full re-hearing of the issues to come to its own conclusion and is not constrained to conduct an error-based review. Hence, the court is conducting a full rehearing, albeit on the materials that were before the Controller, but the court is entitled to come to its own conclusions unconstrained and untrammelled by the decision of the Controller. In that regard, the parties drew the attention of the court to *Carrickdale Hotel v. Controller of Patents* [2004] 3 I.R. 410; *Diesel SPA v. Controller of Patents* [2023] 1 I.R. 1; and *Fitzgibbon v. Law Society of Ireland* [2015] 1 I.R. 516.

23. Because the standard of review in this case involves the court engaging in an untrammelled review of the Controller's decision, it is not necessary to consider the decision in much detail. However, it is important to note the materials that were before the controller for the purposes of the hearing, and also to provide a brief overview of the manner in which the decision was reached.

MATERIALS BEFORE THE CONTROLLER

24. The relevant background to the dispute and the materials that were before the controller were set out in an affidavit sworn on the 6 January 2026 by Laura Scott, a solicitor acting on behalf of Merck.

25. The Basic Patent issued by the European Patent Office is dated the 29 February 2012. It is described as "*Cladribine Regimen for Treating Multiple Sclerosis*".

26. As described in the field of invention "[t]*he invention relates to the use of multiple doses of Cladribine for the treatment of multiple sclerosis, especially relapsing-remitting multiple sclerosis or early secondary progressive multiple sclerosis*".

27. Having set out the background to the invention, the invention is summarised at paragraph 16 as follows:

> *"The invention is directed towards a use of Cladribine for the preparation of a pharmaceutical formulation for the treatment of multiple sclerosis, wherein the preparation is to be orally administered as defined in the claims. Particularly, the invention is directed towards a use of Cladribine for the preparation of a medicament for the treatment of relapsing-remitting multiple sclerosis or early secondary progressive multiple sclerosis and wherein re-treatments are possible."*

28. The summary highlights the sequential steps in the dosing regime and its effects. The patent notes that cladribine (2-CdA) and its pharmacologically acceptable salts may be used in the practice of this invention.

29. Claims 1 to 4 in the Basic Patent were important to the second medicinal use argument made on behalf of Merck; these set out:-

> *"(1) A Cladribine pharmaceutical formulation for use in the treatment of multiple sclerosis, wherein the formulation is to be orally administered following the sequential steps below:* [and then sets out the sequence in which the medication should be administered]

(2) *Use of Cladribine for the preparation of a pharmaceutical formulation for the treatment of multiple sclerosis wherein the formulation is to be orally administered following sequential steps below:* [and the sequential steps are set out]

(3) *A Cladribine pharmaceutical formulation for use in the treatment of multiple sclerosis, wherein the formulation is to be orally administered following the sequential steps below:* [and the steps are set out]

(4) *Use of cladribine for the preparation of a pharmaceutical formulation for the treatment of multiple sclerosis, wherein the formulation is to be orally administered following the sequential steps below:"* [and the steps are set out]

30. The MA for "*Mavenclad-cladribine*" for human use is set out in a Commission implementing decision of 22/08/2017. The MA notes that the authorisation is granted by art. 3 of Regulation (EC) 726/2004. Article 4 of the decision makes clear that the period of validity of the authorisation shall be five years from the date of notification of the decision. The MA identifies in its appendices the therapeutic indications and its method of administration, bearing in mind that a particular feature of the medicine was the pulsed dosage regime which leads to its particular efficacy.

31. In her affidavit Ms. Scott also identifies the earlier Commission decision of the 14 April 2004 granting an MA for "*Litak-cladribine*". The qualitative and quantitative composition of Litak is noted as a 1ml solution of injection containing 2mg of cladribine (2-CdA). The MA notes that therapeutic indication for the Litak is the treatment of hairy cell leukaemia and

involves a single course of Litak given by subcutaneous bolus injection for five consecutive days.

THE COURSE OF THE APPLICATION BEFORE THE CONTROLLER

32. Merck applied to the Controller for a SPC on the 9 February 2018. The application was headed *"Irish patent number 1827461 – application for supplementary protection certificate, "cladribine""*. It is important to acknowledge that at the time the application was submitted there was caselaw from the CJEU (the *Neurim* decision) which suggested an approach to grant SPC for second medical use products. However, by the time that a final decision was made, the CJEU had issued its judgment in *Santen*. Merck's case is predicated on a certain view of the *Santen* decision and draws on earlier caselaw which it says leads to a position where there is a conflict or uncertainty in the current legal position.

33. In the cover letter, Merck notes that an MA dated the 14 April 2004 was granted for the medicinal product Litak with the active principle cladribine for the indication of hairy cell leukaemia. The letter goes on to state "*The indication hairy cell leukaemia is not covered by the basic patent EP 1 827 461 B1 according to the above given deliberations. The Marketing Authorisation EU/1/17/1212 is thus the first Marketing Authorisation in the sense of Regulation (EEC) 469/2009, Article 3, and the Case EuGH C-130/11 ("Neurim").*"

34. The letter appended a form, "*Request for the Grant of a Supplementary Protection Certificate*". The form identifies the applicants, their legal representatives and the Basic Patent, and the title of the invention is given as "*Cladribine Regimen for Treating Multiple*

Sclerosis". The 'product identity' part of the form identifies the "*product (i.e. active ingredient or combination of active ingredients) for which a certificate is requested"* as cladribine.

35. The form notes that cladribine is covered by claim 3 of the Basic Patent and where appropriate also in combination with claim 10 of the Basic Patent. The form notes that the product "*Mavenclad-cladribine*" was first authorised on the 24 August 2017, and the form itself is dated the 9 February 2018. The Controller was furnished with the relevant Commission implementing decision granting marketing authorisation for Mavenclad-cladribine together with the relevant extract from the Official Journal of the European Union. The Controller was also furnished with an annex which was said to explain how cladribine is covered by the basic patent EP 1 827 461 B1 and, finally, the Controller was furnished with an extract from the European Medicines Agency showing the product details for Litak with active principle cladribine. As noted in the European Medicines Agency document, and a point highlighted by Merck, the owner of the patent for Litak and the holder of that MA is a company unrelated to and unconnected to Merck.

36. The progress of the request for an SPC was somewhat protracted. The request was acknowledged on the 14 February 2018 by the Controller. On the 2 March 2020, the Controller wrote to Merck's representatives noting that the Controller's attention had been drawn to an earlier authorisation for a different medicinal product containing cladribine but which is used for a different indication and noted that "*the case law surrounding this type of application (i.e. a so-called Neurim type application) has not yet been resolved*." Hence, the Controller proposed to stay further examination of the SPC request pending a decision from the CJEU in the *Santen* case.

37. Following delivery of the *Santen* judgment by the CJEU, the Controller wrote to Merck's legal representatives on the 1 September 2020. The letter noted the decision that had been given and indicated that the MA filed in support of the application could not be regarded as the first authorisation for the purpose of art. 3(d) of the 2009 Regulation having regard to the analysis of the CJEU. In those circumstances, it was proposed that the application be rejected subject to a response from Merck. Following that letter, Merck also was provided with third-party observations that had been filed and which also drew attention to the decision in *Santen* and argued that the SPC application could not satisfy the requirements of Article 3(d). The letter drew the Controller's attention to a decision by the Netherlands Patent Office which applied the reasoning in *Santen* in its rejection of the corresponding SPC application in that jurisdiction.

38. Merck replied by letter dated the 17 February 2021, making observations. The letter highlighted the clinical history of trials for Mavenclad and its beneficial uses, together with noting the investments required to obtain an MA for the use of cladribine. The letter made submissions which suggested that the situation concerning the application for a SPC for Mavenclad was very different to the situation that obtained in *Santen* and requested that the request be granted. Following further correspondence a hearing was arranged.

39. The preparation for the hearing took a considerable period of time and involved the compilation of supporting evidence and consideration of and responses to third-party observations that had been filed, and the hearing occurred on the 7 August 2025. The hearing occurred before Dr. Fergal Brady who, it should be noted, was a different official to the official that made the earlier decisions proposing to refuse the request for a SPC.

THE DECISION OF THE CONTROLLER

40. Dr. Brady began by outlining and summarising the background to the hearing and noted that at the hearing the plaintiff's arguments were as follows:

(a) that *Santen* had been misapplied in that (i) the IPOI is not correctly applying the appropriate definition for the term "product"; and (ii) the decision to reject the application went against the intended application of the SPC regulation, as understood by reference to the recitals therein and the explanatory memorandum prepared during the drafting of said regulation;

(b) that it is more appropriate to apply the criteria of *Neurim*, rather than those of *Santen*, as the facts of the present case are too distinct from those of the case leading to the *Santen* decision;

(c) that even if *Santen* does apply, the facts of the present case are such that the SPC should be allowed; and

(d) that *Santen* should only apply *ex nunc* and not *ex tunc*.

41. With regard to the background issues concerning the case, Dr. Brady noted that the following were clear and not in any dispute:

> "*The BP clearly protects the pharmaceutical formulation of cladribine for use in the treatment of multiple sclerosis. The MA supporting the request is entirely consistent with the protection afforded by the BP. Accordingly, there is no issue with any aspect of the Request's fulfilling of the first three requirements of Article 3 (that is, a-c). Further, I note a considerable body of evidence supporting the assertion that cladribine, in the treatment of multiple sclerosis,*

is completely distinct from that of its treatment of hairy cell leukaemia, in terms of the pharmaceutical and metabolic effects by which it achieves its effect. I entirely accept this body of evidence is genuine and persuasive, and that this new use for cladribine is the result of extensive and painstaking research and clinical study."

42. Dr. Brady then went on to rehearse the arguments that were made. Those arguments were to some extent replicated and supplemented in the arguments before this Court and it is not necessary to deal with those in any detail, save to note that Dr. Brady rejected the arguments regarding *Santen* and its meaning and effect. At paragraph 20 of the decision, Dr. Brady expressed the view that he could not accept the arguments made by the plaintiff as, "*to do this would require the setting aside of an extensive analysis by the Court in paragraphs 43-47 of its ruling, which make it abundantly clear that it is the settled view of the Court that a new use for an existing product 'does not confer on it the status of a distinct product with the same active ingredient… has been used for the purposes of a different already known therapeutic application' (Santen, para. 47)*". In effect therefore, Dr. Brady considered himself bound by the decision of the CJEU in *Santen*, and that the application of *Santen* meant that the SPC should not be granted.

43. In the circumstances, the Controller refused the request for a SPC, and this led to the commencement of the proceedings before this Court.

44. I emphasised and quoted the observations made by Dr. Brady at paragraph 11 of the decision because these were stressed by Merck in the context of their alternative argument. The evidence before the Controller and therefore the evidence before this Court included a

declaration made by Dr. Ursula Boschert Shafaatin which was dated 11 February 2025. That doctor is a neuroimmunologist "*trained in translational preclinical in vitro and in vivo pharmacology and biomarker research working in the field of neurological diseases of the central and peripheral neuro nervous system*."

45. Dr. Boschert Shafaatin has extensive expertise and qualifications in the area. While she is a person with considerable expertise, she is, by her own admission and as fairly stressed by Merck in submissions, a person who has a close working relationship with the Merck Group. She in fact was the research lead for the development and filing of cladribine in RRMS and therefore was very familiar with the basic patent and its history and clinical overview.

46. Despite that involvement, she declared that she was providing an independent opinion and described why she was of the opinion that there were significant differences between the Mavenclad treatment and the action of Litak which is the first approved indication for cladribine in the treatment of hairy cell leukaemia. In summary, Dr. Boschert Shafaatin states that the treatment with Mavenclad exerted:

> "*(i) a different pharmacological action of its own (a new mechanism of immune reconstitution),*
>
> *(ii) a different immunological action of its own (targets different pathological immune cell type populations), and*
>
> *(iii) a different metabolic action of its own (as it prevents pathologic immune cell activation of specific subtypes also via DCK-independent pathways, not requiring prodrug activation)…"*

THE NATURE OF SECOND MEDICAL USE PATENTS

47. Merck directed the court's attention to *Warner-Lambert Co LLC v. Generics (UK) Ltd (t/a Mylan)* [2019] 3 All ER 95, in which Lord Sumption set out a summary of the background to and rationale for the development of second medical use patents. Lord Sumption explained that traditionally there were two obstacles to obtaining patent protection for second medicinal use products. First, that the product in the process was known from the original patent and therefore failed the test of novelty. Second, its use for a new therapeutic purpose was not itself patentable; this was because Article 52(4) of the European Patent Convention prevented the grant of patent for a method of treatment of the human or animal body.

48. The position altered, beginning in 1984, when the Swiss Federal Intellectual Property Office issued a statement of practice that it would be prepared to grant patents for second medical use patents in a particular form. The enlarged board of appeal of European Patent Office adopted this approach shortly afterwards. The "*Swiss form patents*" were not *product* patents, but *purpose limited process* patents. Analytical problems remained and they were difficult to accommodate within a statutory scheme which had not been designed to address them. As Lord Sumption noted, some of the difficulties associated with Swiss form patents were resolved when the European Patent Convention was revised in November 2000 to provide for *inter alia* the grant of *purpose limited* product patents.

49. The patent in the present case is an example. Cladribine itself is not a novel invention, having already been utilised in Litak. Claims 1 to 4 in the basic patent set out that the effective protection is afforded to the manner in which and the sequence in which the medication dosage

is administered; hence it is the *process* in which cladribine is used rather than the cladribine itself that constitutes the novelty.

THE 2009 REGULATION

50. Supplementary protection certificates are creatures of EU law, and, in effect, when granted they extend the term of patent protection. The need for SPCs, as explained in the recitals to the Regulation, arose from the fact that the period of patent protection for a medicinal product, normally 20 years, starts running from the date when the patent is applied for. However, in the EU it is necessary also to obtain a marketing authorisation for medicinal products and that process, which involves proof from clinical trials, takes time, which eats into the period of patent protection. If granted, an SPC affords the patentee an additional period of protection and thereby compensates to some extent for the time taken to obtain the marketing authorisation.

51. The Regulation (EC) 469/2009 *concerning the supplementary protection certificate for medicinal products* is a codified regulation. As noted in the recitals, the earlier iteration of the regulation (Council Regulation (EEC) 1768/92) had been amended several times and it was considered appropriate that the regulation should be codified. The earlier 1992 Regulation had been the subject of a detailed explanatory memorandum prepared by the Commission for the purposes of the proposed initial regulation concerning supplementary protection certificates. That explanatory memorandum was referred to by the parties, but it requires to be approached with some degree of caution as the wording that is the subject of the explanatory memorandum differs in significant respects from certain of the definitions and terms used in the 2009 Regulation.

52. The essential rationale for the 2009 Regulation and its objects are explained from Recitals 3 through to 5. These provide: -

> "*(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.*
>
> *(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.*
>
> *(5) This situation leads to a lack of protection which penalises pharmaceutical research."*

53. However, the purpose of the Regulation is not directed solely at the level of protection that should be afforded to pharmaceutical research, but as explained at Recital 10, includes public health objectives:

> "*(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product."*

54. The dispute in this case centres on the meaning and effect of Articles 1, 2 and 3 of the regulation.

55. Article 3 sets out four conditions for obtaining a certificate. It provides:-

> "*A certificate shall be granted if, in the Member State in which the application referred to in Article 7* [which provides for an application to be lodged] *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.*"

56. As will be seen, Mavenclad is protected by a basic patent in force. Likewise, there was a valid authorisation to place the product on the market, and no previous SPC had been granted. The main conflict related to the requirement in Article 3(d), that the first MA was the first authorisation to place the "*product*" on the market as a medicinal product. In turn, that requires an understanding of what the word "*product*" means for the purposes of the 2009 Regulation.

57. The relevant definitions are provided in Article 1 of the 2009 Regulation. Accordingly:

- The term "*medicinal product*" is defined as "*any substance or combination of substances presented for treating or preventing disease in human beings or animals or 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.*"

- The word "*product*" when used in the regulation means "*the active ingredient or combination of active ingredients of a medicinal product*".
- Finally, "*basic patent*" means "*a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designed by its holder for the purpose of the procedure for grant of a certificate*."

58. Article 2 of the 2009 Regulation provides:-

> "*Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medical products may, under the terms and conditions provided for in this regulation, be the subject of a certificate.*"

59. Under the Regulation, applications for certificates are to be lodged with the competent office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation to place the product on the market was obtained. By article 10, the authority therein referred to shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in the Regulation.

60. The simple point of legislative interpretation is that when Article 3(d) refers to a MA for a "*product*", it is referring to the active ingredient. If there is an earlier separate MA that authorises a medicinal product that already uses the same active ingredient that would seem to preclude the grant of an SPC for the later medicinal product. The difficulty with that interpretation is that it carries implications for second medical use patents, and in that sense could be understood as not achieving one of the purposes of the Regulation, being the protection of the product of medical research in light of the timescales involved in obtaining an initial MA.

PRIOR CASE LAW IN THE EUROPEAN COURTS

61. A central element in the arguments related to the manner in which the CJEU had addressed similar issues in its case law (or whether the issues in fact were similar) and the development of the caselaw leading to the *Santen* decision.

62. In the first instance there was a body of caselaw relating to the earlier iteration of the 2009 Regulations, which utilised the same language. That case law demonstrated a relatively strict approach to the question of whether a product had been the subject of an earlier separate authorisation.

63. Hence, in *Case C-31/03 Pharmacia Italia SPA*, Pharmacia Italia had been refused an SPC. The background to the dispute was that Pharmacia held a German patent which covered ergoline derivatives and their pharmaceutically acceptable salts and a second sub-claim covered a compound known by the international non-proprietary name of cabergoline. A veterinary medicine product, Galastop, which also included the active ingredient cabergoline

had been authorised in Italy in January 1987. Pharmacia's application in December 1994 for an SPC had been refused on the basis that the first marketing authorisation obtained in the Community was that granted in 1987 in Italy for the veterinary medicinal product which contained cabergoline as an active ingredient. The decision of the patent office in Germany was upheld by the German Federal Patent Court. The question before the court was whether the grant of a certificate in a Member State on the basis of a medicinal products for human use authorised in that state was precluded by marketing authorisation as a veterinary medical product in another Member State or whether the sole determining factor the date on which the product was authorised as a medicinal product for human use.

64. The Court noted that the Regulation did not necessarily draw a distinction in principle between marketing authorisations granted for medicinal products for human use and those granted for veterinary medicinal products. This was on the basis that the term medicinal product as defined in Article 1(a) of the earlier regulation did not distinguish between diseases in human beings and animals. Similarly, other articles did not distinguish between the various authorisation procedures for veterinary medical products and those for medicinal products for human use.

65. The court noted that, pursuant to Article 1(b) of the Regulation, the term "*product*" was defined as an active ingredient or a combination of active ingredients of a medicinal product. Second, it was noted that the certificate is to be granted provided that the product has been granted a marketing authorisation as a medicinal product in accordance with then Directive 65/65 or Directive 81/851 and the protection covered by a certificate is to extend only to the product covered by the marketing authorisation for the corresponding medicinal product

for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

66. On foot of those two observations, the Court found that the decisive factor for the grant of a certificate was not the intended use of the medicinal product, and second that the purpose of the protection conferred by the certificate related to *any* use of the product as a medicinal product without any distinction between whether that was for human use or as a veterinary product. The court held that the term "*first marketing authorisation in the Community*" must be interpreted in the same way in each of the provisions of the Regulation in which it was used, and that the Regulation sought to provide a uniform solution at community level to the problem of inadequate patent protection. In those circumstances, the Regulation prevented the heterogeneous development of national laws which would lead to further disparities and create obstacles to the free movement of medicinal products within the community.

67. Accordingly, the court found that the grant of a certificate in a Member State on the basis of medicinal products for human use can be precluded by a marketing authorisation for that product as a veterinary medicinal product granted in another Member State of the community.

68. Similar reasoning was applied in *Case C-431/04 Massachusetts Institute of Technology*, a reference for a preliminary ruling concerning the interpretation of Article 1(b) of the 1992 Regulation. In that case, the German Federal Patent Court rejected an application for an SPC for the medicinal product Gliadel implant. MIT held a European patent which was applied for on the 29 July 1987. The patent covered *inter alia* the alliance of two elements polifeprosan and carmustine, with polifeprosan being a polymeric biodegradable excipient, and carmustine

the active ingredient. The product was to be used in intravenous chemotherapy for the treatment of brain tumours. The product was in the form of a device which was implanted into the cranium and involved carmustine being released slowly and gradually by the polifeprosan which acted as a biodegradable erodible matrix. A marketing authorisation for Gliadel was granted in Germany in August 1999.

69. The German patent authority found that no SPC could be granted on the basis that polifeprosan could not be considered to be an active ingredient within the meaning of the Regulation, and that carmustine on its own account was an active ingredient already covered by a marketing authorisation.

70. The argument made by MIT was that the polifeprosan was more than a mere excipient or ancillary component, since it enabled the carmustine to be administered in a therapeutically relevant way for the treatment of malignant brain tumours. The reference to the European Court raised the issue of the meaning of the concept of "*combination of active ingredients of a medicinal product*" in Article 1 (b) of the 1992 Regulation.

71. The Court noted that while "*product*" was defined as meaning the active ingredient or a combination of active ingredients of a medicinal product, the Regulation did not define the concept of "*active ingredient*". Accordingly, in the absence of any definition of the concept, the meaning and scope of the terms had to be determined by considering the general context in which they were used and their usual meaning in everyday language.

72. In addressing that issue the court noted that it was common ground that the expression "active ingredient" was generally accepted in pharmacology not to include substances forming

part of a medicinal product which did not have an effect of their own on the human body. The court drew attention to the observation and the explanatory memorandum from 1990 where it stated at point 11 at:-

> *"The proposal for a Regulation therefore concerns only new medicinal products. It does not involve granting a [SPC] for all medicinal products that are authorised to be placed on the market. Only one [SPC] may be granted for any one product, a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of the new [SPC]".*

73. The Court also noted that it was apparent from the memorandum that the pharmaceutical form of the medicinal product, to which any excipient may contribute, does not form part of the definition of "*product*", which according to the court "*is understood to mean an 'active substance' or 'active ingredient' in the strict sense*".

74. Having considered the definition and the explanatory memorandum relating to the creation of a supplementary protection certificate for plant protection products which noted that there needs to be a strict definition of the product, the Court went on to find that the inevitable conclusion was that a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of "*active ingredient*" which is used to define the term "*product*" and therefore the alliance of such a substance with the substance which does not have a therapeutic effect of its own cannot give rise to a "*combination of active ingredients*".

75. In *Case C-202/05, Yissum Research and Development Company of the Hebrew University of Jerusalem v. Comptroller General of Patents,* the argument concerned a second medicinal use issue. The background facts were that since July 1989, Yissum had been the holder of a European patent which concerned a composition for use in the topical treatment of skin disorders. The composition contained a compound known as calcitriol, and the patent also covered the same composition in conjunction with the carrier suitable for the manufacturer of a cream ointment or lotion.

76. In December 2001, a company Galderma Limited was granted authorisation in the UK to place Silkis ointment on the market. That authorisation covered calcitriol as an active ingredient along with carriers. In June 2002 relying on that authorisation, Yissum applied to the patent office for an SPC for calcitriol. In July 2004, the patent office refused the SPC application on the basis that the authorisation to place the product on the market was not the first such authorisation. Other medicinal products containing calcitriol as a sole active ingredient had already been granted authorisation to be placed on the market before the Silkis ointment. Two of the identified products contained calcitriol for the management of hypocalcaemia in patients undergoing dialysis for chronic renal failure and the other consisted of capsules containing calcitriol to be administered orally to patients with chronic renal failure or postmenopausal osteoporosis.

77. On appeal to the national High Court, Yissum argued that the SPC application for calcitriol was for a different therapeutic use and was different to those of the products previously authorised. Yissum also argued that their product concerned a combination of active ingredients, calcitriol and the ointment base, so that the first authorisation to place the product

on the market was really that granted for Silkis ointment. One of the questions referred by the High Court in England and Wales was:-

> "*In a case in which the basic patent protects a second medical application of a therapeutic agent what is meant by 'product' in Article 1 (b) of the Regulation [No. 1768/92] and in particular does the application of the therapeutic agent play any part in the definition of 'product' for the purpose of the Regulation?"*

78. The Court commenced by observing the provisions of Article 1(b) of the 1992 Regulation, and noted that in the MIT case it was found that the concept of "*product*" referred to in Article 1(b) of the Regulation must be interpreted strictly to mean "*active substance*" or "*active ingredient*". It therefore followed "*that the concept of a product" cannot include the therapeutic use of an active ingredient protected by a basic patent.*"

79. The Court went on to note the following:-

> *"19. Moreover, the same interpretation can be inferred from paragraph 20 of the judgment in Case C-31/03 Pharmacia Italia [2004] ECR I-10001, in which the Court held that 'the decisive factor for the grant of the certificate is not the intended use of the medicinal product and… the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medical product'.*"

80. The Court therefore found that the answer to the question must be that Article 1(b) of the Regulation means that in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product.

81. In Case C-322/10 *Medeva BV v. Comptroller of Patents*, a reference for a preliminary ruling concerning the 2009 Regulation, the Court took the opportunity to reiterate the general principles relating to SPCs, but also made some important observations on the interaction between the SPC regime and the patent regime.

82. The underlying dispute concerned the European patent held by Medeva for the preparation of a vaccine for whooping cough which consisted of a combination of two antigens as active ingredients. The patent was applied for in April 1990 and granted by the European Patent Office in February 2009. Medeva filed five SPC applications with the patent office seeking supplementary protection for vaccines that covered a number of conditions. The patent office refused to grant the SPCs, *inter alia*, on the basis that, for four of the applications, more active components or ingredients were specified in the applications for SPCs than were identified in the wording of the claims of the basic patent, and therefore were not protected by the basic patent within the meaning of Article 3 (a) of the 2009 Regulation. The Court of Appeal of England and Wales referred a number of questions to the Court of Justice.

83. The Court of Justice took the opportunity to reiterate a number of general points in relation to the 2009 Regulation:

84. First, that the Regulation establishes a uniform solution at EU level by creating an SPC which may be obtained by the holder of a national or European patent under the same conditions in each member State. Thus, the aim was to prevent the heterogeneous development of national laws leading to further disparity which would be likely to create obstacles to the free movement of medicinal products within the European Union.

85. Second, Article 5 of the 2009 Regulation provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and obligations. Accordingly, Article 3(a) of the Regulation precludes the grant of an SPC relating to active ingredients which are not specified on the wording of the claims of the basic patent.

86. In relation to the question asked by the Court of Appeal whether Article 3(b) of the 2009 Regulation may be interpreted as not precluding the competent national authority from granting an SPC for a combination of two active ingredients which correspond to those specified in the wording of the claims from the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the SPC application contains not only that combination of the two active ingredients but also other active ingredients, the Court reiterated a number of general propositions.

87. First, that the fundamental objective of Regulation 2009 is to ensure sufficient protection to encourage pharmaceutical research which in turn assists in improving public health.

88. Second, the reason given for the adoption of the Regulation was that the period of effective protection under the patent was insufficient to cover the investment put into pharmaceutical research and the Regulation seeks to make up for that insufficiency by creating an SPC for medicinal products.

89. Third, the protection conferred by an SPC is largely intended to cover the cost of research leading to the discovery of new products, that term being used as the common

denominator covering the three different types of patent which can confer entitlement to an SPC.

90. The Court noted that the Court of Appeal had stated that medicinal products placed on the market in particular for complex diseases often consist of combinations of active ingredients for multiple therapeutic uses which can be administered to patients in a single preparation. Similarly, vaccines are often developed in the form of multi-valent vaccines. If the holder of such a basic patent relating to an innovative active ingredient or a combination of active ingredients were to be refused an SPC on the ground that in the commercial version of the medicinal product that active ingredient combination coexists in the medicinal product alongside other active ingredients or combinations which have other therapeutic purposes or may not be protected by another basic patent in force, the fundamental objective of the regulation could be undermined. The Court noted in accordance with Article 4 of the 2009 Regulation that an SPC is designed to protect the "*product*" covered by the marketing authorisation, not the medicinal product as such.

91. The Court also noted that in accordance with Article 5 of the 2009 Regulation, an SPC granted in connection with such a product confers, upon the expiry of the patent, the same rights as were conferred by the basic patent in relation to the product, within the limits of the protection conferred by the basic patent, as provided for in Article 4 of the Regulation. Accordingly, if, during the period in which the patent was valid, the patent holder could oppose, on the basis of his patent, all use for certain uses of his product in the form of a medicinal product consisting of such a product or containing it, the SPC granted in relation to that product would confer the holder the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of the certificate.

92. In those circumstances, the Court found that Article 3 (b) of the 2009 Regulation must be interpreted as meaning that, *provided the other requirements laid down in Article 3 are also met*, that provision does not preclude competent national authority from granting an 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 products of the marketing authorisation is submitted in support of the SPC application contains not only that combination of the two active ingredients but also other active ingredients.

93. The issues that arose in *Santen* in large part were triggered by *Case C-130/11 Neurim Pharmaceuticals (1991) Ltd v. Comptroller-General of Patents*. This judgment from July 2012 was a central feature of the plaintiff's argument. The underlying dispute concerned melatonin, which is a natural hormone and cannot as such be patented. Neurim discovered that appropriate formulations of melatonin could be used as a medicine for insomnia. It subsequently obtained a European patent concerning its formulation of melatonin which was to be sold in the form of medicinal products for human use called Circadin. The marketing authorisation was granted on the 28 June 2007 at a time when the patent protecting the new medicinal products had less than five years to run. The plaintiff applied for an SPC, and in December 2009, the IPO refused to grant that request. This was on the basis that an earlier MA dating from 2001 concerning the product Regulin authorised the use of melatonin in sheep. The purpose of the product was to regulate the seasonal breeding activity of sheep. Accordingly, the refusal was based on the fact that the Circadin marketing authorisation was not the first marketing authorisation relating to melatonin.

94. The Court of Appeal for England and Wales referred five questions to the Court of Justice. The first question involved the court noting that the active ingredient in the two

medicinal products at issue was not, as such, protected by a patent. Second, the basic patent for which the SPC application was made protected the application of that active ingredient which, as a medicinal product for human use, has obtained a valid marketing authorisation. The question that arose therefore in the first instance was whether the provisions of Articles 3 and 4 of the SPC regulation were to be interpreted as meaning that the existence of an earlier marketing authorisation for a veterinary medicinal product was sufficient to preclude the grant of an SPC for the product application which obtained the other marketing authorisation.

95. The Court noted the first three conditions set out in Article 3 of the 2009 Regulation concerned the relevant *"product*" and required it to be protected by a basic patent in force, to have obtained a valid MA as a medicinal product, and not already have been the subject of a certificate. The Court referred to the reasons and purposes underlying the SPC regulation which had been addressed in previous cases and noted that it was apparent from paragraph 29 of the explanatory memorandum concerning the 1992 regulation that:

> "*like a patent protecting a 'product' or a patent protecting process by which a 'product' is obtained, a patent protecting a new application of a new or known product, such as that at issue in the main proceedings, may, in accordance with Article 2 of the SPC Regulation, enable an SPC to be granted and, in that case, in accordance with Article 5 of the Regulation, the SPC confers the same rights as conferred by the basic patent as regards the new use of the product, within the limits laid down by Article 4 of that regulation*."

96. The Court then remarked on an issue that arises in the case of second medical use applications: -

> "*25. Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for a veterinary or human use, for other therapeutic indications, whether or not protected by an earlier placement patent, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product.*
>
> *26. In such a situation, only the MA of the first medicinal product, comprising the product and authorised for a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC, may be considered to be the first MA of 'that product' as a medicinal product exploiting that new use within the meaning of Article 3(d) of the SPC regulation*."

97. The Court, in a marked break with the existing caselaw, therefore found that the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product did not preclude the grant of an SPC for a different application of the same product for which MA has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC. That appeared to be so even if the same active ingredient had been utilised.

98. The next significant decision relied upon by the parties was *Case C-443/12 Actavis UK Ltd v. Sanofi*. That judgment concerned a request for a preliminary ruling concerning the interpretation of Article 3 of the 2009 Regulation. In that case, Sanofi held a European patent which covered, *inter alia*, a family of compounds which included the antihypertensive active ingredients irbesartan. On the basis of a basic patent which was applied for in March 1991, granted in June 1998, and expired in March 2011, marketing authorisations were granted on the 27 August 1997 in respect of the medicinal product Aprovel which contained irbesartan as a single active ingredient and was used to treat primary hypertension. Sanofi obtained its first SPC for that active ingredient in February 1999.

99. In addition, on the basis of its basic patent, a separate marketing authorisation in 1998 was obtained for a medicinal product CoAprovel which comprised a combination of irbesartan and a diuretic which was also used to treat primary hypertension. A second SPC was obtained in relation to that combination, and the certificate was granted in December 1999 and expired in October 2013. The European Medicines Agency had summarised that the combination of the two active ingredients had an additive effect reducing the blood pressure more than either a medicine alone, and it followed that the combination of the active ingredients' curative properties corresponded to the total therapeutic effect that would otherwise be obtained by a separate administration of Aprovel and Hydrochlorothiazide.

100. Actavis intended to market generic versions of Aprovel and CoAprovel and they challenged the validity of the SPC granted in respect of CoAprovel. They argued that the second SPC was invalid insofar as the combination was not protected by the basic patent and that the product had already been the subject of an initial SPC.

101. The Court suggested that the proceedings in question entailed a situation in which the same patent may be regarded as protecting a number of products within the meaning of Article 3(a) of the 2009 Regulation. The question was therefore whether such a patent may permit its holder to obtain more than one SPC.

102. The Court noted, at para. 29, that it was possible on the basis of a patent which protects several different "*products*" to obtain several SPCs in relation to those different products, provided that each of the products is protected as such by that basic patent pursuant to the meaning of Article 3 (a) of the Regulation. However, the Court went on to note that even if the condition in article 3(a) of the 2009 Regulations was satisfied, for the purposes of the application of Article 3(c) of the Regulation, it could not be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time it placed a medicinal product on the market in a member state containing, on the one hand, the principal active ingredient, protected as such by the holder's basic patent and constituting, according to the statements of the referring court, the core inventive advance of that patent, and, on the other, another active ingredient which is not protected as such by that patent.

103. The Court went on to hold that since it was common ground that during the period in which the first SPC was valid, Sanofi was entitled to oppose on the basis of its basic patent the use or certain uses of Irbesartan in the form of a medicinal product, the SPC (now expired) granted for that product also conferred on Sanofi the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of that certificate. It followed that the first SPC permitted Sanofi to oppose the marketing of a medicinal products containing Irbesartan in combination with hydrochlorothiazide for a similar therapeutic use to that of Aprovel so that if one of the pharmaceutical laboratories competitors have marketed a

medicinal product similar to CoAprovel for similar therapeutic use Sanofi would have been able to oppose the marketing of that product by invoking its SPC for irbesartan.

104. Therefore Article 3(c) of the 2009 Regulation was held to preclude a patent holder from obtaining, on the basis of one and the same basic patent, more than one SPC in connection with irbesartan since such SPCs will in fact be connected wholly or in part with the same product. Therefore, the second SPC could not be granted to Sanofi for the combination irrespective of whether that combination was protected as such by the basic patent within the meaning of Article 3 (a) of the Regulation.

105. *C-121/17 Teva UK Ltd v. Gilead Sciences Inc*. was a decision of the Grand Chamber given on the 25 July 2018. The dispute arose in circumstances where Gilead marketed an antiretroviral medicinal product for the treatment of persons infected with HIV under the name Truvada. The product contained two active ingredients, tenofovir disoproxil (TD) and emtricitabine. Gilead was granted a marketing authorisation in November 2005. Gilead also held a European patent filed in July 1997 which was granted in May 2003. The description of the invention indicated that the patent covered a series of molecules which were helpful in the therapeutic treatment of a number of viral infections in humans and animals, and in particular HIV. Claim 25 of the basic patent expressly mentioned TD as one of the claimed compounds. The basic patent also claimed that those compounds may if necessary be associated with other therapeutic ingredients, but those therapeutic ingredients were neither defined or explained the basic patent.

106. In 2008, Gilead obtained an SPC relating to a composition containing TD, "*optionally in the form of a pharmaceutically acceptable salt, hydrate, tautomer or solvate, together with*

emtricitabine". Teva and the other applicants sought to market generic versions of Truvada on the UK market and sought to challenge the validity of the SPC. Part of their claim was that the product was not specified in the wording of the claims, that emtricitabine is not specified in the wording of the claim of the basic patent, and that the expression "*other therapeutic ingredients*" used in the claim does not specify any active ingredient.

107. In considering the question, the Court observed that it was apparent from the information provided by the UK court that the product which was the subject of the SPC at issue was composed of two active ingredients, TD and emtricitabine, and the claim in the basic patent expressly mentions only the first of those two active ingredients. The court noted, at para. 31, that since no harmonised EU patent rules are applicable in the main proceedings, the extent of the protection conferred by the basic patent can be determined only in the light of the non-European Union rules governing patents. In that regard, the Court reiterated that the rules for determining what is "*protected by a basic patent in force*" within the meaning of Article 3(a) of the 2009 regulations are those relating to the extent of the invention covered by such a patent. In that regard, so far as the European patent was concerned, pursuant to article 69 of the European Patent Convention, the extent of the protection conferred by the patent is determined by the claims. As noted at para. 36 of the judgment, the Court already had held that Article 3(a) of the 2009 regulation does not, in principle, preclude an active ingredient which is given a functional definition in the claims of the basic patent issued by the EPO being regarded as protected by the patent, on condition that it is possible on the basis of those claims as interpreted in the light of the description of the invention as required under article 69 of the EPC to conclude that the claims relate implicitly but necessarily and specifically to the active ingredient in question.

108. Therefore, as held at para. 37, a product cannot be considered to be protected by a basic patent in force within the meaning of article 3(a) of the 2009 regulation unless the product which is the subject of the SPC is either expressly mentioned in the claims of that patent or those claims relate to that product necessarily and specifically. This led to the court ruling as follows:-

> "…*Article 3(a) of* [2009 Regulation]*... must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:*
>
> - *the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and*
> - *each of those active ingredients must be specifically and identifiable, in the light of all the information disclosed by that patent.*"

109. In *Case C-443/17 Abraxis Bioscience LLC v. Comptroller General of Patents*, a judgment delivered on the 21 March 2019, the background was that Abraxis marketed under the name Abraxane a medicinal product indicated for the treatment of certain cancers. The product contained a substance called "*nab-paclitaxel*", which is a combination of nanoparticles of paclitaxel coated with albumin and protected by a European patent. Abraxis was granted a marketing authorisation in 2008. Prior to that date, paclitaxel had been marketed in another

form by other companies under previous marketing authorisations. Nevertheless, Abraxis applied for an SPC on the basis of the basic patent at issue and the MA that had been granted for Abraxane. The Comptroller General of Patents turned down the application on the basis of non-compliance with article 3(d) of the 2009 regulation. In that instance, the Comptroller had held that although the provision permits the grant of an SPC for a new and inventive *therapeutic use* of an old active ingredient, its scope did not extend to a new and inventive *formulation* of the old active ingredient. On the basis of the decision in *Neurim*, Abraxis appealed that decision. The High Court decided to stay the proceedings and referred a question to the Court of Justice for a preliminary ruling.

110. The Court of Justice noted at the outset that the question concerned an application for an SPC, the subject of which was a new formulation of an old active ingredient. The information before the court suggested that the new formulation allowed the active ingredient to exercise its therapeutic effects with an increased efficacy.

111. The Court started by determining whether article 1(b) of the 2009 regulation must be interpreted as meaning that a new formulation of an old active ingredient which consists of that active ingredient and a carrier linked together in the form of nanoparticles permitting the active ingredient to exercise its therapeutic effects with increased efficacy may be regarded as a product that is distinct from the product consisting solely of the active ingredient. The Court noted that article 1 stated that the term "*product*" meant the active ingredient or combination of active ingredients of a medicinal product. Given the concept of "*active ingredient*" in the 2009 regulation was not defined, the term must be determined by considering the general context in which they are used and their usual meaning in everyday language. In that regard

they noted case law which demonstrated that "*active ingredient*" could not include substances which do not have an effect of their own on the human or animal body.

112. The Court considered on the basis of the existing case law that a substance which did not have any therapeutic effect of its own and which was used to obtain a certain pharmaceutical form of a medicinal product was not covered by the concept of "*active ingredient*" which was used to define the term "*product*". As a consequence, the alliance of a substance which does have a therapeutic effect of its own cannot give rise to a "c*ombination*" of active ingredients within the meaning of the Regulation. In addition, the fact that the substance without any therapeutic effect of its own renders possible a pharmaceutical form of a medicinal product necessary for the therapeutic efficacy of the substance cannot invalidate that interpretation. The Court noted that those considerations applied equally to a substance such as the albumin in the main proceedings, which acted as a carrier for the active ingredient. Since a carrier does not have any therapeutic effects of its own – although this is a matter which had to be determined by the referring court – it cannot be regarded as being an active ingredient within the meaning of the regulation.

113. As a result, the court found that article 1(b) of the 2009 Regulation must be interpreted as meaning that a new formulation of an old active ingredient which consists of that active ingredient and a carrier which has no therapeutic effect on its own cannot be regarded as being a product distinct from the product consisting solely of that active ingredient, even if that formulation allows the active ingredient to exercise its therapeutic effect with increased efficacy.

114. The Court then went on to determine whether a marketing authorisation granted for a new formulation of an old active ingredient may be regarded as the first marketing authorisation granted for that product as a medicinal product within the meaning of article 3(d) of the 2009 regulation.

115. The Court noted the observation of the Advocate General that in light of the definition of the scope of "*product*" and the settled case law, a literal interpretation of article 3(d) of the 2009 Regulation pre-supposed that the first MA for a product as a medicinal product meant the first MA for a medicinal product incorporating the active ingredient or the combination of active ingredients at issue. On that reasoning, only the authorisation in respect of the first medicinal product placed on the market could be regarded as the first MA within the meaning of article 3(d) of the regulation.

116. A consideration of the recitals and the explanatory memorandum supported a narrow interpretation of article 3(d) of the Regulation. This in turn suggested that the legislature in establishing the SPC regime did not intend to protect all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, but to protect research leading to the first placing on the market of an active ingredient or combination of active ingredients as a medicinal product. That objective would be jeopardised if it was possible to take into account, in respect of a new formulation of an old active ingredient, solely the first MA to be covered by the scope of the basic patent protecting the new formulation and to disregard an MA which had been granted previously in respect of the same active ingredient in another formulation.

117. Significantly, the Court also highlighted that the appellant's interpretation of Article 3(d) risked leading to legal uncertainty and inconsistency as to the circumstances in which an SPC may be obtained. This was because it would be difficult to determine in which specific circumstances an MA granted in respect of a new formulation of an old active ingredient may be covered by that provision. In those premises, the Court found that a marketing authorisation granted for a new formulation of an old active ingredient could not be regarded as being the first MA granted for that product as a medicinal product within the meaning of article 3(d) of the regulation when that active ingredient already has been the subject of an MA.

118. The Court distinguished the situation in *Neurim*, holding that, in that judgment, the Court held that articles 3 and 4 of the 2009 Regulation must be interpreted as meaning that, in a situation such as that in the case which gave rise to that judgment, the mere existence of an earlier MA obtained for a veterinary medicinal product did not preclude the grant of an SPC for a different application of the same product for which an MA had been granted provided that the application is within the limits of the protection conferred by the basic patent relied on for the purposes of the SPC application. Importantly, having regard to Merck's argument about uncertainty in this case, the Court noted at paragraph 42:-

> "*42. However, the court did not, in that judgment, cast doubt on the narrow interpretation of the notion of 'product', referred to in article 1(b) of that regulation, according to which that scope cannot cover a substance which does not correspond to the definition of an 'active ingredient' or to that of a 'combination' of active ingredients…*"

119. The Court also held that the exception to the narrow interpretation of article 3(d) set out in *Neurim* did not refer to cases of a new formulation of the product at issue. Hence, the

exception could not in any event be relied on in the case of an MA granted for a new formulation of an active ingredient which already has been the subject of an MA, even if the MA for that new formulation was the first to come within the scope of the basic patent relied on in support of the SPC application for that new formulation.

120. This leads to the decision in *Case C-673/18 Santen SAS v. Directeur général de l'Institut national de la propriété industrielle*. This was a judgment of the Grand Chamber handed down on the 9 July 2020. Santen held a European patent filed in October 2005 which protected an ophthalmic emulsion in which the active ingredient was ciclosporin, an immunosuppressive agent. Santen had obtained a MA in March 2015 for a medicinal product named Ikervis, in which ciclosporin was the active ingredient. An application for a SPC was refused because a MA had been granted in 1983 for a product named Sandimmun, in which the active ingredient was ciclosporin.

121. The referral to the CJEU was made on the basis of the observations in *Neurim* that Articles 3 and 4 of the 2009 Regulation mean that the mere existence of an earlier MA obtained for a veterinary medicinal product did not preclude the grant of an SPC for a different application of the same product for which an MA had been granted, provided that that application was within the limits of the protection conferred by the basic patent relied on for the purposes of the application for an MA.

122. The Court framed the presenting question in clear terms:

> "*28. In the present case, the questions referred… concern, in essence, the interpretation of Article 3(d) of* [2009 Regulation]*… and, more specifically, the interpretation of the concept of 'first [MA for the product] as a medicinal*

product' for the purpose of that provision, read in the light of the judgment in Neurim."

123. I consider that the objective of the CJEU in *Santen* was broader than merely answering the specific questions that had been referred. This is evident from paras 34 and 35 where the Court noted that the premise of the questions arising from *Neurim* were that "*it is possible… 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."* The Court then observed:

> *"35. In this connection, … even if, formally, the referring court has limited its questions to the interpretation of certain aspects of EU law, that does not prevent this Court from providing the referring court with all the elements of interpretation of EU law which may be of assistance in adjudicating in the case pending before it, whether or not that court has referred to them in the wording of its questions..."*

124. The Court then stated that, to provide a useful answer to the referring court, it was necessary to examine "*whether Article 3(d)… must be interpreted as meaning that an MA may be considered to be the first MA… where it covers a new therapeutic application of an active ingredient… and that active ingredient… has already been the subject of an MA for a different therapeutic application.*" To my mind, this firmly establishes that the decision in *Santen* was intended, as it were, to draw a line in the sand and resolve the potential difficulties that arose from the *Neurim* decision.

125. The Court reiterated the authorities concerning the meaning of "*active ingredient*", and that the term means substances that have, at least, a therapeutic effect of their own. The Court also stated that having regard to Articles 1(b) and 4 of the Regulation, that the term "*product*" is understood for the purposes of the Regulation as meaning "*the active ingredient… of a medicinal product, without its being necessary to limit its scope only to one of the therapeutic applications to which such an active ingredient… may give rise*."

126. The Court was clear that the term "*product*" was not dependent on the manner in which the product was used and that the intended use of the medicinal product does not constitute the decisive factor for the grant of an SPC, reiterating what had been found in the *Pharmacia Italia* case. The Court stated at para. 46 that the "strict view of the term '*product*'" which was explained *inter alia* in the MIT and Abraxis cases, "*was given concrete form in Article 1(b)*" of the Regulation, "*which defines that term by reference to an active ingredient… and not by reference to the therapeutic application of an active ingredient protected by the basic patent…*"

127. This led to the first significant finding for this case at para. 47, that:

> " *…Article 1(b) of [the 2009 Regulation] must be interpreted as meaning that the fact that an active ingredient … 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 … has been used for the purposes of a different, already known, therapeutic application*."

128. The second issue addressed in *Santen* was whether an MA for a new therapeutic application of an active ingredient may be regarded as being the first MA granted for that

product for the purposes of Article 3(d), where that MA is the first MA to fall within the limits of the protection of the basic patent relied on in support of the application for an SPC.

129. In addressing that question – which stressed the interaction between SPC and the basic patent – the Court began by noting that the wording of Article 3(d) did not refer to the limits of the protection of the basic patent. Next, the Court considered the strict definition of the term "*product*" in Article 1(b). The Court at para 51 observed that in that light "*the analysis of the wording of Article 3(d) … presupposes that the first MA for the product as a medicinal product for the purpose of that provision means the first MA for a medicinal product incorporating the active ingredient … irrespective of the therapeutic application of that active ingredient …in respect of which that MA was obtained."*

130. The Court rejected the notion that "*the first MA for the product as a medicinal product*" referred exclusively to the first MA to fall within the limits of the protection of the basic patent. As noted by the Court, if that was the case, that therapeutic application "*might justify the grant of an SPC notwithstanding the fact that the same active ingredient … is covered by a different, already known, therapeutic application which gave rise to an earlier MA.*" The Court expressly rejected the holding at para. 27 of *Neurim* that there was a need to take account of the limits of the protection of the basic patent for the purposes of Article 3(d).

131. This led to the formal finding that Art. 3(d) of the 2009 Regulation:

> "*…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*

... and that active ingredient ... has already been the subject of a marketing authorisation for a different therapeutic application."

132. In making that finding, the Court clearly considered the balance to be drawn between protecting investment in pharmaceutical research and the need to take account of all interests at stake in the pharmaceutical sector, including public health. Likewise, the Court was concerned to ensure that the interpretation set out enhanced rather than compromised the simplicity and predictability of the system for SPCs.

ANALYSIS AND DECISION

133. In the light of the intended clarity of the *Santen* judgment, it seems clear to me that the Merck arguments cannot succeed. In essence the argument seeks an opportunity to re-argue the question of the relationship between Article 3(d) and 3(a), which, on my reading, was resolved in *Santen*.

134. The second Merck argument was that earlier cases had observed for the purposes of Article 3(a) that the extent of the protection conferred by a basic patent was a matter to be determined by national or non-EU law rules governing patents. In this case there was no dispute that Mavenclad was protected by the basic patent in a manner consistent with article 1(c) and therefore that the requirement at article 3(a) was met. However, as the court in Santen expressly stated at para. 53, for the purposes of article 3(d), "*there is no need to take into account the limits of the protection of the basic patent*".

135. Hence, the Article 3 consideration involves separate pieces of analysis. For the purposes of Article 3(a) it will be necessary to consider the extent of the protection afforded by the relevant basic patent and to do so by reference to non-EU law rules. However, *Santen* is clear that the Article 3(d) analysis is constrained by the strict definition of "*product*", being the active ingredient, and the question of whether that active ingredient has been the subject of an earlier MA. Accordingly, the second Merck argument must be rejected.

136. In relation to the first Merck argument, I agree with the Controller's argument that in essence Merck is endeavouring to find an ambiguity where none exists. It may well be arguable at a policy level that the balance struck by the Court in *Santen* – which in reality reflected the thrust of the pre-*Neurim* jurisprudence – is a balance that does not afford sufficient protection for the product of research that leads to MAs for second medical use products. That is a matter for the EU legislature and not a matter for this court. It is a policy argument about the manner in which the 2009 Regulation is drafted rather than a complaint about its interpretation. The CJEU has been very clear in its interpretation of article 3(d), and that is a matter that binds this court.

137. It seems to me that the Controller was correct when it contended at para. 77 of its written submissions that the effect of the decision in *Santen* was to draw *"a clear distinction between new applications for an existing product which has not previously been authorised as a medicinal product, and new applications for a product which has. The former is permissible under the SPC regime, and the latter not*." In the premises, I consider that Merck cannot succeed on its first argument.

138. In relation to the third argument, Merck pressed the need for correspondence between the authorised product and the protected invention, and highlights that one of the objectives of the 2009 Regulation is not achieved if the MA for Litak is found to be the first MA for a substance whose active ingredient is cladribine. In that sense, it was argued that finding Litak's MA to be the first MA for the product protected by Mavenclad basic patent will not compensate Merck for the time lost obtaining its MA for Mavenclad. As noted above it seems to me that this is the clear result of the *Santen* decision. Moreover, in *Santen* the Court expressly found that the strict definition of "*product*" and its application in the context of Article 3(d) achieved a balance between the need to protect the process of pharmaceutical research and the public health objectives of the Regulation.

139. Hence, again, the court cannot find that the decision of the Controller can be impugned on this argument and that the decision clearly was the correct decision in light of the analysis in *Santen*.

140. The final ground argued by Merck was that, based on the scientific evidence before the Controller, the cladribine in Mavenclad had a distinctly different pharmacological and therapeutic action to the cladribine in Litak. According to the argument, those distinct effects meant that the cladribine in Mavenclad should be treated as a different active ingredient to the cladribine in Litak. On that argument, even if there was no ambiguity or uncertainty about the decision in *Santen*, the Controller was wrong to find that the SPC should be refused, and that this court should grant the SPC.

141. I consider that this argument cannot succeed. The current state of the law as explained in *Santen* was directed to simplicity and predictability. The Court has made clear that the

Article 1 definition of product is to be understood and applied strictly. The focus of the statutory test is not on the effect or action of the active ingredient but on the identification of the active ingredient. Here there is no dispute or doubt that the active ingredient is cladribine. That, on my reading of the 2009 Regulation and the caselaw, is the limit of the inquiry in this context. For the purpose of considering an SPC application, I can find no warrant in the 2009 Regulation or the caselaw for a court going further than the identification of the active ingredient and embarking on an inquiry into the pharmacological or other effect of the active ingredient and how that may differ from its effect or action in another substance which obtained an earlier MA.

142. Hence, the four core grounds agitated by Merck cannot succeed.

143. As set out in this judgment it has not been necessary to consider case law from other jurisdictions to reach a conclusion in this case. However, it can be noted that the decision of this court has definite parallels with the decision of the Court of Appeal of England and Wales in *Merck Serono SA v. Comptroller-General of Patents* [2025] EWCA Civ. 45. That was a decision made in the context of an application for an SPC for Mavenclad that was rejected by the Comptroller on much the same bases as the decision of the Controller in this case. The decision of the Court of Appeal was concerned with a number of issues particular to the effects of the UK withdrawing from the EU and the circumstances in which the court could be invited to depart from retained EU law decisions.

144. However, the case involves a very helpful analysis of the decision of the CJEU in *Santen*, which occurred in the context of an argument (not open to Merck in this jurisdiction) that *Santen* was wrongly decided. The Court of Appeal considered that even if it was open to

it to depart from *Santen* it would not do so. The Court of Appeal engaged in a thorough analysis of the 2009 Regulation and its predecessor and the relevant EU caselaw. For the purposes of this judgment, the court notes and respectfully agrees with the observations of Birss LJ at para 57 of his judgment where he stated:

> *"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*."

145. In relation to the question of whether the court should refer a question to the CJEU, I am fully satisfied that there is no lack of clarity which could justify the taking of that step. For the reasons set out above, I am satisfied that, for the purpose of resolving the issues in this case, the decision in *Santen* is very clear. While Merck understandably is concerned about its implications, those concerns in truth are directed to the policy in the Regulation rather than to the question of how the Regulation should be interpreted and applied to the current application.

146. In the premises, I will refuse the appeal. As this judgment is being delivered electronically, I will express the provisional view that, by reference to s. 169 of the Legal Services Regulation Act 2015, the Controller should be entitled to its costs as against Merck with those costs to be adjudicated in default of agreement. However, I will list the matter before me for any final arguments that may be required at 10.30am on Thursday, the 8 October 2026.