Decision in the matter of SPC Request 2018/010.

Applicant: Merck Serono S.A.

Hearing Date: 07 August 2025

Hearing Officer: Dr Fergal Brady

DECISION

Introduction

1. This decision concerns the Request for a Supplementary Protection Certificate numbered 2018/010 (the 'Request'), filed by Merck Serono S.A. (the 'applicant') under Regulation (EC) 469/2009 (the 'SPC Regulation').

2. The Request was filed on 09 February 2018, relying on the basic patent (BP) EP 1827461 B1, a European patent filed on 20 December 2005, which upon grant on 29 February 2012 became a valid granted patent in Ireland. This patent is titled 'Cladribine Regimen for Treating Multiple Sclerosis'.

3. The Request further relied on a European Market Authorisation (MA) no. EU/1/17/1212 for the product 'MAVENCLAD – cladribine' (the MA), notified in the Official Journal of the European Union under Regulation (EC) 726/2004 on 24 August 2017, and which is valid in Ireland.

4. The product, as identified in the Request, is 'Cladribine'. The applicant declared in the request that the product is protected under claim 3 of the basic patent, and also in combination with claim 10 therein.

5. In their Request, the applicant drew attention to an earlier authorisation for the active substance cladribine. This authorisation (EU/1/04/275, held by Lipomed GmBH and notified on 19 April 2004) for the medicinal product 'Litak', concerns the use of cladribine in the treatment of hairy cell leukaemia. In view of this fact, the examining officer, Dr Dolores Cassidy, proposed a stay of examination pending the outcome of case C-673/18 ('Santen') before the Court of Justice of the European Union (CJEU), to which the applicant agreed.

6. Following the conclusion of the Santen case, Dr Cassidy issued a letter on 1 September 2020, notifying the applicant that the application did not comply with Art. 3(d) of the SPC regulation, since the MA presented with the Request for an SPC did not constitute the first MA for the product cladribine.

7. The applicant responded in a letter of 17 February 2021, making a number of arguments in defence of the Request. These were that Santen does not apply because of differences between the nature of the matter being heard in that case and the present Request, that

Santen should only apply *ex nunc*, the applicant having developed a use for cladribine *de novo* before the Santen ruling therefore having the right to legitimate expectation, and that the Request should therefore be more properly considered according to CJEU decision C-130/11 (Neurim), and the request allowed.

8. Dr Cassidy issued a second letter on 9 March 2021, rejecting the *ex nunc* argument, and asserting that Santen does apply, and finding that the Santen decision does not admit the grant of an SPC where the MA relied upon is predated by an earlier one, that hence the Request is ineligible for grant as it contravenes Art 3(d) of the SPC Regulation. She confirmed her decision to reject the Request, subject to the applicant's right to a Hearing in accordance with Section 90 of the Patents Act, 1992.

9. At the Hearing, the applicant presented a number of arguments as to why the SPC should be allowed. These are as follows:

    a. that Santen has been misapplied, such that its application as proposed by Dr Cassidy would contravene principles established by the Court, in that;
        i. the IPOI is not correctly applying the appropriate definition for the term 'product'; and
        ii. the decision to reject the application goes against the intended application of the SPC Regulation, as understood by reference to the Recitals therein and the Exploratory 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*.

10. The fundamental issue, as agreed at the outset of the Hearing by the applicant, is whether the MA presented with the Request meets the requirements of Art. 3(d) of the SPC Regulation, which states that:

    the authorisation referred to in point [3](b) is the first authorisation to place the product on the market as a medicinal product.

    Product, as per Art. 1(b) of the SPC Regulation, is defined as:

    the active ingredient or combination of active ingredients of a medicinal product.

11. I will now consider each of the arguments raised by the applicant, and their relevance to this question. Before I do, I wish to clarify certain background issues concerning the case. The following are clear and not in any dispute. The BP clearly protects a 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 Art. 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 as genuine and persuasive, and that this new use for cladribine is the result of extensive and painstaking research and clinical study. Having clarified these matters, I now turn to consider the matter in hand and the applicant's arguments.

The Arguments

12. The applicant's first argument is that is that Dr Cassidy has applied Art. 3(d) in a manner that goes against established principles laid down by the CJEU over many years, said principles being:
    a. that the term 'product' should take account of new inventive activity of an existing active ingredient, and not merely its chemical or biological constitution, and
    b. that all research leading to a product should be eligible for reward.

13. In support of this, the applicant quotes extensively from various decisions by the CJEU and also from the Exploratory Memorandum from the Travaux Préparatoires leading up to the adoption of the SPC Regulation. In so doing, they seek to assert that the term product cannot be confined to the Art. 1(b) definition of the Regulation, where the BP relates to the application of an active ingredient, as opposed to the ingredient itself.

14. I find the first of these stated principles to be clearly incorrect and the second, while quite correct, to lack relevance to the matter in hand. The difficulty with the Travaux Préparatoires is that they relate to an early draft of the Regulation which differs from the final adopted version, particularly with respect to the points to which the applicant specifically refers. So, whereas in the Travaux Préparatoires draft of the SPC Regulation, Art. 1 defined the terms 'product' and 'product protected by a patent', the final version instead defines 'medicinal product', 'product' and 'basic patent', and does so in significantly different terms. In separating out the term 'product' from that for basic patent, the finalised SPC Regulation makes clear in plain language that 'product' refers to an active ingredient or combination of active ingredients, the focus of which is the substances themselves rather than the manner in which they are active. That this is a correct interpretation of this legal definition is supported extensively through the rulings of the CJEU, particularly in Yissum (C-202/05) and in Santen itself.

15. In Yissum, the Court could not have been clearer, when it ruled that:

    Article 1(b) of Regulation No 1768/92 is to be interpreted as meaning 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.

16. The Santen decision devotes five paragraphs (43-47) to a clear and thorough analysis of the meaning of the term 'product' and fundamentally dismisses any suggestion that the therapeutic application of the active substance(s) is or should be taken into account by that definition. Therefore, without having (as yet) to determine whether Santen applies in the present case, its consideration of the term product is the clearest and most recent consideration of the meaning of the term 'product', as defined in Art. 1(b), and is to my reading emphatic as to the focus of the term on the active substance itself and not its therapeutic indication.

17. On the question of the eligibility of all research for reward, this principle is indeed enshrined in the Regulation, but not without caveat. All research can indeed lead to the grant of an SPC, whether for a product, a process for making it or for a new medical use for it, but only so long as all the conditions set out in the Regulation (and particularly those of Art. 3) are met. So a patent for a process can yield an SPC, as can one for a second medical use, as long as these conditions are met. In the present case, there is no dispute concerning three of the conditions, but only regarding Art 3(d). In the absence of a prior MA for cladribine, this SPC would be readily grantable, and the current proceedings would not have taken place.

18. The second argument relates to whether the criteria of Santen or of Neurim should apply in order to determine the matter. The applicant contends that, since Santen does not consider the particulars of the claims of the basic patent to which it relates, it is not therefore relevant to the present case. This premise is based on the fact that the matter referred in Santen involved a new formulation for the product Ciclosporin, but that the product was being used to treat the same condition, acting with the same pharmacological and therapeutic activity. Since the present case concerns an entirely new and pharmacologically and therapeutically distinct use for cladribine, the applicant seeks to dismiss Santen as not relevant to the present particulars.

19. The applicant further asserts that since 'a point not argued is a point not decided', that Santen therefore should not apply, since it is not established that Santen reverses Neurim where a new use applies.

20. I cannot accept this argument. To do so requires making a new use for a product sufficient to allow a legal distinction under the SPC Regulation for the same product with an earlier known use. 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 where the same active ingredient… has been used for the purposes of a different already known therapeutic application' (Santen, para. 47).

21. Further, I draw the applicant's attention to paragraph 53 of Santen, which states 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.' Since paragraph 27 of Santen provides the rationale for the first (and key)

ruling in the Neurim case, it is clear that the Court, in the Santen ruling, overturns the substance of Neurim.

22. Accordingly, I find that the point has indeed been decided, and that I cannot apply the Neurim criteria in the present case, but am instead bound to follow the decision of the Court given in Santen.

23. The third argument put forward by the applicant is that, even if (as I find it must) Santen does apply, the facts of the present case are such that the Request should still be allowed. This argument relates closely to the two arguments above, in that it attempts to distinguish the present case from Santen on the basis that the product authorised for Litak is not the same product as that authorised for Mavenclad. In support of this, the applicant relies on the considerable evidence provided to support the distinct action of cladribine in treating hairy cell leukaemia and in how it treats multiple sclerosis. I have already stated that I fully accept this clear distinction in pharmacological and therapeutic action, so there is no need to engage in any analysis of same. However, I do note that in both MAs, cladribine is the only listed active ingredient. Accordingly, significant and important as the distinction in therapeutic activity in treatment of these two conditions is, it is clear from the decision in Santen, as rehearsed extensively above, that this distinction does not provide any legal basis to set aside the Litak MA, and that I must, if applying Santen principles, consider that the first MA for cladribine within the meaning of Art. 3(d).

24. The applicant's final argument is that Santen, even inasmuch as it overturns Neurim, should only apply *ex nunc* (that is, from the date of the ruling) rather than *ex tunc* (that is to say, retrospectively). To apply *ex nunc* would in the applicant's view deny them their legitimate expectation, in that they should be allowed to rely on Neurim as the legal facts on the ground at the time the Request was made.

25. The counterargument to this contention in the present case is twofold. In the first instance, I note that Dr Cassidy's first communication with the applicant was not a letter noting deficiencies in the Request, but rather a letter proposing to stay examination of the Request pending the outcome of the Santen proceeding, to which the applicant responded consenting to same. It was within the applicant's right to object to the stay of examination, but they chose instead to allow Santen to proceed to judgment before any substantive examination of the Request was made.

26. Secondly, and more decisively, it is an established principle of the CJEU that decisions interpreting existing statutes are applied *ex tunc* unless otherwise stated by the Court in that decision. This principle is set out in the Court's ruling in joined cases C-66/79, C-127/79 and C-128/79. The first aspect of the decision was given as follows:

> 'The interpretation which, in the exercise of the jurisdiction conferred on it by Article 177 of the EEC Treaty, the Court of Justice gives to a rule of Community law, clarifies and defines where necessary the meaning and scope of that rule as it must be or ought to have been understood and applied from the time of its coming into force.

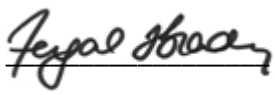
It follows that the rule as thus interpreted may, and must, be applied by the courts even to legal relationships arising and established before the judgment ruling on the request for interpretation, provided that in other respects the conditions enabling an action relating to the application of that rule to be brought before the courts having jurisdiction are satisfied. It is only exceptionally that the Court may be moved, in the same judgment as that ruling on the request for interpretation, to restrict for any person concerned the opportunity of relying upon the provision as thus interpreted with a view to calling in question legal relationships arising and established prior thereto.'

27. By this decision, the Court clearly affirms the principle of *ex tunc* effect for its rulings. It further sets out that any exception to this principle in respect of a decision of the Court would be set out in that decision. Since there is no exception stated in the Santen decision, it is clear that the Court's intention is that the Santen decision applies *ex tunc*, and there is no basis for setting it aside on the basis of legitimate expectation.

28. I therefore find it clear that the present matter, concerning as it does a request for an SPC cladribine based on an MA which is not the first MA to place the product on the market must be considered according to the decision made in Santen. This is what Dr Cassidy has done, and I find no grounds for setting aside or overturning her decision, which I consider to have been correctly made.

The Decision

29. Accordingly, I find 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. As such, the Request does not accord with Article 3(d) of Regulation EC 469/2009, and the examiner is correct to have rejected it on that ground.



Dr Fergal Brady
Hearing Officer
08 October 2025.