Neutral Citation Number: [2023] EWHC 3240 (Ch)

Appeal No: CH-2023-000136

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT
ON APPEAL FROM THE UK INTELLECTUAL PROPERTY OFFICE

Rolls Building
Fetter Lane
London, EC4A 1NL

19 December 2023

Before :

MICHAEL TAPPIN KC
(sitting as a Deputy Judge of the High Court)

- -

Between :

MERCK SERONO S.A.	**Appellant**
- and -	
THE COMPTROLLER-GENERAL OF PATENTS, DESIGNS AND TRADE MARKS	**Respondent**

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- -

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

Hearing date: 12 December 2023

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Approved Judgment

I direct that no official shorthand note shall be taken of this judgment and that copies of this version as handed down may be treated as authentic.

This judgment was handed down remotely at 10.30 am on 19 December 2023 by circulation to the parties' representatives by email and release to The National Archives.

The Deputy Judge:

1. This is an appeal from decision BL O/0484/23 dated 26 May 2023 of Mrs Mary Taylor, a Deputy Director of the UK Intellectual Property Office ("UKIPO"), sitting as a Hearing Officer on behalf of the Respondent ("the Comptroller").

2. On 12 February 2018 the Appellant ("Merck") applied to the UKIPO for a Supplementary Protection Certificate ("SPC") in respect of a product identified as "cladribine". The application relied on, as the basic patent, EP 1827461 B1 entitled "cladribine regimen for treating multiple sclerosis" and, as the relevant marketing authorisation ("MA"), EU/1/17/1212 in respect of the medicinal product "MAVENCLAD" containing cladribine as active ingredient and indicated (in a particular dosing regimen) for the treatment of highly active relapsing remitting multiple sclerosis.

3. The basic patent was filed on 20 December 2005, claiming a priority date of 22 December 2004, and was granted on 29 February 2012. It is due to expire on 19 December 2025. Any SPC granted on Merck's application would come into force on expiry of the basic patent.

4. On 10 September 2021 the UKIPO examiner notified Merck that her view was that its application did not meet the requirements of Regulation (EC) 469/2009 ("the Regulation"). Specifically, her view was that it did not meet the requirements of Article 3(d) of the Regulation as interpreted by the Court of Justice in Case C-673/18 *Santen* in the light of the fact that there had been earlier MAs for medicinal products containing cladribine as active ingredient. Those MAs, namely PL 00242/0232 issued on 3 February 1995 for "LEUSTAT" and EU/1/04/275 issued on 14 April 2004 for "LITAK", were for medicinal products indicated for the treatment of hairy cell leukaemia.

5. Correspondence ensued between Merck's representatives and the examiner, leading ultimately to the hearing before the Hearing Officer on 8 March 2023. In her decision the Hearing Officer held that Merck's application did not satisfy the requirements of Article 3(d) of the Regulation and therefore rejected it under Article 10(2). Merck now appeals to this court.

The Regulation

6. Article 1 of the Regulation contains a number of definitions, of which (a)-(d) are relevant:

> "(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
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> (b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

> (c) 'basic patent' means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
>
> (d) 'certificate' means the supplementary protection certificate;…"

7. Article 3 sets out the conditions for obtaining a certificate. In the form in which it stood when Merck's application was made, it read:

> "A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:
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> (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."

8. Following the UK's exit from the European Union, the Regulation became retained EU law with amendments made by the Patents (Amendment) (EU Exit) Regulations 2019 (SI 2019/801) as from 1 January 2021. One amendment was to Article 3(d), which now reads: *"the authorisation referred to in point (b) is the first UK authorisation to place the product on the market as a medicinal product."*

9. Article 10(1) provides that where an application meets the conditions of the Regulation, the UKIPO shall grant the certificate, while Article 10(2) provides that (following an opportunity to rectify any irregularity) where an application does not meet the conditions of the Regulation, the UKIPO shall reject the application. Article 15(1) provides that the certificate shall be invalid if it was granted contrary to the provisions of Article 3; Article 15(2) allows any person to bring an action for a declaration of invalidity of the certificate.

10. The Regulation replaced and codified Regulation (EEC) 1768/92 ("the original Regulation"), in which Articles 1 and 3 took the same form as those in the Regulation. The original Regulation was accompanied by an Explanatory Memorandum which has been used to interpret both the Regulation and the original Regulation. I was referred to paragraphs 11, 12, 16, 28, 29 and 36 of the Explanatory Memorandum, but it is not necessary to set those out in this judgment.

The Court of Justice case law

11. In Case C-31/03 *Pharmacia Italia*, the Court of Justice was asked to interpret Article 19(1) of the original Regulation. Article 19(1) was a transitional provision which provided that: *"Any product which, on the date on which this regulation enters into force, is protected by a valid basic patent and for which the first [MA] in the Community was obtained after [a certain date] may be granted a certificate."* The question was whether Pharmacia could obtain an SPC in respect of an active ingredient which had been the subject of an MA for veterinary use prior to the relevant date. The Court referred to Articles 1(b) and 3 and said at [20] that: *"The decisive factor for the grant of the certificate is not the intended use of the medicinal product"*; its answer to the question referred was that a prior MA for veterinary use precluded the grant of an SPC.

12. In Case C-431/04 *Massachusetts Institute of Technology*, the Court of Justice was asked whether the definition of 'product' in Article 1(b) could include a combination of an active ingredient and an excipient which allowed the realisation of a pharmaceutical form of the active ingredient. It answered that question in the negative, saying that Article 1(b):

> "must be interpreted so as not to include in the concept of 'combination of active ingredients of a medicinal product' a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication."

13. In Case C-202/05 *Yissum*, the Court of Justice was asked whether: *"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 [original] Regulation and in particular does the application of the therapeutic agent play any part in the definition of 'product' for the purpose of the Regulation?"* The Court dealt with the matter by reasoned order in the light of *MIT* and *Pharmacia*, stating:

> "16. As laid down in Article 1(b) of Regulation No 1768/92, 'product' means the active ingredient or combination of active ingredients of a medicinal product.
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> 17. It is clear from *Massachusetts Institute of Technology*, and, in particular, from paragraphs 19, 21, 23 and 24 of that judgment, that the concept of 'product' referred to in Article 1(b) of Regulation No 1768/92 must be interpreted strictly to mean 'active substance' or 'active ingredient'.
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> 18. It follows that the concept of 'product' cannot include the therapeutic use of an active ingredient protected by a basic patent.
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> 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 medicinal product'.

20. Consequently, the answer to the question referred must be 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."

14. In Case C-130/11 *Neurim*, Neurim had applied for an SPC in respect of 'melatonin'. It relied on its patent for the use of melatonin to treat insomnia, and its MA for such use. Melatonin had, however, been the subject of a prior third party MA for use to improve the reproductive performance of sheep. The Court of Appeal took the view that Neurim deserved an SPC and that if it did not obtain one the Regulation would not be fit for purpose (see [2011] EWCA Civ 228 at [28]-[30]). The questions which it referred included whether Article 3(d) was to be construed as precluding the grant of an SPC based on a later MA which is for a different medicinal product comprising the same active ingredient in circumstances where the limits of the protection conferred by the basic patent do not extend to placing the product the subject of the earlier MA on the market.

15. On 19 July 2012 the Court of Justice handed down its judgment holding that Article 3(d) did not preclude the grant of an SPC in such circumstances, saying:

"25. Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for veterinary or human use, for other therapeutic indications, whether or not protected by an earlier 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.

27. In the light of all the above considerations, the answer to the first and third questions is that Articles 3 and 4 of the SPC Regulation are to be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of an SPC for a different application of the same product for which an 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."

16. In Case C-443/17 *Abraxis*, Abraxis sought an SPC for "paclitaxel formulated as albumin bound nanoparticles", to which it referred as "nab-paclitaxel". It had a patent for nab-paclitaxel, but paclitaxel had been the subject of prior third party MAs. In his judgment ([2017] EWHC 14 (Pat)), Arnold J noted that there were difficulties in reconciling the Court of Justice's judgment in *Neurim* with its decisions in *Pharmacia*, *MIT* and *Yissum* (in particular *Pharmacia* and *Yissum*), as well as with its decisions in Case C-195/09 *Synthon* and Case C-427/09 *Generics*. He said that it was not clear how far the reasoning of the Court in *Neurim* extended and so referred the following question: *"Is Article 3(d) of the SPC Regulation to be interpreted as permitting the grant of an SPC where the marketing authorisation referred to in Article 3(b) is the first authorisation within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?"*

17. In his opinion, Advocate General Saugmansgaard Øe also recognised the difficulty in reconciling the decision in *Neurim* with the decisions in *Pharmacia, MIT* and *Yissum.* He advised that the Court should depart from the 'scope of protection of the basic patent' test adopted in *Neurim*. As an alternative, he proposed confining it to cases in which the prior MA was for non-human use.

18. The Court of Justice did not take up the invitation of the Advocate General. Instead it held that an MA for a new formulation of an old active ingredient could not be regarded as being the first MA granted for that product, when that active ingredient had already been the subject of an MA. It added:

> "41. The case-law arising from [*Neurim*] cannot call into question such an interpretation. In that judgment, the Court held that Articles 3 and 4 of Regulation No 469/2009 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 does not preclude the grant of an SPC for a different application of the same product for which an 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 SPC application.
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> 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' (see, to that effect, order of 14 November 2013 [in Case C-210/13 *GSK*] paragraph 44).
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> 43. Moreover, it should be noted that the exception to the narrow interpretation of Article 3(d) of that regulation, as held in [*Neurim*], does not, in any event, refer to cases of a new formulation of the product at issue. That exception cannot, therefore, in any event, be relied on in the case of an MA granted for a new formulation of an active ingredient which has already 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 SCP [*sic*] application for that new formulation."

19. The question of the scope of the approach in *Neurim* was raised again in Case C-673/18 *Santen*. In that case, Santen had applied for an SPC in respect of "ciclosporin for use in the treatment of keratitis", on the basis of a patent for an ophthalmic solution of ciclosporin and an MA for ciclosporin for use in the treatment of keratitis. However, a medicinal product containing ciclosporin as active ingredient had been the subject of a previous MA for preventing the rejection of solid organ and bone marrow grafts and other indications including the treatment of endogenous uveitis (an inflammation of the uvea, the middle part of the eyeball).

20. In his opinion, Advocate General Pitruzzella advised that the interpretation adopted by the Court in *Neurim* should be abandoned. Having referred to the decisions in *Pharmacia*, *MIT* and *Yissum*, he said this (footnotes omitted):

> "30. At the time when the Court received the reference for a preliminary ruling which led to the Neurim judgment, there was therefore a line of settled case-law establishing a *narrow interpretation* of the concept of 'product'. By interpreting Article 3(d) of Regulation No 469/2009 in such a way that the concept of 'first MA' is divorced from the concept of 'product' within the meaning of Article 1(b) of the regulation and connected with the concept of 'basic patent', for the purposes of Article 1(c), the Neurim judgment effectively circumvented that case-law, without, however, invalidating it, and introduced an artificial separation between two provisions of Regulation No 469/2009 sharing a functional link – the first defining the concept used in the second – and broke down the schematic coherence of the regulation, which is founded on the pivotal role played by the concept of 'product'. In doing so, the Court also confirmed an approach that was expressly contrary to that developed a few years earlier in the order in Yissum.
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> 31. Following the Neurim judgment, the Court confirmed both the narrow interpretation of the concept of 'product' in Article 1(b) of Regulation No 469/2009 and – albeit only in obiter dicta – the approach adopted in that judgment for new therapeutic applications of an old active ingredient, thus perpetuating the contradiction introduced into case-law and the system of that regulation.
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> 32. The Abraxis judgment attempted to mitigate this contradiction by reaffirming the narrow interpretation of the concept of 'product' within the meaning of Article 1(b) of Regulation No 469/2009 and by restoring the link between that provision and Article 3(d) of the regulation. Thus, in paragraph 35 of that judgment, the Court ruled that 'only the authorisation in respect of the first medicinal product placed on the market, consisting of the product concerned, may be regarded as the first marketing authorisation within the meaning of Article 3(d) of Regulation No 469/2009, as defined in Article 1(b) of that regulation'. While affirming an interpretation of Article 3(d) of Regulation No 469/2009 different to and incompatible with that adopted in the Neurim judgment, the Abraxis judgment did not reverse that interpretation, as had been suggested, in essence, by Advocate General

Saugmandsgaard Øe in his Opinion, but relegated it to being an 'exception to the narrow interpretation' of that provision.

33. As I have already mentioned in point 22 of this Opinion, I do not think that the Neurim judgment can be construed as an exception or that the inconsistency in case-law created by it can be resolved by restricting its scope such that it is reduced to a kind of empty shell. Doing so would betray the spirit and letter of that judgment, without eliminating any contradiction within the Court's case-law. The Court is therefore required in the present case to make a clear choice either to reverse the Neurim judgment or to widen the fine mesh of the concept of 'product' currently applied in the case-law."

21. The Advocate General went to explain in detail why, in his opinion, the Court should take the first option, concluding:

"61. Accordingly, in the light of all the above considerations, I agree with Advocate General Saugmandsgaard Øe in his Opinion in [*Abraxis*], that the Court should abandon the 'scope of protection of the patent test' introduced in the Neurim judgment and return to a literal interpretation of Article 3(d) of Regulation No 469/2009. It is for the EU legislature and not the Court to decide whether, and to what extent, the benefit of the SPC should be extended to the development of subsequent pharmacological or medical applications.

62. As regards the method to be used to make such a reversal, I take the view that it is not a satisfactory option to 'marginalise' the Neurim judgment, confining its scope only to cases of a first veterinary MA and a second MA for a medicinal product for human use, which are statistically very rare. First, as I stated above, that judgment does not lend itself to being interpreted as an exception, the application of which is strictly limited to the factual circumstances of the main proceedings which gave rise to it. Second, such marginalisation would not eliminate the contradictions that currently exist in the Court's case-law or their impact on the schematic coherence of the law governing SPCs. I therefore consider it preferable to follow the path taken in the Abraxis judgment, relying, *mutatis mutandis*, on the analysis contained in paragraphs 24 in 40 thereof. In that part of the grounds of the Abraxis judgment, proceeding from a summary of the case-law on the concept of 'product' within the meaning of Article 1(b) of Regulation No 469/2009, the Court arrived at a 'narrow interpretation' of Article 3(d) of the regulation, which, in itself, is incompatible with the reasoning adopted by the Court in the Neurim judgment. Although in the Abraxis judgment the Court did not go as far as reversing the Neurim judgment, merely concluding that that judgment did not, in any event, refer to cases of a new formulation of a known product, it must, in my view, take this step in its forthcoming judgment.

63. I therefore suggest that the Court answer the questions referred for a preliminary ruling by the Cour d'appel de Paris to the effect that Article 3(d) of Regulation No 469/2009, read in conjunction with Article 1(b) of

> that regulation, must be interpreted as meaning that the MA referred to in Article 3(b) of the regulation, relied upon in support of an SPC application relating to a different and new application of an old active ingredient, cannot be considered to be the first MA of the product concerned as a medicinal product where that active ingredient has already been the subject of an authorisation as such."

22. The Advocate General then turned to consider what the position should be if the Court decided to confirm the *Neurim* judgment. In that event he recommended reconsideration of the concept of 'product' in Article 1(b), and explained his preferred answers to the questions posed by the referring court on that footing – see [64]-[74].

23. The Court sat as a Grand Chamber of 15 judges to hear the *Santen* case, and handed down its judgment on 9 July 2020. It noted at [34] that the questions referred were on the premise, arising from the judgment in *Neurim*, that it was possible in some circumstances to obtain an SPC for a new therapeutic application of an active ingredient which has already been the subject of a prior MA. It said at [37] that to provide a useful answer to the referring court it was necessary to examine whether Article 3(d) of the Regulation 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. It then addressed its case law on the meaning of the term 'product', including *Pharmacia*, *MIT* and *Abraxis*, and held at [47] that the fact that an active ingredient is used for a new therapeutic application does not confer on it the status of a distinct product where the same active ingredient has already been used for the purposes of a different therapeutic application.

24. The Court then turned to consider whether an MA granted for a new therapeutic application of an active ingredient may be regarded as being the first MA granted for that product as a medicinal product, for the purpose of Article 3(d), in the case 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. It said that it was not possible to do so without calling into question the definition of 'product', and so said, at [53]:

> "It follows that, contrary to what the Court held in paragraph 27 of the judgment in *Neurim*, to define the concept of 'first [MA for the product] as a medicinal product' for the purpose of Article 3(d) of Regulation No 469/2009, there is no need to take into account the limits of the protection of the basic patent."

25. The Court then said that an analysis of the objectives of the Regulation confirmed that interpretation, referring to various recitals of the Regulation and paragraphs of the Explanatory Memorandum. At [60] it concluded:

> "It follows from the foregoing that the premiss on which the referring court relies, mentioned in paragraph 34 above, must be disregarded and that an MA for a therapeutic application of a product cannot be regarded as the first

> MA for that product as a medicinal product, for the purpose of Article 3(d) of Regulation No 469/2009, where another MA was granted previously for a different therapeutic application of the same product. The fact that the most recent MA is the first MA to fall within the limits of the protection of the basic patent relied on in support of the SPC application cannot call that interpretation into question."

26. Accordingly, the Court ruled as follows:

> "Article 3(d) of Regulation No 469/2009 … must be interpreted as meaning that a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application."

The Hearing Officer's decision

27. After reciting key provisions of the Regulation and quoting from the judgments of the Court of Justice in the cases referred to above, the Hearing Officer turned, in the light of the submissions made to her by Merck, to consider case law of the Court of Justice relating to the temporal effect of its judgments and to the issue of legitimate expectations, namely Cases C-43/75 *Defrenne*, C-61/79 *Denkavit Italiana*, C-441/14 *Dansk Industrie* and C-181/04 to C-183/04 *Elmeka* (all considered further below).

28. Then, after summarising the examiner's view, the Hearing Officer turned to consider the submissions of Merck. She recorded Merck's position as being that *Neurim* should be regarded as the operative judgment as that was the law when Merck's application was filed, and that *Santen* should not be applied because Merck undertook the development of MAVENCLAD with the legitimate expectation that it would be entitled to an SPC on the basis of *Neurim.* She then recorded Merck's submissions regarding *Denkavit Italiana, Dansk Industrie* and *Elmeka* as being, in summary, that the absence of a temporal restriction in a Court of Justice judgment did not prevent a national court from considering a party's legitimate expectations.

29. In the section of her decision headed "Analysis", the Hearing Officer turned to assess the submissions made by Merck. At [42] she recorded that Merck was not arguing before her that there was any relevant factual distinction between its application and *Santen*, and that Merck accepted that if *Santen* was followed the application should be refused. In [43] she said that the question she was being asked to decide was whether to follow *Santen*, which involved deciding whether that judgment applied *ex nunc* or *ex tunc*. At [44] the Hearing Officer referred to the conditions for *ex nunc* application of Court of Justice judgments in *Dansk Industrie* and *Denkavit Italiana*; she then recorded Merck's submission that, notwithstanding the absence of any reference to a temporal restriction in *Santen*, it was open to the UK courts to decide on such a temporal restriction. In [45] she said that the question was what the temporal effect of *Santen* was, not *"whether or not if that judgment were made now would there be a temporal restriction and*

who would make such a decision." In [46] she rejected Merck's suggestion, based on *Elmeka*, that a national court could make a decision on temporal effect of a Court of Justice decision in light of legitimate expectations and legal certainty.

30. At [47] the Hearing Officer said this:

> "There is no temporal restriction in the *Santen* judgment, and no previous case law in relation to SPCs establishing one. As set out in paragraph 18 of *Denkavit Italiana* it is for the CJEU alone to decide on the temporal restrictions. Given the clear power to do so by the body of case law built on *Denkavit Italiana*, the CJEU could have chosen to make a provision for a temporal restriction of the effect of *Santen* when it distanced itself from the earlier judgment of *Neurim*. It did not do so. This being the case I consider that it is clear that the CJEU intended *Santen*, which was a judgment before the UK left the European Union, to apply to matters arising and established before the judgment ruling and hence the CJEU did not set out any temporal restriction. Therefore, the *Santen* judgment must apply to all applications whenever they were made, i.e. it applies *ex tunc*."

31. At [48] the Hearing Officer acknowledged that the delay in processing Merck's application was unfortunate, but said that did not change the fact that *Santen* applied *ex tunc.* At [49] she referred to Merck's statements about the effort taken to bring MAVENCLAD to the market and the role that the *Neurim* decision played in its expectation that it would be granted an SPC. She referred to the fact that the Phase III trials had been commenced prior to the *Neurim* decision and expressed some doubt that the work done to bring MAVENCLAD to the market was done solely to obtain an SPC. (I address this aspect of her decision in more detail below.) The Hearing Officer also noted that *Elmeka* concerned a case where a legitimate expectation arose from the conduct of the administrative authorities, and that there was no suggestion that any authority had given Merck an expectation that an SPC would be granted before clinical trials started.

32. Finally, at [50], she said:

> "In any event, I have already concluded that I must regard the CJEU judgment in *Santen* as applying *ex tunc*. *Santen* clearly provides that a marketing authorisation cannot be considered the first marketing authorisation where it covers a new therapeutic application of the product. As I have noted above, there are two earlier marketing authorisations for cladribine and therefore, I conclude that the marketing authorisation for MAVENCLAD, on which the application relies, is not the first authorisation to place the product, cladribine, on the market as a medicinal product. Thus, the application does not satisfy the requirements of Article 3(d)."

Merck's appeal

33. The parties were agreed that the correct approach to an appeal of this nature was that set out by Joanna Smith J in *Axogen Corp v Aviv Scientific Ltd* [2022] EWHC 95 at [24]. The appeal is by way of review, and the appeal will be allowed if the

decision appealed from is "wrong", which includes an error of law. As will be seen below, the appeal does not turn on any findings of primary fact or multi-factorial assessments by the Hearing Officer.

34. Merck advances three grounds of appeal. It is convenient to take them in reverse order.

35. Ground 3 is that *Santen* was wrongly decided. Merck submits that the Regulation must allow for SPCs in respect of second medical use inventions, and relies on observations of the Court of Appeal in *Neurim* and of Arnold J in *Abraxis*, as well as of Advocate General Léger in *MIT* and Advocate General Trstenjak in *Neurim,* and passages in the Explanatory Memorandum. However, Merck recognises that the High Court has no power to hold that *Santen* was wrongly decided – only the Supreme Court or the Court of Appeal can decide to depart from *Santen* (see s.6 of the European Union (Withdrawal) Act 2018). It therefore reserves that ground of appeal to a higher court (if permission to appeal is granted).

36. Ground 2 is that the facts of this application can be distinguished from *Santen* and so *Santen* should not apply on the present facts. Specifically it is said that in *Santen* the application was based on a patent to a different dosage form of a known active ingredient, which included claims that covered use of the dosage form to treat uveitis (one indication covered by the previous MA), and an MA for indications that were "highly similar" to those in the previous MA, whereas in this case the new therapeutic use is entirely new.

37. As the Hearing Officer noted, such an argument was not run before her. Merck says that the point was reserved for argument in a higher court. This is an odd point to reserve, but the Comptroller did not object to it being run on this appeal.

38. This ground of appeal is easily disposed of. *Santen* is a ruling on the interpretation of Article 3(d) of the Regulation which is expressed in general terms. There is nothing to suggest that it is only applicable on its own facts, or on facts that are related to its facts to some degree. Further, it would have been possible to decide *Santen* on its own facts, for example by reference to the fact that the product was a new formulation of an old active ingredient or to the fact that the MA was not the first MA within the scope of protection of the basic patent. Instead, as is apparent from the opinion of the Advocate General and the judgment of the Court, the issue of whether to reverse the judgment in *Neurim* was squarely raised. The Court, taking the advice of the Advocate General, decided to do so. There is no basis for suggesting that *Santen* can be distinguished on the facts.

Merck's first ground of appeal

39. Ground 1 was Merck's principal argument before this court. Two strands of Merck's argument can be identified, though they were rather interwoven in the submissions. First, it contended that *Santen* should be understood as having *ex nunc* rather than *ex tunc* effect, or should be treated as such because of the expectations of those in the industry as to the continued application of the law as stated in *Neurim*. Secondly, it contended that its own circumstances gave rise to an individual expectation that it would be granted an SPC in accordance with the

law as stated in *Neurim* and that the UKIPO and this court should give effect to that expectation.

40. Before turning to consider the law, I should address the basis of the latter submission. Merck's representatives' letter to the examiner of 10 March 2022 included an overview of the clinical development of MAVENCLAD, explaining the history of the clinical trials program and the outcome of regulatory submissions. The Hearing Officer recited Merck's submissions relating to that history at [40], and included aspects of it in the chronology at [41] of her decision. In brief, Merck conducted three Phase III trials between 2005 and 2009, but the dossier which it submitted to the EMA in 2009 was rejected in 2010 for lack of long-term safety evidence. However, in 2010 certain trials in the multiple sclerosis field were still ongoing, and Merck committed to completing them, resulting by 2016 in the collection of long-term safety data. Discussions with the EMA revealed that it would consider approving cladribine for the treatment of highly active relapsing remitting multiple sclerosis. Merck therefore filed a further dossier in 2016. The EMA indicated that, in order to obtain an MA, Merck needed to commit to doing further Phase IV studies after grant of the MA. Merck agreed to do that and the MA was granted in August 2017.

41. Nothing in the summary of the clinical development of MAVENCLAD included with the letter of 10 March 2022, nor in the submissions of Merck recorded in [40] of the Hearing Officer's decision, suggests that Merck relied on its perceived ability to obtain an SPC pursuant to the *Neurim* decision in deciding to take the course that it did. However, it is plain that Merck submitted to the Hearing Officer that the *Neurim* decision did have some impact on it, as can be seen from [49] of the Hearing Officer's decision, where she said:

> "Mr Selmi presented a lot of information about the effort that the Applicant undertook to get MAVENCLAD on the market (thus making it, in the Applicant's view, a worthy candidate for SPC protection) and the role that the *Neurim* decision played in the Applicant's legitimate expectations that it would be entitled to the SPC. As the facts have been presented to me, the Phase III clinical trials commenced after the marketing authorisations for both LEUSTAT and LITAK had been granted and prior to the *Neurim* judgment in 2012. Thus, whilst I do not wish to downplay the large amount of work undertaken in bringing MAVENCLAD to market, I have some doubt that it was solely undertaken to obtain an SPC given that the clinical trials started prior to the *Neurim* judgment."

42. In its Grounds of Appeal, Merck criticised the Hearing Officer for having "some doubt" that Merck's work was done because of its expectation that it would be granted an SPC pursuant to *Neurim*. In its skeleton argument Merck said:

> "*Neurim* was crucial in the Appellant's decision not to abandon or shelve Mavenclad notwithstanding the erosion of exclusivity under the basic patent with every passing year, because of the legitimate expectation that once an MA was granted, it would be able to recoup the considerable investment, through the grant of an SPC."

43. No statement to this effect was contained in the written materials presented to the UKIPO, and there is no transcript of the hearing before the Hearing Officer, which led to a dispute between the parties at the hearing before me as to whether such a submission had been made to the Hearing Officer. Further, Mr Mitcheson KC, for Merck, added to this statement on instructions during the hearing before me, saying that once the dossier was rejected in 2010 *"work was wound down on this project and then it was picked up again only after the Neurim judgment had come out. So that is why we say we did rely on it and without the impetus of Neurim it may well be that this product would never have reached the market."*

44. I appreciate that, given the relative informality of the examination process, it was not thought necessary to set out the facts in a witness statement. Further, Ms Edwards-Stuart for the Comptroller indicated that no objection was being taken to the absence of formal evidence, and that the UKIPO was not in a position to dispute any facts asserted by Merck. However, it is unsatisfactory for a key aspect of Merck's case on legitimate expectations, namely its reliance on the *Neurim* decision, to emerge in oral submissions to the Hearing Officer and/or to me.

45. In the circumstances, I do not think that the Hearing Officer can be criticised for expressing herself in the way that she did in [49] of her decision. However, if she had been provided with the information presented to me, she may well have expressed herself differently. I am prepared to proceed on the basis that the facts are as stated in Merck's skeleton argument and oral submissions, namely that *Neurim* was crucial in Merck's decision to revive a programme that had been wound down, because it expected to be able to obtain an SPC.

46. At this point it is convenient to record that Mr Mitcheson informed me that whereas, at the date of the hearing before the Hearing Officer, SPCs had been granted in 18 countries (see [48] of the Hearing Officer's decision), that position had changed. He informed me that some of those SPCs had been granted on a basic patent that was a divisional of the patent relied on in Merck's application to the UKIPO and that those SPCs had fallen away when that divisional patent was revoked by the Technical Board of Appeal of the EPO in September 2023. He provided me with a table showing the current state of the SPC applications. Applications have been filed in 14 countries (including the UK) and remain pending in seven and have been granted in seven, of which four (Switzerland, Denmark, France and Sweden) have a system for examining applications (rather than granting them without examination). All seven SPCs were granted before the Court's decision in *Santen*.

47. Mr Mitcheson pointed out that the Comptroller's skeleton argument stated that the UKIPO aims to examine SPC applications within two years of filing. He said that, if the UKIPO had done that in this case, Merck would have obtained an SPC before the Court's judgment in *Santen* was handed down in July 2020. It is not clear that this is so. The Comptroller did not say that the UKIPO aimed to grant SPC applications within two years of filing. Further, Ms Edwards-Stuart informed me that the UKIPO would probably have stayed the examination process once the Advocate General's opinion in *Santen* was issued in January 2020. But in any event, the Comptroller's skeleton argument was merely setting out the UKIPO's aim, not a promise, and Ms Edwards-Stuart told me that it was an internal aim rather than a published one. Further, Merck did not suggest that it

had relied on any statement by the UKIPO as to the timing of processing of SPC applications.

48. In order to address Merck's submissions under Ground 1, it is first necessary to have in mind two matters: the Court of Justice's ability to reverse its earlier decisions and the limited circumstances in which its decisions are to be treated as *ex nunc* rather than *ex tunc*.

49. In advance of the hearing, I asked the parties if they could assist as to any statement regarding the Court of Justice's ability to depart from its previous decisions or examples of cases prior to *Santen* in which it had done so. Mr Mitcheson helpfully referred me to the statement of Advocate General Jacobs in his opinion in Case C-10/89 *Hag II* at [67] that:

> "The Court has consistently recognized its power to depart from previous decisions, as for example by making it clear that national courts may refer again questions on which the Court has already ruled: see [citations omitted] where the Court accepted that a 'materially identical question' could be referred again, and [citations omitted] where the Court expressly reconsidered a previous ruling. That the Court should in an appropriate case expressly overrule an earlier decision is I think an inescapable duty, even if the Court has never before expressly done so."

50. In *Hag II*, the Advocate General advised that the Court should abandon the doctrine of common origin which it had introduced in Case C-192/73 *Hag I*. In that case, the Court had ruled that it was incompatible with the rules on free movement to *"prohibit the marketing in one Member State of a product legally bearing a trade mark in another Member State for the sole reason that an identical trade mark, having the same origin, exists in the first State"*. In its judgment in *Hag II*, the Court stated that it was *"necessary to reconsider the interpretation given in [Hag I] in the light of the case law that has developed"* and held that it was lawful for a proprietor of a trade mark in one Member State to oppose the importation from another Member State of goods lawfully bearing a trade mark in that second State, even if the trade marks originally had a common origin.

51. So, while it may be rare for the Court of Justice to overturn one of its previous decisions, *Santen* is not without precedent, and the ability of the Court to do so has been recognised from an early stage of the development of its case law.

52. The ability of the Court to impose temporal limitations on the effects of its judgments was also recognised at an early stage. In Case C-43/75 *Defrenne* the Court was asked to consider whether Article 119 of the EEC Treaty, which concerned equal pay for equal work, had direct effect. The Court held that it did. However, it "exceptionally" took account of the fact that many undertakings had, for long periods, adopted practices which were contrary to Article 119. Therefore, it concluded:

> "74. In these circumstances, it is appropriate to determine that, as the general level at which pay would have been fixed cannot be known,

> important considerations of legal certainty affecting all the interests involved, both public and private, make it impossible in principle to reopen the question as regards the past.
>
> 75. Therefore, the direct effect of Article 119 cannot be relied on in order to support claims concerning pay periods prior to the date of this judgment, except as regards those workers who have already brought legal proceedings or made an equivalent claim."

53. In Case C-61/79 *Denkavit Italiana* the Court made it clear that the general rule was that its judgments applied *ex tunc*, and that only in exceptional cases was departure from that justified (emphasis added):

> "16. The interpretation which, in the exercise of the jurisdiction conferred upon it by Article 177, 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.
>
> 17. As the Court recognized in its judgment [in *Defrenne*], **it is only exceptionally that the Court may, in application of the general principle of legal certainty inherent in the Community legal order and in taking account of the serious effects which its judgment might have, as regards the past, on legal relationships established in good faith, be moved to restrict for any person concerned the opportunity of relying upon the provision as thus interpreted with a view to calling in question those legal relationships.**
>
> 18. **Such a restriction may, however, be allowed only in the actual judgment ruling upon the interpretation sought. The fundamental need for a general and uniform application of Community law implies that it is for the Court of Justice alone to decide upon the temporal restrictions to be placed on the interpretation which it lays down.**"

54. As can be seen, the Court identified the exceptional cases in which it may decide that its judgment is to be applied only *ex nunc* as being ones in which its judgment may have *"serious effects..., as regards the past, on legal relationships established in good faith"*. It also made it clear that it was for the Court alone to decide, in the judgment itself, whether any temporal restrictions were to be imposed.

55. The exceptional nature of the cases in which a judgment of the Court of Justice may be decided to have *ex nunc* effect was confirmed in Case C-441/14 *Dansk Industrie*. In that case the referring court asked, in essence, whether the principles of legal certainty and protection of legitimate expectations could take precedence

over Community law as interpreted by the Court. In response, the Court said that a national court could not rely on such principles to apply national law which was contrary to Community law. It continued:

> "39. Indeed, the application of the principle of the protection of legitimate expectations as contemplated by the referring court would, in practice, have the effect of limiting the temporal effects of the Court's interpretation because, as a result of that application, such an interpretation would be applicable in the main proceedings.
>
> 40. According to settled case-law, the interpretation which the Court, in the exercise of the jurisdiction conferred upon it by Article 267 TFEU, gives to EU law clarifies and, where necessary, defines the meaning and scope of that law as it must be, or ought to have been, understood and applied from the time of its coming into force. It follows that, unless there are truly exceptional circumstances, which is not claimed to be the case here, EU law as thus interpreted must be applied by the courts even to legal relationships which arose and were established before the judgment ruling on the request for interpretation, provided that in other respects the conditions for bringing a dispute relating to the application of that law before the courts having jurisdiction are satisfied."

56. As will be seen from the above, a legitimate expectation cannot override the *ex tunc* effect of a judgment. On the contrary, as is apparent from *Denkavit Italiana*, an *ex nunc* effect will only arise if the Court decides that the effect of its judgment would have *"serious effects..., as regards the past, on legal relationships established in good faith"* and decides to limit the temporal effect of its judgment in the judgment itself.

57. With that in mind, I turn to consider the Court's judgment in *Santen*. Mr Mitcheson argued that because the Court expressed itself in the present tense in [53] and [60] of its judgment, that indicated that the Court intended its judgment to have only prospective effect. I do not agree. The use of such language by the Court is unremarkable and is of a type commonly used when it interprets a provision. In any event, the Court (sitting as a Grand Chamber of 15 judges) can hardly have been unaware of its case law regarding the requirement for any limited temporal effect to be stated in its judgment. Given that it was reversing its own decision in *Neurim*, if it had intended *Neurim* to continue to apply to applications made before its judgment it would have said so.

58. Indeed, in my judgment it is plain that it did not intend that consequence. If the judgment was only to apply *ex nunc* then it would not have applied to Santen's application. The referring court had asked a number of questions which, if *Neurim* was not being reversed, needed to be answered to enable it to determine Santen's application. The Advocate General had proposed answers to those questions in the event that *Neurim* was not to be reversed. The Court wanted to provide a "useful answer" to the referring court. If the Court had intended its judgment to apply only *ex nunc* then it would surely have answered the referring court's questions rather than saying that the premise of its questions must be disregarded.

59. I therefore agree with the Hearing Officer that the *Santen* judgment applies *ex tunc*.

60. Mr Mitcheson also said that the expectations of those in the industry as to the continuation of the law should be taken into account, and submitted that the courts of this jurisdiction were entitled to do so and to decide that a temporal restriction on the application of the *Santen* judgment should be imposed.

61. He referred me to the judgment of the Swiss Federal Supreme Court of 11 June 2018 in case 4A_576/2017. In that case, the court explained that the Swiss courts had previously adopted what it called the "infringement theory" for compliance with Article 140(b) of the Swiss Patents Act. However, the case law of the Court of Justice had adopted a different test for compliance with Article 3(a) of the Regulation, which the Swiss court called the "disclosure theory". In section 2 of its judgment, the court considered whether it should change the Swiss case law so that it conformed to that of the Court of Justice in that regard, and concluded that it should. In section 3 of its judgment it considered whether that change in the law should apply retrospectively. It considered various articles of the Swiss Civil Code and decisions of the Swiss courts, and then considered the balance between the interests of those who had obtained SPCs under the previous case law and the public interest. It concluded that retrospective application of its change in the case law was not justified.

62. In my judgment this decision does not assist Merck. The Swiss courts are not bound to follow decisions of the Court of Justice as the courts of this jurisdiction are (in the case of decisions before exit day and subject to the ability of the Court of Appeal and the Supreme Court to depart from such decisions). The Swiss court was free to decide to continue to apply the "infringement theory" or to replace it with the "disclosure theory" and, in the latter case, to do so only prospectively or also retrospectively. Further, this provides an example of a court with the power to impose temporal limitations on the effects of its judgments deciding to do so, taking into account the interests of those concerned. It does not support the proposition that a court which is bound by the decision of a higher court can impose a temporal restriction which the higher court has not seen fit to impose. In my judgment it is clear from *Denkavit Italiana* that only the Court of Justice has the power to impose a temporal limitation on the effects of its own judgments. It did not do so in *Santen* and it is not open to this court to decide to impose one.

63. Mr Mitcheson also referred me to the statement of the Enlarged Board of Appeal of the EPO in G9/93:

> "6.1 In principle, any interpretation of the EPC by the Enlarged Board implies that the law has always been in conformity with that interpretation. However, on purely procedural issues there may be reasons of equity for not applying to pending cases the law as thus interpreted. In cases currently pending before the EPO and relying on decision G1/84, which has now been followed for many years, obviously patent proprietors had every reason to expect that self-opposition would be considered admissible. In the present Board's opinion, it would be inequitable now to prevent them from continuing proceedings they embarked on in good faith and which cannot adversely affect the rights of any third party. Its ruling that, contrary to the

> earlier interpretation of the EPC, self-opposition is inadmissible, should therefore not be applied to notices of opposition filed before publication of the present decision."

64. I cannot see how this assists Merck. At most it provides a further example of the highest tribunal in a system recognising that it may be appropriate for its decisions to apply *ex nunc* and deciding to impose a temporal restriction in a particular case. Further, the Enlarged Board indicated that such restrictions should only apply in purely procedural matters. That is confirmed by the extracts from section III.A of the Case Law of the Boards of Appeal of the EPO with which I was provided. Section III.A.2.1 makes it clear that:

> "The principle of legitimate expectations only protects parties from disadvantageous procedural consequences of the omission of procedural steps, in relying on erroneous information from the EPO. It has no bearing on substantive law and cannot render patentable what otherwise would not be."

65. Further, section III.A.2.2.2 states:

> "In G2/07 and G1/08 the Enlarged Board of Appeal held that there could be no "legitimate expectation" that an interpretation of a substantive provision governing patentability given in a decision of the boards of appeal will not be overruled in the future by the Enlarged Board, since recognising such an expectation as legitimate would undermine the function of the Enlarged Board."

66. This echoes the statement of the Court of Justice in *Dansk Industrie* at [39]. If an expectation that the interpretation of substantive law will remain the same (despite the ability of the courts to change their interpretation of the law) is elevated to a right to have the law interpreted as it had previously been, then that will have the effect of creating a temporal limitation on the effects of a judgment when the court with the power to impose such a temporal limitation had decided not to do so.

67. In advance of the hearing I asked the parties whether they were able to assist me with any authorities considering temporal limitation of the effects of judgments of the UK courts which reverse the effects of earlier judgments (e.g. where the House of Lords / Supreme Court has reversed one of its earlier decisions under the Practice Statement (Judicial Precedent) 1966 or where the Court of Appeal has reversed one of its earlier decisions under one of the exceptions to the rule in *Young v Bristol Aeroplane*) and in particular which consider the role of legitimate expectations in such circumstances.

68. Merck responded to that request by referring me to two decisions of the Supreme Court (*Henderson v Dorset* [2020] UKSC 43 and *Peninsula v Dunnes* [2020] UKSC 36) in which the Supreme Court addressed the circumstances in which it will depart from one of its previous decisions (or one of the House of Lords) under the Practice Statement of 1966, and to lectures by Lady Rose and Lord Reed in which they comment on that topic. Those observations emphasise what the

Practice Statement of 1966 itself says, namely that judicial precedent *"provides at least some degree of certainty upon which individuals can rely in the conduct of their affairs"* and so, when considering whether to depart from a previous decision, the court *"will bear in mind the danger of disturbing retrospectively the basis on which contracts, settlement of property, and fiscal arrangements have been entered into"*.

69. However, that does not mean that if the Supreme Court decides, having considered such matters, to depart from a previous decision, those who are adversely affected are entitled to ask the courts to treat them as if the change had not been made, on the basis of an expectation that the law would remain unchanged. Merck indicated that it had not been able to find any authorities dealing with such a submission. Of course, it could be said that the absence of such authorities is because the Supreme Court rarely departs from one of its previous decisions. But, as Mr Mitcheson pointed out, there are decisions of the Supreme Court which do not strictly engage the Practice Statement of 1966 but nevertheless effect a change in the law – the decision in *Actavis v Lilly* [2017] UKSC 48 is a prominent one which retrospectively affected many businesses. Further, the Court of Appeal can, and sometimes does, depart from its previous decisions. If a party adversely affected by a change in the interpretation of the law by the courts could say that the change should not apply to it because it had relied on the law as it previously stood, one would have expected to see numerous cases addressing such submissions.

70. It is striking that no authority has been identified by Merck to support the proposition that a party can avoid the effects of a change in the interpretation of substantive law which is not expressed to be *ex nunc* by showing that it acted on the basis of the previous interpretation of the law. In any event, in the case of a decision of the Court of Justice made before exit day, *Dansk Industrie* stands in the way of such a submission.

71. Merck relied on Cases C-181/04 to C-183/04 *Elmeka*. In that case Elmeka asked the relevant tax authority whether it was obliged to charge VAT on certain bills of lading. The tax authority told Elmeka that the bills of lading were exempt from VAT. Elmeka therefore did not charge VAT on the bills of lading. The tax authority later took the view that the bills of lading were not exempt from VAT and sought to recover from Elmeka the VAT which was chargeable on the bills of lading. The first two questions referred to the Court of Justice addressed the question of whether the bills of lading were exempt from VAT; the Court's answers indicated that they were not.

72. The third question was characterised by the Court as, in essence, whether *"conduct of the national tax authority authorising a taxable person not to pass on VAT to the other party to a contract can, even if that conduct is unlawful, give rise to a legitimate expectation on the part of the taxable person that would preclude subsequent payment of the tax."* In its response to that question the Court said this:

> "31. Under the settled case-law of the Court, the principles of protection of legitimate expectations and legal certainty form part of the Community legal order. On that basis, these principles must be respected by the

> institutions of the Community, but also by Member States in the exercise of the powers conferred on them by Community directives [citations omitted]. It follows that national authorities are obliged to respect the principle of protection of the legitimate expectations of economic agents.
>
> 32. As regards the principle of protection of the legitimate expectations of the beneficiary of the favourable conduct, it is appropriate, first, to determine whether the conduct of the administrative authorities gave rise to a reasonable expectation in the mind of a reasonably prudent economic agent [citations omitted]. If it did, the legitimate nature of this expectation must then be established.
>
> …
>
> 35. In that respect, it falls to the national court to decide whether Elmeka…could reasonably have believed that the tax authority…was competent to rule on the application of the exemption to its activities."

73. Elmeka's position was, in effect, that it would be inequitable for the tax authority to be able to demand payment of VAT that should have been charged on the bills of lading in circumstances where the tax authority had told Elmeka that VAT should not be charged and Elmeka had relied on that representation by not charging VAT, with the consequence that it did not have the money to pass on to the tax authority when it was later demanded. The Court recognised that representations of a competent authority could give rise to a legitimate expectation that payment of VAT would not be demanded; whether they did so was for the national court to decide.

74. I cannot see how this has any relationship to the present case. There has been no representation by any authority upon which Merck could reasonably and legitimately have relied. The courts (either of this jurisdiction or the EU) have never represented that their interpretation of the law will not change. Nor has the UKIPO made any representation that could reasonably have led Merck to believe that it would grant Merck an SPC. On the contrary, the UKIPO will, of course, seek to apply the law as it stands at any given time.

75. Moreover, this is not a case where the expectation relied on concerns only whether a tax authority will demand payment of certain taxes (which has only a *de minimis* impact on third parties). Here, Merck contends that it should be granted a property right which would (if valid) preclude third parties from marketing a generic version of MAVENCLAD for up to five years. Further, the scheme of the Regulation is that the UKIPO shall refuse to grant an SPC if it does not meet the requirements of Article 3(d) (see Article 10(2)), and the SPC is invalid (and can be declared invalid at the suit of any person) if it does not meet the requirements of Article 3(d) (see Article 15). Following the Court of Justice's decision in *Santen* (and subject to Grounds 2 and 3 of Merck's appeal and its contention that *Santen* only operates *ex nunc*) an SPC on Merck's application would not meet the requirements of Article 3(d). How then can the UKIPO grant it given its obligation under Article 10(2), and what would be the position if it did?

76. I asked Mr Mitcheson whether Merck was merely contending that, as a result of its reliance on *Neurim*, it had a right to be granted an SPC which would be subject to any change in the law (so that what would be granted now would be a nullity) or whether it was contending that it had the right to be granted an SPC which would be treated as if the law was as it stood under *Neurim* (and so would be valid). Ms Edwards-Stuart raised effectively the same question in her submissions. Mr Mitcheson's response, ultimately, was that Merck's position was that it was entitled to be granted an SPC but:

> "If there was a third party coming along tomorrow to seek to revoke the SPC based on Santen, then because the situation is different, because it is no longer a relationship with a public body, it is a relationship with a third party, a dispute, because no doubt that third party would have its own legitimate expectations, perhaps based on its own understanding of Santen or whatever position it took; then we accept that the shield that we say is a good enough shield to get a grant in this case before you, may not be sufficient to overcome the attack, any attack that might be made by the third party on validity based on Santen on their own expectations or whatever other points they might have come with. There might be another aspect that they could think of. So, I am not standing here saying that this is a shield forever against everybody under 3(d)."

77. To my mind this illustrates the problem with Merck's contention. The question of validity of an SPC granted on Merck's application will, apparently, not turn on the provisions of the Regulation as interpreted by the courts, but on a battle of legitimate expectations between Merck and whoever the challenger turns out to be. That cannot be right.

78. In my judgment, Merck's expectation that it would be granted an SPC based on *Neurim*, and its reliance on that when deciding to revive its development program, cannot give rise to a right to be granted an SPC if the judgment of the Court of Justice in *Santen* operates *ex tunc*, as I have held it does.

79. I agree with the Hearing Officer that Merck's application does not satisfy the requirements of Article 3(d) applying the Court of Justice's judgment in *Santen* and that therefore Article 10(2) prevents the UKIPO from granting an SPC on Merck's application. I therefore dismiss Merck's appeal.