



**COUNCIL REGULATION (EC) 469/2009
CONCERNING THE CREATION OF A
SUPPLEMENTARY PROTECTION CERTIFICATE
FOR MEDICINAL PRODUCTS**

APPLICANT Merck Serono S.A.

ISSUE Whether application for supplementary protection certificate SPC/GB18/007 meets the requirements of Article 3(d) of the SPC Regulation

HEARING OFFICER Mrs M Taylor

DECISION

Background

- 1 This decision relates to the issue of whether the application, SPC/GB18/007, meets the requirements of Article 3(d) of Council Regulation (EC) No 469/2009 (“the SPC Regulation”), filed in the name of Merck Serono SA. (“the Applicant”).¹
- 2 This Supplementary Protection Certificate (“SPC”) application was filed on 12 February 2018 and relies on basic patent EP(UK) EP1827461 B1, entitled “cladribine regimen for treating multiple sclerosis”, and on centralised European marketing authorisation EU/1/17/1212, covering the medicinal product MAVENCLAD^{®2} indicated for the treatment of highly active relapsing multiple sclerosis. The marketing authorisation for MAVENCLAD was granted following Commission Implementing Decision C(2017)5888 of 22 August 2017.
- 3 The product that is the subject of this SPC application is identified on the associated form SP1 as simply “cladribine”.
- 4 Cladribine, as LEUSTAT[®] and LITAK[®], had previously been the subject of two marketing authorisations, both for the treatment of hairy cell leukaemia. A UK marketing authorisation (PL 00242/0232) for LEUSTAT[®] was granted on 3 February

¹ This decision relates to a SPC that was applied for in 2018. Thus, it relates to the period when the UK was part of the European Union prior to its withdrawal on 31 December 2020. As such, it is necessary to apply the relevant law that was in force at that time in the UK. This is set out in the decision below.

² MAVENCLAD is a registered trade mark. For brevity it will be reproduced as MAVENCLAD throughout this decision.

1995, while a centralised European marketing authorisation (EU/1/04/275) was granted for LITAK® on 14 April 2004.

- 5 Throughout the examination process, the examiner dealing with this application has maintained the view that the Applicant's marketing authorisation is not the first marketing authorisation for the product, cladribine, and the application is contrary to Article 3(d) of the SPC Regulation.
- 6 Following several rounds of correspondence, the matter came before me at a hearing on 8 March 2023, which took place by videoconference. At the hearing, the applicant was represented by Daniel Selmi, of Three New Square IP, with Darren Smyth, Instructing Partner at EIP and Matthias Dotzauer, Senior Patent Counsel at Merck also attending. Senior examiner Simon Grand acted as Hearing Assistant for the Hearing Officer.
- 7 Prior to the hearing I raised two authorities on which I wished to be addressed, and I am grateful to the Applicant for their full list of authorities and detailed skeleton arguments in response, and to Mr Selmi for clearly setting out of the case law during the hearing. In discussing the law below, I have drawn heavily on the information provided.

The Basic Patent

- 8 The basic patent, EP(UK) EP1827461 B1, entitled "cladribine regimen for treating multiple sclerosis", was filed on 20 December 2005, with an earliest priority date of 22 December 2004, and was granted on 29 February 2012. The expiry date of the patent is 19 December 2025.

The Law

- 9 The SPC Regulation provides a patent-like right extending the period of exclusivity in the pharmaceutical field. The period of the extension is determined in relation to the dates of grant of the basic patent and the appropriate marketing authorisation, with a maximum period of five years following expiry of the basic patent.
- 10 Article 1 of the SPC Regulation defines various terms, of which Articles 1(a) to 1(d) are relevant to this decision and are reproduced below:

Article 1

Definitions

For the purposes of this Regulation, the following definitions apply:

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

(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

(c) 'basic patent' means a patent which protects a product as 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;

(e) ...

- 11 Article 3 of the SPC Regulation (at the time of filing the application) concerns the conditions for obtaining an SPC; part (d) of this Article makes it clear that a certificate cannot be obtained if the product authorisation to place the medicinal product including this product onto the market in the EU is not the first authorisation (my emphasis added in bold):

Article 3

Conditions for obtaining a certificate

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

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or, 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.”

- 12 For applications still pending as of 1 January 2021, a transitional form of Article 3(d) reads:

(d) the authorisation referred to in point (b) is the first UK authorisation to place the product on the market as a medicinal product.

Relevant SPC case law from the CJEU³

³ Following the entrance into force of the Treaty of Lisbon on 1 December 2009, the European Court of Justice's official name was changed from the "Court of Justice of the European Communities" to the "Court of Justice" although in English it is still most common to refer to the Court as the European Court of Justice. The Court of First Instance was renamed as the "General Court", and the term "Court of Justice of the European Union" (CJEU) now officially designates the two courts, along with its specialised tribunals. For simplicity CJEU will be used in this decision regardless of whether the judgment referred to was pre-or post-2009.

13 The intended meaning of the term ‘product’ for the purposes of Article 1(b) of the SPC Regulation, which affects what is interpreted as the first authorisation under Article 3(d), has been the subject of a number of referrals to the CJEU since this Regulation’s introduction.

14 In case C-31/03 *Pharmacia Italia*, in relation to the purpose of the protection, the CJEU said:

“20 The decisive factor for the grant of the certificate is not the intended use of the medicinal product and, second, that 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.”

15 In case C-431/04 *Massachusetts Institute of Technology* the CJEU rejected the idea that the product for the purpose of Article 1(b) could include a combination of an active ingredient and an excipient and said:

“31 “Article 1(b) of Regulation No 1768/92 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.”

16 In C-202/05 *Yissum Research & Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents (“Yissum”)* at paragraphs 16-20 the CJEU stated:

“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.

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’.

18 It follows that the concept of ‘product’ cannot include the therapeutic use of an active ingredient protected by a basic patent.

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.”

- 17 On 19 July 2012 in C-130/11, *Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents (“Neurim”)* the CJEU stated (my emphasis):

“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.**”

- 18 In C-443/17 *Abraxis Bioscience LLC v Comptroller General of Patents (“Abraxis”)* the CJEU prohibited the grant of a certificate in the case of a new formulation:

“40 Consequently, an MA granted for a new formulation of an old active ingredient, such as nab-paclitaxel, cannot be regarded as being the first MA granted for that product as a medicinal product within the meaning of Article 3(d) of Regulation No 469/2009, when that active ingredient has already been the subject of an MA.

41 The case-law arising from the judgment of 19 July 2012, *Neurim Pharmaceuticals (1991) (C-130/11, EU:C:2012:489)* 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.”

- 19 The appropriate interpretation of Article 3(d) was again considered by the CJEU with the Grand Chamber of the CJEU decision in C-673/18, *Santen SAS v Directeur-General de l'Institut National de la Propriété Industrielle (INPI)* (“*Santen*”) in 2020 where it was stated at paragraph 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.”

And at paragraph 61 (my emphasis):

“61 In the light of all the foregoing, the answer to the questions referred is that Article 3(d) of Regulation No 469/2009 must be interpreted as meaning that **an MA cannot be considered to be the first MA, 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 an MA for a different therapeutic application.**”

Relevant case law related to temporal effect

- 20 During processing of this application before the examiner, in the skeleton arguments and during the hearing there have been a number of discussions about the temporal effect of CJEU judgments and in particular whether or not they are considered to have effect *ex tunc*, meaning that they apply to applications before the relevant CJEU decision, or whether the CJEU decisions are considered to have effect *ex nunc*, meaning that they only apply to applications after the date of the relevant CJEU decision. There have been a number of CJEU cases considering the issue of temporal effect.
- 21 In C-43/75 *Defrenne v Sabena* the CJEU limited the temporal effects of its judgment so that it only applied *ex nunc*, at paragraph 74 the CJEU stated:

“important considerations of legal certainty affecting all the interests involved, both public and private, make it impossible in principle to reopen [the question at issue in that case] as regards the past”.

- 22 In Case 61/79 *Amministrazione Delle Finanze Dello Stato v Denkavit Italiana SRL* (“*Denkavit Italiana*”) the CJEU set out the general principle that CJEU judgments have *ex tunc* effect and set out when a temporal restriction could apply meaning that the judgment would have *ex nunc* effect (my emphasis):

“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 of 8 April 1976 in Case 43/75, *Gabrielle Defrenne v Société Anonyme Belge de Navigation Aérienne Sabena* [1976] ECR 455, 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.”

23 In a later case C-441/14 *Dansk Industri v Estate of Karsten Eigil Rasmussen* (“*Dansk Industri*”) the CJEU dealt with the inter-relationship between EU case law, national law and general principles prohibiting discrimination and considered temporal effect in some depth saying (my emphasis):

“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”.

24 C-181/04 to C-183-04 *Elmeke NE v Ipourgos Ikonomikon* (“*Elmeke*”) was a case relating to a local tax authority in Greece providing information to *Elmeke*, a shipping company, stating that some of their services were exempt from VAT. The company adhered to that statement and did not pass on the tax to the government. It was subsequently decided by both the national courts and the CJEU that, when interpreting the provisions of Greece’s national tax code consistently with the VAT Directive, those services were not exempt from VAT and so the information provided by the local tax

authority was wrong. Against that background, the Greek national court referred three questions to the CJEU, the last of which related to legitimate expectations. In answering the third question the Court stated (my emphasis):

“26 In its third question, the referring court asks in essence whether, **under the rules and principles of Community law on VAT**, conduct of the national tax authority authorising a taxable person not to pass on the 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.

27 According to the Commission, the principle of protection of legitimate expectations does not permit subsequent payment of VAT that the taxable person did not pass on to the other party to a contract during the tax years in question, and which he did not pay to the tax authority, to be required where the conduct of the latter over a number of years has reasonably led that taxable person to believe that he was not obliged to pass on that tax. At the hearing, however, the Commission added that the fact that the information had not been communicated by the competent tax authority might lead to a different conclusion.

...
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** (see in particular Case C-381/97 Belgocodex [1998] ECR I-8153, paragraph 26, and Case C-376/02 'Goed Wonen' [2005] ECR I-3445, paragraph 32). **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** (see, to that effect, Joined Cases 95/74 to 98/74, 15/75 and 100/75 Union nationale des coopératives agricoles de céréales and Others v Commission and Council [1975] ECR 1615, paragraphs 43 to 45, and Case 78/77 Lührs [1978] ECR 169, paragraph 6). 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 *Elmek*, which operates a tanker to carry petroleum products within Greece on behalf of various charterers, could reasonably have believed that the tax authority of Piraeus was competent to rule on the application of the exemption to its activities.

36 In the light of those observations the answer to the third question must be **that in the framework of the common system of VAT, national tax**

authorities are obliged to respect the principle of protection of legitimate expectations. It falls to the referring court to decide whether, in the circumstances of the main proceedings, the taxable person could reasonably have believed that the decision in question had been taken by a competent authority.”

The Examiner’s view

- 25 The examiner is of the view that the marketing authorisation filed in support of the application does not meet the requirements of Article 3(d) of the Regulation.
- 26 In the examiner’s pre-hearing report dated 1 November 2022 they note that the Applicant does not dispute that the product for which protection is being sought in this application, “cladribine”, has previously received marketing authorisations in the UK and EU. The examiner set out that in *Santen* the CJEU made clear that a marketing authorisation cannot be considered to be the first marketing authorisation where the active ingredient or combination of active ingredients has already been the subject of an earlier marketing authorisation for a different therapeutic application. The examiner objects to the application on the basis that the marketing authorisation for the medicinal product MAVENCLAD is not the first marketing authorisation to place the product (cladribine) on the market and thus the application does not meet the requirements of Article 3(d).

The Applicant’s view

- 27 At the hearing, Mr Selmi was clear that the Applicant does not dispute that the application should be refused if *Santen* is the operative judgment but said that *Neurim* should be applied and therefore the application should be granted. Mr Selmi explained that the question is whether *Santen* needs to be applied retrospectively or whether *Neurim*, the earlier judgment of the CJEU, should be regarded as the operative judgment as this was the case law relevant to Article 3(d) when the application was filed.
- 28 At the hearing Mr Selmi set out the Applicant's position. The Applicant filed the SPC application in respect of MAVENCLAD in 2018. The Applicant has a basic patent relating to the use of MAVENCLAD in the treatment of multiple sclerosis and a marketing authorisation in respect of the same. The examiner objected to the SPC application for the first time in September 2021 relying on the decision in *Santen* as cladribine, the active ingredient, was formerly the subject of a marketing authorisation for an entirely different indication, hairy cell leukaemia. The Applicant understands that the 3.5 years between application and refusal was due to the large volume of applications that the office had to deal with at that time. The Applicant's central point is that when they filed the application the governing law in respect of second medical use SPCs was *Neurim* which expressly ruled that SPCs are available for new therapeutic uses. Mr Selmi stressed that that was a significant operative reason why the Applicant went to the time, effort and expense of undertaking multiple phase III clinical trials and associated development work in order to get a marketing authorisation for MAVENCLAD. It was contended in the skeleton that it may be thought that there is something very wrong with a judgment retrospectively depriving the Applicant of protection under the SPC Regulation, in circumstances where the Applicant undertook the development of MAVENCLAD with the legitimate expectation

that it would be entitled to such protection (because that was the law at the time), and where the refusal would stifle large areas of pharmaceutical research.

- 29 Thus, Mr Selmi stated that the question for the hearing is “is there any basis in law for the UKIPO not to apply *Santen* because of my client's legitimate expectation that it was entitled to an SPC when it filed the application because the governing law as it then stood was *Neurim?*”, with the Applicant contending that the short answer to this should be yes. Both in the skeleton and at the hearing, Mr Selmi argued that *Santen* should not (and must not) be applied on the facts of this case. In doing so the development of the relevant law in respect of the SPC Regulation from the early 2000s to the present day was helpfully presented, before addressing the law on the limitation of the temporal effects of judgments and legitimate expectation, and then considering the facts of this particular application.
- 30 At the hearing Mr Selmi went through the relevant case law related to SPCs from 2004 to 2012: C-31/03 *Pharmacia Italia*, C-431/04 *MIT* and C-202/05 *Yissum*. Mr Selmi set out the UK comments in *Neurim Pharmaceuticals (1991) v The Comptroller General of Patents* [2011] EWCA Civ 228 where, Jacob LJ (giving the judgment of the Court of Appeal) disagreed with Arnold J's decision in the lower court and made a reference to the CJEU, saying at paragraphs 28-30 (Mr Selmi's **emphasis** added):

“Why we are referring

28 We consider that Neurim's arguments are not only tenable: in our view they are right. **Many kinds of valuable pharmaceutical research will not get the encouragement or reward they deserve if they are not.** Pharmaceutical research is not confined to looking for new active compounds. New formulations of old active substances are often sought. Most are unpatentable but from time to time a real invention is made and patented.

29 Moreover there is much endeavour to find new uses for known active ingredients. The European Patent Convention 2000 has indeed made the patenting of inventions in this area clearer. Its effect is that a patent for a known substance or composition for use in a method of treatment is not to be regarded as old (and hence unpatentable) unless use for that method is known. It would be most unfortunate if second medical use patents could not get the benefit of an SPC.

30 In short, if Neurim are wrong, then the Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose. Whether that is so or not is clearly a matter for the EU's highest court.”

- 31 Mr Selmi explained that in his view this was the beginning of a decisive change in attitude to SPCs for new therapeutic uses when in *Neurim* the CJEU allowed an SPC based upon a second marketing authorisation for the same product and subsequently when that decision was considered by the UK Courts in *Abraxis Bioscience LLC v The Comptroller General of Patents* [2017] EWHC 14 (Pat), In that decision Arnold J stated at paragraph 63 “paragraphs 11 and 12 of the Explanatory Memorandum appear to indicate that SPCs should be available for new applications (i.e. new therapeutic uses) of old ingredient, but not for new formulations.” Mr Selmi set out that in *Abraxis* the CJEU distinguished *Neurim* from the facts of *Abraxis*, maintaining *Neurim*, but

endorsing *Neurim* as a limited exception; a limited exception, but nonetheless one that the Applicant wished to rely on to mean that *Neurim* applied to their SPC application.

- 32 The final SPC related CJEU case law which Mr Selmi dealt with was *Santen*, where the CJEU explicitly stated that their judgment was contrary to *Neurim* and refused an SPC for a new therapeutic application. Mr Selmi stressed that in 2018, when the Applicant filed their SPC application for a new therapeutic use, the Applicant had a legitimate expectation that it would be entitled to an SPC for this new therapeutic use on the back of Lord Justice Jacob's reasoning in *Neurim*, the CJEU's reasoning in *Neurim*, Mr Justice Arnold's reasoning in *Abraxis* and the CJEU's own later reasoning in *Abraxis* where the CJEU confirmed that SPCs could be granted for new uses of an active ingredient even if they could not be granted for new formulations.
- 33 Finally, in relation to SPC case law, Mr Selmi noted, "in the space of only 8 years" the CJEU overruled its own earlier decision in *Neurim* which was also in respect of Article 3(d) of the SPC Regulation, having one year earlier affirmed the previous decision in *Abraxis*. Mr Selmi suggested that this is completely unprecedented and could not have anticipated by the applicant or anyone else. He suggested that it would be absurd to require a company to act based on the law as it might become rather than based on the law as it is when an application is filed.
- 34 Mr Selmi then turned to the temporal effect of CJEU caselaw and it was to explore this issue that prior to the hearing I had asked for comments on two CJEU judgments in this area: Case 61/79 *Denkavit Italiana* and Case C-441/14 *Dansk Industri*. Mr Selmi helpfully discussed these cases (with reference also to C-43/75 *Defrenne v Sabena*) and drew my attention to Case C-181/04 *Elmeka*.
- 35 Mr Selmi paraphrased the three requirements listed *Denkavit Italiana* for when rulings exceptionally may have *ex nunc* effect as:
 - a. First, the case must concern legal relationships established "in good faith";
 - b. Second, there must be a risk of "serious effects" (or later, "serious difficulties"); and
 - c. Third, as a procedural limitation, only the CJEU itself was said to be allowed to limit the temporal effects of a judgment.
- 36 Mr Selmi noted that it is important to understand the context of that procedural limitation in c. above and that the Court in *Denkavit Italiana* connected the *ex tunc* effect of preliminary rulings to direct effect. At para 14, *Denkavit Italiana* emphasised that the rules of EU law must be "fully and uniformly applied in all the Member States from the date of their entry into force and for so long as they continue in force". Since preliminary rulings were the vehicle through which uniform interpretation and application of EU law were to be ensured (for those provisions to have direct effect), Mr Selmi said it was completely understandable that the reasoning of the *ex tunc* effect of the CJEU's judgments and the effectiveness of EU law were inter-related.
- 37 At the hearing Mr Selmi emphasised that there is no issue here of direct effect of primary EU legislation arguing that if the Comptroller does not apply *Santen* retrospectively on the facts of this one application, it would have no bearing on the

general applicability of *Santen* or on the primacy of any retained law, much less its impact on the rights and obligations as between the UK and any individuals. Instead, explained Mr Selmi, the facts of this case are different, and the issue comes down to the Applicant's legitimate expectations and how that relates to the retrospective effect of CJEU decisions.

- 38 Mr Selmi then discussed *Dansk Industri*. Mr Selmi pointed out that whilst that judgement does address temporal restriction it does not mean that national tribunals and courts cannot apply the principle of legitimate expectations because to do so would undermine the *ex tunc* effect of CJEU judgments, meaning that the principles established in the Court of Justice judgment in *Denkavit Italiana* remain valid for the CJEU.
- 39 In summarising *Elmeka*, Mr Selmi said that the incorrect information provided by the tax authority gave rise to a legitimate expectation that was protected under EU law even though that meant that the interpretation of the VAT directive in that judgment would not have retrospective effect. During the hearing Mr Selmi said that *Elmeka* opened up the whole issue of *ex nunc* and *ex tunc* effect and was not simply a limited situation where the CJEU were merely asking the national court to make a finding of fact. To back this up he referred to paragraph 32 of the judgment where it said "as regards the principle of the protection of the legitimate expectations..., it is appropriate first to determine whether the conduct ... gave rise to a reasonable expectation." Mr Selmi argued that that would apply generally when any national authority or body is considering legitimate expectations. He went on to suggest that it would be odd if a party says I have a legitimate expectation on the facts that that matter then needs to be referred to the CJEU, who says you may have a legitimate expectation and then refers it back to the national authority to decide. He argued there would be no reason for that step. National authorities could say a party has asserted their legitimate expectations. He suggested, authorities like *Elmeka* would allow me to disapply otherwise binding case law. Mr Selmi drew my attention to paragraph 31 of *Elmeka* where it set out that the principles of protection of legitimate expectations and legal certainty form part of Community legal order and must be respected "by Member States in exercise of the powers conferred on them." He asserted that these should be applied every time a tribunal or a court makes a decision and that an applicant's legitimate expectations should be considered without returning to the CJEU for a decision.
- 40 Mr Selmi asked "With that legal background in mind, where does that leave the SPC application?" and went on to clearly and helpfully reiterate the very extensive development work that the Applicant had undertaken to get a marketing authorisation for MAVENCLAD, secure in the knowledge and with the legitimate expectation that it would be able to recoup the massive investment by getting an SPC, and in addition summarised the Applicant's position:

"This is what that investment entailed. The patent application that serves as a basic patent was filed in 2005. Between 2005 and 2009, there were three pivotal phase three clinical trials with over 2800 patients enrolled. The resulting MA dossier filed with the EMA in 2009 consists of over 1100 documents making up nearly 308,000 pages. That was rejected so that the Applicant had to undertake longer term safety trials.

“By 2016, the development programme of MAVENCLAD had resulted in a characterisation of its long term safety profile, which included up to 10 years follow-up in some patients and more than 12,000 patient years of follow-up overall. Following a later consultation with the EMA in 2016, the EMA considered approving cladribine for the treatment of relapse, remitting multiple sclerosis, essentially limiting the MA to a narrow and very sick patient collective, where the risk to reward was justifiable. The Applicant therefore compiled a second MA dossier incorporating all clinical data consisting of a revised set of over 1100 documents and 206,000 pages, and filed it with the EMA. It became clear from the EMA’s feedback that the EMA would consider granting an MA when the Applicant committed to doing additional phase IV clinical and safety studies subsequent to obtaining EU authorisation and that imposed following up well over 4000 patients treated with MAVENCLAD for up to 10 years to create even more long term safety data on top of the approximately 12,000 patient years of safety data that already been created when filing the first and second dossiers and MAVENCLAD finally received marketing approval on the 22nd of August 2017.”

....

“[B]y way of secondary considerations...just to show what a ground-breaking drug MAVENCLAD is, and all the more reason why it deserves protection, the dosing of MAVENCLAD means that patients only need to take 40 tablets or so in four years as opposed to over 1000 or even thousands of pills for competitor products. So it is a paradigm example of a drug that deserves protection, and my client is entitled to recoup its very considerable investment in respect to the same.”

Analysis

- 41 During the hearing the Applicant has set out a number of relevant marketing authorisations, judgments and steps they have undertaken. I think it is helpful to put these alongside the relevant dates of the application and the basic patent:

Decision	Relevant Date	Application-related events
	3 February 1995	LEUSTAT marketing authorisation granted
	14 April 2004	LITAK marketing authorisation granted
<i>C-31/03 Pharmacia Italia</i>	19 October 2004	
	20 December 2005	Basic patent filed
	2005	Phase III clinical trials begin
<i>C-431/04 MIT</i>	4 May 2006	
	2009	Phase III clinical trial dossier given to EMA and rejected
<i>Neurim v The Comptroller [2011] EWCA Civ 228</i>	8 March 2011	
<i>C-202/05 Yissum</i>	19 May 2012	
<i>C-130/11 Neurim</i>	19 July 2012	

	2016	Long term safety dossier presented to EMA
<i>Abraxis v The Comptroller</i> [2017] EWHC 14 (Pat)	13 January 2017	
	22 August 2017	MAVENCLAD Marketing authorisation granted (with proviso that longer term study of >4000 patients was conducted)
	13 February 2018	SPC application filed
C-443/14 <i>Abraxis</i>	21 March 2019	
C-673/18 <i>Santen</i>	9 July 2020	
	31 December 2020	UK leaves the European Union
	19 December 2025	Basic patent will expire
	19 December 2030	SPC would expire if granted

- 42 Article 3(d) of the SPC Regulation provides that the authorisation should be the first authorisation to place the product on the market as a medicinal product. The SPC application which I am considering was filed on 13 February 2018 and is for cladribine for treating multiple sclerosis and is based upon the market authorisation for MAVENCLAD granted on 22 August 2017. The Applicant and examiner agree that this is not the first marketing authorisation for cladribine and that it has earlier marketing authorisations for the treatment of hairy cell leukaemia (granted in 1995 and 2004). In *Neurim* the CJEU said that “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”. However, in *Santen* the CJEU distanced itself from the *Neurim* judgment and expressly said, that “contrary to what the Court” held in *Neurim*, Article 3(d) means that a marketing authorisation cannot be considered the first marketing authorisation if it covers a new therapeutic use of an active ingredient that has already been the subject of an marketing authorisation for a different therapeutic application. At the hearing, Mr Selmi explained that the Applicant was not presenting any arguments, at this stage, that their application was factually different to that presented in *Santen*. Therefore, Mr Selmi confirmed to me that it is common ground that if *Santen* is followed then the application should be refused on the basis that it does not satisfy Article 3(d) as it relies upon a marketing authorisation which covers a new use of an active ingredient, whereas if *Neurim* is followed then the SPC should be granted.
- 43 Thus, in seeking to reach a decision on whether the application satisfies Article 3(d), I am essentially being asked to decide whether the relevant judgment to follow is *Neurim* or *Santen*. This means considering the temporal effect of the *Santen* judgment and deciding if that judgment applies *ex nunc* or *ex tunc*. Mr Selmi accepted, during the hearing, that there are no CJEU judgments related to SPCs which decide or even discuss the issue of temporal effect of CJEU judgments for SPCs. The key judgments of *Neurim* and *Santen* are completely silent on temporal effect. Therefore, I need to refer to judgments of the CJEU on temporal effects in areas of law unrelated to SPCs.

- 44 In *Denkavit Italiana*, the CJEU set out that judgments must “be applied by the courts even to legal relationships arising and established before the judgment ruling on the request for interpretation”, i.e. they have effect *ex tunc*, and it is only exceptionally that they have a temporal restriction meaning that they may apply *ex nunc*. *Dansk Industri* provides that it is only in “truly exceptional circumstances” that CJEU judgements have a temporal restriction and thus apply *ex nunc*. The decision in *Denkavit Italiana* stated that it was for the CJEU to make the decision regarding temporal restrictions of CJEU decisions (see paragraph 18 of that judgment as set out above). Mr Selmi agreed at the hearing that the procedural limitation (only the CJEU being entitled to impose a temporal restriction) stemmed from *Denkavit Italiana* and was set out in other decisions. Mr Selmi accepted that in the *Santen* judgment the CJEU did not make any reference to temporal restrictions, but Mr Selmi suggested that just because *Santen* does not mention temporal restrictions expressly it does not mean that it is not open for this hearing, or for the UK courts, to decide such restrictions. Mr Selmi pointed out that in the present case, there is no longer the option to go back to the CJEU (due to UK’s exit of the European Union). Thus, Mr Selmi asserted that due to the loss of referral to the CJEU the temporal effect of such CJEU judgments can be decided by domestic courts.
- 45 I think that the point about the UK having left the European Union rather confuses the issue. *Santen* was a judgment of the CJEU made whilst the UK was still a member of the European Union; the decision I need to make is whether or not it applies to this application and not whether or not if that judgment were made now would there be a temporal restriction and who would make such a decision. I need to consider what is the temporal effect of the CJEU’s judgment in *Santen*.
- 46 *Denkavit Italiana* and *Dansk Industri* clearly set out that it is for the CJEU to decide upon the temporal effects of their judgments. Mr Selmi accepted this when he helpfully summarised the tests. However, he suggested that *Elmeka* is a judgment establishing a new principle meaning that the national court could make the decision on temporal effect of a CJEU decision in light of legitimate expectations and legal certainty. I am afraid that I cannot see that this is the case. *Elmeka* is a judgment relating to tax law and, the judgment says in paragraph 36 “in the framework of the common system of VAT, national tax authorities are obliged to respect the principle of protection of legitimate expectations.” Thus, rather than setting out general principles that must be adhered to regardless of the situation, as Mr Selmi appears to be suggesting, *Elmeka* is a limited situation related to the common system of value added tax in which the CJEU asked national courts to make a determination on the facts in the particular case in relation to legitimate expectations. As such, *Elmeka* can be viewed as another example of the CJEU determining the law on legitimate expectations. *Elmeka* does not provide, as Mr Selmi seems to suggest, that there is a general temporal restriction available.
- 47 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*.

- 48 Mr Selmi presented a number of other arguments which I wish for completeness to note. Mr Selmi said that an equivalent SPC was granted in eighteen territories prior to the *Santen* judgment and thus the SPC application has not been granted merely because of the delay in processing in the UK. Whilst this delay is unfortunate it does not change the fact that *Santen* applies *ex tunc* and is the judgment that must be followed when considering this application.
- 49 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. Mr Selmi has encouraged me to note paragraph 32 of the *Elmeka* judgment setting out when legitimate expectations arise. However, paragraph 32 explains when the legitimate expectation arises from the conduct of the administrative authorities. No evidence was presented to me that any authority had given the Applicant any expectation that an SPC for MAVENCLAD would be available prior to clinical trials starting.
- 50 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).

Conclusion

- 51 For the reasons given above, this application does not satisfy Article 3(d) of the SPC Regulation and therefore is rejected under Article 10(2) for failing to meet the conditions laid down in the Regulation.

Appeal

- 52 Any appeal must be lodged within 28 days after the date of this decision.

Mary Taylor

Deputy Director, acting for the Comptroller