Intellectual Property Office

BL O/242/22

18 March 2022

REGULATION (EC) 469/2009 CONCERNING THE SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS

APPLICANT	Janssen Biotech, Inc
ISSUE	Whether application for supplementary protection certificate SPC/GB17/023 meets the requirements of Article 3(c) and Article 3(d) of the Regulation
HEARING OFFICER	Dr L Cullen

DECISION

Introduction

1 This decision relates to supplementary protection certificate (SPC) application SPC/GB17/023 ("the application") for the active substance "*golimumab*" filed in the name of Janssen Biotech, Inc ("the applicant") on 16 March 2017[1]. Golimumab is a tumour necrosis factor alpha (TNF-α) human monoclonal antibody, and is the active ingredient in the medicinal product *"SIMPONI"* [2].

2 The basic patent on which the SPC application relies is EP(UK) 2330129 B1 ("the patent") entitled "*Anti-TNF antibodies, compositions, methods and uses*". The patent was filed on 7 August 2001 and was granted by the European Patent Office (EPO) on 21 September 2016. The patent expired on 6 August 2021. This patent related to the isolation of anti-TNF-α antibodies, specifically "*golimumab*", and therapeutic uses thereof, particularly in the treatment of ulcerative colitis (hereafter "UC").

3 The authorisation provided in support of the application is Commission Implementing Decision C(2013)6224 of 19 September 2013, concerning the authorisation of golimumab in the treatment of UC implementing a Type II Variation to the marketing authorisation EU/1/09/456 granted by decision C(2009)7653 for *"SIMPONI – golimumab"*.

---

[1] *This decision relates to a SPC that was applied for in 2017 and as such it is necessary to apply the relevant law and case law, including that from the Court of Justice of the European Union (CJEU) that applies to this application. This is set out in the decision below.*

[2] *SIMPONI is a registered trademark (RTM) in the UK.*

4 The examiner considered that the present application did not meet the requirements of Article 3(d) of the SPC regulation[3]. They also considered that the application did not meet the requirement of Article 3(c) of the SPC regulation[3]. The examiner's view is set out in the official examination report dated 26 June 2019. In their response, dated 1 March 2021, the applicant disagreed with the view of the examiner. The applicant referred to the decision of the UK court making the reference to the CJEU in *Neurim* as well as the judgment of the CJEU in *Neurim,* in particular, to support their view that a type II variation to the marketing authorisation for SIMPONI meets the requirement of Articles 3(c) and 3(d) of the SPC Regulation. However, as the examiner maintained their objections (see official report dated 25 May 2021), and also noted the failure of the applicant to take account of the CJEU judgment in *Santen* in relation to the relevance of the CJEU judgment in *Neurim,* the applicant requested an oral hearing on the matters at issue in their response dated 24 September 2021. This request for an oral hearing was subsequently withdrawn (in the letter from the Agent dated 15 November 2021). Following an exchange of correspondence between the Hearings team at the Office and the agent it was agreed that the matters at issue would be dealt with on the basis of all the papers on the file.

5 My decision, as set down here, is based on my consideration of all the papers on the file. I was assisted in the preparation of this decision by Senior Examiner Natalie Cole.

The Relevant Law

The SPC Regulation – Regulation EC 469/2009[3]

6 It is a common tenet of EU law that it is defined having regard to both the purpose of the relevant EU legislation - as set out in the recitals - and the articles which provide the substance of the law. In this instance, we are concerned with the SPC regulation[3] and I have reproduced the relevant parts of this legislation below (with my emphasis added in **bold**).

7 Recitals 2-5, 9 and 10 of the SPC Regulation state (emphasis added):

> *'(2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.*
>
> *(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.*
>
> *(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.*
>
> *(5) This situation leads to a lack of protection which penalises pharmaceutical research*

……..

(9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate ***should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community****.*

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

8 Article 1 of SPC Regulation (concerning the creation of a supplementary protection certification for medicinal products[3], referred to as the SPC Regulation, provides the following definitions of "medicinal product", "product" and "basic patent":

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

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

9 Article 2 of the SPC Regulation defines the scope of the Regulation (emphasis added) and reads:

"Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use *or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code*

[3] *Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products; CELEX Document number: 32009R0469; published in Official Journal of the European Union L 152 on 16.06.2009.*

relating to veterinary medicinal products ***may, under the terms and conditions provided for in this Regulation, be the subject of a certificate."***

10 Article 3 of the SPC Regulation defines the conditions for obtaining a certificate (emphasis added) as follows:

> ***"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 the 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"***

11 Article 4 of the SPC Regulation defines the subject matter of protection provided by a certificate (emphasis added) as follows:

> *"Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate."*

Regulation 1610/96 - The Plant Protection Products SPC regulation[4]

12 In the present case we also need to take account of Article 3(2) of the Plant Protection Products SPC Regulation, by virtue of Recital 17 of the same regulation, because it applies *mutatais mutandis* to the SPC Regulation.

13 Recital 17 of the Plant Protection Products SPC regulation reads as follows[5,6]:

> (*17)* ***Whereas the detailed rules*** *in recitals 12, 13 and 14 and* ***in Articles 3(2)****, 4, 8(1)(c) and 17(2)* ***of this Regulation are also valid,*** **mutatis mutandis,**

[4] *Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products; CELEX Document number: 31996R1610; published in Official Journal of the European Union L 198 on 08.08.1996.*

[5] *Council Regulation (EEC) 1768/92 of 18 June 1992 was codified and superseded by Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the creation of a supplementary protection certificate for medicinal products. Annex II to Regulation 469/2009 indicates the correlation between the recitals and Articles in Regulation 1768/92 and those in Regulation 469/2009.*

for the interpretation in particular of *recital 9 and* ***Articles 3****, 4, 8(1)(c) and 17 of Council Regulation (EEC) No 1768/92.*

14 Article 3(2) of the Plant Protection Products SPC regulation reads as follows:

> *"1. ……...*
>
> ***2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product.*** *However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders."*

Relevant Case Law

Court of Justice of the European Union (CJEU)

15 Two judgments from the Court of Justice of the European Union (CJEU) which refer to Article 3 of the SPC Regulation are of particular relevance to the present case[7]. These are:

(i) *C-130/11*, Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents C-130/11 ("*Neurim*")[8].

(ii) *C-673/18,* Santen SAS v Directeur-General de l'Institut National de la Propriété Industrielle (INPI) ("*Santen*")[9].

16 Before examining the particular issues discussed in these judgments, it is helpful to provide some additional explanation about the operation of the CJEU.

Operation of the CJEU – role of the Grand Chamber

17 The CJEU cooperates with the courts of the Member States of the European Union (EU), which are the ordinary courts in matters of European Union (EU) law. To ensure the effective and uniform application of EU legislation and to prevent divergent interpretations, the national courts may refer to the Court of Justice and ask it to clarify a point concerning the interpretation of EU law. Such **references for a preliminary ruling** have helped establish the principles of EU law, in reply to questions referred by

---

[7] *Given the legislative framework that was in place in the UK at the time when the application for the SPC was made in 2017 (i.e., see footnote 1 above, prior to exit of the UK from the European Union in 2020), the decisions of the Court of Justice of the European Union (CJEU) have a binding effect on a lower tribunal in the UK, such as the IPO, in relation to interpretation of the SPC Regulation. See further explanation in decision below.*

[8] *For full text of the C-130/11 Neurim CJEU decision see* ECLI identifier: ECLI:EU:C:2012:489 *CURIA - Documents (europa.eu); EUR-Lex - 62011CJ0130 - EN - EUR-Lex (europa.eu).*

[9] *For full text of the C-673/18 Santen CJEU decision see* ECLI identifier: ECLI:EU:C:2020:531; *CURIA - Documents (europa.eu); EUR-Lex - 62018CJ0673 - EN - EUR-Lex (europa.eu).*

national courts of first instance. There are some circumstances where the national courts must refer certain matters to the Court of Justice, but this is not relevant to the present case.

18 **The CJEU's reply to the request for a preliminary ruling is not merely an opinion but takes the form of a judgment** or, in some circumstances, a reasoned order. The national court to which this reply is addressed is, when deciding the dispute before it, bound by the interpretation of the EU law given by the court. The reply from the CJEU is also binding on other national courts before which the same question or issue is raised.

19 Although the reference for a preliminary ruling can only be made by a national court, all the parties to the proceedings before that court, the Member States and the institutions of the European Union can take part in the proceedings before the CJEU.

20 The CJEU comprises one judge from each member state of the European Union[10]. It forms chambers of three judges or chambers of five judges (each chaired by a judge elected as President of the chamber) to deal with the majority of cases where the national courts of the member states are seeking a preliminary ruling concerning the interpretation of EU legislation.

21 The CJEU can also sit as a Grand Chamber of 15 Judges (which will include the judges elected respectively as President and Vice-President of the Court and at least three of the Presidents of the chambers of five judges) when a Member state or an institution of the EU, such as the European Commission, that is a party to the proceedings, so requests. A request to do so can also be made by a three-member or five-member chamber of the court itself. The circumstances for sitting as a Grand Chamber of 15 judges or as the full court of 27 judges are further elaborated in the Statute of the Court of Justice of the European Union[11] and the Rules of Procedure of the CJEU[12].

Neurim, C-130/11

22 This was a judgment of the five-member Fourth Chamber of the Court of Justice of the European Union (CJEU) in July 2012. In this judgment, the court established certain circumstances where an earlier marketing authorisation for the same product would not contravene Article 3(d). The CJEU ruled that:

> *"1. Articles 3 and 4 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal*

[10] Prior to UK exit and IP completion date (see Analysis Section and footnotes), the CJEU comprised 28 judges. Currently it comprises 27 judges. In the present case, we are concerned with the CJEU as it was before IP completion date.

[11] See Protocol (No. 3) on the Statute of the Court of Justice of the European Union (here), especially Article 16. This Statute of the Court of Justice of the European Union is provided for in Article 281 of the Treaty on the Functioning of the European Union (The TFEU can be found here).

[12] See the Rules of Procedure of the Court of Justice of the EU here, for example Article 60.

product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation 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 supplementary protection certificate.

2. Article 13(1) of Regulation (EC) No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary certificate."

23 In reaching its judgment the CJEU reasoned that:

"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.

……..

30…Therefore, the MA referred to in Article 13(1) of the SPC Regulation is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC."

24 In effect, the judgment of *Neurim* provided that a marketing authorisation granted for a different application was not relevant for the purposes of Article 3(d) provided that the application was based on an authorisation that was the first marketing

authorisation to fall within the limits of protection of the basic patent relied on for the SPC application.

Santen, C-673/18

25 This was a judgment of the fifteen-member Grand Chamber of the Court of Justice of the European Union (CJEU) in July 2020. This was only the second time that the Grand Chamber of the CJEU had convened to decide an SPC case and reflected the significance attached by the court to the issues in question which related to the impact and relevance of the earlier *Neurim* judgment.

26 In S*anten,* the Grand Chamber reconsidered the interpretation of the SPC Regulation provided in *Neurim*. In its answer to the questions referred to it by the Paris Court of Appeal, the Court ruled that (see para 62 of the judgment):

> *"Article 3(d) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application."*

Thus, this finding rejected the basis on which the earlier *Neurim* judgement from the CJEU was founded and refocused the test under Article 3(d) on determining if the SPC application relates to the same product as an earlier SPC application and away from the limits of protection provided by the patent.

27 Paragraphs 43-47 of *Santen* made clear how the term 'product' should be understood in Article 4 by reference to Article 1(b). The relevant parts of paragraphs 43, 46 and 47 state as follows (my emphasis added in bold):

> *"43. Moreover, it follows from a reading of Article 1(b) of Regulation No 469/2009 in conjunction with Article 4 thereof that* ***the term 'product' is understood, for the purposes of applying that Regulation, to mean the active ingredient*** *or combination of active ingredients of a medicinal product,* ***without its being necessary to limit its scope only to one of the therapeutic applications to which such an active ingredient or combination of active ingredients may give rise****…*
>
> …….
>
> *46. That* ***strict view of the term 'product' was given concrete form in Article 1(b)*** *of Regulation No 469/2009, which* ***defines that term by reference to an active ingredient*** *or combination of active ingredients* ***and not by reference to the therapeutic application of an active ingredient protected by the basic patent*** *or a combination of active ingredients protected by that patent.*
>
> *47. It follows from the foregoing consideration that Article 1(b) of Regulation 169/2009 must be interpreted as meaning that* ***the fact that an active***

> ***ingredient,*** *or a combination of active ingredients,* ***is used for the purposes of a new therapeutic application does not confer on it the status of a distinct product where the same active ingredient****, or the same combination of active ingredients,* ***has been used for the purposes of a different, already known, therapeutic application****."*

28 Thus, as the 'product' for the purposes of Article 1(b) is also the same as the product for the purposes of Article 3, the CJEU reasoned that the therapeutic use also does not form part of the product definition in this situation.

29 In *Santen,* the Grand Chamber of the CJEU made clear in paragraphs 53-56 of this judgment that, contrary to the judgment in *Neurim*, when considering the concept of the *"first* [MA for the product] *as a medicinal product"* for the purposes of Article 3(d), there is **no requirement** to take into account the limits of protection of the basic patent. The relevant parts of paragraphs 55 and 56 are as follows (my emphasis added in bold below):

> *"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****.*
>
> …….
>
> *55. Thus, as is apparent from paragraph 11 of the Explanatory Memorandum referred to in paragraph 45 above,* ***the EU legislature intended****, in establishing the SPC regime,* ***to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing a new medicinal product, but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product*** *(see, to that effect, judgment of 21 March 2019, Abraxis Bioscience, C443/17, EU:C:2019:238, paragraph 37).*
>
> …….

30 The Grand Chamber of the CJEU, going on to consider the nature of the relevant first marketing authorisation under Article 3(d) of the Regulation, indicated that:

> *"60. …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."*

31 Thus, in *Santen* the Grand chamber of the CJEU made clear that, unlike it previously held in *Neurim*, 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.

32 It is worth noting that the *Santen* judgment is the first time that the Grand Chamber of the CJEU has made an explicit judgment or statement that an earlier judgment of the Court in relation to the SPC regulation is incorrect. Furthermore, as this judgment was delivered by the Grand Chamber (of 15 judges) because of the importance of the issues being dealt with, it has to be given appropriate recognition and weight in comparison to a decision from a three judge or five-judge chamber (e.g., *Neurim*)

Issues to be decided

33 The first issues to be decided in respect of the present SPC application is whether the application meets the requirement of Article 3(d) of the SPC Regulation. In other words, is the marketing authorisation provided in support of this SPC application, the first marketing authorisation to place the product that is the subject of the SPC application onto the market as a medicinal product?

34 The second issue to be decided is whether the application meets the requirements of Article 3(c) of the SPC regulation, i.e., has the product that is the subject of the present SPC application already been the subject of an SPC certificate?

35 I note that it is common ground between the applicant and the examiner that golimumab is already the subject of granted SPC certificate SPC/GB10/016 in the UK. In considering the answer to this second issue, I will need to take account of the reasons provided by the applicant as to why this earlier SPC does not prohibit the present SPC application.

Arguments and Analysis

36 I will first provide a summary of the main points made in the arguments presented by the examiner and the applicant, before presenting my analysis and conclusions regarding the issues to be decided.

The View of the Examiner

37 The examiner's view is clearly set out in the pre-hearing report of 10 November 2021. After considering the CJEU's judgment in *Santen* and explaining that this judgment is binding case law on the IPO, the examiner came to the view that the SPC application does not meet the requirements of Article 3(d) of the SPC Regulation because there exists an earlier marketing authorisation for the same product, albeit for a different therapeutic indication, and thus the marketing authorisation on which the SPC application relies cannot be considered to be the first authorisation to place the product on the market as a medicinal product as required by Article 3(d).

38 Having regard to the provisions of Article 3(2) of the Plant Protection Products SPC Regulation, which applies *mutatis mutandis* to the SPC Regulation by virtue of Recital 17 of that Regulation, the examiner is also of the view that the SPC application does

not meet the requirements of Article 3(c) because the applicant has previously been granted an SPC for the product "golimumab" (SPC/GB10/016).

The View of the Applicant

39 The applicant, as set out in their letter dated 1 March 2021, submits that assessment of an SPC application should be guided by the purpose of the SPC Regulation, that is to *"improve the protection of innovation in the pharmaceutical sector"*. The applicant considers that because they were unable to market the product (golimumab) for ulcerative colitis until the Type II Variation was approved, they deserve the extension of protection necessary to recoup their investment, and that grant of this SPC is in conformity with the overarching purpose of the SPC Regulation.

40 Further, the applicant asserts that the UK Courts' position favours grant of this type of SPC application. The applicant argues that in *Neurim,* the Court of Appeal, at paragraphs 28-30, was unambiguous in its view that to deny the grant of this type of SPC is to render the SPC Regulation unfit for purpose in its support of pharmaceutical innovation:

> *"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 invention 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 objectives 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."*

41 The applicant contends that in *Neurim,* the CJEU affirmed the Court of Appeal's remarks and held that existence of an earlier marketing authorisation to place the product on the market should not exclude grant of an SPC for the product based on a later marketing authorisation for a different therapeutic indication. The applicant argues that SPC/GB10/016, to which the examiner refers, is based on an earlier marketing authorisation (EU/1/09/546) for golimumab authorised in the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis. However, the present SPC application is based on a new basic patent for the treatment of ulcerative colitis, and the newly-authorised indication is the result of commercial and research investment by the applicant which generated the necessary data to support the new indication for which the product may be marketed. This new indication takes affect at

a later date – the date of the Type II Variation. The applicant concludes that these facts reflect the situation outlined in the Court of Appeal's referral and which were approved by the CJEU in *Neurim*.

42 Thirdly, the applicant argues that the Type II Variation on which the SPC application relies is a valid "first authorisation" within the meaning of Article 3(d), because it required the same type of research investment as a new marketing authorisation, and this research caused precisely the type of delay that the SPC system was designed to compensate. The applicant is of the view that the significant investment to undertake research and provide results from an additional clinical trial meets the requirements of Article 3(d).

43 Lastly, the applicant is of the opinion that the SPC application meets the requirements of Article 3(c) of the Regulation because no SPC has previously been granted for golimumab in respect of UC. The applicant argues that the new basic patent on which the SPC application relies is limited to the product for use in the treatment of ulcerative colitis and that this new basic patent is the result of commercial investment and scientific progress. For this reason, the applicant asserts that the objectives of the SPC Regulation are fulfilled and highlights point 12 of the Explanatory Memorandum to the SPC regulation[13] (*"A* […] *new application of the product may also be protected by a certificate"*) to support their position.

44 The applicant states that subsequent case law from the CJEU updated the original interpretation of Article 3(c), that an SPC may only be granted where *"the product has not already been the subject of a certificate"*, by application of a teleological approach, where the judgment of the CJEU in C-322/10[14] (*Medeva*) held that:

> *"41. …where a patent protects a product, in accordance with Article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent (Biogen paragraph 28)"*

45 The applicant asserts that their comments in relation to Article 3(d) apply to Article 3(c) and that in view of (i) the purpose of the SPC Regulation, (ii) the statements made even in very early case law given by the CJEU, and (iii) the applicant's investment to bring about a new treatment for UC, the following interpretation of Article 3(c) is warranted: that one SPC may be granted per product, per patent, per first authorisation to place the product on the market as a medicinal product in the sense of Article 3(d).

Status of the Relevant Case Law

46 Before considering the arguments presented by the examiner and the applicant (summarised above), I will first determine the status of the relevant case law discussed

---

[13] *Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (presented by the Commission); COM (90) 101 final – SYN 255, Brussels, 11 April 1990. This proposal was the basis for EC Regulation 1768/92 (see footnote 5 above also)*

[14] *For full text of the C-322/10 Medeva v Comptroller General of Patents CJEU decision, see ECLI:EU:C:2011:773; CURIA - Documents (europa.eu); EUR-Lex - 62010CJ0322 - EN - EUR-Lex (europa.eu)*

above in the context of this application and the current relationship between the EU and the UK.

47 The examiner referred to the relevance of the European Union (Withdrawal) Act 2018[15] in their pre-hearing report dated 11 November 2021 identifying the matters to be dealt with by the hearing officer in the present decision. While the Examiner was correct to refer to this Act, it is necessary to examine it in more detail to properly appreciate its significance in this case given that this 2018 Act has been further amended by the European Union (Withdrawal Agreement) Act 2020[16, 17]. I will refer to the European Union (Withdrawal) Act 2018 as amended by the European Union (Withdrawal Agreement) Act 2020 from now on as the EU Withdrawal Act.

48 For the present case, the relevant parts of the EU Withdrawal Act are Section 6 concerning interpretation as it relates to Section 3 which deals with retained EU law (such as EU regulations) and retained EU case law (such as judgments of the CJEU). I have reproduced the relevant parts of these sections of the EU Withdrawal Act below (my emphasis added in bold):

> ***"6 Interpretation of retained EU law***
>
> *(1) A court or tribunal–*
> *(a) is not bound by any principles laid down, or any decisions made, on or after IP completion day by the European court, and*
> *(b) cannot refer any matter to the European Court on or after IP completion day*
>
> *(2) Subject to this and subsections (3) to (6), a court or tribunal may have regard to anything done on or after IP completion day by the European Court, another EU entity or the EU so far as it is relevant to any matter before the court or tribunal.*
>
> *(3)* ***Any question as to the validity, meaning or effect of any retained EU law is to be decided, so far as that law is unmodified on or after IP completion day and so far, as they are relevant to it****–*
> *(a)* ***in accordance with any retained case law*** *and any retained general principles of EU law, and*
> *(b) having regard (among other things) to the limits, immediately before IP completion day, of EU competences*
> *(c) ……*

---

[15] *The European Union (Withdrawal) Act 2018, (see legislation.gov.uk & explanatory notes here).*

[16] *The European Union (Withdrawal Agreement) Act 2020, (see legislation.gov.uk & explanatory notes here).*

[17] *The European Union (Withdrawal Agreement) 2020 Act implements the agreement between the United Kingdom and the EU under Article 50(2) of the Treaty on European Union which sets out the arrangements for the United Kingdom's withdrawal from the EU (the 'Withdrawal Agreement'). This Act was required so that the Withdrawal Agreement will have domestic legal effect and enabled the UK Government to ratify the Withdrawal Agreement. This Act was also the vehicle for the UK Government to give effect to the EEA EFTA Separation Agreement between the UK and Norway, Iceland and Liechtenstein, and the Swiss Citizens' Rights Agreement between the UK and Switzerland. (see Explanatory Notes to the European Union (Withdrawal Agreement) 2020 Act).*

(4) But—

(a) the Supreme Court is not bound by any retained EU case law,

(b) ……..

(ba) a relevant court or relevant tribunal is not bound by any retained EU case law so far as is provided for by regulations under subsection (5A),

(c) no court or tribunal is bound by any retained domestic case law that it would not otherwise be bound by

(5) In deciding whether to depart from any retained EU case law by virtue of subsection (4)(a) or (b), the Supreme Court …….. must apply the same test as it would apply in deciding whether to depart from its own case law.

(5A) ***A Minister of the Crown may by regulations provide for—***

(a) a court or tribunal to be a relevant court or (as the case may be) a relevant tribunal for the purposes of this section,

(b) the extent to which, or circumstances in which, a relevant court or relevant tribunal is not to be bound by retained EU case law,

(c) the test which a relevant court or relevant tribunal must apply in deciding whether to depart from any retained EU case law*, or*

(d) considerations which are to be relevant to—

(i) the Supreme Court or the High Court of Justiciary in applying the test mentioned in subsection (5), or

(ii) a relevant court or relevant tribunal in applying any test provided for by virtue of paragraph (c) above.

(5B) …….
(5C) ……
(5D) ……

(6) Subsection (3) does not prevent the validity, meaning or effect of any retained EU law which has been modified on or after IP completion day from being decided as provided for in that subsection if doing so is consistent with the intention of the modifications.

(6A) …….

(7) In this Act—

"retained case law" means—

(a) retained domestic case law, and
(b) ***retained EU case law****;*

"retained domestic case law" means any principles laid down by, and any decisions of, a court or tribunal in the United Kingdom, as they have effect immediately before IP completion day and so far as they—

……..

*"**retained EU case law**" **means any principles laid down by, and any decisions of, the European Court, as they have effect in EU law immediately before IP completion day and so far as they—***

***(a) relate to anything to which section** 2, **3** or 4 **applies**, and*
(b) are not excluded by section 5 or Schedule 1, (as those principles and decisions are modified by or under this Act or by other domestic law from time to time);

*"**retained EU law**" means anything which, on or after exit day, continues to be, or forms part of, domestic law by virtue of section 2, **3** or 4 or subsection (3) or (6) above (as that body of law is added to or otherwise modified by or under this Act or by other domestic law from time to time);….."*

49 The relevant parts of Section 3 of the EU Withdrawal Act, entitled "*Incorporation of direct EU legislation*" read as follows:

"(1) Direct EU legislation, so far as operative immediately before IP completion day, forms part of domestic law on and after IP completion day.

(2) In this Act "direct EU legislation" means—
*(a) **any EU regulation**, **EU decision** or EU tertiary legislation, as it has effect in EU law immediately before IP completion day and so far as—*

(ai) it is applicable to and in the United Kingdom by virtue of Part 4 of the withdrawal agreement,
(bi) ……
(i) ……
(ii) ……
(iii)……
……"

50 As part of the Withdrawal Agreement, the UK and the EU agreed that the UK's exit would be followed by a time-limited implementation period, which lasted until 11.00 p.m. on 31 December 2020 ('IP completion day')[18, 19]. The EU Withdrawal Act thus

---

[18] The EU Withdrawal Act repealed the European Communities Act 1972 (ECA) on Exit day, 11.00 pm on 31 January 2020, the day the UK left the European Union. The UK and the EU agreed that the exit from the EU on Exit day would be followed by a time-limited implementation period, which would last until 11.00 p.m. on 31 December 2020 ('IP completion day'). One of the amendments that the European Union (Withdrawal Agreement) Act 2020 made to the EU (Withdrawal) Act 2018 was to establish this time-limited implementation period (see footnote 16 above for further details).

[19] SI 2020/1622, entitled 'European Union (Withdrawal) Act 2018 and European Union (Withdrawal Agreement) Act 2020 (Commencement, Transitional and Savings Provisions) Regulations 2020' (see here) brought into force the provisions of the EU Withdrawal Act, including sections 3 and 6 (see discussion above), on IP completion Day.

sets down the basis on which direct EU legislation such as EU regulations[20] as well as EU case law established by the Court of Justice of the European Union (CJEU) will become part of UK domestic law after IP completion day.

51 In relation to the issues at question in the present case, it is necessary to consider the relevance of the *Santen* judgment which was delivered by the CJEU within the implementation period, i.e. after exit day but before IP completion day.

52 It is clear from section 6 of the EU Withdrawal Act that decisions of the CJEU issued before the end of the implementation period[21] continue to apply as retained EU case law. Therefore, any decisions issued by the CJEU up to and including 31 December 2020 will be part of retained EU case law. The CJEU's judgment in *Santen* was issued on 9 July 2020.

53 Furthermore, Section 6(4)(ba) of the EU Withdrawal Act sets out that courts other than the Supreme Court ('relevant courts') may be designated, by way of secondary legislation, to have the ability to depart from retained EU case law. The relevant secondary legislation is Statutory Instrument (SI) 2020/1525[22] and regulation 3 of this SI sets out what constitutes a '*relevant court*'. In the context of this case, the relevant court referred to is the Court of Appeal in England and Wales. Thus, all courts and tribunals below the level of the Court of Appeal, such as the Intellectual Property Office, remain bound by retained EU case law including the judgment in *Santen*.

Article 3(d) of the SPC Regulation

54 Turning now to consider the first issue with respect to Article 3(d) of the SPC Regulation. The applicant does not dispute the examiner's view that the product *"golimumab"* has been the subject of a previous certificate, SPC/GB10/016. This SPC was granted based on a different basic patent, EP1309691 which it turns out is the parent of the basic patent cited in support of the present application, and on an earlier version of the current marketing authorisation EU/1/09/546/001 granted by Commission Implementing Decision C(2009)7653 of 6 June 2009. This earlier SPC relates to golimumab as the active ingredient in the medicinal product "SIMPONI" used in the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis.

---

[20] The SPC Regulation is part of the direct EU legislation and, under Sections 3 and 6 of the EU Withdrawal Act, has been retained in UK domestic law after IP completion day. However, as indicated already in this decision (see footnote 1 above) the SPC application at issue in the present case was applied for in 2017 prior to UK withdrawal for the EU and the end of the associated implementation period.

[21] Part 4 of the Withdrawal Agreement between the UK and the EU under Article 50(2) of the Treaty on European Union which sets out the arrangements for the United Kingdom's withdrawal from the EU ensured that the EU Treaties and other EU law continued to apply in the UK during the implementation period, the time between exit day and IP completion day. In UK law, this was achieved by way of sections 1A and 1B of the EU Withdrawal Act.

[22] SI 2020/1525, entitled 'The European Union (Withdrawal) Act 2018 (Relevant Court) (Retained EU Case Law) Regulations 2020', see here.

I have summarised the relevant details in relation to the present SPC application and the earlier granted SPC in **Table 1** below.

55 The present application is based on EP(UK) 2330129 B1, a divisional from EP(UK) 1309691 B1, and a Type II variation to the current centralised marketing authorisation EU/1/09/546/ which was approved by Commission Implementing Decision C(2013)6224 of 19 September 2013[23]. The latter implementing decision, in its recitals, indicates that the EMA has taken a favourable view of the variation to the terms of the original decision granting the MA and, as a result, this MA should be updated and earlier decision C(2009)7653 should be amended accordingly and that the Annexes to the decision should be replaced. Accordingly, Article 1 of this implementing decision confirmed that Annex I (the Summary of Product Characteristics (SmPC), Annex II (Manufacturing & Condition or Restrictions on Use) and Annex III (Labelling & Package Leaflet) to Decision C(2009)7653 are replaced by the corresponding Annexes (which include the necessary updated material) which are attached to Commission Implementing Decision C(2013)6224.

56 The crux of the disagreement between the examiner and the applicant hinges on whether the Type II Variation on which this SPC application relies fulfils the requirement as the "*first marketing authorisation to place the product on the market as a medicinal product*" as required by Article 3(d) of the SPC Regulation.

Table 1: Details of the current and earlier SPC applications in relation to the active substance 'golimumab'

	Current SPC Application	**Earlier SPC Application**
SPC/GBxx/yyy	17/023	10/016
SPC Application date	Filed 16/03/2017	Filed 01/03/2010
Status of SPC application	In hand	Granted (06/03/2012)
Active Ingredient	***Golimumab***	***Golimumab***
Basic Patent	EP(UK) 2330129 B1	EP(UK) 1309691 B1
Relationship between basic patents	***EP2330129 is a divisional from EP1309691***	
Patent Title	Anti-TNF antibodies, compositions, methods and uses	Anti-TNF Antibodies, compositions, methods and uses
Date of Grant of the Patent by EPO	Granted 21/09/2016	Granted 21/10/2009
Patent Holder	*Janssen Biotech, Inc.*	*Centocor, Inc.*
Marketing Authorisation (EMA)	***EU/1/09/546/***	***EU/1/09/546/***
Medicinal Product	SIMPONI	SIMPONI
Date of Grant of the MA by the European Commission	19/09/2013	06/10/2009

[23] *According to Commission Implementing Decision C(2009)7653 of 6 June 2009, 4 different physical forms of the medicinal product SIMPONI, comprising active ingredient golimumab, were approved identified as EU/1/09/546/001-004 respectively. I will use EU/1/09/546/ to refer to all the physical forms of this medicinal product that have been approved under this centralised EMA marketing authorisation (see EPAR here for SIMPONI for full list of all authorisations for this medicinal product)*

Number & title of MA Grant Decision	***Commission Implementing Decision C(2013)6224 amending the marketing authorisation granted by Decision C(2009)7653***	***Commission Implementing Decision C(2009)7653***
Further detail of Decision	Annex I, II and III to Decision C(2013)6224 replaces Annex I, II and III to C(2009)7653	Annex I (SmPC), Annex II (Manufacturing & Condition or Restrictions on Use) and Annex III (Labelling & Package Leaflet) to Decision C(2009)7653
Therapeutic Condition(s) being Treated	Ulcerative colitis	Rheumatoid arthritis; Psoriatic arthritis, Ankylosing spondylitis

57 The applicant submits that the overarching purpose of the SPC regime is to *"improve the protection of innovation in the pharmaceutical sector"*, referring to Recital 5 of the SPC Regulation and to the Explanatory Memorandum (hereafter "EM") to this Regulation[24]. They argue that *"new applications of products, **explicitly including known products**, are worthy of SPC protection"*, referring to paragraphs 12 and 29 of the EM to support this view.

58 The examiner asserts that paragraph 10 of the EM makes it clear that the SPC regime seeks to balance the aims and interests of the pharmaceutical industry with those of national and Community health policy, which is reflected in Recital 10 of the SPC regulation. The examiner argues that the EM is clear that, even if a product is subject to multiple marketing authorisations to place it on the market, it is only the first authorisation that must be taken into account (paragraph 35), and that the product must not have been the subject of a previous certificate (paragraph 36).

59 Paragraph 35 of the EM states:

> *"it occurs very often that one and the same product is successfully granted several authorizations to be placed on the market, namely each time a modification is made affecting the pharmaceutical form, dose, compositions, indications, etc. In such a case, only the first authorization for the product to be placed on the market in the Member State in which the application is presented is taken into account for the purposes of the proposal for a Regulation."*

[24] *The Explanatory Memorandum to Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (presented by the Commission); COM (90) 101 final – SYN 255, Brussels, 11 April 1990. This EM was prepared in support of Council Regulation (EEC) 1768/92 of 18 June 1992 which was subsequently codified and superseded by Regulation (EC) No 469/2009 of 6 May 2009 concerning the creation of a supplementary protection certificate for medicinal products (see also footnote 5 above).*

60 Paragraph 36 of the EM states:

> *"Lastly, the product must not have been the subject of a certificate in the Member State concerned. The certificate is designed to encourage research into new medicinal products so that the duration of protection it affords, together with the effective duration of protection by patent, is sufficient to enable the investments made in the research to be recovered. However, it would not be acceptable, in view of the balance required between the interests concerned, for this total duration of protection for one and the same medicinal product to be exceeded. This might nevertheless be the case if one and the same product were able to be the subject of several successive certificates.*
>
> *This calls for a strict definition of the product within the meaning of Article 2. If a certificate has already been granted for the active ingredient itself, a new certificate may not be granted for one and the same active ingredient whatever minor changes may have been made regarding other features of the medicinal product (use of a different salt, different excipients, different pharmaceutical presentation, etc.)"*

61 I consider that paragraph 35 of the EM identifies those situations where multiple marketing authorisations may arise, one such situation being modification of the indication, and in my opinion, makes it clear that in such cases, only the first authorisation for the product to be placed on the market is taken into account. Paragraph 36 of the EM makes clear that the purpose of the SPC regime is to provide a system which balances the interests of the pharmaceutical industry with those of national and Community health policy. From this paragraph of the EM it is clear that if one and the same product were subject to several successive certificates, such that the total duration of protection for one and the same product were exceeded, then the SPC regime would not achieve its aim of providing a balanced system.

62 In its interpretation of the SPC Regulation at paragraph 55 of *Santen,* the CJEU makes clear that the intention of the EU legislature, in establishing the SPC regime, was not to protect **all** pharmaceutical research, but rather to protect research that lead to the **first placing on the market of an active ingredient**, or combination of active ingredients, as a medicinal product. The CJEU considered that this interpretation is consistent with paragraph 12 of the EM, making this point in paragraph 58 of the *Santen* judgment, as follows:

> "*That interpretation is not moreover not called into question by paragraph 12 of the Explanatory Memorandum, from which it is apparent that Regulation No 469/2009 is not confined to new products only, since a new process for obtaining a product or a new application of a product may also be protected by an SPC. The condition set out in Article 3(d) of Regulation No 469/2009 may, inter alia, be satisfied where the MA serving as a basis for the SPC application covers a product which was already known before the basic patent was granted but which had never given rise to an MA as a medicinal product."*

The CJEU reasoned that the condition of Article 3(d) of the SPC Regulation may be satisfied, *inter alia*, where a marketing authorisation covers a product, which was

known before the date of the basic patent, but which has never been the subject of a marketing authorisation for a medicinal product.

63 In my opinion, it is clear from paragraphs 10 and 11 of the EM and the CJEU's judgment in *Santen* that, while the proposed Regulation is not confined to new products only but may include a new process for obtaining a known product or a new application of a known product, the purpose of the SPC regime is not to protect all pharmaceutical research but to provide a system that balances the interests of the pharmaceutical industry with those of national and Community health policy. The judgment of *Santen* makes clear that the purpose of the SPC regime is to protect research leading to the first placing on the market of an active ingredient or combination of active ingredients. Therefore, I am not convinced by the applicant's argument that the purpose of the SPC regime is to compensate for the time taken to approve new applications of known products where that product has already been the subject of a certificate.

64 The applicant argues that the Courts in the UK favour the grant of an SPC in the present case. In support of their argument, the applicant refers to the judgment of UK Court of Appeal which made the referral to the CJEU that resulted in the *Neurim* judgment[25].

65 The examiner asserts that the judgment of the Grand Chamber of the CJEU in *Santen* must be taken into consideration when interpreting the SPC Regulation and the relevance of the CJEU judgment in *Neurim*, and when it is, it is clear that this SPC application should not be granted.

66 In my view the focus of the applicant's argument centers on the CJEU judgment in *Neurim*. It is noticeable that the applicant has not directly addressed the examiner's arguments in relation to *Santen* to state why this case is not relevant, or should not be followed, and has not provided any arguments to distinguish the facts of this application from that of *Santen*.

67 As I have explained above, the CJEU judgment in *Santen* forms part of retained EU case law under section 6 of the EU (Withdrawal) Act and as such I cannot ignore this judgment or its impact on the previous judgment of the CJEU *Neurim*, and its interpretation of the SPC Regulation. Moreover, in the absence of any arguments by the applicant, I can see no reason why *Santen* should be disregarded. Therefore, whilst I acknowledge the comments and opinions made by the Court of Appeal in referring *Neurim*, I cannot disregard the judgment of the CJEU in *Santen*.

68 Furthermore, the judgment of the court in *Santen* was made by the Grand Chamber of the Court of Justice (involving 15 judges) rather than the more usual Chamber of five judges and so the significance that the court attached to this judgment cannot be

---

[25] See Neurim Pharmaceuticals (1991) Ltd v The Comptroller-General of Patents [2011] EWCA Civ 228 which was an appeal from an IPO decision (see BL O/384/09 here) via the Patents High Court (see Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents [2010] EWHC 976 (Pat)). This Court of Appeal decision resulted in the reference to the CJEU for a preliminary ruling in case C-130/11 Neurim.

underestimated. This is only the second occasion that the Grand Chamber of the CJEU has been convened to deal with an SPC case[26].

69 The Grand Chamber of the CJEU in *Santen*, when asked questions specifically directed to the scope and effect of the previous *Neurim* judgment concluded in the operative part of the judgment, at paragraph 62, that:

> *"**Article 3(d)** of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products **must be interpreted as meaning that a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient**, or of a combination of active ingredients, **and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application.**"*

The CJEU therefore 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. I am therefore not persuaded by the applicant's argument that *"the existence of an earlier authorisation to place the product on the market as a medicinal product should not exclude grant of an SPC for the product based on a later authorisation for a different indication"*, as previously held in *Neurim*.

70 The applicant is of the opinion that the Type II Variation for "*golimumab*", approved by Commission Implementing Decision C(2013)6224 amending the marketing authorisation granted by Decision C(2009)7653 for "*SIMPONI-golimumab*", a medicinal product for human use", represents a valid authorisation for the purposes of Article 3(d) of the Regulation.

71 The examiner considers that, as explained in of paragraphs 55-60 of *Santen* (reproduced below), the Grand Chamber of the CJEU rejected their previous interpretation of the Regulation in *Neurim*:

> *"55. Thus, as is apparent from paragraph 11 of the Explanatory Memorandum referred to in paragraph 45 above, the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product (see, to that effect, judgment of 21 March 2019, Abraxis Bioscience, C443/17, EU:C:2019:238, paragraph 37).*
>
> *56. That objective would be undermined if it were possible, in order to fulfil the condition set out in Article 3(d) of Regulation No 469/2009, to take*

---

[26] The first occasion was in the Teva v Gilead decision where the CJEU need to establish what were the requirements under Article 3(a) of the SPC regulation and the meaning of "protected by the basic patent in force" which has been a recurring subject in references to the CJEU. For details and full text of the CJEU judgment in C-121/17, Teva and others v Gilead; see identifier: ECLI:EU:C:2018:585; EUR-Lex - 62017CJ0121 - EN - EUR-Lex (europa.eu); CURIA - Documents (europa.eu)

account solely of the first MA to fall within the limits of the protection of the basic patent covering a new therapeutic application of a given active ingredient, or a given combination of active ingredients, and to disregard an MA which had been granted previously for a different therapeutic application of the same active ingredient or of the same combination (see, to that effect, judgment of 21 March 2019, Abraxis Bioscience, C-443/17, EU:C:2019:238, paragraph 38).

57. That interpretation also enables a fair balance to be struck between, on one hand, the objective of the SPC regime, as it is made apparent from recitals 3 to 5 and 9 of Regulation No 469/2009, of compensating for the inadequacy of protection conferred by a patent for the purpose of covering the investment put into research concerning new active ingredients or combinations of active ingredients and, therefore, or encouraging such research and, on the other hand, the EU legislature's intention, as set out in recital 10 of that Regulation, to achieve that objective in a manner that takes into account all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector (see, to that effect, judgement of 21 March 2019, Abraxis Biosciences, C-443/17, EU:C:2019:238, paragraph 36).

58. The interpretation is not moreover called into question by paragraph 12 of the Explanatory Memorandum, from which it is apparent that Regulation No 469/2009 is not confined to new products only, since a new process for obtaining a product or a new application of a product may also be protected by an SPC. The condition set out in Article 3(d) of Regulation No 469/2009 may, inter alia, be satisfied whether the MA serving as a basis from the SPC application covers a product which was already known before the basic patent was granted but which had never given rise to an MA as a medicinal product.

59. Furthermore, as the Advocate General observed in points 55 and 56 of his Opinion, an interpretation of Article 3(d) of Regulation No 469/2009 such as that set out in paragraph 56 above might compromise the simplicity and the predictability which the EU legislature intended the system to have in order to guarantee the implementation of a uniform solution at EU level by the national patent offices. The introduction of a distinction between different therapeutic applications, without that concept even being defined in that Regulation, could lead those national offices to adopt complex and divergent interpretations of the condition laid down in that provision.

60. It follows from the forgoing 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."

72 Thus in *Santen* the CJEU made clear that, contrary to the judgment in *Neurim*, a marketing authorisation cannot be considered to be the first marketing authorisation where (as in the present case) the active ingredient in the medicinal product has already been the subject of an earlier marketing authorisation for a different therapeutic application. Therefore, I am not persuaded by the applicant's argument that the Type II variation – which is different only in terms of the therapeutic indication treated and not in terms of the product being used - filed in support of the present application does represent a valid "*first authorisation to place the product on the market as a medicinal product*" for the purposes of Article 3(d) of the Regulation. In my view, this Type II variation, which authorises the same product, golimumab, in the same medicinal product, SIMPONI, for the treatment of a new therapeutic indication, ulcerative colitis, cannot be considered to be the first marketing authorisation to place the product on the market because there exists an earlier marketing authorisation, i.e., an earlier version of EU/1/09/546 previous to the type II variation, which was approved by the Commission for use of the product golimumab in the treatment of rheumatoid arthritis (RA), psoriatic arthritis (PA) and ankylosing spondylitis (AS).

73 In my view, it is clear that we are not dealing with a different product (i.e., active ingredient) in this SPC application. We are looking at a new therapeutic use of a known product that is in effect being added to the other therapeutic uses that have already been included in the earlier version of the same marketing authorisation for this product which was used to gain the earlier SPC approval. This is reinforced by the fact that the basic patent that the present SPC application relies on is a divisional from that on which the earlier granted SPC is based on concerning the same product (golimumab, see also Table 1 above).

74 Therefore, in my opinion this SPC application does not meet the requirement of Article 3(d) of the SPC Regulation.

Article 3(c) of the SPC Regulation

75 With respect to Article 3(c), I am not convinced by the applicant's argument that because no SPC has previously been granted for golimumab in respect of the disease, ulcerative colitis, then the requirement of Article 3(c) of the SPC regulation is satisfied. The applicant asserts that their arguments and comments made in relation to Article 3(d) also apply to Article 3(c), and refer to the comments of the UK Court of Appeal in paragraph 29 of its referral to the CJEU in *Neurim*, and paragraph 12 of the EM, to support their view. The applicant contends that in view of:

(i) the purpose of the SPC Regulation,
(ii) the statements made even in very early case law given by the CJEU, and
(iii) the applicant's investment to bring about a new treatment for ulcerative colitis,

then their interpretation of Article 3(c) *"that one SPC may be granted per product, **per patent, per first authorisation** to place the product on the market as a medicinal product in the sense of Article 3(d)"* is warranted.

76 However, I am not persuaded by these arguments. In their letter dated 1 March 2021 the applicant argued that *"the original interpretation of Article 3(c) was a literal interpretation, namely that an SPC may only be granted where "the product has not already been the subject of a certificate". This interpretation meant, in effect, that one SPC was granted per product. Subsequently, case law from the CJEU updated this interpretation by application of a teleological approach. The proper interpretation of this requirement changed, such that one SPC may be granted per product per basic patent. For example, in Decision C-322/10 ("Medeva") it was held that: "where a patent protects a product in accordance with Article 3(c) […] only one certificate may be granted for that basic patent (paragraph 41, emphasis added)"*. Having looked at *Medeva*, I can find no mention in paragraph 41 of *"per first authorisation"*, or indeed that the nature of first marketing authorisation is to be taken into account when assessing compliance with Article 3(c), to support the applicant's interpretation of Article 3(c).

77 As I have indicated above, the judgment of the CJEU in *Santen* overturned the CJEU's previous judgment in *Neurim.* While CJEU decisions sometimes do qualify the judgments that went before, I am not aware of any other CJEU judgment in relation to SPCs that has included such an explicit statement that an earlier judgment of the CJEU is not correct. Also, this may explain why the Grand Chamber was convened to deal with the *Santen* case - it was recognised (by those responsible for scheduling cases and organising work at the court)[27] that the Court would need to consider the relationship between the earlier *Neurim* case and the later *Santen* one and that the possibility of finding the earlier case to be in error. In deciding *Santen*, the CJEU, sitting as the Grand Chamber, has indeed made an explicit decision that an earlier judgment of the Court was incorrect.

78 I therefore cannot ignore the relevance of *Santen* or its impact on the previous judgment in *Neurim*. It is clear from paragraphs 43-47 of the CJEU's judgment in *Santen* that the term 'product' is *"understood for the purposes of applying that Regulation, to mean the active ingredient or combination of active ingredients of a medicinal product, without its being necessary to limit its scope only to one of the therapeutic applications to which such an active ingredient or combination of active ingredients may give rise"* (paragraph 43), and that the *"strict view of the term 'product' was given concrete form in Article 1(b) of Regulation No 469/2009, which defines that*

---

[27] See explanation of working of the CJEU on its website here which indicates how the decision to assign the case to a particular chamber is decided. Brief outline provided below:

(a) The national court submits questions to the Court of Justice about the interpretation or validity of a provision of European Union law, generally in the form of a judicial decision in accordance with national procedural rules.

(b) When that request has been translated into all the European Union languages by the Court's translation service, the Registry notifies it to the parties to the national proceedings, and also to all the Member States and the institutions of the European Union. A notice is published in the Official Journal of the European Union stating, inter alia, the names of the parties to the proceedings and the content of the questions. The parties, the Member States and the institutions have two months within which to submit written observations to the Court of Justice.

(c) In all proceedings, once the written procedure is closed, the parties may state, within three weeks, whether and why they wish a hearing to be held. The Court decides, after reading the proposal of the Judge-Rapporteur and hearing the views of the Advocate General, whether (i) any preparatory inquiries are needed; (ii) what type of formation, e.g., 5-judge Chamber, 15-judge Grand Chamber, the case should be assigned to, and (iii) whether a hearing should be held for oral argument, for which the President of the CJEU will fix the date. (see also footnote 12)

term by reference to an active ingredient or combination of active ingredients and not by reference to the therapeutic application of an active ingredient protected by the basic patent or a combination of active ingredients protected by that patent" (paragraph 46). Thus, as the 'product' for the purposes of Article 1(b) is also the same as the 'product' for the purposes of Article 3(a) and Article 3(b), the CJEU reasoned that the therapeutic use does not form part of the product definition for the purposes of Article 3(d) and, in my opinion, by analogy cannot therefore form part of the product definition for the purposes of Article 3(c). Therefore, the fact that the previous SPC (SPC/GB10/016) is based on a basic patent and marketing authorisation for the treatment of rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis, does not mean that this SPC application meets the condition of Article 3(c) merely because the basic patent and the updated marketing authorisation now also includes a different therapeutic application (ulcerative colitis) from a later date than the original therapeutic indications (Rheumatoid arthritis; Psoriatic arthritis, Ankylosing spondylitis).

79 The applicant made reference to the view of the UK Court of Appeal (in making the request for a preliminary reference to the CJEU in *Neurim*) as set down in paragraphs 28-30:

> *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.*

The applicant considers that, given the view of the UK court in making this reference, then this approach should also be the approach adopted by the IPO in deciding to grant SPCs. In the present case, the applicant argues, that as the application relates to a new use of a known product, then it should be granted an SPC.

80 I agree with this view as far as it goes. The SPC regulation does allow for new uses of known products and for new processes to make known products that have gained a patent to be the basis for an SPC application, it is not confined to new products only. However, as is clear from Article 3(2) of Plant Protection Products SPC Regulation the SPC relates to the product. While a patent may describe a new use of a known product, to realise the invention claimed in the patent, one has to use the same

product, and an SPC is based on the product not on its use. The patent, such as in this case, which relates to the new use of a known product, is still a patent to that product and the SPC based on such a patent relates to the product not to the use. The question of what the SPC is granted for is separate to what protection the SPC, once granted, provides. In this instance we are concerned with the question of whether (or not) an SPC can be granted for a known product where the only point of difference is in the use of that product and not the in the product itself.

81 The CJEU judgment in *Santen*, which as I have explained above is binding on me in this instance, makes clear that the "*limits of the protection of the basic patent*" does not play a role in deciding the meaning of the term 'product' for the purposes of deciding whether an application for an SPC meets the requirements of Article 3(d). The applicant is the holder of two patents to the product "golimumab", the parent patent which formed the basis of the earlier SPC and the divisional which is the basis for the present application (see Table 1 above). Both patents relate to the same product although they do disclose different therapeutic applications for this product. However, as mentioned above, Article 3(2) of the of Plant Protection Products SPC Regulation, by virtue of Recital 17 of that same Regulation[28], applies *mutatis mutandis* to Regulation No 469/2009, and makes clear that a holder of more than one patent for the same product shall not be granted more than one certificate for that product.

82 Therefore, in my opinion, because the applicant has previously been granted a certificate (SPC/GB10/016) for the product "golimumab", and the only difference between that certificate and the present application is based on the therapeutic indication (and not on the product), this SPC application does not meet the condition of Article 3(c).

Conclusion

83 Taking all of the above into account, I consider that the product for which the SPC has been applied for "*golimumab*", as referred to in Patents Form 1 filed with this application, SPC/GB/17/023, and based on the approval of a type II variation confirming a new therapeutic application (ulcerative colitis) to European marketing authorisation EU/1/09/546/001 in Commission Implementing Decision C(2013)6224 amending the marketing authorisation granted by Decision C(2009)7653 for "*SIMPONI-golimumab*", a medicinal product for human use approved by Commission Implementing Decision C(2013)6224, does not meet the requirements of Article 3(d) of the SPC Regulation as the "*first authorisation to place the product on the market as a medicinal product*".

84 Furthermore, I consider that as the product for which the SPC has been applied for "*golimumab*", has already been the subject of an earlier granted supplementary

[28] The judgement of the CJEU in case *C-181/95 Biogen Inc. v. Smithkline Beecham Biologicals SA,* reported as [1997] RPC 23, was issued after Regulation 1768/92 came into force but before Regulation 1610/96 came into force (see also footnotes 4 & 5 above). Recital 17 was included in the latter regulation and makes explicit the condition that one SPC per product per patent holder applied to all SPCs – those based on medicinal products as well as those based on plant protection products. Thus, while the same product may be the subject of a number of patents granted to the same patent holder, the holder can only gain an SPC for one of these patents.

certificate in the UK, the present application does not meet the requirements of Article 3(c) of the SPC Regulation that "*the product has not already been the subject of a certificate*".

85 Therefore, the application for SPC/GB17/023 does not meet the conditions laid down in the Article 3 of the SPC Regulation and, as a consequence, is rejected under Article 10(2) for failing to meet the conditions laid down in this Regulation.

Appeal

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

Dr L CULLEN
Deputy Director, acting for the Comptroller