SHARED KNOWLEDGE IS TWICE AS VALUABLE.

The CJEU installs another hurdle for SPCs on functionally defined products and ends second medical use SPCs.

Decisions C-650/17 and C-673/18 of the CJEU

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The Court of Justice of the European Union (CJEU) recently issued to further decisions in relation to Article 3 of the Regulation EC 469/2009 of the European Parliament and of the Council, dated May 6, 2009 ('SPC Regulation') in the cases of *Royalty Pharma* (C-650/17) and *Santen* (C-673/18).

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PATENT ATTORNEYS AND ATTORNEYS-AT-LAW

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Introduction

Supplementary Protection Certificates (SPC) were implemented in Europe in 1993 and extend the duration of protection conferred by a basic patent for a medicinal product that has undergone regulatory approval in order to be placed on the market. The SPC shall compensate patentees for the loss of effective patent term that is caused by the period that elapses between the filing of a patent application for a new medicinal product and the authorization to place the medicinal product on the market. The legal framework is codified in the EC Regulation EC 469/2009 of the European Parliament and of the Council, dated May 6, 2009 (in the following 'SPC Regulation' or simply 'Regulation').

The highest authority responsible for interpreting EU regulations, the Court of Justice of the European Union (CJEU), has quite often been called by national courts to give advice on how to interpret certain aspects of the SPC Regulation. In fact, the SPC Regulation has required over 40 CJEU judgments since 1997 for its interpretation, which shows that there is a rather prominent demand and/or an unfortunate necessity for the interpretation of this law.

The latest judgments of the CJEU again aim to clarify certain aspects of Article 3 of the SPC Regulation. In the case of *Royalty Pharma* (C-650/17) the CJEU has been asked to give guidance on the interpretation of Article 3(a) of the Regulation, which had been subject of many previous decisions [1]. The judgment in the case of *Santen* (C-673/18) concerns the interpretation of Article 3(d) of the Regulation, which equally had been subject of a number of previous decisions [2]. Article 3 reads 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 a basic patent in force;**
>
> (b) a valid [marketing authorization] has been granted in accordance with Directive [2001/83] or Directive [2001/82], as appropriate;
>
> (c) the product has not already been the subject of [an SPC];
>
> **(d) the authorization referred to in point (b) is the first authorization to place the product on the market as a medicinal product**.

In some previous decisions concerning Article 3(a) the CJEU ruled that the product subject of an SPC application must be *specified (or identified) in the wording of the claims* of the basic patent (C-322/10 and C-630/10) to meet Article 3(a). In the case of *Eli Lilly* (C-493/12), the CJEU held that in order for an active ingredient (or product) to be regarded as 'protected by a basic patent in force', it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula; it may suffice when the active ingredient is defined by a **functional definition** in the claims. Article 3(a) does not, in principle, preclude the grant of an SPC for an active ingredient defined by function, on condition that it is possible to reach the conclusion on the basis of the claims, that they relate, **implicitly but necessarily and**

[1] *C-392/97 (Farmitalia), C-322/10 (Medeva), C-518/10 (Yeda Research); C-630/10 (University of Queensland); C-493/12 (Eli Lilly and Co Ltd.); C-443/12 (Actavis/Sanofi); C-631/13 (Arne Forsgren); C-577/13 (Actavis/Boehringer); C-121/17 (Teva UK Ltd.).*

[2] *C-431/04 (Massachusetts Institute of Technology); C-443/12 (Actavis/Sanofi); C-484/12 (Georgetown University); C-577/13 (Actavis/Boehringer).*

specifically, to the active ingredient in question. This particular ruling in *Eli Lilly* left many patent practitioners wondering about its meaning[3].

In the case of *Actavis* (C-443/12), the CJEU introduced a different test into the examination as to whether a given product is protected by the basic patent, namely only products that belong to the "**core inventive advance**" of the basic patent can be subject of an SPC[4]. Unfortunately, the CJEU did not further describe the requirements of how to determine whether a (combination) product belongs to the "core inventive advance" of a basic patent.

In the subsequent ruling of *Teva/Gilead* (C-121/17) the CJEU was asked the single question: "*What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation No 469/2009?*", by the High Court of Justice (England & Wales). Actually, in *Teva/Gilead* (C-121/17) it was the fourth time that the CJEU was asked the question on the criteria for deciding whether the product is protected by a basic patent in force in the sense of Article 3(a) of the Regulation[5]. The Court's answer in that case was:

> Article 3(a) of Regulation No 469/2009 […], must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' […] even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those **claims relate necessarily and specifically** to that combination. For that purpose, from the point of view of a person skilled in the art and **on the basis of the prior art at the filing date or priority date of the basic patent**:
> – the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, **fall under the invention covered by that patent**, and
> – each of those active ingredients must be **specifically identifiable**, in the light of all the information disclosed by that patent.
> (emphasis added)[6]

The decisions of the CJEU still leave room for interpreting as to when a given product is protected by a basic patent in the sense or Article 3(a) of the Regulation. To summarize all requirements of Article 3(a) set by the CJEU in its various decisions:

> (a) the product (or combination) must be "specified [or identified] in the wording of the claims" (*Medeva* and progeny),
>
> (b) whether a product is protected by an EP patent depends on the application of Article 69 EPC and the Protocol, not to rules relating to infringement (*Eli Lilly*);
>
> (c) a structural formula is not necessary, a functional formula will suffice (*Eli Lilly*);
>
> (d) for products that are not expressly

[3] *Franz-Josef Zimmer, Benjamin Quest, and Markus Grammel, Recent Decisions of the European Court of Justice of the European Union on Supplementary Protection Certificates: A Few Answers—Many Questions, 33(5) Biotechnology L. Rep. 171–180 (2014).*

[4] *Paragraph 41 of C-443/12: [The] basic objective of Regulation No 469/2009 is to compensate for the delay to the marketing* ***of what constitutes the core inventive advance*** *that is the subject of the basic patent […]. […] if it were accepted that all subsequent marketing of that active ingredient in conjunction with an unlimited number of other active ingredients, not protected* ***as such*** *by the basic patent but simply referred to in the wording of the claims of the patent in general terms, such as […] 'beta-blocking compound', 'calcium antagonist', 'diuretic' […], conferred entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs."*

[5] *The other occasions were Medeva (C-322/10), Actavis (C443/12) and Eli Lilly (C-491/12).*

[6] *C-121/17, paragraph 57 and ruling.*

specified or identified in the claims, to be protected the claims must "relate, implicitly but necessarily and specifically, to the active ingredient in question" (*Eli Lilly*);

(e) a skilled person in the art must, at the filing date or priority date of the basic patent, have been able to identify that the claims relate necessarily and specifically to the (combination) product (*Teva*),

(f) that the active ingredients must be specifically identifiable in the light of all information disclosed by that patent (*Teva*), and

(g) in case of combination products the combination must fall under the invention covered by that patent (*Teva*).

Given the fact that the CJEU has clearly dismissed the use of an infringement test[7] for the interpretation of Article 3(a), the question when a given product is protected by a basic patent is still open to interpretation.

So this is where the CJEU has left us to date with respect to the question of how to interpret Article 3(a) of the Regulation. On this background, we now want to assess what the recent decision in *Royalty Pharma* might add to the -in our view still somewhat fuzzy- picture of the meaning of Article 3(a).

The Royalty Pharma (C-650/17) Decision

Background of the Referral: The basic patent [8] underlying the case in C-650/17 relates to a method of lowering blood sugar levels in mammals by administering inhibitors of the enzyme dipeptidyl peptidase IV (DP-IV inhibitors). Royalty Pharma applied for an SPC relying on the marketing authorization (MA) for the active substance "Sitagliptin", which is a DP-IV inhibitor used for the treatment of diabetes. However, Sitagliptin was developed by a licensee *after* the priority date of the basic patent[9]. That is, the active substance subject to the SPC application was not explicitly disclosed in the basic patent, but was embraced by the functional claim language (DP-IV inhibitor). The German patent office rejected Royalty Pharma's SPC request based on Art. 3(a) of the SPC-Regulation. Royalty Pharma appealed said decision before the German Federal Patent Court which then referred the case to the CJEU with the following questions:

(1) Is a product protected by a basic patent in force pursuant to Article 3(a) […] only if it forms part of the subject matter of protection defined by the claims and is thus provided to the expert as a specific embodiment?

(2) Is it not therefore sufficient for the requirements of Article 3(a) […] if the product in question satisfies the general functional definition of a class of active ingredients in the claims, but is not otherwise indicated in individualized form as a specific embodiment of the method protected by the basic patent?

(3) Is a product not protected by a basic patent in force under Article 3(a) […] if it is covered by the functional definition in the claims, but was developed only after the filing date of the basic patent as a result of an independent inventive step?

[7] *Paragraph 33 of C-493/12: […], for the purpose of determining whether a product is 'protected by a basic patent in force' within the meaning of Article 3(a) of Regulation No 469/2009, recourse may not be had to the rules governing infringement proceedings […]. See also paragraph 37 of that judgement. Confirmed in C-121/17, No. 33.*

[8] *EP 1 084 705, filed 1997-04-25.*

[9] *Noteworthy, a separate patent, EP 1 412 357 filed 2002-07-05, was obtained for Sitagliptin and the licensee obtained an SPC for Sitaglipin on the basis of that later patent.*

The CJEU addressed the referring Court whether, in the light of the judgment in *Teva/Gilead* (C-121/17, discussed above) it wished to maintain the request for a preliminary ruling; the Federal Patent Court confirmed its request as the earlier case-law, in particular *Actavis* (C-443/12), left the question open, whether the concept of a '**core inventive advance**' would be of any relevance for the purposes of Article 3(a) of the Regulation. The CJEU replied that it did not expressly employ the concept of a 'core inventive advance' in its previous rulings and that it would also not endorse any such concept for the interpretation of Article 3(a) of the Regulation.

Like several times in the past, the CJEU decided to not address the specific questions of the referring court, but reformulated the first and second questions as follows:

> By its first and second questions […] the referring court asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product is protected by a basic patent in force […] if it satisfies a general functional definition used by one of the claims of the basic patent and necessarily comes within the scope of the invention covered by that patent, but is not otherwise indicated in individualized form as a specific embodiment of the method of that patent.

The CJEU, like in the decision of *Teva/Gilead* (C-121/17) and earlier decisions held recourse to Article 69 EPC and the Protocol on the Interpretation of that provision and repeated that it must be possible, on the basis of the claims as interpreted, inter alia, in the light of the description of the invention, to conclude that the claims relate implicitly but necessarily and specifically to the active ingredient in question [10]. The CJEU then employed the two-pronged test developed in *Teva/Gilead* (C-121/17) [11]: (i) the product must, from a skilled person's view, in the light of the description and drawings of the basic patent "necessarily come under the invention covered by that patent" and (ii) the skilled person must be able to "identify that product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date" of the basic patent. The CJEU found that sitagliptin as a DP-IV inhibitor, necessarily comes within the scope of the invention covered by the basic patent even though it is not individually identified in the specification of the basic patent [12]. However, the CJEU reasoned that for determining whether the second condition is satisfied one must ascertain whether the product is "within the limits of what a person skilled in the art is objectively able, at the filing date or priority date of the basic patent, to infer directly and unequivocally from the specification of that patent as filed based on that person's general knowledge" and further considering the prior art at the filing or priority date [13]. The CJEU held that the referring court has to determine whether sitagliptin satisfies this condition.

With regard to the third question, the CJEU reasoned that the subject-matter of the protection conferred by the basic patent must be determined at the filing date or the priority date of that patent. Therefore, products which were developed *after* the filing date or priority date of the basic patent, *following an independent inventive step*, cannot meet the second condition of the two-pronged test mentioned above, i.e. that the skilled person must be able to "identify that product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date. To allow an SPC for subject-matter resulting from research which took place *after* the filing date would be contrary to the objective of the Regulation to encourage research and to ensure that the investments made to such research are covered. The CJEU therefore judged:

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[10] Paragraph 36 of C-121/17 and paragraph 36 of the present ruling.

[11] Paragraph 52 in C-121/17 and paragraph 37 of the present ruling.

[12] Paragraph 38 of the present ruling.

[13] Paragraph 40 of the present ruling.

> 1. Article 3(a) of Regulation (EC) No 469/2009 […] must be interpreted as meaning that a product is protected by a basic patent in force […] if it corresponds to a general functional definition used by one of the claims of the basic patent and necessarily comes within the scope of the invention covered by that patent, but is not otherwise indicated in individualized form as a specific embodiment of the method of that patent, provided that it is specifically identifiable, in the light of all the information disclosed by that patent, by a person skilled in the art, based on that person's general knowledge in the relevant field at the filing date or priority date of the basic patent and on the prior art at that date.
>
> 2. Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product is not protected by a basic patent in force […] if, although it is covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step. (emphasis added)

Discussion:

The *Royalty Pharma* decision adds one further (negative) criterion to the interpretation of Article 3(a) in that the product in question is not protected by a basic patent, if said product is developed after the priority/filing date of the basic patent and is the subject of an own younger patent. In other words, the product in question for which an SPC shall be obtained must not be the subject of a dependent invention, or – in other words – may not be based on an inventive step *vis*-à-*vis the basic* patent.

It seems difficult to believe that the present ruling will finally lead to a uniform application of the Regulation throughout the European national legal landscape. So what can we take home from the *Royalty Pharma* judgment?

The good, the bad … and the ugly

The good: One clear take home message of *Royalty Pharma* is that the CJEU confirms that, where the product which is the subject of the SPC is not in individualized form a specific embodiment of that patent, the grant of an SPC is not, in principle, excluded [14]. Further, the mere fact that the product for which an SPC is sought was developed after the filing date may not necessarily exclude it from being the subject for an SPC. However, in cases where the product which shall be the subject of an SPC is protected by a younger patent and the younger patent is based on an inventive step *vis*-à-*vis the earlier patent claiming the product by a functional definition then the product is not regarded to be protected by the earlier patent under Article 3(a).*

The bad: While we now have a whole catalog of criteria that a product must or must not fulfill in order to be protected by a basic patent under Article 3(a), these criteria are still open to interpretation.

The newest, and probably the most problematic criterion is the condition that the product must not have been developed after the filing date of the application for the basic patent, and the development being based on an *independent inventive step*.

One may speculate that the CJEU wants to maintain the possibility for applicants to obtain an SPC for e.g. a specific antibody that can be developed with standard means based on a patent that defines antibodies by functional terms (e.g. by their binding characteristics), where the applicant has, at its time of filing, not disclosed the specific antibody (or has disclosed different antibodies). Developing a (further) antibody that falls under the functional definition of the patent claim would allow the developer to obtain an SPC under the condition that the development would not be inventive over the basic patent. In other words, the CJEU did

[14] *Paragraph 41 of the present ruling.*

apparently not want to exclude products falling under a functional definition from SPC protection as long as these products could be obtained in an obvious way based on the teachings of the basic patent.

Thus, for determining whether a product, which is not directly disclosed in the basic patent, is protected by the basic patent, one has to determine whether the product would represent a separate (dependent) invention or whether it would be obvious in view of the disclosure of the basic patent (at the filing or priority date of that basic patent). If the product at issue would be inventive over the disclosure of the basic patent, then this product cannot be regarded protected by the basic patent in the sense of Article 3(a) of the Regulation. However, obviousness is a rather difficult and vague criterion. It becomes an increasingly difficult task to assess whether a product which is not literally disclosed in the basic patent can be the subject for an SPC application.

To pick up the above example, what about antibodies that were generated after the filing date and that, in principle, would fall under a functionally defined claim? One may argue that a skilled person could, at the filing date, identify these antibodies to represent an embodiment of the claims of the basic patent and argue further that these antibodies could be produced by means known at the filing date. However, as it often turns out, some particular characteristic of an antibody may give rise to the presence of an inventive step (e.g. particular binding affinity or a very high plasma half-life or the binding to a particularly advantageous epitope). The applicant may have to discuss these questions with patent offices throughout Europe if they want to obtain an SPC with possibly different results in each country. This would be contrary to the incentives of the SPC Regulation (Recital (7) [15]). Moreover, it would be against the previous idea of the CJEU court to keep the SPC granting process “simple”, and while the CJEU did not want to apply an infringement test under Article 3(a) in light of the *Royalty Pharma* case the patent offices now have to perform an inventive step examination.

And the ugly: The situation gets worse for products that were developed after the filing date of the basic patent and that *are* subject of a later patent application. This could then mean that the outcome of the SPC application is dependent on the fate of that subsequent and entirely unrelated patent application. Alternatively, what about a situation such as in *Royalty Pharma*, where a younger patent for a specific antibody (‘anti-Y’) has been obtained (which was a reason for the CJEU to deny an SPC in said case), but becomes challenged in a nullity suit? Is ‘anti-Y’ eligible for an SPC only if the later patent is nullified (or needs it be nullified due to lack of inventive step)? What if the SPC had been denied in view of the younger patent and all time limits for applying for an SPC are over before the younger patent is invalidated? And what about a granted SPC to ‘anti-Y’, where after SPC grant a younger patent for ‘anti-Y’ issues? Is the SPC then null and void? What about the situation where one national patent office rejects the younger application to a given product and other national patent offices grant a patent?

In our view, it is a fundamentally wrong approach to make the grant of an SPC based on the basic patent dependent from the existence and/or fate of younger patents. In view of the decision in the *Royalty Pharma* case one may fear that less legal certainty than we had before exists when it comes to the question whether an SPC application at the end of the day might be successful.

What applicants can do

One possible strategy could be to continue filing patent applications for “snapshots” of the product development once that a first patent with a functionally defined invention (or

[15] *A uniform solution at [Union] level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the [Union] and thus directly affect the functioning of the internal market.*

a generic structural formula) has been obtained. These later patent applications may then be granted as dependent inventions or rejected as being obvious over the earlier filing. In case of grant, the SPC may be based on the younger patent, in case of a rejection, the SPC should be granted on the basis of the earlier patent. Of course such strategy could run into conflict with the deadlines for filing an SPC application.

SECOND MEDICAL USE SPCs

The Santen (C-673/18) Decision

In the past, several judgments of the CJEU addressed questions of what constitutes the first marketing authorization (MA) of a given product in the sense of Article 3(d) of the Regulation. Art. 3 (b) of the SPC Regulation requires that an SPC can only be granted, if a valid authorization to place the product in the market as a medicinal product has been granted in accordance with Directive 2001/83/EC (relating to human medicinal products) or Directive 2001/82/EC (relating to veterinary medicinal products), as appropriate. According to Art. 3 (d) of the SPC Regulation this MA must be the **first** authorization to place the product on the market as a medicinal product. Based on a line of CJEU jurisprudence [16], it was generally thought that an SPC was precluded if the active ingredient in question had been authorized by any earlier MA within the EU, even if the earlier authorization related to a different use in a different species. However, that situation was largely liberated by the judgment in *Neurim* (C-130/11), where the CJEU had addressed the question whether the existence of an earlier MA for a veterinary medicinal product is sufficient to preclude the grant of an SPC for a different product with the same active ingredient for which a later MA has been obtained for a human medicinal product. The CJEU ruled on that question:

> Articles 3 and 4 of Regulation (EC) No 469/2009 […] must be interpreted as meaning 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 a [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]. (editorial shortcuts in [brackets])

In particular, paragraphs 25 and 26 of the reasoning of that decision were clearly linking the relevant MA with the new therapeutic application and allowing for an SPC if that new therapeutic use of the later product and MA is within the limits of protection conferred by the basic patent [17]. The judgment in *Neurim* allowed "second medical use" SPCs and it also seemed warranted to reward pharmaceutical research directed to new treatments of diseases, especially on the background that it was a long standing practice to award applicants patents for a new second medical use. Unfortunately, the *Neurim* judgment has not led to a uniform practice in the different EU member states as evidenced by the proceedings that led to the latest judgment of the CJEU in *Santen* (C-673/18).

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[16] *C-31/03 Pharmacia, C-431/04 MIT, C-202/05 Yissum, C-195/09 Synthon and C-427/09 Generics*

[17] *(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 authorized 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.*

Background of the referral leading to Santen: Santen obtained a MA for a medicinal product marketed under the name 'Ikervis', the active ingredient of which is ciclosporin. That medicinal product is used to treat severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes, causing inflammation of the cornea. The basic patent at issue[18] protects, inter alia, an ophthalmic emulsion with ciclosporin as the active ingredient. The SPC application was rejected by the French patent office, because an earlier MA for a medicinal product with ciclosporin as the active ingredient existed (MA for 'Sandimmun' of 23 December 1983); that medicinal product was presented in the form of an oral solution and was indicated for preventing the rejection of solid organ and bone marrow grafts. Santen appealed the rejection of the French patent office before the Court of Appeal, Paris, which sought clarification on the questions of how the judgment of *Neurim* is to be interpreted, in particular with respect of what represents a 'different application of the same product' and how the therapeutic application to be 'within the limits of the protection conferred by the basic patent' should play any role. The referring court asked:

> (1) Must the concept of a "different application" within the meaning of [the judgment in Neurim] be interpreted strictly, that is to say:
> – as being limited only to the situation where an application for human use follows a veterinary application;
> – or as relating to an indication within a new therapeutic field, in the sense of a new medical specialism, as compared with the earlier MA, or to a medicinal product in which the active ingredient acts differently from the way in which it acts in the medicinal product to which the first MA related;
> – or more generally, in the light of the objectives of [Regulation No 469/2009] of establishing a balanced system taking into account all the interests at stake, including those of public health, must the concept of a "new therapeutic use" be assessed according to stricter criteria than those for assessing the patentability of the invention;
>
> or must it on the other hand be interpreted broadly, that is to say, as including not only different therapeutic indications and diseases, but also different formulations, posologies and/or means of administration?
>
> (2) Does the expression "[application] within the limits of the protection conferred by the basic patent" within the meaning of the judgment [in Neurim], mean that the scope of the basic patent must be the same as that of the MA relied upon and, therefore, be limited to the new medical use corresponding to the therapeutic indication of that MA?' (editorial shortcuts in [brackets])

For clarifying the meaning of the concepts of 'different [therapeutic] application' and '[therapeutic] application … within the limits of the protection conferred by the basic patent' , the CJEU reasoned that it is necessary to examine whether a MA that covers a new therapeutic application of an active ingredient may be considered the first MA, where the same active ingredient had already been subject to a MA for a different therapeutic application [19].

To answer the questions relating to Article 3 of the Regulation, the CJEU first discussed whether the concept of a 'product', as defined in Article 1(b) of the Regulation[20], is in any way dependent on the therapeutic application of the active ingredient. If it were, the therapeutic application would represent a discriminating feature of the product and a new therapeutic application would have to be

[18] *EP 057959306.*

[19] *Paragraph 37 of Santen.*

[20] *(b) "product" means the active ingredient or combination of active ingredients of a medicinal product;*

considered to render a product distinct from a product with the same active ingredient for a different, already known, therapeutic application. Accordingly, a MA for a known product in a new therapeutic application would have to be considered a first MA for the product/therapeutic application "combination".

However, Article 1(b) does not refer to therapeutic indications. From the absence of any (therapeutic use) limitations of the definition of the 'product' in Article 1(b) (and from the wording of Article 4 of the Regulation[21] which does not limit the product protection conferred by an SPC to any specific therapeutic application), the CJEU concluded that the term 'product' as defined in the Regulation is not dependent on a therapeutic application. Thus, the intended use of the medicinal product is irrelevant for the grant of an SPC, the product according to the Regulation is strictly confined to the active ingredient *per se*.

Therefore, the CJEU concluded that Article 1(b) of the Regulation must be interpreted as meaning that the fact that a product is used in a new therapeutic application does **not** confer on it the status of a distinct product where the same active ingredient has been used for the purposes of a different, already known, therapeutic application.

The strict definition of the product now required the CJEU to address, whether the therapeutic application of the MA must be assessed in relation to Article 3(d), i.e. to determine whether a MA can be a first MA **by virtue** of being the first MA *to fall within the limits of the protection of the basic patent*.

However, the CJEU held that the limits of protection of the basic patent should not be decisive for determining whether a MA is the first MA. According to the Court such an approach would necessarily call into question the strict definition of the term 'product' adopted by it. Furthermore Article 1(c), which defines what is meant by 'basic patent' [22], includes the possibility that a basic patent X may cover only one specific therapeutic application of the product. A MA covering this specific therapeutic application would then justify the grant of an SPC even if the same active ingredient is covered by a different, already known, therapeutic application which gave rise to an earlier MA that would not fall within the basic patent X. This would result in an "evergreening" of protection for the product and jeopardize the narrow definition of the term 'product' as defined in the Regulation.

The Court found that the interpretation in *Neurim* might compromise the simplicity and the predictability which the EU legislature intended the system to have in order to guarantee a uniform implementation by the national patent offices. In particular a distinction between different therapeutic applications, without that concept even being defined in the Regulation, could lead those national offices to adopt complex and divergent interpretations. Therefore, the CJEU expressly overturned its reasoning applied in *Neurim*, and held that for the purpose of Article 3(d) of the Regulation in order to determine whether a MA is the 'first [MA for the product] as a medicinal product', there is no need to take into account whether a therapeutic application of a product lies within the limits of the protection of the basic patent.

In view of the above considerations, the CJEU ruled that:

> Article 3(d) of Regulation (EC) No 469/2009 […] must be interpreted as meaning that a [MA] cannot be considered to be the first [MA], for the purpose of that provision, where it

[21] 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 [MA] and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

[22] Article 1 (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

> 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 [MA] for a different therapeutic application.

Discussion

The judgment is a very clear dismissal of "second medical use SPCs" and a clear guidance that an SPC shall be granted for a new product only and not for new uses of a known product.

That a distinction between different therapeutic applications could lead national offices to adopt complex and divergent interpretations of the condition laid down in the Regulation is a debatable statement. In general, patent offices should not have particular problems in granting patents to inventive second medical uses, so why should there be a problem in granting or denying "second medical use" SPCs? The examination as to whether an indication in an SPC request is a new one over optionally existing older SPCs should be doable.

Whether the strict approach now applied by the CJEU in fact is a fair balance between the objective of the SPC regime [23] , (to compensate for the short effective patent protection and the investment put into pharmaceutic research) and the EU legislature's intention [24] (to take all the interests at stake into account, including those of public health) is, in our view, a debatable position. Finding new therapies always requires investments in pharmaceutical research. The *Santen* decision makes it more difficult to recover such investment and, hence, is not a motivation for pharmaceutical companies to find new applications for old drugs.

A recent EU funded study came to the conclusion that only limited motivation exists for the pharmaceutical industry to extend the application of existing medicinal products to further indications in order to prevent off-label use due to the absence of incentives and/or the duration and high costs of the authorization procedure [25] . The study suggests that enhancing the incentives to register new indications would lead to authorized products for more indications for which a proper benefit-risk analysis has been performed and a stronger position for prescribers with regard to liability. The study also supposes that further incentives may also lead to more R&D activities by pharmaceutical companies. Currently, the only EU incentive for registering new medical uses of existing products is one year extra market protection if a new indication is registered in the first eight years after a MA has been granted and if this new indication brings significant clinical benefit over existing therapies. Under the present situation, especially for off-patent products, the competition by generics and/or the low price of such medicinal products already have a negative impact on return for investments in new indications for the pharmaceutical industry.

A further actual EU study on the economic impact of SPCs, pharmaceutical incentives and rewards in Europe from May 2018 [26] found that while the protection for medicinal products in the EU is amongst the strongest in the world, the average effective protection period for medicinal products has *decreased* by approximately two years from 15 to 13 years since 1996. The study also found that a longer effective protection period stimulates research and development into new medicinal products, as was the incentive of the legislator when creating the supplementary protection certificate.

It seems that the situation that lead to the implementation of SPCs in 1993 has not

[23] Recitals 3 to 5 and 9 of the Regulation
[24] Recital 10 of the Regulation

[25] M. Weda et al. Study on off-label use of medicinal products in the European Union, February 2017; section 6.2: http://ec.europa.eu/health/sites/health/files/files/documents/2017_02_28_final_study_report_on_off-label_use_.pdf
[26] ISBN 978-92-79-68050-2; doi: 10.2873/886648.

changed much and that the incentives continue to apply (see recitals (3) to (5) of the Regulation [27]). On this background, the latest decision of the CJEU seems to work against the goal of the SPC Regulation to promote pharmaceutical research, as the ruling in *Santen* does not encourage patentees to investigate new therapies based on known active agents, which therapies nevertheless require extensive research and also require medical products to undergo further regulatory approval.

It is therefore unfortunate that the CJEU has now narrowed down the concept of what a medicinal product is, namely to merely the active ingredient (or the combination of active ingredients) as such, irrespective of the intended use.

At the present time a further referral addressing the "second medical use" SPC is pending before the CJEU (C-354/19, *Novartis AG*). In C-354/19 the referring court asks:

> In view of the fundamental purpose which the [SPC] for medicinal products is intended to fulfil, namely that of stimulating pharmaceutical research in the European Union, does Article 3(c) of Regulation No 469/2009, having regard to Article 3(2) of Regulation No 1610/96, preclude an applicant who has previously been granted [an SPC] in respect of a product protected by a basic patent in force in respect of the product *per se*, from being granted [an SPC] for a new use of the product in a case […] in which the new use constitutes a new therapeutic indication which is specifically protected by a new basic patent?

However, in view of the *Santen* decision it is reasonable to predict that the outcome of this referral will provide no remedy for the pharmaceutical industry.

It is to be expected, that the CJEU will stick to its "new" and strict interpretation of what a product according to the SPC Regulation is, and this "new" definition does not regard a product for a new use to qualify as something for which an SPC could be granted.

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[27] *Recital (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.*
Recital (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.
Recital (5) This situation leads to a lack of protection which penalises pharmaceutical research.

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