Product, Medicinal Product, Basic Patent: The Relationship of Concepts in Regulation 469/2009 Overlooked by the CJEU

Krystyna Szczepanowska-Kozłowska

Accepted: 9 November 2021 / Published online: 24 November 2021
© The Author(s) 2021

Abstract The CJEU *Santen* judgment defined the concept of a product for the purposes of Regulation 469/2009 on the supplementary protection certificate for medicinal products (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 (Codified version), [2009] OJ L152/1, as last amended by Regulation (EU) 2019/933 of 20 May 2019, [2019] OJ L153/1). Leaving aside the practical implications of this judgment in terms of the possibility of obtaining a supplementary protection certificate for a product protected by a patent for a second or further medical application (“application patent”), it is worth considering the reasoning the Court relies on to arrive at the thesis it formulates. While the Court’s response and the resulting impact will be treated differently depending on whether the actual extension of patent protection in the pharmaceutical industry is assessed as appropriate and desirable or whether the justification for said protection is questioned, the manner in which the provisions of Regulation 469/2009 are proposed to be interpreted raises doubts as to whether the final outcome of the interpretation is correct.

Keywords Regulation (EC) 469/2009 · Supplementary protection certificate · CJEU *Santen* judgment · Product patent · Medicinal patent · Application patent

1 Introduction

Although a concise text, formulated in apparently clear language, the SPC Regulation has quite often been the subject of CJEU preliminary rulings. Suffice it

K. Szczepanowska-Kozłowska (✉)

Professor, Dr. iur. hab.; Department of Intellectual Property and Intangible Goods, Faculty of Law and Administration, Warsaw University, Warsaw, Poland
e-mail: k.szczepanowska_kozlowska@wpia.uw.edu.pl

to say that during the period of its existence (including the previous text of the Regulation¹) it has been the subject of approximately 40 rulings. Of course, not all of them had, and have, the same relevance to rightholders seeking to obtain a supplementary protection certificate. As in the case of other exclusive rights, which provide rightholders with the exclusive use of the protected good, in the case of the right in question the provisions of the Regulation that determine the conditions for its granting are also of great importance. In the case of the application of the SPC Regulation, the situation is specific in that, although the SPC is an exclusive right that operates at the EU level, it is granted by national authorities. Thus, unlike EU uniform laws, the SPC operates independently in each territory. Undoubtedly, this formulation of the supplementary protection certificate is an obvious consequence of the absence of a patent of a unitary nature which would be valid throughout the European Union. The fact that the granting of supplementary protection certificates in individual countries is decided by national authorities necessarily leads to divergent interpretations of the provisions of the SPC Regulation. It is not uncommon in practice that the holder of the same European patent, which is valid in the territory of individual EU Member States, cannot obtain a supplementary protection certificate in all countries where the patent is in force. This is often the reason why preliminary questions are referred to the Court of Justice by national authorities deciding on the granting of a certificate and intended to contribute to a uniform interpretation of the SPC Regulation. However, the fact that these rulings are made in light of specific facts makes it difficult to detach the ruling from the realities and sometimes very specific circumstances of the case. This gives rise to further doubts as to the correct application of the CJEU's ruling by the national court. Although the same CJEU judgment may be interpreted differently by national courts, as pointed out, for example, in connection with the ruling in *Neurim*,² such a radical change of approach to the interpretation of the provisions of the Regulation as that proposed by the CJEU in judgment C-673/18³ does not seem to be a remedy. In particular, notwithstanding the conclusions on the possibility of obtaining a supplementary protection certificate where the basic patent is a patent for second and further medical applications that flow directly from the judgment, the CJEU's considerations raise questions regarding its correctness if the methods of interpretation applied in that judgment are taken into account.

It is not the purpose of this article to assess the factual implications of the judgment, and in particular to attempt to seek answers as to how the *Santen* judgment will affect research into second and further therapeutic applications of known substances. Therefore, obvious arguments suggesting the relevance in medical therapies of medicinal products based on known medical substances in subsequent applications will be outside the scope of consideration. However, it is

¹ Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182, 2 July 1992, pp. 1–5.

² CJEU, 19 July 2011, Case C-130/11, *Neurim Pharmaceuticals* (1991); see also Romandini (2018), Ch. 11, pp. 229–239 and Annex I, National reports EU.

³ CJEU, 9 July 2020, Case C-673/18, *Santen SAS*.

worth considering to what extent the methods applied by the CJEU are convincing for the achieved interpretation result.

Regardless of whether we believe that the SPC should be granted for a further use of a known substance or we do not share such an opinion, the interpretation of the provisions of the Regulation and the justification of the judgment must raise doubts in the light of the common and generally accepted principles of interpreting legal texts. Although the CJEU also sees in this judgment the need to interpret the definitions in the context in which they appear, it interprets the concept of a product in isolation from other definitions contained in the Regulation, including, in particular, the definition of the basic patent, failing to recognise the interdependence of these concepts. A literal, strict interpretation of the concept of a product affects the understanding of other terms used in the Regulation, which in turn leads to the lack of internal consistency of the Regulation, and to severing the necessary link with patent law. Moreover, the application of the proposed interpretation of the concept of a product, in connection with other judgments of the CJEU, leads to the actual exclusion of a use patent from the conceptual category of a basic patent, and this is even true in the case of a patent for a first medical use, which in turn contradicts the intentions of the CJEU, so strongly emphasised in the said judgment. Referring to the Explanatory Memorandum⁴ as a justification for the adopted interpretation also seems to be incorrect, as the CJEU does not seem to notice the difference between a product and a medicinal product. However, apart from the conclusions resulting from the analysis of the Explanatory Memorandum, there is also the question of how correct is the interpretation of the legal text based on the documents from the preparatory works in the situation of such a significant time lapse since their creation and, no less important, huge changes in the understanding of the concept of a product in patent law.

Regardless of the above, doubts arise whether the proposed interpretation indeed serves the purposes of the Regulation, consisting in balancing the interests of entities innovating in the pharmaceutical industry and the general interest in the widest possible access to these innovations. It seems that such a balancing of interests means simply excluding the possibility of obtaining an SPC for many medicinal products, which is inconsistent with the function that the Regulation was supposed to fulfil.

Going through the facts and the justification of the *Santen* judgment in Sect. 2, it is argued in Sect. 3 that the manner of interpretation used by the CJEU is incorrect. If a similar interpretation would be applied to other definitions, such as a basic patent, the result could be impossible to reconcile with the CJEU's express intention to use the context in which we employ such definitions. This inevitably leads to the question, discussed in Sect. 4, as to whether the SPC Regulation gives grounds to treat basic patents differently depending on whether they are patents for a first or further medical use. In Sect. 5 it is argued that the historical document explaining

⁴ COM (90) 101 final, 11 April 1990, Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, Explanatory Memorandum, accessed at: Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products. COM (90) 101 final, 11 April 1990 - Archive of European Integration (pitt.edu), ("Explanatory Memorandum").

the purpose and the scope of the SPC Regulation does not amount to the interpretation proposed by the CJEU. It also provides grounds to state in Sect. 6 that the importance of the method based on the historical background for the correct interpretation of normative acts should be limited. The changes that have taken place in the operating environment of the provision in question since the date of its enactment stand in the way of such an interpretation. Finally, in Sect. 7 the factual and legal circumstances that have been overlooked by the CJEU are analysed.

2 CJEU *Santen* Judgment

For further consideration, it is necessary to recall the facts of the case against which *Santen* was decided. Santen SAS is the holder of a European patent protecting in particular an ophthalmic emulsion in which the active ingredient is ciclosporin. It obtained an MA for a medicinal product “Ikervis” for the treatment of severe keratitis in adult patients. On the basis of the European patent and the obtained MA, Santen SAS filed with the competent national authority an application for an SPC for a product called “Ciclosporin for use in the treatment of keratitis”. The national authority rejected that application for an SPC, stating that the MA granted to Santen SAS was not the first authorisation within the meaning of Art. 3(d) of the Regulation, since an MA was granted in 1983 for the medicinal product “Sandammun” which also had ciclosporin as its active ingredient, indicated for preventing the rejection of solid organ and bone marrow grafts and for other therapeutic indications, including the treatment of endogenous uveitis, an inflammation of all or part of the uvea, the middle part of the eyeball. The court hearing the appeal filed by Santen SAS entertained doubts and referred questions to the CJEU for a preliminary ruling. These doubts related primarily to the consequences of the *Neurim* judgment, which had been handed down nearly a decade earlier. In essence, those questions concerned the issue whether an SPC could be granted for a product used in a subsequent medicinal product, the therapeutic indications of which are different from those of the medicinal product for which an MA was previously granted. According to the referring court, it was necessary to clarify how the concept of a new therapeutic application should be understood in the light of the *Neurim* judgment.

However, the CJEU pointed out that even if the referring court limited its questions to the interpretation of certain aspects of EU law, the Court is not bound by such an interpretation and may also rule on all the elements of interpretation of EU law that may be of assistance.⁵ Therefore, ultimately the CJEU did not refer to the concept of a therapeutic application as such, but considered that the understanding of a “product” and determination whether this concept, as defined in Art. 1(b) of the SPC Regulation, allowed to speak of a different product in a situation of a new therapeutic application and was relevant for the outcome.⁶ It pointed out that, under Art. 1(b) of the SPC Regulation, a “product” means the

⁵ Para. 35.

⁶ Paras. 37–39.

active ingredient or a combination of active ingredients and that the meaning and scope of those terms must be determined by considering the general context in which they are used and their usual meaning in everyday language.⁷ Referring to its case law, it ultimately held that an active ingredient is a substance which has, at least, a therapeutic effect of its own.⁸ Then, relying on the wording of Art. 1(b) in conjunction with Art. 4 of the SPC Regulation, it concluded that it was not necessary to limit the term “product” only to one of the therapeutic applications. It emphasised that, in the light of Art. 4 of the SPC Regulation, any protection conferred on the product by the SPC extends only to the product covered by the MA and covers any use of that product as a medicinal product. According to the CJEU, this leads to the conclusion that the term “product” is not dependent on the manner in which that product is used and that the intended use of the medicinal product does not constitute a decisive factor for the grant of an SPC.⁹ According to the CJEU, such a conclusion is also supported by the origins of the SPC Regulation itself. In this case the Court referred to the Explanatory Memorandum to the Proposal for the Regulation concerning the creation of a supplementary protection certificate of 11 April 1990,¹⁰ stating that

the term “product” is understood to mean an active ingredient in the strict sense and that minor changes to the medicinal product such as a new dose, the use of a different salt or ester or even of a different pharmaceutical form will not lead to the issue of a new SPC.¹¹

This led the CJEU to conclude that the use of the active ingredient for a new application does not confer on it the status of a distinct product.¹² Consequently, the CJEU concluded that the question of whether an MA is the first MA granted for the product should be determined without reference to the scope of protection of the basic patent, since no such reference is made in Art. 3(d) of the SPC Regulation.¹³ That provision refers to a medicinal product containing an active ingredient regardless of its therapeutic application for which an MA has been granted. The CJEU made it clear that, contrary to the interpretation made in the *Neurim* judgment, the limits of the protection of the basic patent should not be taken into account in order to define the concept of the first MA for the product as a medicinal product. Next, the Court referred to the objectives of the Regulation and emphasised that it is apparent from the Explanatory Memorandum to the Proposal for the Regulation, which it cited, that the SPC regime is intended to support only research leading to the first placing on the market of an active ingredient. That objective would be undermined if an MA which had been granted previously for a different therapeutic application could be disregarded. According to the Court, only such an

⁷ Para. 41.

⁸ Para 42.

⁹ Paras. 42–44.

¹⁰ See *supra* note 5.

¹¹ Para. 45.

¹² Para. 47.

¹³ Para. 50.

interpretation enables a fair balance to be struck between all the interests at stake, that is to say, to ensure that the rightholder is duly protected and encouraged to continue working on new substances and to safeguard the protection of public health. After all, this does not exclude new applications from certificate protection as long as the previously known substance was not used as a medicinal product.¹⁴ Moreover, an interpretation taking account of the new therapeutic application of a product might “compromise the simplicity and the predictability of the system”, which the EU legislature intended the system to have. And, as the Court ultimately finds, “[t]he 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”.¹⁵ Finally, the Court concluded that Art. 3(d) of Regulation 469/2009 must be interpreted as meaning

that a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application.

3 The Concept of Product – Does the Context Matter?

At the outset, it is worth recalling that the SPC Regulation itself expressly mandates that a product whose use as a medicinal product is to be protected by a supplementary protection certificate must remain under the protection of the basic patent, including the application patent. As defined in Art. 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 the grant of a certificate. That provision expressly stipulates that the protection of a product conferred by a patent may be direct protection, relating to the product as such; may be indirect protection, relating to the patent protecting in the first instance the method of manufacture of the product; and, finally, may be protection resulting from the application of the product.¹⁶

The concept of an application patent included in the definition of a basic patent is not limited to the first medical application patent, but applies to the entire category of application patents, regardless of whether it protects the first or subsequent medical application. Based on a literal interpretation, we should assume that, since the definition is not limited to the first application, the definition of a basic patent applies to any application patent, whether it is the first or subsequent medical application. Referring to the literal interpretation and in accordance with the CJEU’s guidance flowing from this judgment, taking into account the context in which we

¹⁴ Paras. 55–58.

¹⁵ Para. 59.

¹⁶ See also Grabinski (2015).

refer to a particular concept,¹⁷ a similar conclusion would have to be considered justified against the background of the definition of the concept of a product. Since the Regulation does not limit the concept of a product, it covers all products that can be protected by patent law, thus covering purpose-limited products.

The CJEU, however, adopts a different line of reasoning. Referring to a literal interpretation, it considers that, in the absence of an explicit reference to a therapeutic indication in the definition of a product, the concept of a product does not cover purpose-limited products. If these two definitions (product and application patent) are juxtaposed – “considering the general context in which they are used and their usual meaning in everyday language” (as the CJEU points out in relation to the concept of a product in paragraph 41 of the reasons) – it appears that they cannot be reconciled. Indeed, the proposed definition of a product leads directly to the exclusion of patents for second and subsequent medical applications, contrary to the conceptual category of an application patent, which relates to any medical application. It is questionable whether such an understanding of the concept of a product, which cannot be reconciled with another definition in the Regulation, is appropriate.

Firstly, the question arises whether the correct interpretation of a legal text may be based on a method of interpretation in which one of the key concepts of a regulation is interpreted in isolation from a concept of equal importance. Moreover, such an interpretation also directly leads to discrimination between a patent for second and further medical applications. Such discrimination is explicitly ruled out both by the Explanatory Memorandum cited by the CJEU and, primarily, by the fact that the grounds for limiting the significance of those patents can hardly be found in the applicable provisions of law, particularly the European Patent Convention, to which I will return.

Secondly, despite declaring that concepts must be interpreted “considering the general context in which they are used and their usual meaning in everyday language”, the CJEU, while accepting the everyday language meaning, completely disregards the context in which the concept is used. However, it may be that when the CJEU refers to the “general context”, it only has in mind an understanding of the term in everyday language, rather than a search for its meaning in a so-called “speech setting”.¹⁸ Indeed, the Regulation unquestionably relates to products protected by patents, including application patents. This circumstance should be taken into account when seeking the proper context for this expression. The impossibility of reconciling the proposed understanding of the concept of a product with the definition of a basic patent, as indicated above, would apparently call into question the validity of such an interpretation.

The Polish literature emphasises that the linguistic interpretation of a legal act takes precedence. Only if this does not lead to satisfactory results is the systematic and functional interpretation applied.¹⁹ It seems that the same methods of

¹⁷ Para. 41.

¹⁸ “[T]he speech setting of a given linguistic element, which is directly or indirectly related to this element and modifies its semantic and syntactic function”, Radwański and Zieliński (2012), p. 522.

¹⁹ Radwański and Zieliński (2012), p. 517.

interpretation, as well as their hierarchy, are used by the CJEU.²⁰ Consequently, there should be no doubt that a legal provision cannot be isolated from its context, that is, from the other provisions of the act in question. Therefore, it should be interpreted taking into account the meaning of the other provisions contained in the act in question. It also seems that referring to the context in which a provision is placed is in line with established case law of the CJEU. As the Court itself has noted on several occasions, in order to interpret European Union law, account must be taken not only of its wording but also of the context in which it is placed and the objectives of the legislation of which it forms a part.²¹

When seeking the proper context to clarify the definition of a product, it would be advisable to refer to patent law. After all, the fact that this is a patentable product cannot be disregarded. However, when defining the concept of a product, the CJEU did not refer to its understanding in patent law, and did not even explain why the meaning of that concept should not be sought in patent law. It is patent law that creates the “speech setting”, which, I believe, corresponds to the “context” to which the Court so often refers.

It must sound trivial in this context to expect a certain consistency of regulation, not only at the level of the SPC Regulation itself, but also at the level of patent law, within the ambit of which the SPC plainly falls. It is questionable whether reference to the wording of the provision in question is sufficient, where the term has a well-established meaning both in patent law doctrine and case law.

4 Is a Basic Patent Equivalent to an Application Patent?

Even if we were to consider that the understanding of a product in patent law is irrelevant to its interpretation under the SPC Regulation, resorting to pure linguistic wording might seem justified. But then it is also questionable whether the interdependence that exists between the concept of a product and the concept of a basic patent can be disregarded under the SPC Regulation itself.

The right under the SPC is a *sui generis* right, as, for example, stated in the Explanatory Memorandum cited by the CJEU. However, one cannot disregard the fact that this is the right that remains linked to the patent, named in the SPC Regulation as the so-called “basic patent”, in a close and inseparable way. It is worth recalling, for example, that the existence of an SPC is entirely dependent on the existence of the patent throughout the period of protection and the validity of that patent. It is apparently questionable whether this interrelation between these rights does not also entail the need to seek an interpretation of the terms used in the Regulation so that their understanding is characterised by a certain convergence. All the more so, as it was the supplementary protection certificate that was supposed to

²⁰ Schermers and Waelbroeck (2001), p. 10 and below; on mutual interdependence of various interpretation methods applied to Art. 1(b) of the Regulation, see Schell (2013), p. 512, who also suggests using a systemic and purposive interpretation.

²¹ CJEU, 23 January 2018, Case C-367/16, *Piotrowski*, para. 40; CJEU, 7 February 2018, Case C-304/16, *American Express*, para. 54; CJEU, 7 June 2018, Case C-44/17, *Scotch Whisky Association*, para. 27; CJEU, 17 May 2018, Case C-325/16, *Industrias Químicas del Vallés*, para. 27.

compensate the rightholders for the shorter actual patent protection of the invention in the field of medicine related to the formalities required to market a medicinal product. It should be noted that such an expectation can easily be countered by the argument that the rules governing the obtaining of a patent, including a European patent, are not governed by EU law as opposed to the SPC. This could lead to the conclusion that there is no argument of a systemic nature that provides sufficient justification for interpreting the terms used in the SPC Regulation in such a way that they coincide with the understanding of those terms in patent law. Such an interpretation, however, would, in my view, be devoid of any sense, since, after all, it goes without saying, that there can be no escape from the basic patent and one of the grounds for granting a certificate under Art. 3(a) of the SPC Regulation is that the product must be protected by a basic patent in force.

Importantly, therefore, although there is a stand-alone product definition in the SPC Regulation, at the same time that product must be protected by a basic patent in force as a condition for obtaining an SPC. It should be noted that the product definition proposed by the CJEU, if applied in connection with the need to determine whether a basic patent in force protects a product, must lead to the conclusion that it will not be altogether possible to obtain an SPC where the basic patent is an application patent, even where it is a patent for the first medical application. Although the CJEU infers²² that it will be possible to obtain an SPC for patents for first medical applications in the reasoning of judgment C-673/18, in practice it will not be possible for them to meet the condition under Art. 3(a) of the SPC Regulation. At this point, it is worth recalling that the CJEU has already dealt with the interpretation of Art. 3(a) of the SPC Regulation²³ on several occasions. Although in these judgments the CJEU did not refer to the definition of a product as such, they nevertheless led to the formulation of at least two principles. Firstly, the claims of the basic patent define what is protected and an SPC can only be granted for the product identified in the claims.²⁴ Secondly, the product covered by the certificate must necessarily and specifically fall under the invention covered by that patent.²⁵

Having regard that these statements were made in connection with the interpretation of Art. 3(a) of the SPC Regulation, one cannot lose sight of the fact that the concept of a product is inextricably linked to the specific invention and the patent that protects it. The product must be the invention that is protected and identified in the claims. There is no doubt that in the case of an application patent the invention is not a substance or a combination of substances, as the same is not new, but the therapeutic application of such substance. Indeed, a basic patent for an application, even including a patent for the first medical application, will not protect an active substance or a combination of substances as such, but a specific use of an active substance or a

²² Para. 58.

²³ See, in particular, Romandini (2019), pp. 9–24.

²⁴ CJEU, 24 November 2011, Case C-322/10, *Medeva*, para. 25; CJEU, 25 November 2011, Case C-6/11, *Daiichi*, para. 30; CJEU, 12 December 2012, Case C-493/12, *Eli Lilly*, para. 34; CJEU, 25 July 2017, Case C-121/17, *Teva UK*, para. 34; CJEU, 25 November 2011, Case C-630/10, *University of Queensland*, para. 31.

²⁵ CJEU, 25 July 2017, Case C-121/17, *Teva UK*, para. 52.

combination of substances, which is not the same thing. If we apply the definition of a product proposed by the CJEU in the *Santen* judgment, not only for the purposes of Art. 3(d) of the SPC Regulation but also for the purposes of Art. 3(a), then a product understood as a substance or a combination of substances without a limitation arising from the application will never enjoy the protection of the basic patent, which is an application patent. In other words, an application patent never protects a product as such, whether it is a patent for the first or subsequent medical application. This means that it will not be possible to argue that the product is protected by the basic patent. Since the CJEU provides a binding definition of a product against the background of the SPC Regulation, it will have to be applied in all cases set out in Art. 3 of the SPC Regulation, i.e. both for the assessment whether the product is covered by the basic patent and for the assessment whether the obtained authorisation is the first authorisation relating to the product. It is impossible to give the concept of a product a different meaning depending on whether one is dealing with the conditions set out in Art. 3(a) or Art. 3(d) of the SPC Regulation. Consequently, it is appropriate to conclude that by giving a product such a definition, the CJEU practically excluded the possibility of obtaining an SPC for any application patents, which clearly contradicts the definition of a basic patent. Thus, contrary to the CJEU's statement that obtaining an SPC will be possible for patents covering the first medical application, the use of this concept of a product practically excludes application patents from the possibility of obtaining an SPC for inventions protected by them.

5 Explanatory Memorandum – What Does It Say?

Proposing an interpretation of a product that excludes from that concept an active substance with a specific application, the CJEU referred to the documents accompanying the introduction of Regulation 1792/90 in the form of the Explanatory Memorandum to the Proposal for a Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products²⁶ and argued that such an understanding of the concept of a product stems from that document. In the reasoning for its judgment, the Court quoted a passage from that document, stating that it indicated that

the term “product” is understood to mean an active ingredient in the strict sense and that minor changes to the medicinal product such as a new dose, the use of a different salt or ester or even of a different pharmaceutical form will not lead to the issue of a new SPC.²⁷

The reference to preparatory works or documents accompanying drafts of given legal acts is justified by the method of the so-called “systemic interpretation”,²⁸

²⁶ CJEU, 9 July 2020, Case C-673/18, *Santen SAS*, para. 45.

²⁷ CJEU, 9 July 2020, Case C-673/18, *Santen SAS*, para. 45.

²⁸ It refers to the classification proposed by Schermers and Waelbroeck (2001), p. 16, who indicate “historical background” as one of the elements that the CJEU takes into account in the framework of systemic interpretation.

which is used by the CJEU in a number of judgments, although its conclusions should not always be considered valid, to which I will return. However, reference to the Explanatory Memorandum does not at all make it convincing that such an interpretation of the concept of a product is justified. Firstly, it should be noted that the document clearly indicates that no type of patent can be discriminated against. It was emphasised that it is a new invention, regardless of the patent by which it is protected.²⁹ Secondly, it must be stressed that the passage of reasoning quoted by the CJEU appears to be taken out of context. Although similar statements appear in the document cited by the CJEU in several places, it seems that in paragraph 45 of the *Santen* judgment the CJEU refers to a passage of reasoning located in paragraph 11 of the Explanatory Memorandum. However, a reading of this paragraph leads to the conclusion that, for the sake of clarity, it should be cited together with paragraph 12, which clarifies the difference between a new medicinal product (to which, incidentally, the CJEU citation refers) and a new product.

11. The proposal for a Regulation therefore concerns only *new medicinal products*. It does not involve granting a certificate for

a: medicinal products that are authorised to be placed on the market. Only one certificate may be granted for any one product. a product being understood to mean an active substance in the strict sense. Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate.

12. However, the proposal is *not confined to new products only*. *A new process for obtaining the product or a new application of the product may also be protected by a certificate* [own emphasis]. All research, whatever the strategy or final result, must be given sufficient protection.

It should be noted that paragraph 12 of the Explanatory Memorandum, cited above, emphasises that the protection under the Regulation is intended only for *new medicinal products*, making it clear that it does not only apply to *new products*, but also to those products that are protected *in a new application*. Both paragraphs 11 and 12 of the Explanatory Memorandum distinguish between the concepts of a product and a medicinal product. I therefore take the view that the requirement, set out in the two sentences above, that the product should be understood in the “strict sense” as the active substance only means contrasting the concept of a product with that of a medicinal product, emphasising that the latter is not only an active substance but also other elements. A product is an active substance, while a medicinal product also has other components. Nor is there any suggestion in the provisions of this document that it somehow favours a certain type of research carried out, i.e. the synthesis of specific substances rather than the use of existing

²⁹ “The proposal does not provide for any exclusions. In other words, a pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled.”

ones. Indeed, any research, regardless of its strategy or final outcome, deserves to be protected.

It is also worth quoting another passage from the Explanatory Memorandum, which also contains text referring to a strict understanding of the concept of a product:

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.). In conclusion, it should be noted that, although one and the same product may be the subject of several patents and several authorisations to be placed on the market in one and the same Member State, the supplementary protection certificate will only be granted for that product on the basis of a single patent and a single authorisation to be placed on the market, namely the first chronologically given in the State concerned (the first authorisation in the Community being taken only to calculate a uniform duration of different certificates for one and the same product).³⁰

This passage refers to Art. 3(c) of the Regulation and the requirement therein that the product concerned has not already been the subject of a certificate. However, assuming that the SPC Regulation knowingly uses the term “product” as the subject matter of the SPC, it must be assumed that this is the same product to which Art. 3(a) of the SPC Regulation refers, i.e. the product disclosed in the claims of the basic patent. It should be noted that here the document explicitly refers to a restrictive interpretation of Art. 2 of the Regulation, which in turn refers to the relationship between a product protected by a patent and a medicinal product subject to the MA procedure. Pursuant to Art. 2 of the SPC Regulation:

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

³⁰ Explanatory Memorandum, para. 36

2001 on the Community code relating to veterinary medicinal products may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

In my view, the strict interpretation of that provision referred to by the Explanatory Memorandum means that the product protected by the patent is, as it were, “translated” into a medicinal product for which an MA is granted. It is a question of highlighting and capturing the special protection conferred by the supplementary protection certificate for a product that has been authorised as a medicinal product and is identified in the marketing authorisation, while being protected by a patent. Consequently, it is emphasised that it is the changes made to a *medicinal product*, with the same product protected by the same patent, which cannot give rise to the grant of an SPC.³¹ Clear attention is brought to the relationship between the patented product and the medicinal product for which an MA has been granted. Both that passage and paragraphs 11 and 12 of the Explanatory Memorandum, cited above, refer to “minor” changes to the medicinal product which, through the product, remains linked to the same patent, and not to a change in the product, which remains unchanged for the duration of the patent. However, the passages referred to above can in no way support the conclusion that the concept of a product does not take account of its application. Such reasoning is simply devoid of logic and, in my view, unjustified in the light of the text of the Explanatory Memorandum, which makes clear, in several places, that the SPC is intended to provide additional protection for any research in the pharmaceutical industry provided that it leads to a new invention that can be patented, whether it concerns a new product or a known product.

The proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled.³²

It is clear that the document provides a warning against the excessive protection that might result from a certificate if it were granted in a situation involving even the most minor changes to a medicinal product which, even if they result in the need for another marketing authorisation, cannot lead to a further extension of protection. It is therefore not a question of excluding from protection a product for which an application patent has been obtained, but of modifying the medicinal product, which may require a new marketing authorisation, for example by using a different salt, excipients or dosage form. Another authorisation for the same medicinal product because of a change in the salt, excipients or dosage form cannot constitute grounds

³¹ The same fragment of the Explanatory Memorandum is pointed out by Schell (2013), p. 513; a similar conclusion can be found in Gassner (2014), p. 54.

³² Explanatory Memorandum, para. 29.

for granting a new certificate of protection, since there is the necessary relationship between the product, the basic patent protecting it and the medicinal product associated with the product protected by that patent.

The position referred to in the reasoning for the CJEU's judgment (set out in paragraph 11 of the Explanatory Memorandum), as well as the position referred to in this article (set out in paragraph 12 and paragraphs 29 and 36 of the Explanatory Memorandum), relates expressly to the relationship between the need to obtain an additional marketing authorisation when any of the characteristics of a medicinal product have changed, and not when the product obtains an additional therapeutic application that is an invention. The document even stresses that a product does not have to be new to be the subject of a supplementary protection certificate.

The Explanatory Memorandum makes it clear that the fact that the product is different cannot be inferred solely on the basis that changes have been made to a medicinal product which requires a separate marketing authorisation. This further confirms the conceptual difference between a product and a medicinal product, and between a product protected by a patent and a medicinal product protected by a certificate within the limits of the patent. However, there is no basis for this circumstance to affect the definition of a product. It is also worth noting that the concept of a product in the Regulation is closely related to a patent and not to a marketing authorisation, as also indicated by the document cited by the CJEU.³³

6 Historical Background

Even if one were to accept that the CJEU is correct in its argument about what follows from the Explanatory Memorandum, and even if one were to accept that, at the time of the enactment of the SPC Regulation, the concept of a product could in fact only refer to such a product in its first medical application, one cannot escape the question as to whether reference to the historical background can lead to a challenge to an interpretation that takes account of the common understanding of the concept of a product in patent law which existed at the time it was made.

The Court based much of its reasoning for its judgment and approach on the Explanatory Memorandum to the Proposal for the Regulation, which, in its view, makes it possible to accept that the purpose of the supplementary protection certificate was to protect investment by the pharmaceutical industry in research relating to the creation of new molecules and not in research leading to new applications of known substances. However, this seems to be a subjective interpretation by the Court of the Explanatory Memorandum's objective of promoting innovation in the pharmaceutical sector.³⁴ Apart from the fact that not all of the Court's theses relating to the objectives of the Regulation appear to be correct, in my opinion there are no grounds, first of all, to formulate a thesis that the SPC Regulation differentiates between innovations in the pharmaceutical sector,

³³ Explanatory Memorandum, para. 28.

³⁴ Explanatory Memorandum, paras. 5–8.

allowing, consequently, only inventions that are new substances to be protected thereunder.

The Court's reaching back to the Explanatory Memorandum to the Proposal for the SPC Regulation is certainly a search for justification for the interpretation adopted in the so-called "will of the legislator". It seems, however, that any reference to the will of the legislator understood in this way should be made with great caution. It has been repeatedly pointed out that this method of functional interpretation should be used when other methods of interpretation fail or lead to absurd results. It is also argued that when reaching for the will of the legislator, one should not reach for the real and actual role of the actual legislator, but the so-called rational legislator, whose will should be read exclusively on the basis of the text of the enacted law, trying to rationalise and objectivise it, *inter alia*, by referring to the objectives (functions) of legal institutions in the totality of normative material.³⁵ Not always are the declared intentions of the legislator actually reflected in the normative text, and it is ultimately this act that creates binding norms without questioning the right of the CJEU to seek justification in the texts accompanying the normative text and, without undermining the importance of the historical method for the correct interpretation of normative acts, it seems rather justified to refer to such sources in those situations where there is a relatively short period of time between the entry into force of a given legal act and its validity.³⁶ This is surprising given that almost 30 years have passed since the entry into force of the Supplementary Protection Certificate Regulation. The CJEU has repeatedly indicated in its case law that the origins of the provision should also be taken into account where appropriate.³⁷ However, it is impossible to overlook the fact that this procedure does not always seem to be fully justified due to a completely changed reality in which the interpreted legal norm functions in comparison with the one existing at the moment of its enactment. The most glaring examples are those cases where changes induced by the digital environment are involved.³⁸ It is difficult to accept arguments going back to the historical background which, for obvious reasons, should be reviewed in the light of the changes that have taken place in the operating environment of the provision in question since the date of its enactment. It seems, however, that the view that such an interpretation should only be subsidiary to linguistic, systemic and functional interpretation remains valid.³⁹ Although, in the reasoning for the *Santen* judgment, the CJEU seeks to verify the result of its interpretation by referring, in a manner of speaking, to the context in which the

³⁵ Resolution of the Supreme Court, 17 January 2000, Case III CZP 49/00, published in *Orzecznictwo Sądu Najwyższego Izba Cywilna* 2001 np. 4, point 53.

³⁶ See, in relation to the application of the historical method of interpretation by the French courts, Germain (2003), p. 202.

³⁷ CJEU, 3 October 2013, Case C-583/11 P, *Inuit Tapiriit Kanatami et al./Parliament and Council*, para. 50; CJEU, 1 July 2015, Case C-461/13, *Bund für Umwelt und Naturschutz Deutschland*, para. 30; and also CJEU, 18 May 2017, Case C-617/15, *Hummel Holding*, para. 22; CJEU, 10 December 2018, Case C-621/18, *Wightman et al.*, para. 47; CJEU, 19 December 2019, Case C-263/18, *Tom Kabinet*, para. 38.

³⁸ CJEU, 19 December 2019, Case C-263/18, *Tom Kabinet*, para. 38.

³⁹ Helios (2003), pp. 156, 158; on the necessity of using purposive and systemic interpretations, see also Schell (2013), p. 512.

concept of a “product” is used, it expressly rejects that context in its subsequent interpretation by dissociating that concept, as it were, from the concept of a basic patent. Nor is it convincing to review the findings made on the basis of the Explanatory Memorandum by reference to the purpose of the SPC Regulation. As indicated above, it is impossible to agree with the Court that the purpose of the SPC Regulation was merely to obtain additional protection only for products that are new. Although the Court expressly admits that new applications of a product may also be protected by an SPC, the definition of a product practically excludes the possibility of protecting products that are protected by application patents. Although the *Santen* judgment may ultimately be characterised by a teleological interpretation which is typically followed by the Court of Justice,⁴⁰ it is difficult to accept that the purpose of the SPC Regulation is to exclude certain innovations simply because they have a second or subsequent medical application.⁴¹

7 What the Court Has Omitted

Even leaving aside the Court’s previous body of case law relating to an SPC, the question must arise as to the extent to which a body interpreting a legislative act may fail to take account of the changes that have taken place in the immediate legal environment in which the Regulation operates, that is to say, in patent law, the link between which and an SPC is emphasised, both in the text of the SPC Regulation itself and in the accompanying Explanatory Memorandum. This must again lead us to the question of how far in interpreting the terms in the SPC Regulation we can detach ourselves from patent law.⁴² Since the CJEU has elected to resort to the Explanatory Memorandum, it is again worth recalling that the Explanatory Memorandum makes it clear that: “Consequently, the term ‘product’ is not understood to mean a proprietary medicinal product or a medicinal product in the wider sense, but in the narrower sense of product used in patent law which, when applied to the chemical and pharmaceutical field, means the active ingredient”.⁴³

Undoubtedly, the CJEU is correct that a product is an active substance or a combination of such substances. Certainly this understanding of a product is appropriate for a product patent that protects a substance or a combination of substances as such. Yet, this is not the only understanding of a product in patent law.

In order to fully answer the question of how the concept of a product is understood in patent law, it seems necessary to briefly introduce the subject matter of protection in the case of so-called “application patents”.

The concept of an application patent has evolved considerably over the life of the SPC Regulation, which also found its normative expression in the provisions of the

⁴⁰ Schermers and Waelbroeck (2001), p. 20 and below.

⁴¹ Stief and Wenzel (2020), p. 1060, note the incompatibility of the proposed interpretation with the current development of research in the pharmaceutical industry.

⁴² The need for an interpretation taking into account patent law was also noted by Schell (2013), p. 509.

⁴³ Explanatory Memorandum, para. 28.

European Patent Convention and led to the amendment of its Art. 54.⁴⁴ At this point, it should be recalled that Art. 54(5) of the EPC, as originally drafted,⁴⁵ provided for an exception allowing for the patentability of substances or their composition even if they were known at the date determining priority but their use in therapy, diagnosis or treatment was new. As indicated,⁴⁶ the introduction of an exception for the pharmaceutical industry, allowing for the patentability of substances known but used in a new application, was dictated by two considerations. Firstly, the development of chemical synthesis meant that more and more substances were becoming known, and consequently research into new applications became increasingly important. Secondly, it was emphasised that the inventive step of establishing a new medical application in a situation where countless new substances and their possible compositions existed was no different from other cases of inventive step.⁴⁷

Initially, in the early years of the EPC being in operation, it was assumed that the patentability of a substance or its composition known in the state of the art was only possible if it was a first medical application, that is, a significant one that could be used in therapy, surgery or diagnostics. Thus, where any use in the treatment of humans or animals is already known in the state of the art, then the application of the exception in Art. 54(5) of the EPC is excluded.⁴⁸ Very soon, however, and apparently as early as the early 1980s, it was pointed out against the background of the original wording of Art. 54(5) of the EPC that there was no justification for excluding second and further medical applications.⁴⁹ In particular, it was argued that since the so-called first medical application can be regarded as a patentable invention, there is no justification to exclude subsequent applications from patentability, all the more so since often these subsequent applications may have even greater medical significance.⁵⁰ It was emphasised that the same arguments that allow the importance of research into the use of known substances to be taken into account are rather equally valid for the recognition of the patentability of second and further medical applications.⁵¹ Finally, it was argued that the wording of the EPC itself did not exclude the patentability of further applications. It was also pointed out that the preparatory documents of the Convention do not explicitly support an interpretation that excludes second and subsequent medical applications from patentability.⁵²

⁴⁴ Corresponding changes were also made to national patent laws.

⁴⁵ “The provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.”

⁴⁶ Stieger (1982), p. 141.

⁴⁷ Stieger (1982), p. 141.

⁴⁸ Schulte (1978), p. 31; Mathèly (1978), p. 116; Panel (1977), p. 74; von Pechmann (1977), p. 109.

⁴⁹ Klöpsch (1982), p. 457.

⁵⁰ Klöpsch (1982), p. 460.

⁵¹ Klöpsch (1982), p. 461.

⁵² Klöpsch (1982), pp. 462–463.

Ultimately, however, as we know, the approach to patentability of second and subsequent medical applications against the original wording prevailed, as expressed by the European Patent Office in the landmark decision G-5/83 *Second medical indication/EISAI* and a number of subsequent decisions.⁵³ Against the background of the original wording of the EPC, it can be safely assumed that the patentability of the first and further medical applications resulted from the practice of the EPO rather than from the explicit wording of the legal norm. At the same time, this patentability of the second and subsequent medical applications involved a special way of wording the claims.⁵⁴ The so-called “Swiss-type” use claims implied that the patent protection in such a case was not for a product, but for a process for manufacturing a product with special properties.

In 2000,⁵⁵ with the amendment of the EPC, Art. 54(5) of the EPC was also modified, explicitly allowing for product protection limited by application and thus extending the special regulation for pharmaceutical patents. The patentability of second and subsequent medical applications is explicitly stipulated in the text of the EPC. The inserted Art. 54(5) of the EPC expressly provides for “the patentability of any substance or composition referred to in paragraph 4 [known in the state of the art] for any specific use in a method referred to in Article 53(c) [of the EPC], provided that such use is not comprised in the state of the art”. This wording also leaves no doubt that the EPC allows the patentability of a known substance as a product, subject to use in a surgical or therapeutic method of treating humans or animals and a diagnostic method used on humans or animals. A substance or composition is therefore granted the protection of a product patent with the limitation resulting from the new medical application of such a product. A patent granted on such a substance or composition is no longer a patent on a method of preparation as it was under the original wording of the EPC, but a product patent.⁵⁶ Consequently, the way in which claims are formulated has also changed.⁵⁷ Unlike the Swiss-type formula, which defined an invention as a process of manufacture, the claims describing a patent for a subsequent medical use protect the purpose-limited product. As Schneider aptly put it, the application becomes a component of the definition of a patentable product.⁵⁸

Having the above in mind, it seems rather that the European legislature, while introducing the Regulation and preparing its Explanatory Memorandum, was aware of the ground-breaking changes that took place in the first half of the 1980s with

⁵³ Decision of EBA, 5 December 1984, G-5/83, *Second medical indication/EISAI*. Also in six other cases: G-1/83, *Bayer*; G-2/83, *Dr Karl Thomae*; G-3/83, *Ciba-Geigy*; G-4/83, *Dr Karl Thomae*; G-6/83, *Pharmuka*; and G-7/83, *CH Boehringer Sohn*.

⁵⁴ Swiss-type use claims; for more on the issue of formulating reservations in the case of the second and further medical applications before the amendment to Art. 54(5) EPC, see Utermann (1986), pp. 47–53.

⁵⁵ The Act revising the Convention on the Grant of European Patents, done at Munich on 5 October 1973, dated 29 November 2000, entered into force on 13 December 2007.

⁵⁶ On the complexity of the issue of patenting new applications, see: Holman, Minssen and Solovy (2018), pp. 131–161; Holman (2017), pp. 1–56; Bostyn (2016), pp. 191–201.

⁵⁷ Decision of EBA, 19 December 2010, G-2/08, *Abbot Respiratory*, which concluded that the Swiss-type claims were no longer necessary and should no longer be allowed.

⁵⁸ Schneider (2008), p. 519; Bostyn (2016), pp. 157–158.

respect to the patentability of chemical substances. It is impossible to assume that it was unaware of the changes taking place in research conducted by the pharmaceutical industry as a result of the ease of chemical synthesis and the growing need to discover new applications. This seems to be indicated by the Explanatory Memorandum itself, which observes that the enormous quantity of substances produced in laboratories does not translate into quantities of medicinal products placed on the market.⁵⁹ For some reason, it was also made clear that the SPC Regulation intended to cover any research, regardless of the strategy or result.⁶⁰

On the other hand, the proposed definition of a product, which excludes further medical applications, means that the purpose of the SPC Regulation, clearly stated both in the Explanatory Memorandum and in the Recital, is questionable.⁶¹

In the reasoning for the *Santen* judgment, the CJEU refers to its previous case law, pointing in particular to the *Yissum* judgment.⁶² However, reference to this ruling does not give such a clear picture of the approach that for the time being the Court had with regard to the concept of a product as would appear from its reference. It seems that such reference is somewhat of a simplification of the views expressed by the CJEU itself in that judgment. Firstly, it should be noted that the *Yissum* judgment is based on the assumption that the concept of a product against the background of Regulation 1792/92 was settled by the earlier judgment in Case C-431/04.⁶³ This judgment interpreted the concept of a product in light of Art. 1b of Regulation 1792/92. However, reference to the reasoning for that judgment shows that the context of the Court's final conclusion was somewhat different, since it concerned the question whether only substances that have an independent therapeutic effect, or also those which do not have such an effect but – as in the present case – serve the purpose of applying a medicinal product, can be covered by the concept of a product. It is true that the Court held in that judgment that the concept of a product must be understood strictly, but what is unquestionable is that by that holding the Court was referring to the question of the therapeutic function of a component of a medicinal product, indicating that a product is only that substance which produces a therapeutic effect. And it is precisely that assertion concerning the strict understanding of a product as having a therapeutic effect that was referred to by the CJEU in its *Yissum* judgment, when it held that “the term ‘product’ does not include the therapeutic use of an active ingredient protected by a basic patent”.⁶⁴ That issue, however, was not at all settled in judgment C-431/04, and the *Yissum*

⁵⁹ Explanatory Memorandum, para. 5: “Out of a total of about 10,000 substances synthesised by a research laboratory, a few hundred will be selected for the filing of patents. out of which only one to three will actually be authorised to be placed on the market.”

⁶⁰ Explanatory Memorandum, para. 12: “However, the proposal is not confined to new products only. A new process for obtaining the product or a new application of the product may also be protected by a certificate. All research, whatever the strategy or result, must be given sufficient protection.”

⁶¹ Against the background of the *Neurim* judgment, such a danger was pointed out by Schell (2013), p. 513.

⁶² CJEU, 17 April 2007, Case C-202/05, *Yissum Research and Development Company of the Hebrew University of Jerusalem v Comptroller-General of Patents*.

⁶³ CJEU, 4 May 2006, C-431/04, *Massachusetts Institute of Technology*.

⁶⁴ CJEU, 17 April 2007, Case C-202/05, *Yissum*, para. 18.

judgment lacks any further argumentation as to why the strict understanding of the concept of a product as a substance having a therapeutic effect does not include its application. In addition, the CJEU's arguments set out in this judgment refer to the judgment in Case C-31/03,⁶⁵ as the Court indicates that it is from this judgment that a similar view can be inferred. The CJEU cites the following statement from judgment C-31/03:

the decisive factor for the grant of the certificate is not the intended use of the medicinal product and [...] that the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product.

The CJEU therefore emphasises that it is not the intended use of the medicinal product that determines whether a certificate should be granted, stressing that the scope of the protection afforded by a certificate covers any use of the product as a medicinal product without distinction as to whether it is a product for human or veterinary use.⁶⁶ This ultimately leads to the thesis that where a basic patent protects another use of a medicinal product, that use does not fall within the definition of the term “product”. The quoted wording may be somewhat distracting. On express reading, it would mean that, in the situation of an application patent, the scope of protection conferred by the certificate is broader than in the case of a basic patent, since it covers *any* use of the product as a medicinal product without referring to the specific use of such a medicinal product resulting from the accepted marketing authorisation but reflecting a use protected by the basic patent. One should not lose sight of the view that the definition of a medicinal product in Art. 1(a) of the SPC Regulation is also abstract in the sense that it does not refer to a basic patent, which does not mean, however, that the scope of the marketing authorisation is not linked to the basic patent. If a basic patent for an application is concerned, this application is also reflected in the marketing authorisation for the medicinal product.

But even if one were to consider that the Court in the *Yissum* judgment fully knowingly restricted the concept of a product, the question arises as to whether the amendment made in the meantime to the provisions of the EPC and the understanding of the concept of a product in patent law should not be taken into account in the interpretation made today? Even if the Court believes that these changes are irrelevant, one would expect that, in knowingly stripping away the ability to obtain a supplementary protection certificate for application patents, it would explain why the concept of a product under the SPC Regulation should be stripped away from its patent roots.

⁶⁵ CJEU, 19 October 2004, Case C-31/03, *Pharmacia Italia SpA*.

⁶⁶ CJEU, 17 April 2007, Case C-202/05, *Yissum*, para. 19.

8 Final Remarks

The *Santen* judgment is a ground-breaking judgment, as it excludes the possibility of obtaining an SPC for products protected by patents for second and further medical applications. It also seems that the effects of this judgment go beyond the exclusion of protection for medicinal products for which basic patents are patents for second and further medical applications. The use of the concept of a product as proposed by the CJEU to determine the existence of material conditions for granting an SPC, defined in Art. 3 of the Regulation, may not only lead to the exclusion of products protected by patents for second and further medical applications, but also to a complete exclusion of products protected by application patents from protection. Despite its clarity and unambiguity, the judgment must raise objections due to the manner and methods used to interpret the text of the Regulation. The result of the interpretation that is achieved is incompatible with those methods of interpreting the law, which the Court itself refers to both in this and in other judgments, including the need to take into account a broad context in which the provision is applied. Hence, it must be surprising that the main motive for the resolution is a historical analysis of the law. Undoubtedly, the unambiguity of the judgment, resulting from a strictly literal understanding of the concept of a product, detached from other definitions contained in the provisions of the Regulation, will force the unambiguous practice of competent authorities in individual EU states in the field of interpretation of Art. 3 of the Regulation. Undoubtedly, the unambiguity of the practice of applying a given legal act is a value in itself. When putting forward the interpretation in question, the CJEU implements in a certain way the assumption underlying the origin of the SPC, that obtaining an SPC should be simple and predictable. However, the basic flaw of the justification and interpretation is the lack of an analysis of whether such understanding of the concept of a product, and consequently the shaping of the premises for obtaining an SPC, corresponds to its other goal, namely, the motivation to conduct research in the pharmaceutical industry.

Open Access This article is licensed under a Creative Commons Attribution 4.0 International License, which permits use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons licence, and indicate if changes were made. The images or other third party material in this article are included in the article's Creative Commons licence, unless indicated otherwise in a credit line to the material. If material is not included in the article's Creative Commons licence and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder. To view a copy of this licence, visit <http://creativecommons.org/licenses/by/4.0/>.

References

- Bostyn SJR (2016) Personalized medicine, medical indication patents and patent infringement. *I.P.Q.* 2:151–201
- Brückner C (2012) Ergänzende Schutzzertifikate für Arzneimittel in der neueren Rechtsprechung des EuGH. *GRUR Int* 61(12):1097–1101
- Gassner U (2014) Recent developments in the area of supplementary protection certificates. *Pharm Policy Law* 16:45–72. <https://doi.org/10.3233/PPL-14037>
- Germain C (2003) Approaches to statutory interpretation and legislative history in France. *Duke J Comp Int Law* 13:195–206. <https://scholarship.law.duke.edu/djcil/vol13/iss3/9>
- Grabinski K (2015) Ergänzende Schutzzertifikate. In: Benkard G, Grabinski K (eds) *Patentgesetz*, 11th ed. PatG § 16a
- Helios J (2003) *Pojmowanie wykładni prawa europejskiego w orzecznictwie Trybunału Sprawiedliwości*, Wrocław
- Holman CM (2017) In defense of secondary pharmaceutical patents: a response to the UN's Guidelines for Pharmaceutical Patent Examination. *Ind L Rev* 50(759):1–56
- Holman CM, Minssen CT, Solovy EM (2018) Patentability standards for follow-on pharmaceutical innovation. *Biotechnol Law Rep* 37:131. SSRN: <https://ssrn.com/abstract=3197925>
- Klöpsch G (1982) The patentability of pharmaceuticals according to the European Patent Convention. *IIC* 13(4):457–470
- Lückermann A, Schroeder M (2020) Schutzzertifikate für Second-Medical-Use-Produkte? Ein Blick auf die gegenwärtige Entwicklung der Rechtsprechung und deren praktische Auswirkungen. *PharmaRecht* 11:662–668
- Mathèly P (1978) *Le droit européen des brevets d'invention*. Journal des notaires et des avocats, Paris
- Panel F (1977) *La protection des inventions en droit européen des brevets*. Librairies techniques, Paris
- Radwański Z, Zieliński M (2012) *System Prawa Prywatnego*, t.1, red. M. Safjan. CH Beck, Warsaw
- Rollins T, Dagg N, Baldwin S (2017) The definition of the product in SPC Regulation. *Eur Intellect Prop Rev* 39(9):555–564
- Romandini R (2018) Conditions for granting SPC: Art. 3(b) and (d) Reg. 469/2009. In: Romandini R, Hilty RM, Kur A (eds) *Study on the legal aspects of supplementary protection certificates in the EU*. Ch. 11, pp 229–239 and Annex I, National reports EU. Accessed 2 October 2021
- Romandini R (2019) Art. 3(a) SPC legislation: an analysis of the CJEU's ruling in *Teva (C-121/17)* and a proposal for its implementation. *GRUR Int* 68(1):9–24
- Romandini R, Hilty RM, Kur A (eds) (2018) *Study on the legal aspects of supplementary protection certificates in the EU – Final report*. Publication Office of the EU, 31 May 2018
- Schell J (2013) Neurim – ein neuer Erzeugnisbegriff bei ergänzenden Schutzzertifikaten? *GRUR Int* 62(6):509–513
- Schermers HG, Waelbroeck D (2001) *Judicial protection in the European Union*. Kluwer
- Schneider D (2008) Patenting of pharmaceuticals – still a challenge. *IIC* 39(5):511–525
- Schulte R (1978) *Patentgesetz*, 2nd ed. Carl Heymanns, Cologne
- Stief M, Wenzel R (2020) Das Ende von SPCs für neue Indikationen? Zugleich Besprechung von EuGH “*Santen*”. *GRUR* 122(10):1057–1061
- Stieger W (1982) Article 54(5) of the Munich Patent Convention: an exception for pharmaceuticals. *IIC* 13(2):137–161
- Utermann J (1986) Purpose-bound process claim for pharmaceuticals – two solutions for the second indication. *IIC* 17(1):41–59
- Valtere L (2021) Back to the roots: a first marketing authorisation is the first marketing authorisation – *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*. *GRUR Int* 70(1):36–43
- von Pechmann E (1977) Patentschutz der 2. Indikation. Zur Patentfähigkeit bekannter therapeutischer Stoffe in anderer medizinischer Anwendung. *Mitt* 68(3):106–110