The judgment of the CJEU in the Santen case: A new medical use of an existing product and an SPC eligibility

When it comes to conditions of the grant of a supplementary protection certificate (SPC), we covered this matter in our previous Legal Report that was published over summer. We indicated that issues related to SPCs are a subject of extensive, continuously expanding caselaw of the Court of Justice of the European Union (CJEU). Whereas the last time we focused on the decision of April 30, 2020 in the case C-650/17 Royalty Pharma Collection Trust against Deutsches Patent- und Markenamt where the CJEU had to ascertain to what extent a particular active ingredient that we want to obtain an SPC for, should be individually disclosed in the patent claims so that it can be covered by the patent protection, this time we would like to turn your attention to another more recent judgment that concerns a different aspect of SPCs.

In this Legal Report we would like to examine a newer decision of the CJEU, one that was announced on July 9, 2020, **in the case C-673-18 Santen SAS against Directeur général de l'Institut national de la propriété industrielle**. The Court in Luxembourg had to take a position on permissibility of obtaining an SPC for new applications of medici-

nal products. Its decision had been eagerly anticipated by scholars and professionals in the field and its importance manifests itself in the fact that it goes against the trend of the existing body of rulings. We would like to begin by succinctly recapitulating the key facts about an SPC and then we would like to proceed to presenting the state of facts in the case with a purpose of illuminating the legal problem that occurred. Subsequently we will follow closely the CJEU's decision along with the reasoning behind it and we would like to reflect on what consequences in practice can this judgment lead to.

The key facts about an SPC

Having already written quite a lot about an SPC in our most recent Legal Report as well as in one of the articles in our cycle "Patents Without Secrets" (available only in the Polish language), in this place we would like to limit ourselves to recalling just some crucial information.

In order to answer an essential question what an SPC actually is, it needs to be stated that **is an intellectual property right protecting medicinal products, as well as plant protection products.** The introduction of such an institution into the European legal system was necessitated by the special nature of the innovative activity in the pharmaceutical sector, where development of new products generates particularly considerable costs and is extremely time-consuming. The regulations pertaining to that matter can be found in **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.** Specific provisions address such issues as:

- A subject eligible for the grant of an SPC: it shall be the holder of the basic patent or his successor in title (Article 6);
- The subject matter of an SPC protection: only the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate (Article 4);
- The scope of protection: an SPC confers the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations (Article 5);
- Duration of an SPC: the certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of 5 years; at the same time the duration of the certificate may not exceed 5 years from the date at which it takes effect (Article 13 (1-2)).

The rule that merits a special attention is Article 3 of Regulation No. 469/2009 that indicates which conditions must be met so that the grant of an SPC is permissible:

(a) the product is protected by a basic patent in force;
(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
(c) the product has not already been the subject of a certificate;
(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.

While in the Royalty Pharma case the legal problem concerned the first of those conditions and it was necessary to carry out a meticulous interpretation of the phrasing "the product is protected by a basic patent in force", **when it comes to the Santen case it is the last one of those conditions that comes to the fore:** "the authorisation to place the product on the market as a medicinal product is the first authorisation granted for the given product". Therefore let us take a look at how we should understand this requirement in the context of new applications of medicinal products.

The state of facts in the case

On June 3, 2015 Santen, a Japanese company specialising in ophthalmology, filed an application for an SPC in France. The application concerned a product called "Ciclosporin for use in the treatment of keratitis".

Considering conditions for the grant of an SPC, we should begin by taking necessary steps to identify the basic patent and the market authorisation. **The basic patent** at issue is a European patent FR No 057959306 filed on 10 October 2005, held by Santen. The subject matter of the protection derived from the basic patent is an ophthalmic emulsion in which the active ingredient is ciclosporin, an immunosuppressive agent. **The authorisation to place the product on the market as a medicinal product** in this case was issued by the European Medicines Agency (EMA) for a medicinal product marketed under the name "Ikervis" based on ciclosporin as an active ingredient. From now on we will refer to those in order to determine whether conditions for the grant of an SPC have been met.

Four months after Santen had filed the aforementioned application for an SPC, **the Director General of Institut National de la Propriété Industrielle (INPI) announced a decision to reject an application** on the grounds of Santen's failure to fulfill conditions

set forth in Regulation No. 469/2009, and more precisely — the last one of the four: the authorisation to place the product on the market as a medicinal product was not the first one to be granted for it. As it was demonstrated in the reasons for the decision, as early as in December of 1983 an authorisation had been granted for "Sandimmun", a product whose active ingredient was ciclosporin as well.

The question presents itself whether an authorisation to place "Sandimmun" on the market could have been actually treated as identical with the one granted for „Ikervis" On the one hand, the same active ingredient, ciclosporin, was used in their development, but on the other — their applications differed completely. The first one was employed in post-transplant treatment, while the one created by Santen was applied in treatment of keratitis.

Taking into account the circumstances described in the previous paragraph, **Santen did not accept the decision of the INPI and filed an appeal with cour d'appel de Paris**, requesting its revocation. Cour d'appel de Paris, considering the state of facts, on October 9, 2018 made a decision **to stay proceedings and refer the case to the CJEU for preliminary ruling** (which was exactly what Santen demanded in its alternative request).

The questions of the referring court

Below we would like to recall the questions that the appellate court in Paris referred to the Court in Luxembourg:

"1) Must the concept of a "different application" within the meaning of [the judgment in *Neurim*] be interpreted strictly (…) or must it (…) 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 [market authorisation] relied upon and, therefore, be limited to the new medical use corresponding to the therapeutic indication of that [market authorisation]?"

The CJEU, confronted with these questions, came to a conclusion that **what the referring court was actually asking about was the matter of the proper interpretation of the condition set forth in Article 3(d) of Regulation on the SPC** and in order to carry out such an interpretation, it was necessary to determine the precise meaning of concepts **"different therapeutic application"** and **"therapeutic application within the**

limits of the protection conferred by the basic patent" that have been formulated in an earlier judgment, one that has been mentioned in the questions of the referring court, i.e., the Neurim case.

Because of that key reference, we have to leave ciclosporin aside for a moment and move a little bit back in time to get a better understanding of the context of the earlier decision.

The Neurim Case

The CJEU's judgment in the case C-130/11 is listed among the most important decisions regarding SPCs. The parties to the proceedings where Neurim Pharmaceuticals (1991) Ltd and Comptroller-General of Patents representing the the United Kingdom Intellectual Property Office (IPO).

This time the ingredient at the center of the dispute was melatonin. Neurim, a pharmaceutical company, since 1992 was a holder for a patent for its own formulation of melatonin (basic patent), while in 2007 (so only 5 years before the expiry of the patent) it obtained an authorisation to place on the market a medicinal product for human use named "Circadin". Similarly, as in the Santen's case, its application for an SPC has been rejected. The IPO determined that melatonin had already been covered by the market authorization — it identified an earlier market authorization from 2001 granted for "Regulin", a veterinary medicinal product, made for use in sheep, whose active ingredient was melatonin. The resemblance of states of facts in those two cases is thus evident and impossible to overlook.

In the Neurim case the CJEU decided that Articles 3 and 4 of Regulation No. 469/2009 shall be interpreted as meaning that the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for **a different application** of the same product for which a marketing authorisation has been granted. It made however a crucial stipulation: the application must remain **within the limits of the protection conferred by the basic patent** relied upon for the purposes of the application for the SPC.

The approach taken by the Court could be described as rather permissive — it radically broke with the line of reasoning supported in its judgments in previous cases such as Pharmacia Italia (C-31/03) as well as Yissum (C-202/05). Nonetheless, it soon turned out that the reversal of the position was not sufficient to clarify all the doubts; contrarily, it started to cause numerous controversies and generate significant discrepancies in rulings of the European courts. When replying to questions referred to it by the cour d'appel de Pa-

ris, the CJEU had to make a clear choice between the restrictive and the permissive interpretation of the condition formulated in the Article 3(d) of Regulation No. 469/2009.

The reasoning presented by the CJEU in the Santen case

The resolution of the CJEU marks yet another turn in its position on this matter: this time the restrictive interpretation had the upper hand. Coming back to the judgment that is the main subject of this Legal Report, let us take a closer look at the line of reasoning presented by the CJEU in its justification of the decision in the Santen case.

The Court begins by examining the concept of a "product", pointing out the condition of Article 3(d) is closely tied to it. The legal definition of this term can be found in Article 1(b) of the Regulation: it is the active ingredient or combination of active ingredients of a medicinal product. In order to determine what exactly should be understood under the term "active ingredient", we need to reach out to the caselaw of the Court: it refers to substances which have, at least, one therapeutic effect of their own (in other words, for the purposes of applying Regulation No. 469/2009, that term concerns substances producing a pharmacological, immunological or metabolic action of their own). It is thus imperative to find an answer to the question: **does the change in the application of the active ingredient mean that we are dealing with a different (new) medicinal product?**

In the Santen case, the CJEU answers this question negatively. It relies among others on the textual interpretation of the provision of Article 1(b) of the Regulation, emphasizing that there is a reason why the definition refers to the active ingredient or their combination instead of therapeutical application. The Court mentions also the preparatory works during which it has been directly indicated that the concept of the product shall be understood as the active ingredient (or their combination) in the strict sense, and for the purpose of issuing a new SPC changes that concern for example a different dosage or a modified pharmaceutical form shall not be considered sufficient (paragraph 11 of the Explanatory Memorandum of 11 April 1990 to the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final).

In the context of assessment whether the condition of Article 3(d) has been fulfilled, we should not refer to a therapeutical application of an active ingredient, but the active ingredient itself. **The use of the same active ingredient in various products determines identity of those products.**

Another matter that required clarification was how is permissibility of the grant of an SPC affected by the fact that the market authorisation that Santen obtained in 2015 was

actually the first one issued for the product protected by the basic patent (let us remind you that the basic patent was granted in 2005). The CJEU states unequivocally: the wording of the condition in question does not refer to the scope of the basic patent. Establishing such ties, as the Court notices, would certainly lead to undermining a strict definition of the term "product", one that it approves in the judgment. It is where its approach stands in the most stark contrast to its interpretation presented in the Neurim case — in the grounds of the judgment it claims that, contrarily to what it held in *Neurim*, **to define the concept of first market authorization for a medicinal product there is no need to take into account the limits of the protection of the basic patent.**

To support this thesis the CJEU relies on the teleological method of interpretation and it demonstrates that the purpose guiding the European legislature when shaping the SPC system **"**was not to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product". It indicates that such an interpretation is the most suitable one for capturing and reconciling different purposes of the Regulation as expressed in its preamble, i.e., ensuring sufficiently strong protection for inventors that would incentivize the research in the pharmaceutical field, as well as taking duly into account all the interests at stake, including those of the public health sector. It also observes that if it accepted a different approach, the predictability of the SPC system could be put at risk and excessive complications could ensue (at this point the arguments made earlier by the Advocate General in the case are repeated).

To sum up, **the scope of the basic patent remains irrelevant when it comes to determining whether a given product is not the same as one for which a market authorization was issued earlier.**

Summary

If the Neurim judgment has been until now considered one of the most important decisions made by the CJEU in the field of the SPC, Santen will undoubtedly take its place. Dispelling the doubts and resolving some disputes that have lasted for years, the most recent voice of the Court in Luxembourg on the permissibility of the grant of an SPC for new applications of medicinal products sounded loud and clear (which is not that common for its judgments in that area).

In the operative part of the judgment the CJEU decidedly stated that Article 3(d) of Regulation No. 469/2009 **"**must be interpreted as meaning that **a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of**

that provision, where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application".

It is hard to imagine that the thesis expressed that directly and unambiguously could lead to as heated debates as the approach chosen in the Neurim case. In the commentaries published after the announcement of the judgment, we can find recurring opinions hailing the decision as a step towards **the simplification of the system**; it is commonly expected to contribute in a major way to a **greater uniformity of rulings**.

Even so we can encounter some more critical opinions: some observers are worrying that it might lead to weakening of stimuli to carry out innovative activity in the pharmaceutical sector in the European Union. These concerns cannot be easily rejected as unreasonable: **the broad scope of restrictions imposed on the permissibility of obtaining of a protection might discourage innovators from conducting research on new therapeutical applications of active ingredients that are already present in the market**.

