The conditions for granting an SPC: a product is covered by patent claims if it was identifiable at a filing date (the judgment of the CJEU in Royalty Pharma case)

The conditions for granting a supplementary protection certificate (SPC) laid down in the EU law quite often raise some serious doubts and notoriously cause problems in practice. The Court of Justice of the European Union (CJEU) has frequently presented its position on that matter: the judgment in the case C-650/17 Royalty Pharma Collection Trust against Deutsches Patent- und Markenamt of April 30, 2020, fits into this rich, systematically expanded case law of the Court in which it either elaborates on or clarifies certain issues related to the institution of the SPC.

This time the Court in Luxembourg was confronted with a dilemma: 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, considering that the claims include only a functional definition instead of a structural description? Furthermore, it had to ascertain how a possibility of granting the supplementary protection certificate is affected by the fact that a given ingredient has been developed after a filing date.

We will begin this issue of the WTS Legal Report by presenting the basic information concerning the SPC, putting a spotlight on the key provisions involved in the judgment. Subsequently, we will recap a factual situation in the case and afterwards we would like to closely follow a line of reasoning and argumentation put forward by the CJEU.

The SPC: basic information

If you would like to deepen your understanding of the SPC, we kindly invite you to take a look at a recent article in our cycle *Patents without secrets* (currently available only in Polish language) that we dedicated specifically to the matter of supplementary protection certificates. However let us remind you at this moment a few crucial facts about the SPC.

An SPC is an intellectual property right protecting medicinal products, as well as plant protection products. It serves a purpose of compensating for time and cost consuming nature of research and development of products in the pharmaceutical sector. Time that elapses between a date when an application is filed and a moment when a market authorization is granted, quite often leads to a loss of patent protection. This institution introduced by the EU legislator serves to improve situation of producers of medicinal products and aims to prevent them from moving their innovative activity to other more competitive regions.

Currently the SPC is regulated by 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. The subjective scope of an SCP is defined by Article 6 of the Regulation: the certificate shall be granted to the holder of the basic patent or his successor in title. The subject matter of protection is meanwhile designated in Article 4: within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate. Such a certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations (Article 5).

One of the most important issues regarding the SPC is **duration of the certificate.** According to the rule formulated in Article 10(1) of Regulation, 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 five years. If T is a duration of an SPC, it can be presented in the following fashion:

T = date of the first authorisation to place the product on the market in the Community — date of lodging an application for a basic patent — 5 years

It must be pointed out that **the duration of the certificate may not exceed five years from the date at which it takes effect** (Article 10(2)). In one particular case it might be extended by six months: it shall occur if conditions of Article 36 of Regulation (EC) No. 1901/2006 on medicinal products for paediatric use are met, i.e., in case of studies conducted in compliance with an agreed paediatric investigation plan with participation of paediatric population.

The relevant legal provisions for the CJEU's judgment

In order to obtain a supplementary protection certificate, one has to fulfill the following conditions enumerated in Article 3 of Regulation No. 469/2009:

(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.

In the case that we are discussing in this Legal Report, **the first of those conditions comes to the center of our attention:** the legal problem that first DPMA had to deal with, then Bundespatentgericht and finally the CJEU concerned the proper interpretation of the expression included in Article 3(a): "the product is protected by a basic patent in force".

Bearing in mind that a basic patent in given circumstances was an European patent, we need to consult Article 69 of the Convention on the Grant of European Patents signed in Munich in 1973 (EPC). According to this provision, **the extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims.** The patent claims provide thus a fundamental point of reference in determining an actual scope of protection: it is worth to recall a statement on that question the CJEU presented in the Royalty Pharma judgment: the Court, invoking Protocol on the Interpretation of Article 69, declared that claims "must ensure both a fair protection for the patent proprietor and a reasonable degree of legal certainty for third parties", while "they must not serve merely as a guideline, nor can they be interpreted as meaning that the extent of the protection conferred by a patent is that defined by the narrow, literal meaning of the wording used in the claims".

Facts in the case

The plaintiff Royalty Pharma holds European patent (DE) EP 1 084 705 (the basic patent); the application was filed in 1997. The object of protection is a solution that permits to regulate levels of blood sugar — namely, a method for lowering blood sugar levels in mammals through the administration of inhibitors of the enzyme dipeptidyl peptidase IV (DP IV). The patent claims have not however disclosed any specific active ingredients of inhibitor — which some time later became a source of significant doubts and controversies.

In 2014 Royalty Pharma turned to DPMA (Deutsches Patent- und Markenamt, i.e., German Patent and Trademark Office), **filing an application for an SPC for sitagliptin, one of inhibitors of DP IV** — the motion was based on the basic patent and an authorisation to place a medicinal product under the name "Januvia" on the market. It is necessary to point out that sitagliptin was developed after the priority date by a licensee who was successful in his efforts to obtain a patent, as well as an SPC covering it.

Three years later, in 2017, **the application of Royalty Pharma was rejected by decision of DPMA** on grounds of failure to fulfill to a condition defined by Article 3(a) of Regulation No. 469/2009, i.e., the requirement that the product is protected by a basic patent in force. **The office came to a conclusion that the product in question has not been disclosed in a sufficient manner in claims of the basic patent.** Inhibitors were defined in a functional way — without distinguishing their specific kinds; and even though DPMA demonstrated that sitagliptin fell into a scope of the functional definition, the patent failed to disclose the product specifically, "with the result that the precise active ingredient was not provided to the expert". The major problem revealed itself: **what is a sufficient and necessary level of individualisation of a given product in patent claims.**

As a consequence of filing an appellation by Royalty Pharma, the case reached federal patent court — Bundespatentgericht. The complaint was based on a premise that a patent does not have to indicate chemical name or structure of a particular active ingredient under protection, since in the light of the main goal — which is an extension of patent protection for a given product — it is sufficient to describe functional properties of the ingredient. Taking note of some discrepancies that occur in case law of European courts in the area of interpretations of Article 3(a) of the Regulation, **Bundespatentgericht decided to suspend proceedings and refer a case to the CJEU for a preliminary ruling.** It phrased following questions:

"(1) **Is a product protected** by a basic patent in force pursuant to Article 3(a) of Regulation [No. 469/2009**] 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) of Regulation [No. 469/2009] **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 individualised 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) of Regulation [No. 469/2009] **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**?"

In simpler terms, it has to be highlighted that in its questions Bundespatentgericht tried to determine whether the condition under Article 3(a) of the Regulations requires that a product is provided to the expert as a specific embodiment, or is it sufficient if it satisfies the general functional definition. Furthermore, it made an attempt to ascertain how a possibility of granting an SPC for a product is impacted by a fact that it was developed through an independent inventive step (let us not forget that sitagliptin was a result of an autonomous activity of a licensee).

The Royalty Pharma case in the context of the existing case law of the CJEU

The ruling in the Royalty Pharma case did not, so to speak, just come out of thin air: it should be seen as an addition to already elaborate body of rulings of the CJEU on matters relating to the SPC. Particularly, it should be treated as a sequel of sorts to the reasoning presented by the Court in Luxembourg in its **judgment of July 25, 2018 in he case C-121/17 Teva UK Ltd against Gilead Sciences Inc.** This decision was pronounced after the request for preliminary ruling made by the federal patent court had been submitted in the case of Royalty Pharma. The legal question, that the CJEU had to find an answer to that time, dealt with the interpretation of Article 3(a) as well, and more precisely: permissibility of granting an SPC for a product consisting of several active ingredients that produce a combined effect.

The CJEU proposed in its judgment **a two-stage test the passing of which allows an applicant to obtain a supplementary protection certificate in a case when a medicinal product is a compound of active ingredients which are not indicated directly in patent claims.** The test involves verifying whether from a 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:

a) the combination of active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent (stage one);
b) each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent (stage two).

In other terms, according to the test proposed in the Teva v. Gilead case, **granting of a supplementary protection certificate requires to determine that patent claims mention a given product in a manner that is necessary and specific.**

It should be also noticed that due to similarity of questions in the cases Teva v. Gilead and Royalty Pharma v. DPMA, the CJEU, after releasing its judgment in the former, reached out Bundespatentgericht to ask whether it sustains its motion for a preliminary ruling. Such a will was reaffirmed by the federal patent court; it pointed out to a need to "promote uniform practice at Member-State level in the various situations described in Article 3(a) of Regulation No. 469/2009".

The decision of the CJEU

In the first paragraphs of its ruling the Court addressed doubts raised by the federal patent courts with regard to a concept of a "core inventive advance" and its implications for interpretation of Article 3(a) of Regulation No. 469/2009 — such a connection has been emphasized by an advocate general in its opinion in the case Teva v. Gilead case, however it has been omitted from the principal judgment. It should be therefore underscored that the CJEU unequivocally declared that **a subject matter of protection guaranteed by the SPC shall be limited to the technical specifications of an invention covered by the basic patent, in accordance with patent claims; it is unreasonable to delimitate a scope of protection by searching for a "core inventive advance".**

The CJEU consistently applied the test designed in the Teva v. Gilead case. Claiming that in general Article 3(a) of the Regulation does not preclude extending patent protection to an active ingredient that satisfies a definition included in the claims of the basic patent, it stated that it is essential to demonstrate that the product is necessarily and specifically covered by one of those claims. It is of utmost importance to fulfill two cumulative conditions: necessity and specificity, while the appropriate evaluation shall be carried out from a point of view of a specialist in a given field and the prior art on the date of application or the priority date of the basic patent.

The CJEU found that first of the conditions was clearly fulfilled: it asserted that sitagliptin as an inhibitor of DP IV falls within the scope of a definition formulated in the claims

of the basic patent. Subsequently, it approached the issue of specificity as far more controversial: here a question arose whether the patent claims disclosed the product in a manner that was accurate and detailed enough to be considered sufficient in terms of the requirement established by Article 3(a). The Court signaled that **it is the referring court that is responsible for examining whether an expert in a field would be able to infer "directly and unequivocally" from the specification in the patent claims that a product for which an SPC is granted lies within the limits of the subject matter of the patent.** Mere fact that the product has not been individualised as a specific embodiment, does not therefore preclude the grant of an SPC.

Eventually the CJEU claimed in its judgment that Article 3(a) shall be interpreted in such a way that **a given product that has not been individualised as a specific embodiment of the method covered by the patent, is protected by the basic patent in force if:**

a) it satisfies a general functional definition included in one of the claims of the basic patents and **necessarily fits within the scope of the invention** covered by the basic patent;
b) It is specifically identifiable by a person skilled in the art who relies on their **general knowledge in the appropriate field available at the filing date or priority date of the basic patent and on the prior art at that date.**

When replying to the third question posed by Bundespatentgericht, the CJEU had to examine a relation between a possibility of the grant of an SPC and a fact that a product has been developed after the filing date and, moreover, following an independent inventive step. The Court recalled that for the purposes of Article 3(a) of the regulation, the subject matter of protection granted by the basic patent must be determined at the filing date or priority date of that patent. In that case it becomes irrelevant whether the product corresponds to a functional definition provided by the claims, or whether it falls beyond its limits. Accepting a different solution would manifestly violate the premise discussed above, i.e., the requirement that the product should be specifically identifiable by a person skilled in the art who relies on their general knowledge in the appropriate field available at the filing date or priority date of the basic patent and on the prior art at that date. The CJEU pointed out that it would run against very objectives of Regulation No. 469/2009: after all, as the Court acknowledged, "the grant of the additional period of exclusivity by the use of SPCs is intended to encourage research and, to that end, to ensure that the investments made in such research are covered".

Hence the CJEU reached a conclusion that "**a product is not protected by a basic patent in force, within the meaning of that provision, 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". Against all odds this thesis is not as unambiguous as it may seem and subsequent controversies should be expected to come up in practice. Indeed, the matter of the correct interpretation of "an independent inventive step" might soon call for further clarifications: it is highly probable that in future cases pending before the CJEU the need to indicate criteria for assessment of that independence will emerge.

Finally, the reasoning presented by the CJEU implicates that **Royalty Pharma shall not obtain a supplementary protection certificate protecting sitagliptin** — the basic patent will not protect an active ingredient that, despite satisfying the functional definition in the claims, has been developed after a filing date through an independent inventive step of another subject.

Summary

To summarize, it is worth to once again highlight the key aspects of the ruling of the CJEU in the Royalty Pharma case:

- The CJEU reaffirmed adequacy of the test designed in the Teva v. Gilead case to evaluate whether a given product, which is not expressly indicated in the patent claims, can fit into the subject matter of an SPC — in that case fulfillment of the conditions of necessity and specificity is examined.

- If a given ingredient satisfies a functional definition included in the patent claims, that is sufficient to demonstrate that a condition of necessity has been met.

- In order to determine whether the second condition has been fulfilled, it is necessary to demonstrate that in the light of all the information disclosed by the basic patent the given product can be specifically identified 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.

- A filing date or a priority date provides a main point of reference when it comes to evaluating whether the second condition has been met. Taking into account the results of research carried out later would lead to unjust effects. The fact that sitagliptin has not been developed through an independent inventive step of Royalty Pharm stands in the way of granting a supplementary protection certificate to the company.

