CJEU CONFIRMS: SUPPLEMENTAL PROTECTION CERTIFICATE APPLICATION REQUIRES ISSUED MARKETING AUTHORIZATION

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Intellectual Property Alert

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A recent decision of the CJEU in Europe raises concerns for pharmaceutical companies who wish to supplement the protection of their products with SPCs. With its decision C 567/16 the court follows a strict approach and decided that for the purposes of the SPC regulation an "end-of-procedure"-notice is not an equivalent to an issued marketing authorization. As a result, pharmaceutical companies without an issued marketing at the time of filing a SPC application are at risk of losing the opportunity of supplementary protection offered by a SPC which, in turn, may give competitors the opportunity to enter the market and, thus, have significant effects on the commercialization of a product. In the following we will discuss this case in detail.

I. INTRODUCTION AND BACKGROUND

The Supplementary Protection Certificate ("**SPC**") forms a decisive part of the medicinal product- related research and development ("**R&D**") landscape of innovative pharmaceutical companies operating in Europe. A SPC is both a **compensation** for complex and time-consuming development necessary to get approval for the respective medicinal products and an incentive for the pharmaceutical industry to research new medicinal products, as a SPC provides supplemental exclusive protection for up to five years on top of the patent term of 20 years. A SPC has been shown to have particular significance for the development of combined active ingredients and medicinal products based thereon.

According to Article 3(a) and (b) of the Regulation (EC) No 469/2009 ("**SPC-Regulation**") the following requirements need to be met in the respective member state: The medicinal product shall be protected by a basic patent in force, and a valid authorization to place the product on the market as medicinal product ("**Marketing Authorization**" or "**MA**") has been granted. The basic patent in force can be either a granted national patent or a national part of a granted European Patent in force, i.e., not revoked nor expired. A Marketing Authorization can be granted either under the centralized or the decentralized procedure, as further specified in Directive 2001/83/EC ("**MA-Code**"), Regulation (EC) No 726/2004 and the applicable national regulations implementing and supplementing European regulation. Due to this complex system of patent protection and regulatory requirements on one hand and their interrelation with European and national regulations on the other hand, various questions have arisen in view of the interpretation of the legal framework and need to be addressed by the European Court of Justice ("**CJEU**").

With its most recent decision (C-567/16) regarding SPCs, the CJEU addressed (a) whether an "end of procedure" notice issued by a reference member state under a decentralized procedure might be equivalent to an issued MA within the meaning of the SPC-Regulation, and (b) whether the requirements set out in Article 3(b) of the SPC-Regulation can be retrospectively fulfilled during the grant procedure of the SPC in cases where the SPC application as of the filing date does not comply with all the requirements of Article 3(b) of the SPC-Regulation.

II. UNDERLYING FACTS OF THE CASE

Merck & Co. Inc., holds a patent covering the active ingredient ezetimib and its compositions comprising ezetimib and other active ingredients. The patent was granted on May 19, 1999, and is in force until September 13, 2014. In September 2013, after several years of development of a tablet comprising both active ingredients, ezetimib and atorvastatine, MSD, a subsidiary of Merck & Co., filed applications for MAs for the respective medicinal product called Atozet under the decentralized procedure in various EU member states and defined Germany as reference member state. The German Authority (*BfArM*) issued an "end of procedure" notice to MSD stating the (successful) end of the decentralized procedure on September 10, 2014. Pursuant to Article 28 (5) of the MA-Code, each member state then has 30 days to grant the marketing authorization. Due to these timelines, MSD was forced into a race against the time, as Articles 3(a) and (b) of the SPC-Regulation state that at the time of an application the following is needed: a basic patent in force, i.e., not expired, and a granted MA.

Having the close expiration date of the patent in mind, MSD applied for a SPC in the United Kingdom one day before the expiry of the basic patent, i.e., on September 12, 2014, referring to the "end of procedure" notice from Germany. Remarkably, the British MA was not issued until October 10, 2014, whereas the French MA had already been issued on September 12, 2014. In November 2014, MSD supplemented its SPC application before the United Kingdom Intellectual Property Office ("**UKIPO**") with both MAs.

While the intellectual property offices of some member states issued a SPC (Denmark, Greece, Italy, and Luxembourg) or at least stated that the requirements of Article 3(b) had been fulfilled — and consequently accepted an "end of procedure" notice as being equivalent to an issued MA — the UKIPO denied the grant of the SPC. The UKIPO rejected the SPC application, arguing that no valid MA had been issued at the time of the SPC application, and this irregularity cannot be rectified in accordance with Article 10 (3) of the SPC-Regulation. The intellectual property offices of Sweden and Portugal rejected the respective SPC application due to similar reasons.

MSD appealed the decision and brought it before the referring court. As the competent court, the High Court of Justice (England and Wales) Chancery Division, Patent Court, while expressing its view supporting the UKIPO's opinion, decided to stay the proceedings in light of the deferring opinions in other member states and to refer the following questions to the CJEU for a preliminary ruling:

"1. Is an end of procedure notice issued by the reference Member State under Article 28(4) of Directive [2001/83] before expiry of the basic patent to be treated as equivalent to a granted marketing authorisation for the purpose of Article 3(b) of [the SPC- Regulation], such that an applicant for [a SPC] in the Member State in question is

entitled to apply for and be granted [a SPC] on the basis of the end of procedure notice?

2. If the answer to question 1 is no: in the circumstances in question, is the absence of a granted marketing authorisation in the Member State in question at the date of the application for [a SPC] in that Member State an irregularity that can be cured under Article 10(3) of [the SPC-Regulation] once the marketing authorisation has been granted?"

III. THE DECISION

In essence, the CJEU confirmed the UKIPO's decision. This recent decision reflects the strict, literal approach of the interpretation of the SPC-Regulation as set out in several previous decisions of the CJEU.

In the present case, arguments considering the general aim of the SPC-Regulation to provide supplemental protection to compensate for a lack of protection in the period that elapses between the filing date of a patent and the grant of the MA for a medicinal product did not convince the CJEU and were, in fact, not even discussed by the CJEU. Two lines of arguments, the literal wording of the respective articles and the systematic arguments, led to the court's strict interpretation of the SPC-Regulation.

a) First Question – Article 3(b) of the SPC-Regulation:

In detail, Article 3(b) of the SPC-Regulation sets out the conditions for obtaining a SPC and states that *"a certificate shall be granted if […] at the date of that [SPC] application […] a valid authorisation to place the product on the market as medicinal product has been granted […]."*

Applying this strict approach, the CJEU stated that the word "granted" in Article 3(b) of the SPC-Regulation can only be understood as meaning that the action has been completed.

Consequently, for the purposes of the SPC-Regulation, an "end of procedure" notice, being just one of the steps towards an issued MA, cannot be treated as a legal equivalent for a formally issued MA. Following this approach, the September 10, 2014 notice cannot be an MA in accordance with Article 3(b) of the SPC-Regulation;, consequently, on September 12, 2014, no valid MA existed.

Even though an "end of procedure" notice confirms that the respective product is safe and defines the identity of the product to which the SPC relates, an "end of procedure" notice does not authorize the applicant to place the medicinal product on a particular market, which is the most important effect of a MA. Having the aim of the SPC-Regulation in mind, the period between the grant of the MA, triggering the actual time to place the product on the market, and the filing date of the patent is the relevant period that should be compensated by a SPC. Consequently, the literal interpretation of Article 3(b) is also in line with CJEU's former decision Forsgren (C-631/13), which stated that a patented product cannot lead to the grant of a SPC unless a MA has been granted for the respective medicinal product.

b) Second Question – Article 10(3) of the SPC- Regulation:

In response to the second question, the CJEU stated that the fact that no valid MA had been issued at the time of the filing of a SPC application is not an irregularity that could be cured under Article 10(3) of the SPC-Regulation.

The CJEU particularly points at the wording of Article 3(b) of the SPC-Regulation, which states that *"a certificate shall be granted if […] at the date of that [SPC] application […] a valid authorisation […] has been granted […]."*

The CJEU further referred to the wording of Article 10(3) of the SPC-Regulation, which states that where the SPC application does not meet the conditions laid down in Article 8 (referring back to Article 3(b)), the intellectual property office shall ask the applicant to rectify the irregularity. According to the CJEU, the wording of Article 10 of the SPC-Regulation makes it clear that an irregularity affecting the SPC application can be rectified; however, it cannot be used to provide the essential requirements for a first-time SPC application. The CJEU argues that Article 10 merely provides the applicant with the opportunity to address "*irregularities*," which the CJEU interprets as mere administrative defects of the SPC application. However, this possibility of correction has to be seen independently from the fact that the requirements to obtain a SPC as set out in Article 3 of the SPC-Regulation are to be met at the time of the filing of the SPC application.

IV. CONCLUSION – PRACTICAL CONSIDERATIONS

The CJEU's interpretation of the requirements of the SPC-Regulation in this decision might lead to situations which are particularly difficult to handle. In the present case, the (necessary) delay in the development of a medicinal product ready to be placed on the market might result in a situation where a supplemental protection in addition to the patent protection and exclusivity rights is not applicable. Even though it is the aim of the SPC-Regulation to encourage sophisticated research conducted by innovative pharmaceutical companies and to provide sufficient protection for their products taking a regulatory MA procedure into account, it was not possible for MSD to successfully apply for a SPC in a timely manner. This situation might be an indicator for future referral questions to be answered by the CJEU.

The present case also emphasizes the importance of a well-coordinated and close interrelation of different units within pharmaceutical companies. The R&D department is constantly informing the Regulatory and Product Launch department about the progress of the development of products being prepared to be placed on the market. Regulatory and Product Launch can then decide on a centralized or decentralized procedure, taking, inter alia, the R&D timeline into account.

The patent department handles and drafts patent portfolios affected by or protecting the future product in a way that a basic patent is still in force once a MA for the product has been granted.

In summary, the decision of the CJEU discussed herein is a difficult decision for innovative pharmaceutical companies as, at least in some circumstances, timing is the limiting factor that prevents innovators from benefiting from supplemental protection. On a related note, the European Commission is currently undertaking a public consultation on SPCs and patent research exemptions. The objective of this consultation is to evaluate the needs of the industry and, where appropriate, recalibrate certain aspects of patent and SPC protection. The deadline for submissions to the Commission Consultation was January 4, 2018. We will publish any further information in due time.

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