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EU PATENT TERM EXTENSIONS: ZEROING IN ON ZERO-TERM SPCs

Patent holders beware: The European Court of Justice has been requested to decide on zero-term Supplementary Protection Certificates ("SPC") for patents covering pharmaceutical products for human use. The current patchwork of national practice will therefore be soon harmonized—one way or the other. This *Commentary* provides a background to the request submitted by the German Federal Patent Court, summarizes the request, and alerts patent holders to the potential impact of the upcoming decision.

BACKGROUND

SPCs are granted under the European legislation (originally by Regulation no. 1768/92/EEC, codified by Regulation no. 469/2009/EC, the "SPC Regulation") to extend protection for, among others, pharmaceutical products. At first glance, it therefore seems counterintuitive that a zero-term or even negative-term SPC should be sought by patent holders, let alone granted by some European patent offices. However, an SPC may be extended in turn under Regulation (EC) 1901/2006 (the "Pediatric Regulation"). Given the economic benefits of extending exclusivity by a few months (especially for a blockbuster drug), manufactures have demonstrated a keen interest in obtaining zero- or negative-term SPCs.

The Pediatric Regulation aims at facilitating the development and accessibility of medicinal products for use in the pediatric population. To improve the information available on the use of medicinal products in the pediatric populations, the regulation establishes a system of both obligations and incentives to ensure that performing clinical trials in the pediatric population becomes an integral part of the development of medicinal products for the general population.

Provided that (a) all the measures included in a pediatric investigation plan ("PID") approved by the European Medicines Authority EMA are complied with, (b) a medicinal product is authorized in all Member States, and (c) relevant information on the results of

studies in pediatric populations is included in the product information, a reward is granted in the form of a six-month extension of the SPC. An application for an extension of the duration of the SPC pursuant to the Pediatric Regulation is only admissible where a certificate is granted pursuant to the SPC Regulation.

An SPC supplements the protection of a basic patent covering the active ingredient of a medicinal product for which marketing authorization has been granted by providing additional exclusivity for up to a maximum of five years. The goal of the SPC Regulation is to grant a patent holder at least 15 years of exclusivity, taking into account the long time required for development and approval of a medicinal product. Thus, given a full patent term of 20 years from the date of filing a patent, the term of an SPC is calculated by subtracting five years from the period between the filing date of the basic patent and the date of issuance of the marketing authorization. For example, if a marketing authorization issues seven years after the filing date of the basic patent, the SPC will have a term of two years. Accordingly, if the marketing authorization issues less than five years after the filing date of the basic patent, the calculation results in a negative term. For example, if the marketing authorization issued four years and eight months after the patent application, the calculation would result in a negative term of four months.

Patent holders who have been granted a marketing authorization for a medicinal product in Europe and intend to avail themselves of the incentive of the Pediatric Regulation have begun filing SPC applications for such negative terms, which, taking into account the six-month extension, still result in an overall positive extension of protection.

A dispute has arisen regarding the question of whether a positive term is a prerequisite for issuing an SPC. The formal requirements for the grant of an SPC are met if, at the time of filing the application, (a) the product is protected by a (basic) patent in force, (b) a valid authorization to place the product on the market as a medicinal product has been granted, (c) the product has not already been the subject of an SPC, and (d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product. If these conditions are met, an SPC shall be granted.

A number of patent offices hold, however, that the grant of an SPC should not be considered when the term calculated according to the SPC Regulation is zero or negative. The reasoning provided in support of this position is that the patent holder is already awarded 15 years of exclusivity or more from the first authorization to place the product on the market. The object and purpose of the SPC Regulation, *i.e.*, to grant a minimum of 15 years of exclusivity, does not justify the issuance of an SPC.

Accordingly, the patent offices in Austria and Switzerland implemented guidelines for the examination of SPC applications that expressly exclude the grant of zero-term SPCs; the German Patent Office equally has taken a negative stance on zero-term SPCs.

However, several national patent offices, including those in the UK, the Netherlands, Ireland, Estonia, and Bulgaria, accept applications for an SPC with a negative term, while the Greek Patent Office granted an SPC with a zero term.

THE REQUEST OF THE GERMAN FEDERAL PATENT COURT

The German Federal Patent Court has now considered the matter after the German Patent Office rejected an SPC application that would have resulted in a negative-term SPC. In view of the diverging decisions made by patent offices of various member states, the Court issued an interlocutory decision. It has requested the European Court of Justice ("ECJ") to provide an interpretation of the European legislation with regard to the availability (or unavailability) of zero- or negative-term SPCs.

In its decision, the German Federal Patent Court held that neither the Pediatric Regulation nor the SPC Regulation provide for the grant of an SPC with zero or negative term. In particular, the SPC Regulation was only meant to provide supplementary protection if the time between the filing of

the patent application and the first authorization to place the product on the market was longer than five years. The Court further argues that there is no indication that anything changed due to the Pediatric Regulation in how the term "supplementary protection certificate" should be defined. In fact, the Pediatric Regulation in several instances simply refers to the SPC Regulation, indicating that the term is used in the same meaning. The German Court further considered that the word "term" commonly refers to a time span in which something takes place (*e.g.*, the time span for which a contract is valid). The Court held that there was no indication in the wording of the SPC Regulation that the day on which the basic patent expires should serve only as the calculated starting point for a subtraction (certificate with negative term) and subsequent addition (extension of term).

At the same time, the German Court acknowledges in support of zero- or negative-term SPCs that it is systematically justifiable to consider the provision on the term of an SPC only after the formal and material conditions for the grant of an SPC are met. The Court further added that the SPC Regulation did not exclude *expressis verbis* a negative term as the result of the calculation of the certificate's term. It was also taken into consideration by the Court that the Pediatric Regulation was aimed at achieving goals completely separate from those that were decisive for the creation of SPCs through the SPC Regulation. The Court therefore came to the conclusion that it cannot be excluded that the coming into force of the Pediatric Regulation modified the SPC system. The Court held that if the Pediatric Regulation was given greater weight than the SPC Regulation, it would be obvious to reward the largest number of manufacturers of medicinal products possible by granting the six-month extension of term if these manufacturers conducted the required pediatric studies.

OUTLOOK

It will probably take at least two years until the ECJ will consider the question referred to it by the German Federal Patent Court. Until then, manufacturers of medicinal products who consider filing zero- or negative-term SPCs will face legal uncertainty as to whether a six-month extension of term based on the provision of the Pediatric Regulation will be granted—even in those countries that so far have been receptive to the concept. If worse comes to worst, the ECJ may put an end to the practice of zero- or negative-term SPCs. It is unlikely that the European Commission might come to the rescue of manufacturers by proposing amendments to either the Pediatric Regulation or the SPC Regulation. The Commission takes the stance that zero- or negative-term SPCs should not be granted, even in light of the object and purpose of the Pediatric Regulation.

Some manufacturers are currently weighing their options for voluntary applications under the Pediatric Regulation for products that have already obtained a marketing authorization, but within a five year period as of patent application. They should keep in mind that the possible reward of an extension of the zero or negative term might not materialize.

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