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SPC term clarified

Ever since EU Regulation 1768/92 implemented supplementary protection certificates (SPCs) in the European Union, the unclear wording of various provisions of the Regulation has led to numerous decisions by courts throughout Europe.

Recently, the German Federal Patent Court had a chance to comment on Article 13 of the Regulation, which concerns the duration of an SPC.

Article 13 (1) stipulates that the duration of an SPC is to be calculated as the time between the filing date of the basic patent application and the first marketing authorization within the European Community minus five years. Article 13(2) limits the maximum length of protection to five years.

There is no unambiguous definition provided by the Regulation for the term “first marketing authorization within the European Community” as it is used in Article 13. However, the ECJ has interpreted this term as referring to a marketing authorization in accordance with Directive 65/65/EU. Directive 65/65/EU was implemented in 1965 to harmonize the legal framework for obtaining marketing authorizations for medicinal products throughout Europe.

The German Patent and Trademark Office (GPMA) in the first instance had based its calculation of the duration of the SPC on a marketing authorization in Portugal that was granted in March 1990. The applicant requested that the calculation be instead based on a British marketing authorization of April 1995. The difference in duration would have amounted to about four years.

The applicant did not consider the Portuguese authorization to be the *first* marketing authorization in the sense of Article 13 (1), as Portugal had not implemented Directive 65/65/EU by March 1990. Nevertheless, the GPMA held that *any* marketing authorization within the European Union could be considered for the purposes of Article 13 (1) as long as a member state’s legal framework for granting marketing authorizations at the respective time was in *essence* in line with Directive 65/65/EU.

The Federal Patent Court, however, did not agree, holding that only marketing authorizations of member states which had implemented Directive 65/65/EU at the date of the issue of the authorization can be used as a basis on which to calculate the duration of an SPC.

Applicants should therefore check carefully that the Authority that grants the SPC indeed applies the first *relevant* marketing authorization in the European Union. The difference can amount to up to five years of market exclusivity.