

# **Current Issues of Supplementary Protection Certificates for Medicinal Products in the Case Law of the European Court of Justice**

## **Abstract**

Supplementary protection certificates (SPCs) are a sui generis industrial property right. Under the conditions, which are explained in more detail in this thesis, they can be obtained for the active ingredients of certain products. The type of products eligible for SPC protection are, inter alia, medicinal products which are characterized by their social importance and therefore by the need to ensure their safety, efficacy and quality. Given that the process of providing these guarantees is both costly and time consuming and that the commercialization of the product is conditional on such guarantees, the period for which medicinal products can benefit from patent protection is therefore shortened. The aim of the SPCs is to compensate for this shortening by an additional period of protection in order to incentivise research that has a positive effect on human health and quality of life.

This work analyzes the evolution of the case law of the Court of Justice with regard to an interpretative shift or clarification, in particular as regards the substantive conditions for obtaining a certificate and provisions pertaining to the term of the SPC as laid down in the SPC Regulation for medicinal products. For this purpose the work is divided into three main parts. The first part introduces the SPC and its development, including the circumstances of and reason for its creation, its legislative framework as well as the recent amendment of the regulation. This part should serve to understand the basic meaning of the SPC and thus enable its closer study in the second and third parts. The second part dealing with the case law is a crucial part and its scope corresponds to this. The judgments are divided into chapters according to the specific substantive conditions for obtaining the SPC to which they relate. The individual chapters introduce the relevant provisions first and then illustrate the development of their interpretation up to the most recent decisions after which there is room for their analysis, evaluation, or even polemics with the opinions of practicing experts. For Part Three, the same applies as to Part Two, except that it deals with the term of the SPC instead of the conditions for obtaining it.

Finally, the conclusion discusses the tendencies in terms of the number of questions referred to the Court of Justice, summarizes the various interpretative conclusions and also notes the apparent tendency towards a restrictive interpretation in recent judgments.

**Key words: Supplementary protection certificates, Medicinal products, Court of Justice**