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Application and Importance of Supplementary Protection Certificates for Medicinal Products in the European Union

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The book focuses on supplementary protection certificates for medicinal products (SPC) created on the basis of the Council Regulation (EEC) no. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (currently 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). Since an SPC extends patent protection for a product, it provides an important advantage to innovative pharmaceutical companies in the European Union. The author discusses in detail various aspects of the legal mechanism of an SPC. She also presents similar legal concept in the USA as a benchmark for comparison of the European solution. The publication challenges the question of the importance and impact of an SPC on the European pharmaceutical market, among others, from a competition law perspective, as well as the role of an SPC in the context of other legal instruments available, such as market exclusivity and data exclusivity. This is particularly important as the current circumstances on the European pharmaceutical market differ much from those when the legal regime of the SPC was adopted. The publication also elaborates on the shortfalls of the current SPC system and identifies those areas which require amendments to address issues resulting from the rapidly changing situation on the pharmaceutical market in the European Union.