European Union

“Abraxis Bioscience”

**Decision of the European Court of Justice (Fourth Chamber)
21 March 2019 – Case No. C-443/17**

*Abraxis Bioscience LLC v. Comptroller General of
Patents*

Regulation (EC) No 469/2009, Arts. 1(b), 3(b) and (d)

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Keywords Supplementary protection certificate (SPC) · Medicinal products · First marketing authorisation · New formulation of a known active ingredient · Conditions for granting

1. Article 3(d) of 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, read in conjunction with Article 1(b) of that regulation, must be interpreted as meaning that the marketing authorisation referred to in Article 3(b) of that regulation, relied on in support of an application for a supplementary protection certificate concerning a new formulation of an old active ingredient, cannot be regarded as being the first marketing authorisation for the product concerned as a medicinal product in the case where that active ingredient has already been the subject of a marketing authorisation as an active ingredient.

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