

# Supplementary Protection Certificates (SPC)

Stief

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# Supplementary Protection Certificates (SPC)

A Handbook

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Marco Stief

  
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## Foreword

Supplementary Protection Certificates (SPCs) are often referred to as *sui generis* protective rights, both because of the unique form of protection they provide as well as their legal nature.

Since SPCs always presuppose the existence of already approved and marketed medicinal products, their significance in economic terms is immense. Even in cases where an SPC extends the effects of a patent for only a few days, this short period of time may generate revenue for the SPC holder reaching into the millions – because of certain characteristics of the pharmaceutical market.

One peculiarity of an SPC is that while it is an intellectual property right which is granted in respect of a national basic patent, its legislative basis is a European Community Regulation. This explains the CJEU's jurisdiction in numerous SPC cases and consequently in issues that are intrinsically similar to issues arising under patent law. In contrast to patent law, for SPCs there is a central judicial authority for national diverging interpretations of the Regulation which created the SPC in its first version of 18 June 1992. The same goes for the codified version of the SPC Regulation of 6 May 2009.

From time to time, the CJEU's case law raises more questions than it answers, potentially resulting in decisions being implemented in a variety of different ways across national patent offices and courts. The handbook covers relevant legislation as well as case law on SPCs at both the European and national level in selected European countries. The work of outlining national practices on the grant, protective effect, term and infringement proceedings surrounding SPCs was undertaken as part of a collaborative effort by distinguished and highly experienced patent attorneys and lawyers from the countries concerned.

The handbook provides valuable insights into the world of SPCs for medicinal products. It is aimed at patent attorneys, lawyers and people in pharmaceutical companies and patent departments, not only at EU level, but also at national level, specifically in Germany, the UK, France, Italy, the Netherlands and Switzerland. It allows a comparison of the current legal status quo between these countries as well as an overview of regulations and case law decisions made at EU level. The handbook also covers the implementation of CJEU case law at national level, the practices of the different national patent offices and an Annex section containing the text of the most significant European and national case law and legal sources on SPCs. It includes new legislation, case law and literature up to mid-2021.

The second edition of this handbook specifically addresses more recent developments including the economic and legal studies on SPCs launched by the European Commission and published between 2017 and 2018 as well as SPC manufacturing waivers introduced in 2019. It also discusses the implications of Brexit on the European and UK SPC regime.

Munich, July 2021

Marco Stief

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## Abbreviations

### European Law

*For full reference to rules of law see Annex B*

RegSPC .....	Regulation 469/2009/EC of 6 May 2009 concerning the Supplementary Protection Certificate [SPC] for medicinal products (OJ L 152 of 16 June 2009, p. 1)
RegSPC-Plant Protection Products .....	Regulation 1610/96/EC of 23 July 1996 concerning the creation of an SPC for plant protection products (OJ L 198 of 8 August 1996, p. 30)
RegCAP .....	Regulation 726/2004/EC of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use (OJ L 136 of 30 April 2004, p. 1)
RegGCP .....	Regulation 536/2014/EU of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158 of 27 May 2014, p. 1)
RegMPP .....	Regulation 1901/2006/EC of 12 December 2006 on medicinal products for paediatric use (OJ L 378 of 27 December 2006, p. 1)
DirMPH .....	Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311 of 28 November 2001, p. 67)
DirMPV .....	Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311 of 28 November 2001, p. 1)
EPC .....	European Patent Convention
TFEU .....	Treaty on the Functioning of the European Union
CFREU .....	Charter of Fundamental Rights of the European Union

### Other Abbreviations

API .....	active pharmaceutical ingredient
Art .....	Article
B.S.L.R. ....	Bio-Science Law Review (journal)
Cf./cf. ....	confer
CIPA .....	Chartered Institute of Patent Attorneys
CJEU .....	Court of Justice of the European Union
EC .....	European Community
EEA .....	European Economic Area
EEC .....	European Economic Community
EFTA .....	European Free Trade Association
e.g. ....	exempli gratia
EIPR .....	European Intellectual Property Review (journal)
EMA .....	European Medicines Agency
EPO .....	European Patent Office
et seq./et seqq. ....	et sequens/et sequentes
EU .....	European Union
EuZW .....	Europäische Zeitschrift für Wirtschaftsrecht (journal)
FD-GewRS .....	Fachdienst Gewerblicher Rechtsschutz (journal)
GRUR .....	Zeitschrift GRUR e. V. (journal)

## Abbreviations

GRUR Int. ....	Zeitschrift GRUR e. V., internationaler Teil (journal)
GRUR-Prax. ....	Zeitschrift GRUR e. V., Praxisteil (journal)
i.e. ....	id est
IIC ....	International Review of Intellectual Property and Competition Law (journal)
J.I.P.L.P. ....	Journal of Intellectual Property Law & Practice
lit. ....	littera
MA ....	Marketing Authorisation
Mitt. ....	Mitteilungen deutscher Patentanwälte (journal)
mn. ....	marginal number
MPR ....	Zeitschrift für Medizinprodukterecht (journal)
No./no. ....	Number
OJ ....	Official Journal
p. ....	page
para./paras. ....	paragraph(s)
PCPIP ....	Paris Convention for the Protection of Industrial Property
Pharm Ind. ....	Die Pharmazeutische Industrie (journal)
PharmR ....	Zeitschrift für Pharmarecht (journal)
resp. ....	respectively
sic! ....	Zeitschrift für Immaterialgüter-, Informations- und Wettbewerbsrecht (journal)
SPC ....	Supplementary Protection Certificate
TRIPS ....	Agreement on Trade-Related Aspects of Intellectual Property Rights
v. ....	versus
ZEuP ....	Zeitschrift für Europäisches Privatrecht (journal)
ZfZ ....	Zeitschrift für Zölle und Verbrauchsteuern (journal)

  
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