

**Stief / Bühler**

**Supplementary  
Protection Certificates  
(SPC)**

**A Handbook**

**C.H.BECK · Hart · Nomos**

Stief/Bühler  
Supplementary Protection Certificates (SPC)



# Supplementary Protection Certificates (SPC)

edited by

Marco Stief  
Dirk Bühler

C. H. BECK · Hart · Nomos  
2016

*Published by*

Verlag C. H. Beck oHG, Wilhelmstraße 9, 80801 München, Germany,  
eMail: [bestellung@beck.de](mailto:bestellung@beck.de)

*Co-published by*

Hart Publishing, 16C Worcester Place, Oxford, OX1 2JW, United Kingdom,  
online at: [www.hartpub.co.uk](http://www.hartpub.co.uk)

and

Nomos Verlagsgesellschaft mbH & Co. KG Waldseestraße 3–5, 76530 Baden-Baden,  
Germany, eMail: [nomos@nomos.de](mailto:nomos@nomos.de)

Published in North America (US and Canada) by Hart Publishing,  
c/o International Specialized Book Services, 930 NE 58<sup>th</sup> Avenue, Suite 300,  
Portland, OR 97213-3786, USA, eMail: [orders@isbs.com](mailto:orders@isbs.com)

ISBN 978 3 406 64856 4 (Beck)  
ISBN 978 1 84946 486 4 (Hart Publishing)  
ISBN 978 3 8487 0299 2 (Nomos)

© 2016 Verlag C. H. Beck oHG  
Wilhelmstr. 9, 80801 München

Printed in Germany by  
Beltz Bad Langensalza GmbH  
Neustädter Straße 1–4, 99947 Bad Langensalza

Typeset by  
Reemers Publishing Services GmbH, Krefeld

Einbandgestaltung: Druckerei C.H. Beck Nördlingen

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## Foreword

Supplementary Protection Certificates (SPCs) are often referred to as *sui generis* protective rights, doing justice both to their meaning and their underlying peculiarities.

Since SPCs always refer to approved and marketed medicinal products, their economic significance is prodigious. Even if a SPC is granted for only a few days, this may yield the certificate holder – given the particular characteristics of the pharmaceutical market – revenue amounting to millions.

The peculiarity of SPCs is that although it is a property right that is always granted ancillary to a patent, it was created by a European Community Regulation. This explains the ECJ's competence in SPCs and thus for issues that are inherently similar to those of patent law. In contrast to patent law, there is for SPCs a central judicial authority with nationally diverging interpretations of the Regulation which created the SPC, in its first version on the 18<sup>th</sup> June 1992.

From time to time, the ECJ's case law poses more questions than are answered, potentially resulting in it being implemented in a variety of different ways by national patent offices and courts.

This manual will for the first time cover relevant legislation, as well as case law in connection with SPCs, both at the European and national level in selected European countries, whereas the information presented is from the perspective of pharmaceutical companies. Regarding its application, distinguished patent attorneys and lawyers with relevant and extensive experience from the countries concerned collaborated as regards the issuing, protective effect, term and infringement proceedings of SPCs.

The handbook provides, both patent attorneys and lawyers, as well as employees of pharmaceutical companies and patent departments, a profound insight into the field of SPCs for medicinal products; not only at the EU level, but also specifically in Germany, Switzerland, Italy, the United Kingdom, the Netherlands and France. This facilitates a comparison of the legal matter, between the aforementioned countries, as well as in relation to regulations and supplementary case law decisions made at the EU level. Also covered, are the granting practices of national patent offices and the court rulings on SPCs in the ECJ in the aforementioned countries. The ECJ's decisions on the interpretation of the regulation finally complete the picture and provide the basis for a harmonized application of the law

This manual takes account of changes in the law and those decisions at the EU level that are most important for the SPC, in Germany, Switzerland, Italy, the United Kingdom, the Netherlands and France up to mid-2015.

Munich, September 2015

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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
RegSPC-Plant Protection Products .....	Regulation 1610/96/EC of 23 July 1996 concerning the creation of an SPC for plant protection products
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
RegMPP .....	Regulation 1901/2006/EC of 12 December 2006 on medicinal products for paediatric use
DirMPH .....	Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use
DirMPV .....	Directive 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products
DirGCP .....	Directive 2001/20/EC of 4 April 2001 on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
EPC .....	European Patent Convention
TFEU .....	Treaty on the Functioning of the European Union
CFREU .....	Charter of Fundamental Rights of the European Union

## Other Abbreviations

Art. ....	Article
AS .....	Official collection of the Swiss federal law
Bd. ....	Band
CAS .....	Chemical Abstracts Service
Cf./cf. ....	confer
CJEU .....	Court of Justice of the European Union
CHF .....	Swiss Franc
consid. ....	consideration
DCI .....	International Non-proprietary Name; also abbreviated as INN
EC .....	European Community
ed. ....	edition
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)
GRUR Int. ....	Zeitschrift GRUR e. V., internationaler Teil (journal)
GRUR-Prax. ....	Zeitschrift GRUR e. V., Praxisteil (journal)
i. c. w. ....	in conjunction with
i. e. ....	id est
IIC .....	International Review of Intellectual Property and Competition Law (journal)
INN .....	International Non-proprietary Name, also abbreviated as DCI
IUPAC .....	International Union of Pure and Applied Chemistry
lit. ....	littera

## Abbreviations

MA .....	Marketing Authorisation
Message PatA 1993 .....	Dispatch concerning the amendments of the Federal Act on Patents for Inventions and concerning the federal resolution on the amendments of the European Patent Convention of 18 August 1993, BBl (Bundesblatt) 1993, 706 <i>et seqq.</i>
Message PatA 1998 .....	Dispatch concerning the amendments of the Federal Act on Patents for Inventions of 19 January 1998, BBl (Bundesblatt) 1998, 1633 <i>et seqq.</i>
Mitt. ....	Mitteilungen deutscher Patentanwälte (journal)
mn. ....	marginal number
MPR .....	Zeitschrift für Medizinprodukterecht (journal)
NAS .....	New Active Substance
NCE .....	New Chemical Entity
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
Rs. ....	legal matter/proceeding
sicl .....	Zeitschrift für Immaterialgüter-, Informations- und Wettbewerbsrecht (journal)
SPC .....	Supplementary Protection Certificate
SR .....	Classified compilation of Swiss federal law
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)