

Stief / Bühler

**Supplementary
Protection Certificates
(SPC)**

A Handbook

C.H.BECK · Hart · Nomos

Stief/Bühler
Supplementary Protection Certificates (SPC)

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edited by
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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 18th 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)