

Supplementary Protection Certificates (SPC)

Stief

Second edition 2021
ISBN 978-3-406-76240-6
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Supplementary Protection Certificates (SPC)


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Supplementary Protection Certificates (SPC)

A Handbook

edited by

Marco Stief


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Second edition

2021



Published by

Verlag C.H.Beck oHG, Wilhelmstraße 9, 80801 München, Germany,
email: bestellung@beck.de

Co-published by

Hart Publishing, Kemp House, Chawley Park, Cumnor Hill, Oxford, OX2 9PH, United Kingdom,
online at: www.hartpub.co.uk

and

Nomos Verlagsgesellschaft mbH & Co. KG, Waldseestraße 3–5, 76530 Baden-Baden, Germany,
email: nomos@nomos.de

Published in North America by Hart Publishing

An Imprint of Bloomsbury Publishing 1385 Broadway, New York, NY 10018, USA

Suggested citation:

[Author], in: Stief,

Supplementary Protection Certificates (SPC),

2nd ed. 2021, p. [#], mn. [#]

beck-shop.de
DIE FACHBUCHHANDLUNG
www.beck.de

ISBN 978 3 406 76240 6 (C.H.BECK)

ISBN 978 1 5099 5721 7 (HART)

ISBN 978 3 8487 8362 5 (NOMOS)

© 2021 Verlag C.H.Beck oHG

Wilhelmstr. 9, 80801 München

Printed in Germany by

Beltz Grafische Betriebe GmbH

Am Fliegerhorst 8, 99947 Bad Langensalza

Typeset by

Reemers Publishing Services GmbH, Krefeld

Cover: Druckerei C.H.Beck Nördlingen



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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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