

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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Survey of Contents

Foreword	V
Contributors	VII
Abbreviations	XVII

PART I GENERALS OF THE SUPPLEMENTARY PROTECTION CERTIFICATE IN THE EUROPEAN LAW

A. Purpose, History and Legal Character of the Certificate	3
I. Overview	3
1. Background and Economic Relevance of the Supplementary Protection Certificate	3
2. Area of Application	4
II. Relationship between Grant of the Patent and Authorisation under Pharmaceutical Law	5
1. Overview of the Drug Authorisation Procedures	6
2. Differentiation between Preparatory Actions and Actual Authorisation Procedure	6
3. The Early Patent Application	7
4. The Reduction of the Patent Duration and its ‘Countermeasures’	8
5. Possible Alternatives to the Supplementary Protection Certificate	9
III. History	10
IV. Legal Character	11
B. Substantive Granting Prerequisites	12
I. General	12
II. Product	12
III. Basic Patent	13
1. Discrepancy between Basic Patent and Authorisation	15
2. Multiple Basic Patents and Patentees	16
IV. First Marketing Authorisation	16
1. General Principles	16
2. Senior and Extraterritorial Authorisations	18
V. No Earlier Certificate – Multiple SPCs for the same product	19
C. Calculation of Term	22
I. General	22
II. Relevant Date for the Calculation of Term	23
1. Grant of the Basic Patent	23
2. Lodging the Basic Patent Application	23
3. Grant of the First Marketing Authorisation	24
III. Negative Terms	25
D. Subject Matter and Scope of Protection	27
I. General	27
II. Specific Problems of the Scope of Protection	27
1. Salt Issue	27
2. Use Patents	29
3. Substance Combinations	32
E. Rights, Limitations and Obligations	41
I. Rights of the Certificate Holder	41
1. Rights of Use and Exclusivity	41
2. Licenses	41
3. Right to the SPC (Art. 6 RegSPC)	42
II. Limitations and Obligations	43

Survey of Contents

F. Grant Procedure	44
I. General	44
II. Application	44
1. General Application Requirements	44
2. Form and Content of the Application	44
3. Application Period	46
4. Application regarding the Term Extension of an SPC	47
5. Application Fees	48
6. Publication of an Application Notice	48
III. Grant and Announcement	49
IV. Fees to Maintain the SPC	50
G. Expiry, Invalidity and Revocation	51
I. Reasons for Expiry pursuant to Art. 14 RegSPC	51
II. Reasons for Invalidity pursuant to Art. 15 RegSPC	52
III. Revocation of a Term Extension	53
IV. Announcement	53
H. Remedies	54

PART II SPECIALITIES IN OTHER JURISDICTIONS

I. The SPC in Germany	55
I. National Pharmaceutical and Patent Law	55
II. Application of the Art. 3 RegSPC conditions	56
III. Calculation of the term of the SPC	60
IV. Rights, Limitations and Obligations	60
V. SPC Grant, Termination and Remedies	61
1. Grant	61
2. Termination	64
J. The SPC in the United Kingdom	66
I. National Law relating to SPCs	66
II. Application of the Art. 3 RegSPC conditions	67
1. Article 3(a) RegSPC	68
2. Article 3(b) RegSPC	74
3. Article 3(c) RegSPC	74
4. Article 3(d) RegSPC	75
5. Third party MAs	76
III. SPC application procedure	77
1. Applications for SPCs	77
2. Applications for SPC extensions	79
IV. Invalidation of SPCs and/or SPC extensions	79
K. The SPC in France	81
I. French national patents and pharmaceutical law	81
II. The conditions for obtaining an SPC	82
1. Article 3(a) of the Regulation	82
2. Article 3(b) of the Regulation	84
3. Article 3(c) of the Regulation	84
4. Article 3(d) of the Regulation	85
III. Grant procedure for SPCs in France	85
IV. Scope of protection	86
V. Duration of SPCs	87
VI. Waiver of SPCs	88
VII. Paediatric extensions	88
L. The SPC in Italy	90
I. National Pharmaceutical and Patent Law	90
II. SPC Obtaining Provisions and Term	92
III. Subject Matter and Scope of Protection	93

Survey of Contents

IV. Rights, Limitations and Obligations	94
V. SPC Grant, Termination and Remedies	95
1. Grant	95
2. Termination	97
M. The SPC in The Netherlands	98
I. National Pharmaceutical and Patent Law	98
1. Patents	98
2. NLOC and Dutch patent register	98
3. Medicines Evaluation Board	99
II. SPC Obtaining Provisions and Term in the Dutch Context	99
1. Application	99
2. Publication	100
3. Grant procedure	100
4. Third party observations	100
III. Subject Matter and Scope of Protection	101
1. Product protected	101
2. One SPC per patent?	103
3. Further medical use	104
IV. Rights, Limitations and Obligations	105
V. License	106
VI. Termination and Remedies	106
VII. Court proceedings	107
N. The SPC in Switzerland	108
I. Sources of Law and Legislative History	109
1. Patent Law	109
2. Pharmaceutical Law	109
3. Legislative History	110
II. Substantive Granting Prerequisites	110
1. Overview	110
2. The Term “Product”	111
3. Protection by a Basic Patent	113
4. First MA of the Product	114
5. First SPC for the Product	116
6. Time Limit for Filing the Application	118
III. Application, Examination, Grant, and Remedies	118
1. Application and Fees	118
2. Examination and Announcement	119
3. Grant	119
4. Remedies	120
IV. Subject-Matter of Protection and Effects	120
1. Subject-Matter of Protection	120
2. Effects	121
V. Term of Protection	121
1. General	121
2. Paediatric Extension	122
VI. Premature Lapse and Suspension	122
VII. Nullity	123
VIII. Swiss Federal Patent Court	123

ANNEXES

Annex A: Selected Decisions of the European and Swiss Case Law	125
A1. Court of Justice of the European Union	125
I. Biogen v. SmithKlineBeecham Biologicals, C-181/95 of 23 January 1997	125
II. Yamanouchi v. Comptroller-General of Patents, Designs and Trademarks, C-110/95 of 12 June 1997	125
III. Idarubicin Farmitalia v. Deutsches Patent- und Markenamt, C-392/97 of 16 September 1999	126
IV. Omeprazol Hässle v. ratiopharm, C-127/00 of 11 December 2003	126
V. Pharmacia Italia v. Deutsches Patent- und Markenamt, C-31/03 of 19 October 2004	128

Survey of Contents

VI. Novartis Novartis v. Comptroller-General of Patents, Designs and Trademarks, C-207/03, Ministre de l'Economie v. Millenium Pharmaceuticals, C-252/03 of 24 January 2005	128
VII. Massachusetts Institute of Technology v. Deutsches Patent- und Markenamt, C-431/04 of 4 May 2006	128
VIII. i-21 Germany v. Arcor, C-392/04, C-422/04 of 19 September 2006	130
IX. Yissum Research and Development Company v. Comptroller-General of Patents, C-202/05 of 17 April 2007	130
X. AHP Manufacturing v. Bureau voor de Industriële Eigendom, C-482/07 of 3 September 2009	131
XI. Memantine Synthron v. Merz Pharma, C-195/09 of 28 July 2011	131
XII. Galantamin Generics UK v. Synaptech, C-427/09 of 28 July 2011	132
XIII. Medeva v. Comptroller-General of Patents, Designs and Trademarks, C-322/10 of 24 November 2011	132
XIV. Georgetown University v. Comptroller-General of Patents, Designs and Trademarks, C-422/10 of 24 November 2011	133
XV. Daiichi Sankyo Company v. Comptroller-General of Patents, Designs and Trademarks, C-6/11 of 25 November 2011	133
XVI. Yeda Research and Development Company, Aventis Holdings v. Comptroller-General of Patents, Designs and Trademarks, C-518/10 of 25 November 2011	134
XVII. University of Queensland v. Comptroller-General of Patents, Designs and Trademarks, C-630/10 of 25 November 2011	134
XVIII. Merck Sharpe & Dohme v. Deutsches Patent- und Markenamt, C-125/10 of 8 December 2011	134
XIX. Novartis v. Actavis Deutschland, C-574/11 of 9 February 2012 and with the same result: Novartis v. Actavis UK, C-442/11 of 9 February 2012	135
XX. Neurim Pharmaceuticals v. Comptroller-General of Patents, Designs and Trademarks, C-130/11 of 19 July 2012	136
XXI. AstraZeneca v. European Commission, C-457/10 of 6 December 2012	136
XXII. Referral: Actavis UK v. Sanofi, C-443/12 of 3 October 2012	137
XXIII. Referral: AstraZeneca v. Comptroller-General of Patents, Designs and Trademarks, C-617/12 of 18 December 2012	139
XXIV. Referral: Bayer CropScience v. Deutsches Patent- und Markenamt, C-11/13 of 6 December 2012	139
XXV. Referral: GlaxoSmithKline Biologicals v. Comptroller-General of Patents, Designs and Trademarks, C-210/13 of 21 March 2013	139
XXVI. Eli Lilly and Company Ltd. V. Human Genome Sciences Inc., C-493/12 of 12 December 2013	140
XXVII. Georgetown University v. Octroicentrum Nederland (referred to as Georgetown II in the text) C-484/12 of 12 December 2013	140
XXVIII. Merck Canada Inc. v. Accord Healthcare Ltd. and others, C-555/13 of 13 February 2014 ...	141
XXIX. Referral: Seattle Genetics, C-471/14 of 15 October 2014	141
XXX. Novartis v. Actavis Deutschland, C-574/11 of 9 February 2012	141
XXXI. Actavis v. Boehringer Ingelheim, C-577/13 of 14 November 2013	141
XXXII. Arne Forsgren v. Comptroller-General of Patents, Designs and Trademarks, C-631/13 of 15 January 2015	143
A2. German Courts	145
Federal Court of Justice (Bundesgerichtshof, BGH)	145
I. Trioxan, X ZB 9/70 of 6 July 1971	145
II. Idarubicin III, X ZB 21/00 of 17 July 2001	145
III. Sumatriptan, X ZB 12/01 of 29 January 2002	145
IV. Custodiol II, X ZR 73/01 of 12 March 2002	145
V. Anti-Helicobacter-Präparat, X ZB 1/08 of 8 July 2008	146
VI. Doxorubicin, X ZB 4/08 of 14 October 2008	146
Federal Patent Court (Bundespatentgericht, BPatG)	146
VII. Abamectin, 15 W (pat) 71/97 of 21 June 1999	146
VIII. Porfimer, 15 W (pat) 59/03 of 23 June 2005	146
IX. Finasterid, 3 Ni 2/06 of 15 March 2007	147
X. Subdiuretische Dosis, 3 Ni 49/07 of 16 June 2009	147
XI. Tenofovir, 15 W (pat) 24/07 of 12 May 2011	147
XII. Ranibizumab, 3 Ni 28/11 of 2 May 2012	147
XIII. Insulin Glargine 14 W (pat) 13/07 of 31 May 2011	148

Survey of Contents

XIV. Telmisartan, 3 Ni 5/13 of 4 February 2013	148
Düsseldorf Regional Court (LG Düsseldorf)	148
XV. Valsartan, 4 b O 280/10 of 8 March 2011	148
A3. UK Courts	150
Court of Appeal of England & Wales	150
I. E I Du Pont Nemours & Co. v UK Intellectual Property Office 2009 EWCA Civ 966, 2010 R.P.C. 6	150
II. Medeva BV v Comptroller General of Patents, Designs and Trade Marks 2010 EWCA Civ 700; 2010 R.P.C. 27	150
III. Neurim Pharmaceuticals (1991) Ltd v Comptroller General of Patents 2011 EWCA Civ 228; 2011 R.P.C. 19	150
IV. Medeva BV v Comptroller General of Patents, Designs and Trade Marks 2012 EWCA Civ 523; 2012 R.P.C. 26	151
High Court of England & Wales	151
V. Takeda Chemical Industries Ltd v Comptroller General of the Patent Office (No.3) 2003 EWHC 649 (Pat); 2004 R.P.C. 3	151
VI. Gilead Sciences, Inc's SPC Applications 2008 EWHC 1902 (Pat)	151
VII. Astellas Pharma Inc v Comptroller-General of Patents 2009 EWHC 1916 (Pat)	152
VIII. Novartis Pharmaceuticals UK Ltd v MedImmune Ltd 2012 EWHC 181 (Pat); 2012 F.S.R. 23	152
IX. Eli Lilly & Company v Human Genome Sciences Inc 2012 EWHC 2290 (Pat)	153
X. Actavis Group PTC EHf and Actavis UK Limited v Sanofi and Sanofi Pharma Bristol-Myers Squibb SNC 2012 EWHC 2545 (Pat); 2013 R.P.C. 24	153
XI. Eli Lilly & Company v Human Genome Sciences Inc 2012 EWHC 2857 (Pat)	153
XII. Dr Reddy's Laboratories (UK) Ltd and Dr Reddy's Laboratories Ltd v Warner-Lambert Company LLC 2012 EWHC 3715 (Pat); 2013 R.P.C. 31	154
XIII. Glaxosmithkline Biologicals SA v Comptroller-General of Patents, Designs and Trade Marks 2013 EWHC 619 (Pat); 2013 R.P.C. 26	154
XIV. Actavis Group and Actavis UK v Boehringer Ingelheim Pharma 2013 EWHC 2927 (Pat) ..	154
XV. Eli Lilly & Company v Human Genome Sciences Inc 2014 EWHC 2404 (Pat)	155
Comptroller of Patents	155
XVI. Takeda Chemical Industries Ltd's Applications 2004 R.P.C. 2	155
XVII. Abbott Laboratories' SPC Application 2004 R.P.C. 20	156
A4. French Courts	157
Supreme Court	157
I. Decision of 3 April 2007 of the Supreme Court of Paris, "Diagnosis of AIDS"	157
II. Decision of 19 March 2013 of the Supreme Court, "azoxystrobine + folpel"	157
Court of Appeal of Nancy	158
III. Decision of 14 June 2010 of the Court of Appeal of Nancy, "Extract of Timothy-Grass"	158
Court of Appeal of Paris	158
IV. Decision of 15 February 2013 of the Court of Appeal of Paris, "varicella-zoster virus"	158
V. Decision of 5 July 2013 of the Court of Appeal of Paris, "Peginterferon alpha 2a"	158
VI. Decision of 11 September 2013 of the Court of Appeal of Paris, "perflutren"	159
A5. Italian Courts	160
I. Decision 20/1978 Constitutional Court	160
II. Court of Milan Irbesartan Hydrochlorotiazide 57598/12 of 22/12/2012	160
III. Court of Rome case 23499 of 19/05/2003	160
IV. Court of Milan case 57598/2012 of 10 July 2014	160
V. Commissione dei Ricorsi case 6895 of 20/06/2002	160
VI. Commissione dei Ricorsi case 6353 of 19/04/1996	161
VII. Commissione dei Ricorsi case 6491 of 16/12/1997 and 6497 of 17/01/2000.	161
A6. Dutch Courts	162
District Court of The Hague, Administrative Law Division	162
I. Genzyme Biosurgery v. NLOC of 3 June 2004	162
II. Stallergenes v. NLOC of 4 November 2009	162
III. Aventis v. NLOC of 28 May 2008	162
IV. Actavis v. NLOC of 23 September 2009	162

Survey of Contents

District Court of The Hague, Civil Law Division	163
V. Sanofi v. Teva of 14 September 2012 (later revoked, see Teva v. Sanofi of 27 August 2013) ...	163
VI. Mylan B.V. v. Janssen Pharmaceuticals Inc. of 11 December 2013	163
Court of Appeal of The Hague, Civil Law Division	163
VII. SKF v. Centrafarm of 19 May 1994	163
VIII. Pfizer v. UVIT & Pfiver v. VGZ of 24 July 2012	163
IX. APE v. PTC of 23 April 2013	163
X. Teva v. Sanofi of 27 August 2013	163
Council of State	164
XI. Yeda v. NLOC of 19 August 2009	164
XII. Yeda v. Aventis en NLOC of 27 May 2009	164
XIII. Syngenta v. NLOC of 18 February 2015	164
A7. Swiss Courts	165
Federal Administrative Court	165
I. “Panitumumab”, No. B-3245/2010, Decision of 18 August 2011 of the Federal Administrative Court	165
II. “Exenatide”, No. B-1019/2010, Decision of 20 October 2010 of the Federal Administrative Court	165
III. “Etanercept”, BVGE 2010/48, No. B-3064/2008, Decision of 13 September 2010 of the Federal Administrative Court	166
Federal Supreme Court	167
IV. “Alendronsäure II”, No. 4A_52/2008, Decision of 29 April 2008 of the Federal Supreme Court	167
V. “Fluoxetin”, No. 4P.11/1999, Decision of 27 May 1999 of the Federal Supreme Court	167
VI. “Arzneimittel”, No. 4A.7/1998, Decision of the Federal Supreme Court of 17 November 1998	167
VII. “Fosinopril”, 124 III 375, Decision of the Federal Supreme Court of 10 July 1998	168
Federal Appeal Commission for Intellectual Property	169
VIII. “Differin Gel”, No. PA 02/03, Decision of 21 January 2005 of the Federal Appeal Commission for Intellectual Property	169
IX. “Ciclosporin”, No. PA 03/97, Decision of the former Federal Appeal Commission for Intellectual Property of 30 April 1999	169
Annex B: Selected Legal Sources	171
B1. International Treaties	171
B2. European Primary Law	173
B3. European Regulations	176
B4. European Directives	193
B5. National Law	196
I. Germany	196
II. United Kingdom	204
III. France	208
IV. Italy	213
V. Netherlands	221
VI. Switzerland	229

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)