Stief / Bühler

# Supplementary Protection Certificates (SPC)

## A Handbook

C.H.BECK · Hart · Nomos

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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

Marco Stief
Dr. Dirk Bühler

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Gabor Abbas completed a Master degree in molecular biology at the University of Leiden. During his study he worked as a patent assistant at the EPO. After obtaining his M.Sc. degree he commenced working as a trainee patent attorney at Algemeen Octrooien Merkenbureau B.V. (AOMB). During his time at AOMB he qualified as a Dutch and European patent attorney. Gabor was involved in patent matters in the pharmaceutical area including providing advice on and the prosecution of SPC applications.

Currently, Gabor is employed as a patent attorney by Shell International B.V. working in the Intellectual Property department of Legal Services.

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Dr Dirk Bühler is a German and European patent attorney and partner in the Munich office of Maiwald Patentanwalts GmbH.

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Dirk represents clients in the pharmaceutical and biotech industry ranging from start-ups to large multi-national companies before the EPO and the German courts. His practice focuses on complex prosecution matters and contentious inter partes appeal, nullity and multi-national infringement proceedings.

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He assists his clients in constituting their patent portfolio and is specialised in patent litigation. He also has a particular expertise in the field of supplementary protection certificates (SPCs).

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Peter has a particular interest in patent/SPC disputes in the Life Sciences field and is experienced in working with a diverse range of technologies, including pharmaceutical products and formulations, biotechnology, and medical devices.

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Kilian is a frequent speaker and author relating to the IP sector and wrote his doctoral thesis on SPCs for medicinal products. He studied law at the University of Lucerne, Switzerland and at the Peking University, China and holds a Master of Laws degree from the The John Marshall Law School, USA.

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Marco was deeply involved in IP attorney and paralegal education in Italian and European law and practice (tutor for the CEIPI, Strasbourg; European Patent Academy),

Selected publications: "How to identify Patent Infringements in the Nanotechnology Sector" in Nanotechnology Commercialization for Managers and Scientists (Helwegen, Escoffier, eds.), Pan Stanford Pub.

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He teaches IP and Patent Law at the University of Dresden and Pharmaceutical Law at the University of Marburg. Before joining Maiwald, Marco worked for Clifford Chance and Freshfields and as Director Legal (Global IP & Pharma) for the Fresenius group. He is the author of numerous expert papers as well as being co-author of the Handbook of Patent Law, published in German and English, and co-author and editor of the "*Handbuch Pharmaverträge*" (Handbook of Pharmaceutical Contracts).

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Alex is most active in the resolution of intellectual property and technology contract disputes particularly in the Life Sciences field. Alex has an international practice acting mainly in matters of a multi-jurisdictional character. He regularly advises clients on international patent enforcement and defensive strategies and coordinates the implementation of those strategies. His fluency in French and German allowed him to spend periods working in leading law firms in Paris and Düsseldorf.

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Tom is included in the list of recommended professionals in the 2015 edition of IAM Patent 1000 – The World's Leading Patent Practitioners. Tom has extensive experience in Dutch and Belgian patent litigation and coordinates multi-jurisdictional cases for international clients. His clients are biotech companies, universities, research institutes, chemical and pharmaceutical companies, food and dairy industries in the Netherlands and abroad.

Tom studied biology in Groningen, Netherlands and received his Ph.D. at the University of Berne, Switzerland in 1993, and was a post-doctoral fellow at the Max Planck Institute in Berlin, Germany. Before joining AOMB in 2011, Tom was a partner of the patent law firms EP&C and Zacco in the Netherlands.

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# Survey of Contents

# 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 |

| | |
|---|---|
| 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, BBI (Bundesblatt) 1993, 706 *et seqq.* |
| Message PatA 1998 | Dispatch concerning the amendments of the Federal Act on Patents for Inventions of 19 January 1998, BBI (Bundesblatt) 1998, 1633 *et seqq.* |
| 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 |
| sic! | 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) |