Supplementary Protection Certificates (SPC)

Stief

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A Handbook

edited by

Marco Stief

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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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List of Authors

Ben Brigou is an Intellectual Asset Manager at Tessenderlo Group, a diversified industrial group with headquarters in Brussels, Belgium. Before this, he trained and qualified as a Dutch patent attorney in the pharma team at the Dutch private practice firm NLO and worked in the Regulatory Affairs department of a pharmaceutical multinational. Ben passed the EQE in 2021 and holds an MSc in Chemistry (magna cum laude) from the Free University of Brussels-VUB.

Dr Matthew Burton is a Dutch and European patent attorney. He was recognised as a "Rising Star 2020/21" in the Netherlands in the MIP IP Stars ranking. After several years in private practice in The Netherlands, where he was particularly active representing clients in Opposition/Appeals before the European Patent Office, and litigating before the Dutch courts in The Hague, he now works in the life science industry. He studied at the Universities of Durham (UK) and Würzburg (Germany) and holds a Master in Chemistry and PhD in Chemical Biology from the University of Durham (UK).

Dr Thierry Caen is in charge of all Santarelli's patent activities in the field of pharmacy, chemistry and biotechnology. He works within a team of nine patent attorneys and patent engineers. Thierry is a French and European Patent Attorney. He is a Doctor of Pharmacy (Université Louis Pasteur, Strasbourg). He also holds an advanced degree in patent litigation in Europe from Strasbourg University (EPI CEIPI course, 2006). He began his intellectual property career as a patent attorney in the patent departments of major French chemical and pharmaceutical groups (1985–1997). He joined Santarelli in 1998 and became a partner in 2004. Thierry 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.

Peter Damerell is a partner at Powell Gilbert LLP, a London based specialist intellectual property law firm. He specialises in complex and high value litigation before the UK Courts (in particular concerning life sciences) and contributing to and co-ordinating multi-jurisdictional patent litigation strategies. He received his education at the University of Oxford.

Luca Giove is an Italian qualified lawyer specialised in Intellectual Property, both in and out of court. He is a founding partner of the firm GR Legal (www.grlegal.it). He gained vast experience in Intellectual Property litigation before the Italian Specialised Divisions. He has regularly taken part in proceedings involving parallel actions in other jurisdictions related to chemical-pharmaceutical, bio-technological, electronic and mechanical patents, as well as trade secrets. He is the author of many articles published in journals such as "Il Diritto Industriale", "La Giurisprudenza Italiana" and the "Oxford Journal of Intellectual Property Law and Practice". He was an adjunct professor at the University of Padua (Italy) for "Patent and Biotechnology Law" for many years where he still teaches Patent Law to PhD students. He holds a law degree from the University of Padua (Italy) and an LLM from SOAS (London, UK).

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Dr Kilian Schärli is a partner and notary public of Meyerlustenberger Lachenal's IP team and co-head of the firm's DLT/blockchain team, which are consistently ranked as one of the top Swiss teams by peers and clients. He specialises in all areas of intellectual property law, pharmaceutical law and regulatory affairs. Kilian is a skilled IP litigator and has experience in both advising and representing clients from the pharmaceutical, fintech, engineering, advertising/media and consumer goods industries in complex national and international disputes. Kilian is ranked and recommended for his work in Chambers, The Legal 500, and IAM Patent 1000. The latter stipulates that "there is no one else with a deeper understanding of SPCs than Kilian – he is spot-on in his advice and comes up with tactical solutions." He 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.

Dr Marco Stief is a partner and head of the legal department of the IP law firm Maiwald in Munich. He is an internationally recognised expert in the field of intellectual property and has extensive experience in patent infringement litigation and regularly advises companies on complex IP transactions and on a wide variety of technology-related contracts. For many years, the Intellectual Asset Management (IAM) magazine has listed Marco Stief among the top 300 "World's Leading IP Strategists" as well as among the top 1000 "World's Leading Patent Professionals". He is mentioned in the German JUVE-Handbook as one of the top 8 German patent litigators under the age of 50, emphasising that his clients in particular praise his pragmatic approach and exceptional legal expertise. In 2018 Marco Stief was admitted to the circle of the best 6 patent litigators in Germany by Who is Who Legal. In its October 2015 issue, the journal "WirtschaftsWoche" praised Marco as one of the best lawyers for IP law in Germany, and Legal500 recommends him as "pragmatic, fast, results-oriented and always meeting the highest professional standards". Marco teaches intellectual property law at the University of Dresden as well as patent law and international contract law at the University of Marburg. He is the author of numerous expert papers and co-author of the "Handbook of Patent Law" published in both German and English. He is co-author and editor of the German "Handbook of Pharmaceutical Contracts".

Dr Robert Wenzel is a research associate at Maiwald Munich and R&D engineer at a public research centre. He studied law and mechanical engineering at Technical University of Dresden and Queen Mary, University of London and was awarded the Lohrmann Medal for being the year's best graduate of TU Dresden Law School in 2012. He is co-author of several articles on supplementary protection certificates and wrote a PhD thesis on SPCs for medical devices. His thesis also provides a critical analysis of the treatment of SPCs by the European legislator and the Court of Justice of the EU and was referenced by the European Commission's "Study on the Legal Aspects of Supplementary Protection Certificates in the EU" in 2018. Robert holds an LLB, an LLM in IP law as well as an MSc.

Alex Wilson is a partner and founder member of Powell Gilbert LLP, a London based specialist intellectual property law firm. He specialises in UK and multi-jurisdictional intellectual property and technology contract disputes, particularly in the life sciences field. He regularly lectures on intellectual property matters at conferences and is the author of numerous articles on this subject. He received his education at University College London.

Dr Tom H. Wittop Koning is European and Dutch patent attorney and has been partner of several Dutch and international IP firms. Early 2018, Tom started his own boutique firm Biopatents IP Consultancy in Delft, the Netherlands. Tom studied biology in Groningen, Netherlands and received his PhD at the University of Berne, Switzerland in 1993 and was a post-doctoral fellow at the Max Planck Institute in Berlin, Germany.

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)

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)